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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, 2017
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, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act ☐

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, 2017, totaled approximately $128,175,791 based on the closing stock price as reported by the NASDAQ Global Select Market.

As of February 28, 2018, there were 106,021,055 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, 2017, are incorporated by reference into Part III of this report.	Part III - ITEMS 10, 11, 12, 13, 14

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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:

Risks and uncertainties related to Qsymia® (phentermine and topiramate extended release):

- 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 any data and/or information relating to post-approval clinical studies required for Qsymia;
- our ability to work with FDA to significantly reduce or remove the requirements of the clinical post-approval cardiovascular outcomes trial, or CVOT;
- the impact of the indicated uses and contraindications contained in the Qsymia label and the Risk Evaluation and Mitigation Strategy, or REMS, requirements;
- our ability to sell through the Qsymia retail pharmacy 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 dialog with the European Medicines Agency, or EMA, relating to the U.S.-based 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 any required CVOT, the assessment by the EMA of the application for marketing authorization, and their agreement with the data from any required CVOT;
- our or our current or potential partners' ability to successfully seek and gain 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, or our current or potential partners', 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 ensure that the entire supply chain for Qsymia efficiently and consistently delivers Qsymia to our customers and partners;
- our ability to accurately forecast Qsymia demand;
- the number of Qsymia prescriptions dispensed;
- the impact of promotional programs for Qsymia on our net product revenue and net income (loss) in future periods;

Risks and uncertainties related to STENDRA® (avanafil) or SPEDRA™ (avanafil):

- our ability to manage the supply chain for STENDRA/SPEDRA for our current or potential collaborators;
- risks and uncertainties related to the timing, strategy, tactics and success of the launches and commercialization of STENDRA/SPEDRA by our current or potential collaborators;
- 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 avanafil tablets;
- the ability of our partners to maintain regulatory approvals to manufacture and adequately supply our products to meet demand;

Risks and uncertainties related to our business:

- our history of losses and variable quarterly results;
- substantial competition;
- our ability to minimize expenses that are not essential to expanding the use of STENDRA/SPEDRA and Qsymia or that are not related to product development;
- 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 successfully develop or acquire a proprietary formulation of tacrolimus as a precursor to initiating our clinical development process;
- our ability to identify and acquire development and cash flow generating assets;
- risks related to the failure to obtain or retain federal or state controlled substances registrations and noncompliance with Drug Enforcement Administration, or DEA, or state controlled substances regulations;
- 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 develop a proprietary formulation and to demonstrate through clinical testing the quality, safety, and efficacy of our current and future investigational drug candidates;
- the timing of initiation and completion of clinical trials and submissions to U.S. and 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, specifically the $250 million of convertible notes due in 2020:
- the impact, if any, of changes to our Board of Directors or senior 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. *Business*

Overview

VIVUS is a biopharmaceutical company developing and commercializing innovative, next-generation therapies to address unmet medical needs in human health. We have 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. STENDRA® (avanafil) is approved for erectile dysfunction, or ED, by FDA and by the EC under the trade name SPEDRA in the EU. Tacrolimus is in active clinical development for the treatment of patients with pulmonary arterial hypertension, or PAH.

Business Strategy Review

In 2016, we initiated a business strategy review to maximize long-term stockholder value. The result of this review was for us to focus our efforts in three areas moving forward: (i) build our portfolio of development and cash flow generating assets, (ii) maximize the value of and monetizing our legacy assets (Qsymia and STENDRA/SPEDRA), and (iii) identify opportunities to address our outstanding debt balances. In 2017, we acquired tacrolimus and ascomycin for the treatment of PAH, we licensed Qsymia in South Korea, and we reacquired the rights for SPEDRA in Africa, the Middle East, Turkey, and the Commonwealth of Independent States, or CIS, including Russia. We are continuing our evaluation of alternatives for addressing our outstanding debt, specifically the $250 million of convertible notes due in 2020.

Development Programs

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 pathologic proliferation of epithelial and vascular smooth muscle cells in the lining of these blood vessels and excess vasoconstriction. Pulmonary blood pressure is normally between 8 and 20 mmHg at rest as measured by right heart catheterization. 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 current medical therapies for PAH involve endothelin receptor antagonists, PDE5 inhibitors, prostacyclin analogues, selective prostaglandin I2 receptor agonists, and soluble guanate cyclase 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 bone morphogenetic protein receptor type 2, or BMPR2, signaling that is prevalent in PAH patients and may therefore address a fundamental cause of PAH.

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 occurs two to four times more frequently in females.

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. Under this agreement, we paid Selten an upfront payment of $1.0 million, and we will pay additional 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.

In October 2017, we held a pre-IND meeting with FDA for our proprietary formulation of tacrolimus for the treatment of PAH. FDA addressed our questions related to preclinical, nonclinical and clinical data and the planned design of clinical trials of tacrolimus in class III and IV PAH patients, and clarified the requirements needed to file an IND to initiate a clinical trial in this indication. As discussed with FDA, we currently intend to design and conduct clinical trials that could qualify for Fast Track and/or Breakthrough Therapy designation.

Tacrolimus for the treatment of PAH has received Orphan Drug Designation from FDA in the United States and the EMA in the EU. We are focusing on the development of a proprietary oral formulation of tacrolimus to be used in a clinical development program and for commercial use. We anticipate completing the development of our proprietary formulation of tacrolimus, filing an IND with FDA, and initiating enrollment in a Phase 2 clinical trial during 2018.

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 in patients who do not respond well to typical antihypertensive medications. We expect no future development until we have concluded our discussions with FDA regarding our CVOT for Qsymia.

Additional Opportunities

We will continue to evaluate potential in-licensing opportunities to build our portfolio of product and product candidates, with a primary focus in 2018 on cash flow generating assets.

Commercial Products

Qsymia

FDA approved Qsymia 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 the 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. through a small specialty sales force who promote Qsymia to physicians. Our sales efforts are focused on maintaining a commercial presence with high volume prescribers of anti-obesity products. Our marketing efforts have focused on rolling out unique programs to encourage targeted prescribers to gain more experience with Qsymia with their obese or overweight 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 digital strategies deliver clear and compelling communications to potential patients. We utilize a patient savings plan to further drive Qsymia brand preference at the point of prescription and to encourage long-term use of the brand.

In September 2017, we entered into a license and commercialization agreement, or the Alvogen License Agreement, and a commercial supply agreement, or the Alvogen Supply Agreement, with Alvogen Malta Operations (ROW) Ltd, or Alvogen. Under the terms of the Alvogen License Agreement, Alvogen will be solely responsible for obtaining and maintaining regulatory approvals for all sales and marketing activities for Qsymia in South Korea. We received an upfront payment of $2.5 million in September 2017 and are eligible to receive additional payments upon Alvogen achieving marketing authorization, commercial launch and reaching a sales milestone. Additionally, we will receive a royalty on Alvogen's Qsymia net sales in South Korea. Under the Alvogen Supply Agreement, the Company will supply product to Alvogen.

STENDRA/SPEDRA

STENDRA is an oral phosphodiesterase type 5, or PDE5, inhibitor that we have licensed from Mitsubishi Tanabe Pharma Corporation, or MTPC. FDA approved STENDRA 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 a license and commercialization agreement, or the Menarini License 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 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 31 countries within the territory granted to Menarini pursuant to the Menarini License Agreement. In addition, Menarini licensed rights directly from MTPC to commercialize avanafil in certain Asian territories. 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. Menarini obtains SPEDRA exclusively from us.

In September 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. Metuchen will reimburse us for payments made to cover royalty and milestone obligations to MTPC during the term of the Metuchen License Agreement, but will otherwise owe us no future royalties. Metuchen obtains STENDRA exclusively from us.

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 Commonwealth of Independent States, or CIS, including Russia, or the Sanofi Territory. Sanofi was responsible for obtaining regulatory approval in its territories. In March 2017, we and Sanofi entered into the Termination, Rights Reversion and Transition Services Agreement, or the Transition Agreement, effective February 28, 2017. Under the Transition Agreement, effective upon the thirtieth day following February 28, 2017, the Sanofi License Agreement terminated for all countries in the Sanofi Territory. In addition, under the Transition Agreement, Sanofi provided us with certain transition services in support of ongoing regulatory approval efforts while we seek to obtain a new commercial partner or partners for the Sanofi Territory. We pay certain transition service fees to Sanofi as part of the Transition Agreement.

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 Africa, the Middle East, Turkey, the CIS, including Russia, Mexico and Central America.

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	Obesity	*United States* Commercially available *EU* Marketing Authorization Application, or MAA, denied in 2014 *South Korea* Not yet commercially available	Worldwide rights available, except for South Korea South Korea commercial rights licensed to Alvogen
Qsymia	Obstructive Sleep Apnea	Phase 2 study completed	Worldwide rights available
Qsymia	Diabetes	Phase 2 study completed	Worldwide rights available
STENDRA/SPEDRA (avanafil)	Erectile dysfunction	*United States* Commercially available *EU* Commercially available	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
Tacrolimus	PAH	Phase 2a study completed IND to be filed in 2018	Worldwide rights available

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 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,

healthcare provider training, distribution through certified home delivery and retail pharmacies, an implementation system and a time-table for assessments.

Upon receiving approval to market Qsymia, FDA required that we perform additional studies of Qsymia including a CVOT. To date, there have been no indications throughout the Qsymia clinical development program nor post-marketing experience of any increase in adverse cardiovascular, or CV, 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 have held several meetings with FDA to discuss alternative strategies for obtaining 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 have submitted information from this study to FDA in support of a currently pending supplemental New Drug Application (sNDA) seeking changes to the Qsymia label. 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.

We have granted an exclusive license to Alvogen to commercialize and promote Qsymia for the treatment of obesity in South Korea.

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/SPEDRA 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.

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.

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 January 3, 2017, we granted Hetero 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.

Tacrolimus for the Treatment of Pulmonary Arterial Hypertension

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 pathologic proliferation of epithelial and vascular smooth muscle cells in the lining of these blood vessels and excess vasoconstriction. Pulmonary blood pressure is normally between 8 and 20 mmHg at rest as measured by right heart catheterization. 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 occurs two to four 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 I, II, III, or IV, with the most impaired patients being class IV.

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 I and II 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 III or IV 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. We paid Selten an upfront payment of $1.0 million, and we will pay additional 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.

In October 2017, we held a pre-IND meeting with FDA for our proprietary formulation of tacrolimus for the treatment of PAH. FDA addressed our questions related to preclinical, nonclinical and clinical data and the planned design of clinical trials of tacrolimus in class III and IV PAH patients, and clarified the requirements needed to file an IND to initiate a clinical trial in this indication. As discussed with FDA, we currently intend to design and conduct clinical trials that could qualify for Fast Track and/or Breakthrough Therapy designation.

Tacrolimus for the treatment of PAH has received Orphan Drug Designation from FDA in the United States and the European Medicines Agency in the EU. We are currently focusing on the development of a proprietary formulation of tacrolimus to be used in a clinical development program and for commercial use and filing an IND with FDA.

Other Programs

We have licensed and will evaluate opportunities 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 approximately twelve months in which to complete its initial review of a standard NDA and respond to the applicant, and approximately 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 (CSA) and implementing regulations from the Drug Enforcement Administration (DEA), 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. As a Schedule IV controlled substance under the CSA, Qsymia is subject to DEA and state regulations relating to controlled substances including prescription procedures and limitations on prescription refills. In addition, the parties who perform our clinical and commercial manufacturing, distribution, dispensing and clinical studies for Qsymia are required to maintain necessary DEA registrations and state licenses. The DEA periodically inspects facilities for compliance with its rules and regulations.

In addition to regulations in the U.S., we or our partners are subject to a variety of foreign regulations governing clinical trials, commercial sales, and distribution of our investigational drug candidates. We or our partners must obtain separate approvals by the comparable regulatory authorities of foreign countries before we or our partners 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. The Centers for Medicare and Medicaid Services, or CMS, the federal agency that administers Medicare and the Medicaid Drug Rebate program, issued final regulations that became effective on April 1, 2016 to

implement the changes to the Medicaid Drug Rebate program under the Affordable Care Act. 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 $4.1 billion in 2018, 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, certain legislative changes to and regulatory changes under the Affordable Care Act have occurred in the 115th U.S. Congress and under the Trump Administration. For example, the Tax Cuts and Jobs Act enacted on December 22, 2017, eliminated the shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code of 1986, commonly referred to as the individual mandate, beginning in 2019. Additional legislative changes to and regulatory changes under the Affordable Care Act remain possible. 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 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 updated the agreement with participating manufacturers. The Affordable Care Act also obligates the Secretary of the Department of Health and Human Services to create regulations and processes to improve the integrity of the 340B program. 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 effective date of the regulation has been delayed until July 1, 2018. 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. 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 is 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, which, in general, represents the lowest price available from the manufacturer to any entity in the U.S. in any pricing structure, calculated to include all sales and associated rebates, discounts and other price concessions. Our failure to comply with these price reporting and rebate payment options could negatively impact our financial results.

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 drug 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 or otherwise also could affect our 340B ceiling price calculations and negatively impact our results of operations.

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 pricing 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 $181,071 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 $18,107 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.

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 through Tricare retail network pharmacies. 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 Statute, 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. Liability under the Anti-Kickback Statute may be established without proving actual knowledge of the statute or specific intent to violate it. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Although there are a number of statutory exemptions and regulatory safe harbors to the federal Anti-Kickback Statute 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 imposes civil penalties against individuals and entities for, among other things, 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. More recently, federal enforcement agencies are and have been investigating certain pharmaceutical companies' product and patient assistance programs, including manufacturer reimbursement support services, relationships with specialty pharmacies, and grants to independent charitable foundations. 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;
- the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also imposes obligations, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- 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. the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also imposes obligations, with respect to safeguarding the privacy, security and transmission of individually identifiable health information; 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 Centers for Medicare and Medicaid Services within the U.S. Department of Health and Human Services, or 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 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; 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, imprisonment, 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 $52.4 million relating to license and milestone payments through December 31, 2017. 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.

Sanofi

On December 11, 2013, we entered into 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 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.

In March 2017, we and Sanofi entered into the Termination, Rights Reversion and Transition Services Agreement, or the Transition Agreement, effective February 28, 2017. Under the Transition Agreement, effective upon the thirtieth day following February 28, 2017, the Sanofi License Agreement terminated for all countries in the Sanofi Territory as a termination by Sanofi for convenience notwithstanding any notice requirements contained in the Sanofi License Agreement. The Commercial Supply Agreement and the Manufacturing and Supply Agreement will continue in effect. In addition, under the Transition Agreement, Sanofi will provide us with certain transition services in support of ongoing regulatory approval efforts while we seek to obtain a new commercial partner or partners for the Sanofi Territory. We will pay certain transition service fees to Sanofi as part of the Transition Agreement.

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. We paid Selten an upfront payment of $1.0 million, and we will pay additional 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.

Alvogen Malta Operations (ROW) Ltd

In September 2017, we entered into a license and commercialization agreement, or the Alvogen License Agreement, and a commercial supply agreement, or the Alvogen Supply Agreement, with Alvogen Malta Operations (ROW) Ltd, or Alvogen. Under the terms of the Alvogen License Agreement, Alvogen will be solely responsible for obtaining and maintaining regulatory approvals for all sales and marketing activities for Qsymia in South Korea. We received an upfront payment of $2.5 million in September 2017, which was recorded in license and milestone revenue in the third quarter of 2017, and are eligible to receive additional payments upon Alvogen achieving marketing authorization, commercial launch and reaching a sales milestone for a potential total of $7.5 million. Additionally, we will receive a royalty on Alvogen's Qsymia net sales in South Korea. Under the Alvogen Supply Agreement, we will supply product to Alvogen.

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 Application No. 15/203,601	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	Expiring 06/09/2029
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. 6,495,154	Expiring 11/21/2020
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 Application No. 15/782,153	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 Pharma Solutions, LLC, or 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 small specialty 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 also provide the Q and Me® Patient Support Program online which supports Qsymia 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.

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 received two notifications under paragraph IV of the Hatch-Waxman Act challenging certain of our Qsymia patents, and we filed suit against both challengers. In June 2017, the Company entered into a settlement agreement with Actavis Laboratories FL, Inc., Actavis, Inc., and Actavis PLC, collectively referred to as Actavis, and in August 2017, the Company entered into a settlement agreement with Dr. Reddy's Laboratories, S.A. and Dr. Reddy's Laboratories, Inc., collectively referred to as DRL. The settlement agreement with Actavis will permit Actavis to begin selling a generic version of Qsymia on December 1, 2024, or earlier under certain circumstances. The settlement with DRL will permit DRL to begin selling a generic version of Qsymia on June 1, 2025, or earlier under certain circumstances. It is possible that one or more additional companies may file an Abbreviated New Drug Application, or ANDA, and could receive FDA approval to market a generic version of Qsymia before the entry dates specified in our settlement agreements with Actavis and DRL. If a generic version of Qsymia is launched, our business will be negatively impacted.

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 these types of bariatric procedures. 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.

STENDRA for the treatment of ED competes with PDE5 inhibitors in the form of oral medications including Viagra® (sildenafil citrate), marketed by Pfizer, Inc. and now available in generic form; 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 $5.3 million, $5.6 million and $10.1 million in 2017, 2016 and 2015, respectively, in research and development expenses, primarily to support the approval efforts, post-marketing requirements, and clinical programs for Qsymia and STENDRA/SPEDRA and the development of tacrolimus for pulmonary arterial hypertension.

Employees

As of February 28, 2018, we had 52 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.

Financial Information About Geographic Areas

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, Nominating and Governance, and Corporate Development Committees are available free of charge on our website listed above.

Item 1A. ***Risk Factors***

Set forth below and elsewhere in this Annual Report on Form 10-K and in other documents we file with the Securities and Exchange Commission, or the SEC, are risks and uncertainties that could cause actual results to differ materially from the results contemplated by the forward-looking statements contained in this Annual Report on Form 10-K. These are not the only risks and uncertainties facing VIVUS. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations.

Risks Relating to our Business

Our success will depend on our ability and that of our current or future collaborators to effectively and profitably commercialize Qsymia® and STENDRA/SPEDRA.

Our success will depend on our ability and that of our current or future collaborators to effectively and profitably commercialize Qsymia and STENDRA/SPEDRA, 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;
- manage our alliances with MTPC, Menarini and Metuchen to help ensure the commercial success of avanafil;
- manage costs;
- 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;
- comply with state and federal controlled substances requirements;
- maintain and defend our patents, if challenged;
- ensure that the active pharmaceutical ingredients, or APIs, for Qsymia and STENDRA/SPEDRA and the finished products are manufactured in sufficient quantities and in compliance with requirements of FDA and DEA 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/SPEDRA, from APIs to finished products, efficiently and consistently delivers Qsymia and STENDRA/SPEDRA 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 and STENDRA/SPEDRA, 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:

- successfully develop or acquire a proprietary formulation of tacrolimus as a precursor to the clinical development process;
- 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 and future development programs 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 strategic business plan may cause uncertainty regarding the future of our business, and may adversely impact employee hiring and retention, our stock price, and our revenue, operating results, and financial condition.

In 2016, we initiated a business strategy review with an outside advisor. 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 Qsymia and STENDRA/SPEDRA in their respective licensed territories.

We rely on our collaboration partners, including Alvogen, MTPC, Menarini and Metuchen, to successfully commercialize Qsymia and STENDRA/SPEDRA in their respective territories, including obtaining any necessary approvals and we cannot assure you that they will be successful. Our dependence on our collaborative arrangements for the commercialization of Qsymia and STENDRA/SPEDRA, including our license agreements with Alvogen, MTPC, Menarini and Metuchen, 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 the 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 territories 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 September 2016, Auxilium terminated its agreement with us to commercialize STENDRA in the U.S. and Canada and, in March 2017, Sanofi terminated its agreement with us to commercialize STENDRA/SPEDRA in Africa, the Middle East, Turkey, and the CIS, including Russia.

In addition, under our license agreement with MTPC, we are obligated to ensure that Menarini, Metuchen, and any future sublicensees comply with the terms and conditions of our license agreement with MTPC, and MTPC has the right to terminate our license rights to avanafil upon any uncured material breach. Consequently, failure by Menarini, Metuchen, or any future sublicensees to comply with these terms and conditions could result in the termination of our license rights to avanafil on a worldwide basis, which would delay, impair, or preclude our ability to commercialize avanafil.

If any of our collaboration partners fail to successfully commercialize Qsymia or STENDRA/SPEDRA, our business may be negatively affected and we may receive limited or no revenues under our agreements with them.

There have been substantial changes to the Internal Revenue Code, some of which could have an adverse effect on our business.

The Tax Cuts and Jobs Act made substantial changes to the Internal Revenue Code, effective January 1, 2018, some of which could have an adverse effect on our business. In addition to reducing the top corporate income tax rate, changes that could impact our business in the future include (i) eliminating the ability to utilize net operating losses, or NOLs, to reduce income in prior tax years and limiting the utilization of NOLs generated after December 31, 2017 to 80% of future taxable income, which could affect the timing of our ability to utilize NOLs, and (ii) limiting the amount of business interest expenses that can be deducted to 30% of earnings before interest, taxes, depreciation and amortization.

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/SPEDRA with Menarini 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/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/SPEDRA 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/SPEDRA in territories that are not covered by our current commercial collaboration agreements, such as Africa, the Middle East, Turkey, the CIS, Mexico and Central America. We may be unable to enter into agreements with third parties for STENDRA/SPEDRA for these territories on favorable terms or at all, which could delay, impair, or preclude our ability to commercialize STENDRA/SPEDRA 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, or our partners, 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/SPEDRA 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 Alvogen, Menarini, Metuchen and any potential future collaborators in certain territories, intend to market Qsymia and STENDRA/SPEDRA outside the U.S., which will subject us to risks related to conducting business internationally.

We, through Alvogen, Menarini, Metuchen and any potential future collaborators in certain territories, intend to manufacture, market, and distribute Qsymia and STENDRA/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 year ended December 31, 2015, we recorded inventory impairment and commitment fees totaling $29.5 million, primarily to write off excess inventory related to Qsymia.

We maintain significant inventories and evaluate these inventories on a periodic basis for potential excess and obsolescence. During the year ended December 31, 2015, we recognized total charges of $29.5 million, primarily for Qsymia inventories on hand in excess of projected demand. The inventory impairment charges were based on our

analysis of the then-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/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, including 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, including compliance with relevant state and federal laws.

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 single-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 or our suppliers will be able to obtain or maintain the necessary regulatory approvals or state and federal controlled substances registrations for current or 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 or our suppliers will be able to obtain or maintain the necessary regulatory approvals or registrations for these suppliers in a timely manner or at all.

Sanofi Chimie manufactures and supplies 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. Sanofi Winthrop Industrie manufactures and supplies 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 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;

- 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 or post-market safety study or trial 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.

Upon receiving approval to market Qsymia, FDA required that we perform additional studies of Qsymia including a cardiovascular outcome trial, or CVOT. We estimate the cost of a CVOT as currently designed to be between $180 million and $220 million incurred over a period of approximately five years. We have held several meetings with FDA 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. 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 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. 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 have submitted information from this study to FDA in support of a currently pending supplemental New Drug Application (sNDA) seeking changes to the Qsymia label. 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.

As for the EU, even if FDA were to determine that a CVOT is no longer necessary, there would be no assurance that the EMA would reach the same conclusion. There can be no assurance that we will be successful in obtaining FDA or EMA agreement that we have demonstrated 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 may not be able to maintain compliance with the continued listing requirements of The Nasdaq Stock Market.

On October 4, 2017, we received a letter from The Nasdaq Stock Market, or Nasdaq, indicating that, based upon the closing bid price of our common stock for the preceding 30 consecutive business days, we no longer meet the continued listing requirement of maintaining a minimum bid price of $1 per share, as set forth in Nasdaq Listing Rule 5450(a)(1). As provided in the Nasdaq rules, we have 180 calendar days, or until April 2, 2018, to regain compliance with the continued listing requirement. In order to regain compliance, the closing bid price of our common stock on The Nasdaq Global Select Market must be at least $1 per share for a minimum of ten consecutive business days during this 180-day period. If we fail to regain compliance with the continued listing requirement noted above during the applicable compliance period, we may apply for an additional 180-day cure period. If we fail to regain compliance during the additional cure period, our common stock will be subject to delisting by Nasdaq. If Nasdaq delists our common stock, the delisting could adversely affect the market liquidity of our common stock and the price of our common stock.

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.

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 these types of bariatric procedures. 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. We received two notifications under paragraph IV of the Hatch-Waxman Act challenging certain of our Qsymia patents, and we filed suit against both challengers. In June 2017, the Company entered into a settlement agreement with Actavis Laboratories FL, Inc., Actavis, Inc., and Actavis PLC, collectively referred to as Actavis, and in August 2017, the Company entered into a settlement agreement with Dr. Reddy's Laboratories, S.A. and Dr. Reddy's Laboratories, Inc., collectively referred to as DRL. The settlement agreement with Actavis will permit Actavis to begin selling a generic version of Qsymia on December 1, 2024, or earlier under certain circumstances. The settlement with DRL will permit DRL to begin selling a generic version of Qsymia on June 1, 2025, or earlier under certain circumstances. It is possible that one or more additional companies may file an Abbreviated New Drug Application, or ANDA, and could receive FDA approval to market a generic version of Qsymia before the entry dates specified in our settlement agreements with Actavis and DRL. If a generic version of Qsymia is launched, this will 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.

STENDRA for the treatment of ED competes 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 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, Sanofi Chimie manufactures and supplies 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. Sanofi Winthrop Industrie manufactures and supplies 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 and Metuchen 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 and Metuchen.

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, patients 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 Statute, 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. Liability under the Anti-Kickback Statute may be established without proving actual knowledge of the statute or specific intent to violate it. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Although there are a number of statutory exemptions and regulatory safe harbors to the federal Anti-Kickback Statute 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 imposes civil penalties against individuals and entities for, among other things, 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. More recently, federal enforcement agencies are and have been investigating certain pharmaceutical companies' product and patient assistance programs, including manufacturer reimbursement support services, relationships with specialty pharmacies, and grants to independent charitable foundations. 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;

- The federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also imposes obligations, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- 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. Some states restrict the ability of manufacturers to offer co-pay support to patients for certain prescription drugs. Other states and cities require identification or licensing of state representatives. 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 Centers for Medicare and Medicaid Services within the U.S. Department of Health and Human Services, or 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 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; 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, imprisonment, 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.

In addition, Qsymia is a controlled substance and subject to DEA and state regulations relating to manufacturing, storage, record keeping, reporting, distribution and prescription procedures and requirements related to necessary DEA registrations and state licenses. The DEA periodically inspects facilities for compliance with its rules and regulations. Failure to comply with current and future regulations of the DEA, relevant state authorities or any comparable international requirements could lead to a variety of sanctions, including revocation or denial of renewal of DEA registrations, fines, injunctions, or civil or criminal penalties, and could result in, among other things, additional operating costs to us or delays in distribution of Qsymia and could have an adverse effect on our business and financial condition.

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, which, in general, represents the lowest price available from the manufacturer to any entity in the U.S. in any pricing structure, calculated to include all sales and associated rebates, discounts and other price concessions. Our failure to comply with these price reporting and rebate payment options could negatively impact our financial results.

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 $4.1 billion in 2018, based on the dollar value of its branded prescription drug sales to certain federal programs identified in the law.

CMS issued final regulations that became effective on April 1, 2016 to implement the changes to the Medicaid Drug Rebate program under the Affordable Care Act. Moreover, certain legislative changes to and regulatory changes under the Affordable Care Act have occurred in the 115th United States Congress and under the Trump Administration. For example, the Tax Cuts and Jobs Act enacted on December 22, 2017, eliminated the individual mandate, beginning in 2019. Additional legislative changes to and regulatory changes under the Affordable Care Act remain possible. 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 program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B drug 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 updated the agreement with participating manufacturers. The Affordable Care Act also obligates the Secretary of HHS to create regulations and processes to improve the integrity of the 340B program. 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 effective date of the regulation has been delayed until July 1, 2018. 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 $181,071 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 $18,107 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 $181,071 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. 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 is 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 $4.1 billion in 2018, 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.

CMS issued final regulations that became effective on April 1, 2016 to implement the changes to the Medicaid Drug Rebate Program under the Affordable Care Act.

There can be no assurance that future healthcare legislation or other changes in the administration or interpretation of government healthcare or third-party reimbursement programs will not have a material adverse effect on us. Healthcare reform is also under consideration in other countries where we intend to market Qsymia. Moreover, certain legislative changes to and regulatory changes under the Affordable Care Act have occurred in the 115th United States Congress and under the Trump Administration. For example, the Tax Cuts and Jobs Act enacted on December 22, 2017, eliminated the individual mandate, beginning in 2019. Additional legislative changes to and regulatory changes under the Affordable Care Act remain possible. 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 may receive additional notices of ANDA filings for Qsymia submitted by generic drug companies asserting that generic forms of Qsymia would not infringe on our issued patents. As a result of these potential filings, we may commence additional litigation to defend our patent rights, which would result in additional litigation costs and, depending on the outcome of the litigation, might result in competition from lower cost generic or follow-on products earlier than anticipated.

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 received a Paragraph IV certification notice from Actavis Laboratories FL, Inc. 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 filed suit against Actavis Laboratories FL, Inc., Actavis, Inc., and Actavis PLC, collectively referred to as Actavis, to defend our patent rights. We 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 filed a second lawsuit against Actavis. We 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 filed a third lawsuit against Actavis. The lawsuits were consolidated into a single suit.

On June 29, 2017, the Company entered into a settlement agreement with Actavis resolving the suit against Actavis. On July 5, 2017, the U.S. District Court for the District of New Jersey entered an order dismissing the suit. In accordance with legal requirements, we have submitted the settlement agreement to the U.S. Federal Trade Commission and the U.S. Department of Justice for review.

We 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 filed suit against Teva to defend our patent rights. We 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 filed a second lawsuit against Teva. The lawsuits were consolidated into a single 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.

On August 28, 2017, the Company entered into a settlement agreement with DRL resolving the suit against DRL. On September 6, 2017, the U.S. District Court for the District of New Jersey entered an order dismissing the suit. In accordance with legal requirements, we have submitted the settlement agreement to the U.S. Federal Trade Commission and the U.S. Department of Justice for review.

The settlement agreements with Actavis and DRL resolve all patent litigation brought by VIVUS against generic pharmaceutical companies that have filed ANDAs seeking approval to market generic versions of Qsymia.

The settlement agreement with Actavis will permit Actavis to begin selling a generic version of Qsymia on December 1, 2024, or earlier under certain circumstances. The settlement with DRL will permit DRL to begin selling a generic version of Qsymia on June 1, 2025, or earlier under certain circumstances. It is possible that one or more additional companies may file an ANDA and could receive FDA approval to market a generic version of Qsymia before the entry dates specified in our settlement agreements with Actavis and DRL, including if it is determined that the generic product does not infringe our patents, or that our patents are invalid or unenforceable. Although we intend to vigorously enforce our intellectual property rights relating to Qsymia, in the event there is a future ANDA filer, there can be no assurance that we will prevail in a future defense of our patent rights. If a generic version of Qsymia is introduced, 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 obtain marketing authorization by the EC for Qsiva in the EU;
- our ability to manage costs;
- 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/SPEDRA 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. We paid Selten an upfront payment of $1.0 million, and we will pay additional 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, 2017, 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, 2017, we had $226.3 million in cash, cash equivalents and available-for-sale securities. While at December 31, 2017, 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, 2017. 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. The Ninth Circuit issued a decision on January 16, 2018, affirming the district court's dismissal of the action. The deadline for Plaintiffs to seek rehearing in the Ninth Circuit has now expired, and unless Plaintiffs elect to file a petition for certiorari in the Supreme Court, the matter is concluded.

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 $843.6 million as of December 31, 2017, and we may continue to incur substantial operating losses for the future.

We have generated a cumulative net loss of $843.6 million for the period from our inception through December 31, 2017, 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, 2017, we had approximately $640.4 million and $276.2 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 December 31, 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;
- 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 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. Product sales of Qsymia may never increase 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 and with Metuchen to commercialize STENDRA in the U.S., Canada, South America and India, 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 NOLs 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 submitted the plan to a vote at the 2017 annual meeting of stockholders, and stockholders ratified the plan at the 2017 annual meeting of stockholders. 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 Comments***

None.

Item 2. ***Properties***

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 received an abatement of the monthly rent for the first four months on the lease term. 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.

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. The Ninth Circuit issued a decision on January 16, 2018, affirming the district court’s dismissal of the action. The deadline for Plaintiffs to seek rehearing in the Ninth Circuit has now expired, and unless Plaintiffs elect to file a petition for certiorari in the

Supreme Court, the matter is concluded. 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.

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.

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 were consolidated into a single suit (Case No. 14-3786 (SRC)(CLW)).

On June 29, 2017, the Company entered into a settlement agreement with Actavis resolving the suit against Actavis. On July 5, 2017, the U.S. District Court for the District of New Jersey entered an order dismissing the suit. In accordance with legal requirements, we have submitted the settlement agreement to the U.S. Federal Trade Commission and the U.S. Department of Justice for review.

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.

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 were consolidated into a single suit (Case No. 15-2693 (SRC)(CLW)). 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.

On August 28, 2017, the Company entered into a settlement agreement with DRL resolving the suit against DRL. On September 6, 2017, the U.S. District Court for the District of New Jersey entered an order dismissing the suit. In accordance with legal requirements, we have submitted the settlement agreement to the U.S. Federal Trade Commission and the U.S. Department of Justice for review.

The settlement agreement with DRL resolves all patent litigation brought by VIVUS against generic pharmaceutical companies that have filed ANDAs seeking approval to market generic versions of Qsymia.

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 Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.***

VIVUS's common stock trades publicly on the NASDAQ Global Select Market under the symbol "VVUS." The following table sets forth for the periods indicated the quarterly high and low sales prices of our common stock as reported on the NASDAQ Global Select Market.

	Three Months Ended			
	March 31	June 30	September 30	December 31
2017				
High	$ 1.30	$ 1.38	$ 1.32	$ 1.01
Low	1.04	0.99	0.86	0.48
2016				
High	$ 1.42	$ 1.85	$ 1.32	$ 1.47
Low	0.92	1.02	0.93	1.03

Stockholders

As of February 28, 2018, there were 106,021,055 shares of outstanding common stock that were held by 2,775 stockholders of record and no outstanding shares of preferred stock. On February 28, 2018, the last reported sales price of our common stock on the NASDAQ Global Select Market was $0.43 per share.

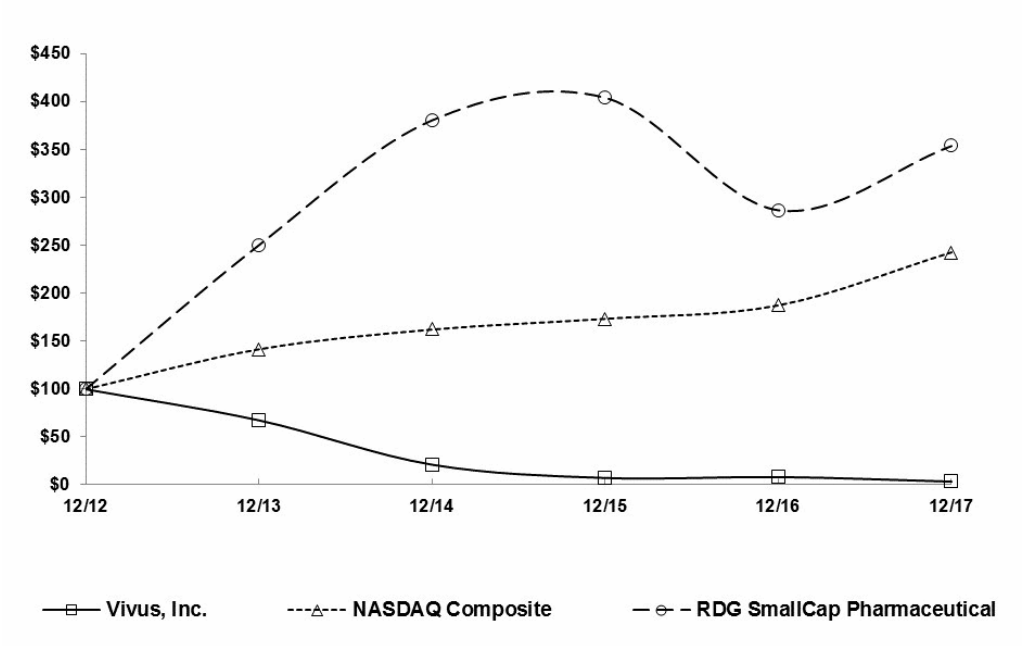
Dividends

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, 2012 through December 31, 2017 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 12/31/2012 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 2017	21,496	$ 0.71	21,496	
November 2017	1,021	$ 0.66	1,021	
December 2017	1,021	$ 0.53	1,021	
Total	23,538	$ 0.70	23,538	9,189

(a) In the fourth quarter of 2017, 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,				
	2017	**2016**	**2015**	**2014**	**2013**
Income Statement Data:					
Total revenue	$ 65,373	$ 124,258	$ 95,430	$ 114,181	$ 81,082
Total operating expenses	$ 62,580	$ 68,573	$ 155,707	$ 164,892	$ 235,696
Income (loss) from operations	$ 2,793	$ 55,685	$ (60,277)	$ (50,711)	$ (154,614)
(Loss) income from continuing operations	$ (30,511)	$ 23,302	$ (93,107)	$ (82,647)	$ (174,946)
Net (loss) income	$ (30,511)	$ 23,302	$ (93,107)	$ (82,647)	$ (174,456)
Basic net (loss) income per share—Continuing operations	$ (0.29)	$ 0.22	$ (0.90)	$ (0.80)	$ (1.72)
Diluted net (loss) income per share—Continuing operations	$ (0.29)	$ 0.22	$ (0.90)	$ (0.80)	$ (1.72)
Balance Sheet Data:					
Working capital	$ 224,643	$ 255,159	$ 214,143	$ 301,789	$ 371,934
Total assets	$ 264,968	$ 305,776	$ 277,202	$ 366,938	$ 431,796
Long-term debt	$ 235,683	$ 241,318	$ 231,390	$ 227,783	$ 213,106
Accumulated deficit	$ (843,565)	$ (813,054)	$(836,356)	$(743,249)	$ (660,602)
Stockholders' (deficit) equity	$ (9,338)	$ 18,185	$ (7,085)	$ 82,518	$ 153,369

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, 2017, 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. We have 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. STENDRA® (avanafil) is approved for erectile dysfunction, or ED, by FDA and by the EC under the trade name SPEDRA in the EU. Tacrolimus is in active clinical development for the treatment of patients with pulmonary arterial hypertension, or PAH.

Business Strategy Review

In 2016, we initiated a business strategy review to maximize long-term stockholder value. The result of this review was for us to focus our efforts in three areas moving forward: (i) build our portfolio of development and cash flow generating assets, (ii) maximize the value of and monetizing our legacy assets (Qsymia and STENDRA/SPEDRA), and (iii) identify opportunities to address our outstanding debt balances. In 2017, we acquired tacrolimus and ascomycin for the treatment of PAH, we licensed Qsymia in South Korea, and we reacquired the rights for SPEDRA in Africa, the Middle East, Turkey, and the Commonwealth of Independent States, or CIS, including Russia. We are continuing our

evaluation of alternatives for addressing our outstanding debt, specifically the $250 million of convertible notes due in 2020.

Development Programs

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 pathologic proliferation of epithelial and vascular smooth muscle cells in the lining of these blood vessels and excess vasoconstriction. Pulmonary blood pressure is normally between 8 and 20 mmHg at rest as measured by right heart catheterization. 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 current medical therapies for PAH involve endothelin receptor antagonists, PDE5 inhibitors, prostacyclin analogues, selective prostaglandin I2 receptor agonists, and soluble guanate cyclase 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 bone morphogenetic protein receptor type 2, or BMPR2, signaling that is prevalent in PAH patients and may therefore address a fundamental cause of PAH.

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 occurs two to four times more frequently in females.

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. Under this agreement, we paid Selten an upfront payment of $1.0 million, and we will pay additional 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.

In October 2017, we held a pre-IND meeting with FDA for our proprietary formulation of tacrolimus for the treatment of PAH. FDA addressed our questions related to preclinical, nonclinical and clinical data and the planned design of clinical trials of tacrolimus in class III and IV PAH patients, and clarified the requirements needed to file an IND to initiate a clinical trial in this indication. As discussed with FDA, we currently intend to design and conduct clinical trials that could qualify for Fast Track and/or Breakthrough Therapy designation.

Tacrolimus for the treatment of PAH has received Orphan Drug Designation from FDA in the United States and the European Medicines Agency in the EU. We are focusing on the development of a proprietary oral formulation of tacrolimus to be used in a clinical development program and for commercial use. We anticipate filing an IND with FDA, completing the development of our proprietary formulation of tacrolimus and initiating enrollment in a Phase 2 clinical trial during 2018.

Commercial Products

Qsymia

FDA approved Qsymia 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 the 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. through a small specialty sales force who promote Qsymia to physicians. Our sales efforts are focused on maintaining a commercial presence with high volume prescribers of anti-obesity products. Our marketing efforts have focused on rolling out unique programs to encourage targeted prescribers to gain more experience with Qsymia with their obese or overweight 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 digital strategies deliver clear and compelling communications to potential patients. We utilize a patient savings plan to further drive Qsymia brand preference at the point of prescription and to encourage long-term use of the brand.

In September 2017, we entered into a license and commercialization agreement, or the Alvogen License Agreement, and a commercial supply agreement, or the Alvogen Supply Agreement, with Alvogen Malta Operations (ROW) Ltd, or Alvogen. Under the terms of the Alvogen License Agreement, Alvogen will be solely responsible for obtaining and maintaining regulatory approvals for all sales and marketing activities for Qsymia in South Korea. We received an upfront payment of $2.5 million in September 2017 and are eligible to receive additional payments upon Alvogen achieving marketing authorization, commercial launch and reaching a sales milestone. Additionally, we will receive a royalty on Alvogen's Qsymia net sales in South Korea. Under the Alvogen Supply Agreement, the Company will supply product to Alvogen.

STENDRA/SPEDRA

STENDRA is an oral phosphodiesterase type 5, or PDE5, inhibitor that we have licensed from Mitsubishi Tanabe Pharma Corporation, or MTPC. FDA approved STENDRA 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 a license and commercialization agreement, or the Menarini License 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 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 31 countries within the territory granted to Menarini pursuant to its license and commercialization agreement. In addition, Menarini licensed rights directly from MTPC to commercialize avanafil in certain Asian territories. 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. Menarini obtains SPEDRA exclusively from us.

In September 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. Metuchen will reimburse us for payments made to cover royalty and milestone obligations to MTPC during the term of the Metuchen License Agreement, but will otherwise owe us no future royalties. Metuchen obtains STENDRA exclusively from us.

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 Commonwealth of Independent States, or CIS, including Russia, or the Sanofi Territory. Sanofi was responsible for obtaining regulatory approval in its territories. In March 2017, we and Sanofi entered into the Termination, Rights Reversion and Transition Services Agreement, or the Transition Agreement, effective February 28, 2017. Under the Transition Agreement, effective upon the thirtieth day following February 28, 2017, the Sanofi License Agreement terminated for all countries in the Sanofi Territory as a termination by Sanofi for convenience notwithstanding any notice requirements contained in the Sanofi License Agreement. In addition, under the Transition Agreement, Sanofi will provide us with certain transition services in support of ongoing regulatory approval efforts while we seek to obtain a new commercial partner or partners for the Sanofi Territory. We will pay certain transition service fees to Sanofi as part of the Transition Agreement.

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 Africa, the Middle East, Turkey, the CIS, including Russia, Mexico and Central America.

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 was approved by our stockholders at our annual meeting of stockholders held on October 27, 2017 and 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.

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

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, prior to the first quarter of 2017, we did not have sufficient information to reliably estimate expected returns of Qsymia at the time of shipment, and therefore revenue was recognized when units were dispensed to patients through prescriptions, at which point, the product is not subject to return.

Beginning in the first quarter of 2017, with 48 months of returns experience, we now believe that we have sufficient data and experience from selling Qsymia to reliably estimate expected returns. Therefore, beginning in the first quarter of 2017, we began recognizing revenue from the sales of Qsymia upon shipment and recording a reserve for expected returns at the time of shipment.

In accordance with this change in accounting estimate, we recognized a one-time adjustment of $7.3 million of revenues, net of expected returns reserve and gross-to-net charges, in the first quarter of 2017 relating to products that had been previously shipped.

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 reserves for product returns, certain prompt pay discounts and allowances offered to our customers, program rebates and chargebacks. These product revenue allowances are estimated and recognized as a reduction of revenue at the time of product shipment. We also offer discount programs to patients. Calculating these reserves and allowances 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 reserves and allowances on a quarterly basis. Amounts accrued for product revenue allowances are adjusted to reflect actual experience and when trends or significant events indicate that adjustment is appropriate.

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

	Product returns	Discount programs	Wholesaler/ Pharmacy fees	Cash discounts	Rebates/ Chargebacks	Total
Balance at January 1, 2015	$ —	$ (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*	(9,251)	(20,806)	(6,673)	(1,344)	(1,174)	(39,248)
Payments	1,397	17,429	6,870	1,362	991	28,049
Balance at December 31, 2017	$ (7,854)	$ (4,384)	$ (1,083)	$ (195)	$ (284)	$ (13,800)

* Current provision related to sales made during current period includes $38.7 million, $27.2 million and $28.7 million for product revenue allowances related to revenue recognized during the years ended December 31, 2017, 2016 and 2015, respectively. The remaining amounts for the respective years were recorded on the consolidated balance sheets as deferred revenue at the end of each period.

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, 2017 or 2016.

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, 2017, 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,		
	2017	2016	2015
Net product revenue	$ 44,983	$ 48,501	$ 54,622
License and milestone revenue	7,500	69,400	11,574
Supply revenue	10,407	2,291	26,674
Royalty revenue	2,483	4,066	2,560
Total revenue	$ 65,373	$ 124,258	$ 95,430

Net Qsymia product revenue

Net product revenue for 2016 and 2015 was recognized when units were dispensed to patients through prescriptions. Beginning in the first quarter of 2017, we began recognizing revenue from the sales of Qsymia upon shipment and recording a reserve for expected returns at the time of shipment. Net product revenue for 2017 includes a one-time adjustment of $7.3 million related to shipments which had previously been deferred. 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,		
	2017	2016	2015
Gross Qsymia product revenue	$ 85,044	$ 73,689	$ 83,338
Returns & allowances	(9,251)	—	—
Discount programs	(20,129)	(15,994)	(18,441)
Wholesaler/Pharmacy fees	(7,728)	(6,849)	(5,913)
Cash discounts	(1,697)	(1,474)	(1,656)
Rebates/Chargebacks	(1,256)	(871)	(2,706)
Net product revenue	$ 44,983	$ 48,501	$ 54,622

Prescriptions are as follows:

	Year Ended December 31,		
	2017	2016	2015
Prescriptions dispensed (in thousands)	395	442	566
Units shipped (in thousands)	441	442	526

Units shipped represent our direct shipments into the sales channel. We expect Qsymia net product revenue in 2018 to remain flat or decrease from 2017 levels due to market conditions.

License and milestone revenue

License and milestone revenue for 2017 consisted of a one-time $5.0 million payment earned for a license to certain clinical data related to phentermine and $2.5 million of license fees earned under the Alvogen License Agreement. License and milestone revenue for 2016 consisted of the $69.4 million earned for the granting of the license under the Metuchen License Agreement. License and milestone revenue for 2015 consisted of $11.6 million in license and milestone revenue with respect to STENDRA/SPEDRA, primarily attributable to the achievement of milestones under the Menarini agreement related to the approval of the Time-to-Onset Claim in the EU.

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, returned the U.S. and Canadian commercial rights for STENDRA to us on September 30, 2016. Also, on September 30, 2016, we entered into the Metuchen License Agreement and the Metuchen Supply Agreement, providing Metuchen with, among other rights, commercial rights to sell STENDRA/SPEDRA in the U.S., Canada, South America, and India. The Metuchen License Agreement does not include future royalties to us on the sales of STENDRA/SPENDRA in the Metuchen Territory. Our former partner, 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. We expect royalty revenue in 2018 to continue approximately at 2017 levels.

Cost of goods sold

	Year Ended December 31,		
	2017	2016	2015
Qsymia cost of goods sold	$ 7,537	$ 7,523	$ 8,720
STENDRA/SPEDRA cost of goods sold	9,650	3,079	25,437
Cost of goods sold	$ 17,187	$ 10,602	$ 34,157

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/SPEDRA shipped to our commercialization partners includes the inventory costs of API and tableting. Cost of goods sold increased overall in 2017 as compared to 2016 due primarily to increased STENDRA/SPEDRA supply revenue. The change in cost of goods sold as a percentage of net product and supply revenue was due to the sales mix between Qsymia and STENDRA/SPEDRA during the periods. The decrease in cost of goods sold in 2016 as compared to 2015 is due primarily to the decrease in both Qsymia product revenue and STENDRA/SPEDRA supply revenue.

Selling, general and administrative

	Years Ended December 31,			% Change Increase/(Decrease)	
	2017	2016	2015	2017 vs 2016	2016 vs 2015
	(In thousands, except percentages)				
Selling and marketing	$ 16,638	$ 21,775	$ 52,988	(24)%	(59)%
General and administrative	23,492	30,604	26,399	(23)%	16 %
Total selling, general and administrative expenses	$ 40,130	$ 52,379	$ 79,387	(23)%	(34)%

The decrease in selling and marketing expenses for 2017 compared to 2016 was due primarily to the cost saving efforts to reduce marketing programs and lower promotional activities for Qsymia. 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 general and administrative expenses in 2017 compared to 2016 was primarily due to the results of our continuing efforts to cut costs and lower spending for corporate activities. 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.

We expect selling and marketing expenses in general to remain flat or decrease in 2018 from 2017 as we continue our efforts to commercialize Qsymia in an efficient manner. General and administrative expenses could fluctuate significantly due to the timing of activities within and outcomes of our business strategy review.

Research and development

	Years Ended December 31,			% Change Increase/(Decrease)	
Drug Indication/Description	2017	2016	2015	2017 vs 2016	2016 vs 2015
	(In thousands, except percentages)				
Qsymia for obesity	$ 31	$ 1,335	$ 3,328	(98)%	(60)%
STENDRA for ED	127	147	840	(14)%	(83)%
PAH	2,189	—	—	N/A	N/A
Share-based compensation	345	493	398	(30)%	24 %
Overhead costs*	2,571	3,617	5,536	(29)%	(35)%
Total research and development expenses	$ 5,263	$ 5,592	$ 10,102	(6)%	(45)%

* 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 overall decrease in total research and development expenses in 2017 as compared to 2016 was primarily due to lower overhead costs as a result of our efforts to reduce discretionary spending and reductions in share-based compensation expense, partially offset by increases in spending for the development of tacrolimus for the treatment of PAH. 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.

We expect that our research and development expenses will increase in 2018 as we continue to complete our post-marketing requirements for Qsymia, specifically an adolescent safety and efficacy trial, and increase development activities for tacrolimus for the treatment of PAH. In addition, our research and development expenses could increase materially 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,		
	2017	2016	2015
Inventory impairment	$ —	$ —	$ 29,522
Employee severance and related costs	—	—	2,503
Share-based compensation	—	—	36
Total inventory impairment and other non-recurring expense	$ —	$ —	$ 32,061

In 2015, we recorded inventory impairment charges primarily for Qsymia API inventory in excess of expected demand. Also 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.

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. Other expense and income were not significant. We expect interest and other expense (income) for 2018 to remain relatively consistent with the levels from 2017.

Provision for (Benefit from) income taxes

We recorded a net provision for income taxes of $2,000 for the year ended December 31, 2017, as compared to $70,000 for the year ended December 31, 2016, and $3,000 for the year ended December 31, 2015. The tax provisions for all years are the result of certain state tax liabilities.

We periodically evaluate the realizability of our net deferred tax assets based on all available evidence, both positive and negative. The realization of net deferred tax assets is dependent on our ability to generate sufficient future taxable income during periods prior to the expiration of tax attributes to fully utilize these assets. We weighed both positive and negative evidence and determined that there is a continued need for a full valuation allowance on our deferred tax assets in the U.S. as of December 31, 2017.

LIQUIDITY AND CAPITAL RESOURCES

Cash. Cash, cash equivalents and available-for-sale securities totaled $226.3 million at December 31, 2017, as compared to $269.5 million at December 31, 2016. The decrease is primarily due to cash used in the funding of our operations, partially offset by cash received for product sales and license and milestone payments. We received payments for license and milestone revenue of $7.5 million, $70.0 million and $11.6 million in 2017, 2016 and 2015, 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, 2017, was $12.2 million, as compared to $9.5 million at December 31, 2016. Currently, we do not have any significant concerns related to accounts receivable or collections. As of February 28, 2018, we had collected 90% of the accounts receivable outstanding at December 31, 2017.

Liabilities. Total liabilities were $274.3 million at December 31, 2017, compared to $287.6 million at December 31, 2016. The increase in total liabilities was primarily due to timing differences in our various liability accounts.

Summary Cash Flows

	Years Ended December 31,		
	2017	2016	2015
	(in thousands)		
Cash provided by (used for):			
Operating activities	$ (16,364)	$ 38,165	$ (46,332)
Investing activities	24,012	(40,078)	67,404
Financing activities	(26,039)	(8,699)	(8,851)

Operating Activities. The decrease in cash from operating activities in 2017 as compared to 2016 was primarily due to the cash received in 2016 from the license agreement with Metuchen in addition to increases in accounts receivable balances, partially offset by increases in accounts payable and accrued liabilities. 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, in addition to decreased spending on inventory, partially offset by increases in accounts receivable.

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, 2017, 2016 and 2015 consist primarily of our repayments of $26.1 million, $8.7 million and $9.0 million, respectively, under our Senior Secured Notes.

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 pursue development and commercial opportunities, which could come in the form of a license, a co-development agreement, a merger or acquisition or in some other form, or to 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 and manufacture quantities of our 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, 2017, 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, 2017. The amounts below do not include contingent milestone payments or royalties, and assume the agreements and commitments will run through the end of terms, as such no early termination fees or penalties are included herein:

	Payments Due by Period				
Contractual obligations	**Total**	**2018**	**2019 - 2021**	**2022 - 2023**	**Thereafter**
			(in thousands)		
Operating leases	$ 2,798	$ 737	$ 2,061	$ —	$ —
Purchase obligations	18,762	18,762	—	—	—
Notes payable	256,187	6,187	250,000	—	—
Interest payable	29,263	11,763	17,500	—	—
Total contractual obligations	$ 307,010	$ 37,449	$ 269,561	$ —	$ —

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. We received an abatement of the monthly rent for the first four months on the lease term. 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.

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 $18.8 million as of December 31, 2017. We have no purchase commitments for raw material supplies for Qsymia at December 31, 2017, and have open purchase orders totaling $472,000.

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. 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. We paid Selten an upfront payment of $1.0 million, and we will pay additional 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, 2017, 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, 2017, by approximately $1.3 million. In general, money market funds are not subject to market risk because the interest paid on such funds fluctuates with the prevailing interest rate.

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

VIVUS, INC.

1. Index to Consolidated Financial Statements

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

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Stockholders and Board of Directors
VIVUS, Inc.
Campbell, California

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of VIVUS, Inc. (the "Company") as of December 31, 2017 and 2016, the related consolidated statements of operations, comprehensive (loss) income, stockholders' (deficit) equity, and cash flows for each of the three years in the period ended December 31, 2017, and the related notes and financial statement schedule listed in the accompanying index (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2017 and 2016, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2017, in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the Company's internal control over financial reporting as of December 31, 2017, based on criteria established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") and our report dated March 13, 2018 expressed an unqualified opinion thereon.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ OUM & CO. LLP

San Francisco, California
March 13, 2018
We have served as the Company's auditor since 2005.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Stockholders and Board of Directors
VIVUS, Inc.
Campbell, California

Opinion on Internal Control over Financial Reporting

We have audited VIVUS, Inc.'s (the "Company's") internal control over financial reporting as of December 31, 2017, based on criteria established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (the "COSO criteria"). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2017, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the consolidated balance sheets of the Company as of December 31, 2017 and 2016, the related consolidated statements of operations, comprehensive (loss) income, stockholders' (deficit) equity, and cash flows for each of the three years in the period ended December 31, 2017, and the related notes and financial statement schedule listed in the accompanying index and our report dated March 13, 2018 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Item 9A, Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit of internal control over financial reporting in accordance with the standards of the PCAOB. 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.

Definition and Limitations of Internal Control over Financial Reporting

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.

/s/ OUM & CO. LLP

San Francisco, California
March 13, 2018

VIVUS, INC.

CONSOLIDATED BALANCE SHEETS

(In thousands, except par value)

	December 31,	
	2017	**2016**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 66,392	$ 84,783
Available-for-sale securities	159,943	184,736
Accounts receivable, net	12,187	9,478
Inventories	17,712	16,186
Prepaid expenses and other current assets	7,178	8,251
Total current assets	263,412	303,434
Property and equipment, net	542	788
Non-current assets	1,014	1,554
Total assets	$ 264,968	$ 305,776
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY		
Current liabilities:		
Accounts payable	$ 10,072	$ 4,707
Accrued and other liabilities	21,475	15,686
Deferred revenue	2,075	19,174
Current portion of long-term debt	5,147	8,708
Total current liabilities	38,769	48,275
Long-term debt, net of current portion	230,536	232,610
Deferred revenue, net of current portion	4,674	6,449
Non-current accrued and other liabilities	327	257
Total liabilities	274,306	287,591
Commitments and contingencies		
Stockholders' (deficit) equity:		
Preferred stock; $1.00 par value; 5,000 shares authorized; no shares issued and outstanding at December 31, 2017 and 2016	—	—
Common stock; $.001 par value; 200,000 shares authorized; 105,977 and 104,874 shares issued and outstanding at December 31, 2017 and 2016, respectively	105	105
Additional paid-in capital	834,730	831,750
Accumulated other comprehensive loss	(608)	(616)
Accumulated deficit	(843,565)	(813,054)
Total stockholders' (deficit) equity	(9,338)	18,185
Total liabilities and stockholders' (deficit) equity	$ 264,968	$ 305,776

See accompanying notes to consolidated financial statements.

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

	Year Ended December 31,		
	2017	2016	2015
Revenue:			
Net product revenue	$ 44,983	$ 48,501	$ 54,622
License and milestone revenue	7,500	69,400	11,574
Supply revenue	10,407	2,291	26,674
Royalty revenue	2,483	4,066	2,560
Total revenue	65,373	124,258	95,430
Operating expenses:			
Cost of goods sold	17,187	10,602	34,157
Selling, general and administrative	40,130	52,379	79,387
Research and development	5,263	5,592	10,102
Inventory impairment and other non-recurring charges	—	—	32,061
Total operating expenses	62,580	68,573	155,707
Income (loss) from operations	2,793	55,685	(60,277)
Interest and other expense:			
Interest expense	33,231	32,888	33,317
Other expense (income), net	71	(575)	(490)
Interest expense and other expense, net	33,302	32,313	32,827
(Loss) income before income taxes	(30,509)	23,372	(93,104)
Provision for income taxes	2	70	3
Net (loss) income	$ (30,511)	$ 23,302	$ (93,107)
Basic and diluted net (loss) income per share:			
Basic net (loss) income per share	$ (0.29)	$ 0.22	$ (0.90)
Diluted net (loss) income per share	$ (0.29)	$ 0.22	$ (0.90)
Shares used in per share computation:			
Basic	105,741	104,385	103,926
Diluted	105,741	104,969	103,926

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

	Year Ended December 31,		
	2017	2016	2015
Net (loss) income	$ (30,511)	$ 23,302	$ (93,107)
Unrealized gain (loss) on securities, net of taxes	8	(355)	(233)
Comprehensive (loss) income	$ (30,503)	$ 22,947	$ (93,340)

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, January 1, 2015	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
Sale of common stock through employee stock purchase plan	51	—	38	—	—	38
Vesting of restricted stock units	1,052	—	—	—	—	—
Share-based compensation expense	—	—	2,942	—	—	2,942
Net unrealized loss on securities	—	—	—	8	—	8
Net loss	—	—	—	—	(30,511)	(30,511)
Balances, December 31, 2017	105,977	$ 105	$ 834,730	$ (608)	$ (843,565)	$ (9,338)

See accompanying notes to consolidated financial statements.

VIVUS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Year Ended December 31,		
	2017	2016	2015
Cash flows from operating activities:			
Net (loss) income	$ (30,511)	$ 23,302	$ (93,107)
Adjustments to reconcile net (loss) income to net cash (used for) provided by operating activities:			
Depreciation and amortization	811	1,080	1,387
Amortization of debt issuance costs and discounts	20,442	18,666	17,174
Amortization of discount or premium on available-for-sale securities	768	944	2,282
Share-based compensation expense	2,942	2,284	3,590
Loss on disposal of property and equipment	—	342	—
Inventory impairment charge	—	—	29,522
Changes in assets and liabilities:			
Accounts receivable	(2,709)	(481)	2,598
Inventories	(1,526)	(2,584)	(8,487)
Prepaid expenses and other assets	1,069	1,516	2,639
Accounts payable	5,365	(2,353)	(3,370)
Accrued and other liabilities	5,859	(1,524)	(889)
Deferred revenue	(18,874)	(3,027)	329
Net cash (used for) provided by operating activities	(16,364)	38,165	(46,332)
Cash flows from investing activities:			
Property and equipment purchases	(21)	(211)	(310)
Purchases of available-for-sale securities	(31,097)	(135,997)	(213,536)
Proceeds from maturity of available-for-sale securities	37,470	60,050	281,250
Proceeds from sales of available-for-sale securities	17,660	36,080	—
Net cash provided by (used for) investing activities	24,012	(40,078)	67,404
Cash flows from financing activities:			
Repayments of notes payable	(26,077)	(8,738)	(8,998)
Sale of common stock through employee stock purchase plan	38	39	147
Net cash used for financing activities	(26,039)	(8,699)	(8,851)
Net (decrease) increase in cash and cash equivalents	(18,391)	(10,612)	12,221
Cash and cash equivalents:			
Beginning of year	84,783	95,395	83,174
End of period	$ 66,392	$ 84,783	$ 95,395
Supplemental cash flow disclosure:			
Interest paid	$ 15,350	$ 15,368	$ 18,756
Income taxes paid	$ 47	$ 59	$ 58
Non-cash investing activities:			
Unrealized gain (loss) on securities	$ 8	$ (355)	$ (233)

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. The Company has 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. 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 patients with 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, 2017, the Company's accumulated deficit was approximately $843.6 million. Based on current plans, management expects to incur further losses for the foreseeable future. Management believes that the Company's existing capital resources combined with anticipated future cash flows will be sufficient to support its operating needs at least for the next twelve months. However, the Company anticipates that it may require additional funding to 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, 2017, 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

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, 2017 and 2016, all cash equivalents were invested in money market funds or U.S. Treasury securities. These investments are recorded at fair value (see Note 2).

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, 2017 or 2016. The allowance for cash discounts is $195,000 and $213,000 at December 31, 2017 and 2016, 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.

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. The Company began shipping Qsymia in September 2012 and grants rights to its customers to return unsold product from six months prior to and up to 12 months subsequent to product expiration. This has resulted in a potential return period of from 24 to 36 months depending on the ship date of the product. As the Company had no previous experience in selling Qsymia and given its lengthy return period, the Company was not initially able to reliably estimate expected returns of Qsymia at the time of shipment, and therefore recognized revenue when units were dispensed to patients through prescriptions, at which point, the product is not subject to return, or when the expiration period had ended.

Beginning in the first quarter of 2017, with 48 months of returns experience, the Company now believes that it has sufficient data and experience from selling Qsymia to reliably estimate expected returns. Therefore, beginning in the first quarter of 2017, the Company began recognizing revenue from the sales of Qsymia upon shipment and recording a reserve for expected returns at the time of shipment.

In accordance with this change in accounting estimate, in the first quarter of 2017 the Company recognized a one-time adjustment relating to products that had been previously shipped, consisting of $17.9 million of gross revenues, adjusted for an expected returns reserve of $5.7 million and estimated gross-to-net charges of $4.9 million, for a net impact of $7.3 million in revenues. The Company also recorded increased cost of goods sold of $0.6 million and marketing expense of $0.7 million associated with the change in accounting estimate. The increase in net product revenue resulted in a decrease in net loss of $6.0 million or $0.06 per share for 2017.

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 shipped to customers 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 $3.2 million, $3.9 million and $12.6 million in 2017, 2016 and 2015, 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, 2017, 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, 2017, 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):

	2017	2016	2015
Net income (loss)	$ (30,511)	$ 23,302	$ (93,107)
Basic:			
Weighted-average shares outstanding	105,741	104,385	103,926
Basic net income (loss) per share	$ (0.29)	$ 0.22	$ (0.90)
Diluted:			
Weighted-average shares outstanding used in basic calculation	105,741	104,385	103,926
Dilutive potential shares	—	584	—
Weighted-average shares outstanding used in diluted calculation	105,741	104,969	103,926
Diluted net income (loss) per share	$ (0.29)	$ 0.22	$ (0.90)

For the years ended December 31, 2017, 2016, and 2015, potentially dilutive outstanding stock options and RSUs of 13,499,000, 10,122,000 and 7,167,000, respectively, were not included in the computation of diluted net loss per share because the effect would have been anti-dilutive.

Recent Accounting Pronouncements Adopted

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 the lower of cost or 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." This 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 Company adopted this standard in the first quarter of 2017, and it did not have a material impact on the Company's condensed consolidated financial statements.

In March 2016, the FASB issued Accounting Standards Update 2016-09, *Compensation – Stock Compensation* (*Topic 718*): *Improvements to Employee Share-Based Payment Accounting*. This 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. The Company adopted this standard in the first quarter of 2017, and it did not have a material impact on the Company's condensed consolidated financial statements.

Recent Accounting Pronouncements Not Yet Adopted

In May 2014, the FASB issued Accounting Standards Update No. 2014-09, *Revenue from Contracts with Customers*. This 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 this 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." The Company plans to adopt this standard in the first quarter of 2018 using the modified retrospective basis. The Company has analyzed the effect of this standard on its consolidated financial statements and currently does not expect the adoption of this standard to have a material impact on the Company's net product revenues and supply revenues in the first quarter of adoption or on the timing of future recognition of net product revenues and supply revenues, as the Company expects that revenues generated will continue to be recognized upon the shipment of products to customers. Similarly, the Company does not expect a material impact on the recognition of royalty revenue. The Company does not expect the adoption of this standard to have a material impact on the Company's license and milestone revenue in the first quarter of adoption; however, the Company does expect that the timing of recognition of future milestone revenue related to current license and supply agreements as well as the timing and allocation of revenue related to any future license and supply agreements entered into by the Company may be impacted.

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. This 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, this 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, 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 overall recognition of expense will be similar to current guidance, though possibly in different classifications, 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 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, 2017			
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	$ 66,392	$ —	$ —	$ 66,392
U.S. Treasury securities	21,070	1	(139)	20,932
Corporate debt securities	139,481	16	(486)	139,011
Total	226,943	17	(625)	226,335
Less amounts classified as cash and cash equivalents	(66,392)	—	—	(66,392)
Total available-for-sale securities	$ 160,551	$ 17	$ (625)	$ 159,943

	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

As of December 31, 2017, the Company's available-for-sale securities have original contractual maturities up to 67 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, 2017			
	Level 1	Level 2	Level 3	Total
Cash and money market funds	$ 66,392	$ —	$ —	$ 66,392
U.S. Treasury securities	20,932	—	—	20,932
Corporate debt securities	—	139,011	—	139,011
Total	$ 87,324	$ 139,011	$ —	$ 226,335

	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

Note 3. Accounts Receivable

Accounts receivable consist of the following (in thousands):

	Balance as of	
	December 31, 2017	December 31, 2016
Qsymia	$ 10,400	$ 8,982
STENDRA/SPEDRA	1,982	709
	12,382	9,691
Qsymia allowance for cash discounts	(195)	(213)
Net	$ 12,187	$ 9,478

There was no allowance for doubtful accounts at December 31, 2017 or 2016.

Note 4. Inventories

Inventories consist of the following (in thousands):

	Balance as of	
	December 31, 2017	December 31, 2016
Raw materials	$ 13,663	$ 9,412
Work-in-process	2,264	2,984
Finished goods	1,785	3,110
Deferred costs	—	680
Inventories	$ 17,712	$ 16,186

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, 2017	December 31, 2016
Prepaid sales and marketing expenses	$ 1,538	$ 1,767
Prepaid insurance	1,124	1,182
Other prepaid expenses and assets	4,516	5,302
Total	$ 7,178	$ 8,251

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, 2017	December 31, 2016
Computers and software	$ 1,965	$ 1,965
Furniture and fixtures	185	516
Manufacturing equipment	213	213
Leasehold improvements	513	492
	2,876	3,186
Accumulated depreciation	(2,334)	(2,398)
Property and equipment, net	$ 542	$ 788

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, 2017	December 31, 2016
Accrued employee compensation and benefits	$ 3,642	$ 3,014
Reserve for product returns	7,854	—
Product-related accruals	5,751	671
Accrued interest on debt (see Note 13)	410	1,509
Accrued manufacturing costs	1,238	6,835
Accrued non-recurring charges (see Note 10)	—	5
Other accrued liabilities	2,580	3,652
Total	$ 21,475	$ 15,686

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 $0.3 million at December 31, 2017 and 2016, 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,		
	2017	2016	2015
Inventory impairment (see Note 4)	$ —	$ —	$ 29,522
Employee severance and related costs	—	—	2,503
Share-based compensation (see Note 15)	—	—	36
Total inventory impairment and other non-recurring expense	$ —	$ —	$ 32,061

As discussed in Note 1, 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.

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

	Severance obligations
Balance of accrued costs at December 31, 2014	$ 3,280
Charges	2,474
Payments	(5,344)
Balance of accrued costs at December 31, 2015	410
Charges	—
Reclassifications	(268)
Payments	(137)
Balance of accrued costs at December 31, 2016	5
Charges	—
Reclassifications	—
Payments	(5)
Balance of accrued costs at December 31, 2017	$ —

Note 11. Deferred Revenue

Deferred revenue consists of the following (in thousands):

	Balance as of	
	December 31, 2017	December 31, 2016
Qsymia deferred revenue - current	$ —	$ 17,558
STENDRA deferred revenue - current	2,075	1,616
Deferred revenue - current	$ 2,075	$ 19,174
STENDRA deferred revenue - non-current	$ 4,674	$ 6,449

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. Beginning in the first quarter of 2017, the Company began recognizing product revenue from the sales of Qsymia upon shipment. SPEDRA deferred revenue relates to a prepayment for future royalties on sales of SPEDRA.

Note 12. License, Commercialization and Supply Agreements

MTPC

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. The Company maintains royalty obligations to MTPC which have been passed through to our commercialization partners.

Menarini

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 transferred 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.

Auxilium

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.

Sanofi

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 March 23, 2017, the Company and Sanofi entered into the Termination, Rights Reversion and Transition Services Agreement, or the Transition Agreement, effective February 28, 2017. Under the Transition Agreement, effective upon the thirtieth (30th) day following February 28, 2017, the Sanofi License Agreement terminated for all countries in the Sanofi territory. In addition, under the Transition Agreement, Sanofi will provide the Company with certain transition services in support of ongoing regulatory approval efforts while the Company seeks to obtain a new commercial partner or partners for the Sanofi territory. The Company will pay certain transition service fees to Sanofi as part of the Transition Agreement.

Metuchen

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 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. 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 Metuchen License Agreement will terminate upon the expiration of the last-to-expire payment obligations under the Metuchen License Agreement; upon expiration of the term of the Metuchen License Agreement,

the exclusive license granted under the Metuchen 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.

Alvogen

In September 2017, the Company entered into a license and commercialization agreement, or the Alvogen License Agreement, and a commercial supply agreement, or the Alvogen Supply Agreement, with Alvogen Malta Operations (ROW) Ltd, or Alvogen. Under the terms of the Alvogen License Agreement, Alvogen will be solely responsible for obtaining and maintaining regulatory approvals for all sales and marketing activities for Qsymia in South Korea. The Company received an upfront payment of $2.5 million in September 2017, which was recorded in license and milestone revenue in the third quarter of 2017, and is eligible to receive additional payments upon Alvogen achieving marketing authorization, commercial launch and reaching a sales milestone. Additionally, the Company will receive a royalty on Alvogen's Qsymia net sales in South Korea. Under the Alvogen Supply Agreement, the Company will supply product to Alvogen.

Note 13. Long-Term Debt

Convertible Senior Notes Due 2020

In May 2013, the Company closed offerings of $250.0 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. Total net proceeds from the Convertible Notes were approximately $241.8 million. The Convertible Notes are convertible at a conversion rate of approximately $14.86 per share 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, 2017, total interest expense related to the Convertible Notes was $32.6 million, including amortization of $19.3 million of the debt discount and $1,023,000 of deferred financing costs. 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.

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, 2017, the interest expense related to the Senior Secured Notes was $3.2 million, including amortization of deferred financing costs amounting to $153,000. 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.

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

	December 31, 2017
Convertible Senior Notes due 2020	$ 250,000
Senior Secured Notes due 2018	6,187
	256,187
Less: Debt issuance costs	(1,040)
Less: Discount on convertible senior notes	(19,464)
	235,683
Less: Current portion	(5,147)
Long-term debt, net of current portion	$ 230,536

Future estimated payments as of December 31, 2017 are as follows:

2018	$ 17,950
2019	11,250
2020	256,250
Total	285,450
Less: Interest portion	(29,263)
Senior Secured Notes	$ 256,187

Note 14. Stockholders' Equity

Common Stock

The Company is authorized to issue 200,000,000 shares of common stock. As of December 31, 2017 and 2016, there were 105,977,000 and 104,874,000 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, 2017 and 2016, 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, November 2016 and October 2017, the Company's stockholders approved increases to the total number of shares reserved under the 2010 Plan by 5,950,000, 5,000,000 and 7,000,000 shares, respectively, for a total of 26,350,000 shares.

Restricted Stock Units

Beginning in 2012, the Company began issuing restricted stock 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, 2015	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
Granted	450,000	1.17
Vested	(621,851)	1.48
Forfeited	(78,366)	1.50
Restricted stock units outstanding, December 31, 2017	291,540	$ 1.78

Stock Options

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

	Years Ended December 31,					
	2017		2016		2015	
	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	9,568,143	$ 4.62	5,722,105	$ 7.97	5,956,459	$ 12.09
Granted	5,184,800	$ 1.06	4,980,835	$ 1.06	3,499,200	$ 2.46
Exercised	—	$ —	—	$ —	—	$ —
Cancelled	(506,201)	$ 2.17	(1,134,797)	$ 5.89	(3,733,554)	$ 9.38
Options outstanding at end of year	14,246,742	$ 3.41	9,568,143	$ 4.62	5,722,105	$ 7.97
Options exercisable at end of year	6,479,390	$ 6.10	3,740,459	$ 9.62	3,042,888	$ 11.48
Weighted average grant-date fair value of options granted during the year		$ 0.50		$ 0.55		$ 1.44

At December 31, 2017, stock options were outstanding and exercisable as follows:

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number Outstanding at December 31, 2017	Weighted-Average Remaining Contractual Life	Weighted-Average Exercise Price	Number Exercisable December 31, 2017	Weighted-Average Exercise Price
$ 0.70 — $ 1.00	763,000	6.81 years	$ 0.71	125,000	$ 0.70
$ 1.06 — $ 1.06	4,495,050	5.07 years	$ 1.06	2,171,851	$ 1.06
$ 1.12 — $ 1.12	4,117,100	6.07 years	$ 1.12	—	$ —
$ 1.15 — $ 25.74	4,871,592	3.72 years	$ 7.94	4,182,539	$ 8.88
$ 1.06 — $ 25.74	14,246,742	4.99 years	$ 3.41	6,479,390	$ 6.10

The aggregate intrinsic value of outstanding options as of December 31, 2017 was $0. At December 31, 2017, 11,043,868 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:

	2017	2016	2015
Expected life (in years)	4.27	4.33	4.69
Volatility	57.0 %	65.8 %	70.8 %
Risk-free interest rate	1.80 %	1.36 %	1.28 %
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, 2017, 1,783,614 shares have been issued to employees and there are 216,386 shares available for issuance under the ESPP. The weighted average fair value of shares issued under the ESPP in 2017, 2016 and 2015 was $0.23, $0.33 and $0.69 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:

	2017	2016	2015
Expected life (in years)	0.5	0.5	0.5
Volatility	47.4 %	50.0 %	63.4 %
Risk-free interest rate	1.2 %	0.5 %	0.2 %
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):

	2017	2016	2015
Cost of goods sold	$ 53	$ 147	$ 132
Selling, general and administrative	2,544	1,644	2,862
Research and development	345	493	398
Non-recurring charges	—	—	198
Total share-based compensation expense	$ 2,942	$ 2,284	$ 3,590

Total share-based compensation cost capitalized as part of the cost of inventory was $9,000, $33,000 and $23,000 for the years ended December 31, 2017, 2016 and 2015, respectively.

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

	2017	2016	2015
Restricted stock units	$ 924	$ 1,591	$ 1,409
Stock options	2,002	675	2,143
Employee stock purchase plan	16	18	38
	$ 2,942	$ 2,284	$ 3,590

As of December 31, 2017, unrecognized estimated compensation expense totaled $ 3.9 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 2.4 years and for the ESPP was less than 6 months.

Note 16. Commitments

Lease Commitments

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 received an abatement of the monthly rent for the first four months on the lease term. 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 lease at December 31, 2017, were as follows (in thousands):

2018	$ 531
2019	548
2020	564
2021	435
	$ 2,078

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, 2017 and 2016, are as follows (in thousands):

	2017	2016
Deferred tax assets:		
Net operating loss carry forwards	$ 152,947	$ 220,053
Research and development credit carry forwards	17,426	16,550
Share-based compensation	5,248	7,579
Accruals and other	13,741	21,833
Depreciation	(36)	75
Deferred revenue	1,486	3,123
	190,812	269,213
Valuation allowance	(190,812)	(269,213)
Total	$ —	$ —

The net decrease in the valuation allowance in 2017 and 2016 was $78.4 million and $15.2 million, respectively. As of December 31, 2017, the Company had no significant deferred tax liabilities.

On December 22, 2017, the Tax Cuts and Jobs Act was signed into law. Among other changes is a permanent reduction in the federal corporate income tax rate from 35% to 21% effective January 1, 2018. As a result of the reduction in the corporate income tax rate, the Company will need to revalue its net deferred tax asset at December 31, 2017. We estimate that this will result in a reduction in the value of our net deferred tax asset of approximately $98.4 million, which will be offset by the change in valuation allowance of $98.4 million.

As of December 31, 2017, the Company had approximately $640.4 million and $276.2 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, 2017, the Company has federal and state research credit carryforwards of approximately $13.2 million, and $5.3 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 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 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 December 31, 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.

In March 2016, the FASB issued ASU 2016-09, *Improvements to Employee Share-Based Payment Accounting*. This guidance affects entities that issue share-based payment awards to their employees and is designed to simplify several aspects of accounting for share-based payment award transactions which include the income tax consequences, classification of awards as either equity or liabilities, classification on the statement of cash flows and forfeiture rate calculations. The Company adopted this standard in the first quarter of 2017. Under ASU 2016-09, excess tax benefits and deficiencies are required to be recognized prospectively as part of provision for income taxes rather than additional paid-in capital. The Company's cumulative effect of windfall tax attributes are approximately $17.4 million. After applying the valuation allowance, no adjustment was recorded to the beginning retained earnings balance.

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

	2017	2016	2015
Income (loss) before income taxes:			
Domestic	$ (30,371)	$ 23,592	$ (92,967)
International	(138)	(220)	(137)
Income (loss) before taxes	$ (30,509)	$ 23,372	$ (93,104)

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

	2017	2016	2015
Current:			
Federal	$ —	$ —	$ —
State	2	70	3
Foreign	—	—	—
Total current provision (benefit) for income taxes	$ 2	$ 70	$ 3
Deferred:			
Federal	$ —	$ —	$ —
State	—	—	—
Foreign	—	—	—
Total deferred provision for income taxes	$ —	$ —	$ —
Total provision (benefit) for income taxes from continuing operations	$ 2	$ 70	$ 3

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

	2017	2016	2015
Tax at U.S. federal statutory rate	(35)%	35 %	(35)%
State income taxes, net of federal tax effect	(1)	4	(2)
Change in valuation allowance	(310)	(67)	31
Permanent items	24	28	6
Tax credits	(1)	—	—
Tax Cuts and Jobs Act impact	323	—	—
Effective tax rate	— %	— %	— %

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

	2017	2016	2015
Unrecognized tax benefits as of January 1	$ 65	$ 38	$ —
Gross increase/(decrease) for tax positions of prior years	—	2	—
Gross increase/(decrease) for tax positions of current year	45	25	38
Unrecognized tax benefits balance at December 31	$ 110	$ 65	$ 38

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

	2017	2016
Total unrecognized tax benefits	$ 110	$ 65
Amounts netted against deferred tax assets	(110)	(65)
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,					
	2017			2016		
	U.S.	ROW	Total	U.S.	ROW	Total
Qsymia—Net product revenue	$ 44,983	$ —	$ 44,983	$ 48,501	$ —	$ 48,501
Qsymia—License revenue	5,000	2,500	7,500	—	—	—
STENDRA/SPEDRA—License revenue	—	—	—	69,400	—	69,400
STENDRA/SPEDRA—Supply revenue	5,909	4,498	10,407	765	1,526	2,291
STENDRA/SPEDRA —Royalty revenue	—	2,483	2,483	1,649	2,417	4,066
Total revenue	$ 55,892	$ 9,481 (1)	$ 65,373	$ 120,315	$ 3,943 (2)	$ 124,258

	2015		
	U.S.	ROW	Total
Qsymia—Net product revenue	$ 54,622	$ —	$ 54,622
STENDRA/SPEDRA—License and milestone revenue	—	11,574	11,574
STENDRA/SPEDRA—Supply revenue	16,602	10,072	26,674
STENDRA/SPEDRA —Royalty revenue	418	2,142	2,560
Total revenue	$ 71,642	$ 23,788 (3)	$ 95,430

(1) $7.0 million of which is attributable to Germany.

(2) $3.9 million of which is attributable to Germany.

(3) $23.7 million of which is attributable to Germany.

Major customers

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

	2017	2016	2015
McKesson	37 %	34 %	37 %
Amerisource Bergen	32 %	35 %	31 %
Cardinal Health, Inc.	29 %	29 %	30 %

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

	2017	2016
Amerisource Bergen	42 %	40 %
McKesson	28 %	30 %
Cardinal Health, Inc.	28 %	21 %

Major suppliers

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. Catalent Pharma Solutions, LLC, or Catalent, is the Company's sole source of clinical and commercial supplies for Qsymia. Sanofi Chimie manufactures and supplies 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. Sanofi Winthrop Industrie manufactures and supplies 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. Third-party manufacturers may not be able to meet the Company's needs with respect to timing, quantity or quality.

During the years ended December 31, 2017, 2016 and 2015, 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 0%, 27% and 11%, 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, 2017, 2016 and 2015 were $272,000, $272,000 and $406,000, 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. The Ninth Circuit issued a decision on January 16, 2018, affirming the district court's dismissal of the action. The deadline for Plaintiffs to seek rehearing in the Ninth Circuit has now expired, and unless Plaintiffs elect to file a petition for certiorari in the Supreme Court, the matter is concluded. 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.

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.

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 were consolidated into a single suit (Case No. 14-3786 (SRC)(CLW)).

On June 29, 2017, the Company entered into a settlement agreement with Actavis resolving the suit against Actavis. On July 5, 2017, the U.S. District Court for the District of New Jersey entered an order dismissing the suit. In accordance with legal requirements, we have submitted the settlement agreement to the U.S. Federal Trade Commission and the U.S. Department of Justice for review.

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.

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 were consolidated into a single suit (Case No. 15-2693 (SRC)(CLW)). 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.

On August 28, 2017, the Company entered into a settlement agreement with DRL resolving the suit against DRL. On September 6, 2017, the U.S. District Court for the District of New Jersey entered an order dismissing the suit. In accordance with legal requirements, we have submitted the settlement agreement to the U.S. Federal Trade Commission and the U.S. Department of Justice for review.

The settlement agreement with DRL resolves all patent litigation brought by VIVUS against generic pharmaceutical companies that have filed ANDAs seeking approval to market generic versions of Qsymia.

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
2017				
Total revenue	$ 27,012	$ 11,227	$ 15,193	$ 11,941
Total gross profit	20,845	7,657	11,679	8,005
Operating expenses	19,778	16,214	12,767	13,821
Net (loss) income	(1,056)	(13,386)	(5,994)	(10,075)
Basic and diluted net (loss) income per share	$ (0.01)	$ (0.13)	$ (0.06)	$ (0.10)
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

Note 22. Subsequent Events

On February 26, 2018, the Company and Allan L. Shaw entered into a Consulting Agreement, or the Consulting Agreement, effective February 1, 2018. The Consulting Agreement provides that the Company will recommend at the next meeting of the Compensation Committee of the Board of Directors that Mr. Shaw be granted a stock option to purchase 300,000 shares of the Company's common stock at a price per share equal to the fair market value as determined by the closing price of the Company's common stock on the date of grant. On March 9, 2018, the Compensation Committee of the Board of Directors of the Company authorized and approved the grant to Mr. Shaw of a stock option to purchase 300,000 shares of the Company's common stock at a price per share equal to the closing price of the Company's common stock on the date of grant ($0.49 per share). The shares will vest in accordance with a vesting schedule subject to Mr. Shaw continuing to provide services under the Consulting Agreement on the relevant vesting dates.

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, 2015	$ 150	$ 1,933	$ (1,919)	$ 164
Fiscal year ended December 31, 2016	$ 164	$ 1,679	$ (1,630)	$ 213
Fiscal year ended December 31, 2017	$ 213	$ 1,344	$ (1,362)	$ 195

* Amount charged to operations during fiscal years ended December 31, 2017, 2016 and 2015, includes $1,697,000, $1,474,000 and $1,656,000, 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 Disagreements with Accountants on Accounting and Financial Disclosure***

None.

Item 9A. ***Controls and Procedures***

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 Interim 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 Interim 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 Interim 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 Interim 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, 2017.

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, 2017. This report, which expresses an unqualified opinion on the effectiveness of our internal controls over financial reporting as of December 31, 2017, 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 Information***

None.

PART III

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

The information required by this item is hereby incorporated by reference from the information under the captions "Election of Directors," "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 2018 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 Compensation*

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 Owners and Management and Related Stockholder Matters*

Equity Compensation Plan Information

Information about our equity compensation plans at December 31, 2017, 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)	14,538,282	$ 3.34	4,260,254
Equity compensation plans not approved by stockholders(b)	—	—	—
Total	14,538,282	$ 3.34	4,260,254

(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 4,043,868 shares for the 2010 Equity Incentive Plan and 216,386 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 Relationships and Related Transactions, and Director Independence***

The information required by this item is incorporated by reference from the information under the caption "Certain Relationships and Related Transactions" and "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 Schedules***

(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.

VIVUS, INC.
REPORT ON FORM 10-K FOR
THE YEAR ENDED DECEMBER 31, 2017
EXHIBIT INDEX

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)*	2010 Equity Incentive Plan
10.11(25)*	Stand-Alone Stock Option Agreement with Michael P. Miller dated as of April 30, 2010
10.12(26)†	Agreement effective as of December 28, 2000, between the Registrant and Tanabe Seiyaku Co., Ltd.
10.13(27)	Amendment No. 1 effective as of January 9, 2004, to the Agreement effective as of December 28, 2000, between the Registrant and Tanabe Seiyaku Co., Ltd.
10.14(28)	Termination and Release executed by Tanabe Holding America, Inc. dated May 1, 2007
10.15(29)†	Second Amendment effective as of August 1, 2012, to the Agreement dated as of December 28, 2000, between the Registrant and Mitsubishi Tanabe Pharma Corporation (formerly Tanabe Seiyaku Co., Ltd.)
10.16(30)†	Third Amendment effective as of February 21, 2013, to the Agreement dated as of December 28, 2000, between the Registrant and Mitsubishi Tanabe Pharma Corporation (formerly Tanabe Seiyaku Co., Ltd.)
10.17(31)†	Settlement and Modification Agreement dated July 12, 2001, between ASIVI, LLC, AndroSolutions, Inc., Gary W. Neal and the Registrant
10.18(32)†	Assignment Agreement between Thomas Najarian, M.D. and the Registrant dated October 16, 2001
10.19(33)†	Master Services Agreement dated as of September 12, 2007, between the Registrant and Medpace, Inc.

Exhibit Number	Description
10.20(34)†	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
10.21(35)†	Commercial Manufacturing and Packaging Agreement by and between the Registrant and Catalent Pharma Solutions, LLC dated as of July 17, 2012
10.22(36)	Lease Agreement effective December 11, 2012, by and between the Registrant and SFERS Real Estate Corp. U.
10.23(37)†	Purchase and Sale Agreement effective as of March 25, 2013, between the Registrant and BioPharma Secured Investments III Holdings Cayman LP
10.24(38)	Capped Call Confirmation dated May 15, 2013, by and between the Registrant and Deutsche Bank AG, London Branch
10.25(39)*	Form of Amended and Restated Change of Control and Severance Agreement
10.26(40)†	License and Commercialization Agreement dated July 5, 2013, between the Registrant and Berlin-Chemie AG
10.27(41)†	Commercial Supply Agreement dated as of July 5, 2013, between the Registrant and Berlin-Chemie AG
10.28(42)	Agreement dated July 18, 2013, by and between the Registrant and First Manhattan Co.
10.29(43)*	Letter Agreement dated July 18, 2013, by and among the Registrant, First Manhattan Co. and Peter Y. Tam
10.30(44)	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
10.31(45)†	Commercial Supply Agreement dated July 31, 2013, by and between the Registrant and Sanofi Chimie
10.32(46)*	Employment Agreement dated September 3, 2013, by and between the Registrant and Seth H. Z. Fischer
10.33(47)†	License and Commercialization Agreement dated as of October 10, 2013, by and between the Registrant and Auxilium Pharmaceuticals, Inc.
10.34(48)†	Commercial Supply Agreement dated as of October 10, 2013, by and between the Registrant and Auxilium Pharmaceuticals, Inc.
10.35(49)*	Letter Agreement dated November 4, 2013, by and between the Registrant and Timothy E. Morris
10.36(50)†	Manufacturing and Supply Agreement dated November 18, 2013, by and between the Registrant and Sanofi Winthrop Industrie
10.37(51)†	License and Commercialization Agreement dated December 11, 2013, by and between the Registrant and Sanofi
10.38(52)†	Supply Agreement effective as of December 11, 2013, by and between the Registrant and Sanofi Winthrop Industrie
10.39(53)†	Patent Assignment Agreement, dated August 24, 2014, by and between the Registrant and Janssen Pharmaceuticals, Inc.
10.40(54)*	Letter Agreement dated April 13, 2015, by and between the Registrant and Guy P. Marsh
10.41(55)*	Form of Second Amended and Restated Change of Control and Severance Agreement
10.42(56)*	Letter Agreement dated July 20, 2015, by and between the Registrant and Wesley W. Day, Ph.D.
10.43(57)*	Letter Agreement dated August 17, 2015, by and between the Registrant and Svai S. Sanford
10.44(58)	Letter Regarding Termination Notice dated December 30, 2015, from Auxilium Pharmaceuticals, Inc. and Endo Ventures Limited to the Registrant
10.45(59)	Letter Regarding Termination Notice dated as of June 30, 2016, from Auxilium Pharmaceuticals, Inc. and Endo Ventures Limited to the Registrant
10.46(60)	Letter Regarding Termination Notice dated as of August 29, 2016, from Auxilium Pharmaceuticals, LLC and Endo Ventures Limited to the Registrant
10.47(61)	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.
10.48(62)	Office Lease effective September 2, 2016, between the Registrant and AG-SW Hamilton Plaza Owner, L.P.

Exhibit Number	Description
10.49(63)†	License and Commercialization Agreement dated as of September 30, 2016, by and between the Registrant and Metuchen Pharmaceuticals LLC
10.50(64)†	Commercial Supply Agreement dated as of September 30, 2016, by and between the Registrant and Metuchen Pharmaceuticals LLC
10.51(65)†	Patent Assignment Agreement dated as of January 6, 2017, by and between the Registrant and Selten Pharma, Inc.
10.52(66)†	License Assignment Agreement dated as of January 6, 2017, by and between the Registrant and Selten Pharma, Inc.
10.53(67)†	Termination, Rights Reversion and Transition Services Agreement dated March 23, 2017, by and between the Registrant and Sanofi
10.54(68)†	Settlement Agreement dated June 29, 2017, by and between the Registrant and Actavis Laboratories FL, Inc.
10.55*††	Confidential Separation, General Release and Post-Separation Consulting Agreement effective December 31, 2017, between the Registrant and Seth H. Z. Fischer
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 Interim 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 Interim 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, 2017, 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) Income, (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 4.1 filed with the Registrant's Registration Statement on Form S-8 filed with the SEC on December 15, 2017.

(25) 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.

(26) Incorporated by reference to Exhibit 10.15 filed with the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2012, filed with the SEC on February 26, 2013.

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

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

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

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

(31) Incorporated by reference to Exhibit 10.20 filed with the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2012, filed with the SEC on February 26, 2013.

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

(33) 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.

(34) 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.

(35) 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.

(36) 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.

(37) 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.

(38) 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.

(39) 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.

(40) 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.

(41) 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.

(42) 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.

(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 24, 2013.

(44) 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.

(45) 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.

(46) 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.

(47) 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.

(48) 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.

(49) 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.

(50) 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.

(51) 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.

(52) 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.

(53) 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.

(54) 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.

(55) 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.

(56) 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.

(57) 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.

(58) 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.

(59) 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.

(60) 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.

(61) 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.

(62) 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.

(63) 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.

(64) 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.

(65) Incorporated by reference to Exhibit 10.55 filed with the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2016, filed with the SEC on March 8, 2017.

(66) Incorporated by reference to Exhibit 10.56 filed with the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2016, filed with the SEC on March 8, 2017.

(67) Incorporated by reference to Exhibit 10.3 filed with the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2017, filed with the SEC on May 3, 2017.

(68) 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, 2017, filed with the SEC on August 3, 2017.

SIGNATURES

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

VIVUS, INC.,
a Delaware Corporation

By: /s/ Thomas B. King
Thomas B. King
Interim Chief Executive Officer
(Principal Executive Officer)

Date: March 13, 2018

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints each of Thomas B. King 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/ Thomas B. King Thomas B. King	Interim Chief Executive Officer (Principal Executive Officer) and Director	March 13, 2018
/s/ David Y. Norton David Y. Norton	Chairman of the Board of Directors and Director	March 13, 2018
/s/ Mark K. Oki Mark K. Oki	Chief Financial Officer and Chief Accounting Officer (Principal Financial and Accounting Officer)	March 13, 2018
/s/ Jorge Plutzky, M.D. Jorge Plutzky, M.D.	Director	March 13, 2018
/s/ Eric W. Roberts Eric W. Roberts	Director	March 13, 2018
/s/ Herman Rosenman Herman Rosenman	Director	March 13, 2018
/s/ Allan L. Shaw Allan L. Shaw	Director	March 13, 2018

Exhibit 10.55

***** 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.**

CONFIDENTIAL SEPARATION, GENERAL RELEASE AND POST-SEPARATION CONSULTING AGREEMENT

This Confidential Separation, General Release and Post-Separation Consulting Agreement (the "**Agreement**") is being entered into between Seth H.Z. Fischer ("Executive") and VIVUS, Inc. (the "Company") in connection with the termination of Executive's employment with the Company on December 31, 2017 (the "**Separation Date**").

Whereas, in connection with Executive's termination of employment effective as of December 31, 2017, Executive is eligible to receive the severance benefits provided in Section 4 of the Employment Agreement (the "**Employment Agreement**") dated August 30, 2013, subject to the terms and conditions set forth therein including (but not limited to) entering into this Confidential Separation Agreement and General Release in favor of the Company under Section 4.11 of the Employment Agreement and the provisions of Section 8 of the Employment Agreement.

Whereas, in consideration for such severance benefits provided under Section 4 of the Agreement (the "**Severance Benefits**") and in full satisfaction of any and all obligations of the Company in the Employment Agreement, the parties wish to resolve any and all disputes, claims, complaints, grievances, charges, actions, petitions, and demands that Executive may have against the Company and any of the Releasees as defined below, including, but not limited to, any and all claims arising out of or in any way related to Executive's employment with or separation from the Company.

Whereas, the Company wishes to retain Executive as a consultant following the termination of his employment relationship so that Executive may advise the Company's executives on matters within Executive's expertise.

Now, therefore, Executive covenants and agrees as follows:

1. Unpaid Wages and Vacation. Executive and the Company acknowledge and agree that Executive has been paid, or will be paid, all outstanding, accrued compensation, salary, bonuses, and commissions, together with any accrued but unused vacation (the "Accrued Compensation," as defined in Section 4.2 of the Employment Agreement), through the Separation Date in accordance with applicable law.

2. Benefits. As of Executive's Separation Date, Executive is not eligible to accrue additional benefits under any of the Company's benefit plans, including, but not limited to, any dental or medical insurance, long term care plans, retirement or 401(k) plans, vacation leave, sick leave, long term disability insurance, life insurance, or personal accident insurance. Executive may be eligible to participate in a Consolidated Omnibus Budget Reconciliation Act of 1986, as amended ("**COBRA**") continuation coverage program or any similar state medical and dental insurance continuation coverage program and exercise conversion rights with respect to any group life insurance. Executive shall be entitled to payment of Accrued Amounts under the terms and conditions of any Company benefit plans or programs.

3. Acknowledgement. Executive acknowledges and agrees that, other than the payments described in Section 1 of this Agreement and the Severance Benefits as defined in Section 4 below, he has

no entitlement to additional compensation or benefits due from his employment. Executive further agrees that any Severance Benefit is not compensation for Executive's services rendered through Executive's Separation Date, but rather constitutes consideration for the promises contained in this Agreement.

4. Severance Benefits. In consideration of Executive entering into this Agreement (and not revoking it) and agreeing to fully abide by its terms, and in full satisfaction of any and all obligations of the Company to Executive in the Employment Agreement, the Company shall pay to Executive following the Effective Date of this Agreement the following "Severance Benefits":

(a) Twelve (12) equal monthly severance payments each in the amount of $60,083.34, which is the equivalent of the monthly Base Salary which Executive was receiving as of the Separation Date, for a total payment of $721,000.08, with the first payment beginning no later than January 31, 2018;

(b) Twelve (12) equal monthly severance payments each in the amount of $48,066.67, which is the equivalent of one-twelfth (1/12th) of the Executive's Target Bonus for the fiscal year in which the termination occurred, for a total payment of $576,800.04, with the first payment beginning no later than January 31, 2018; and

(c) A single, lump sum cash payment in the amount of $576,800.04 which is equivalent to the prorated amount of the Executive's Target Bonus for the fiscal year in which the termination occurred, with any such prorated bonus to be paid January 31, 2018.

The Company will withhold the appropriate federal, state and local taxes, as determined by the Company, from all Severance Benefits paid under this Agreement. The Company's obligation to pay Severance shall automatically terminate upon Executive's breach of any of the provisions of this Agreement, and any Severance Benefits already paid to Executive prior to such breach shall become immediately due and repayable to the Company.

5. Consulting Services.

(a) Following the Separation Date, and at the request of the Company, Executive will consult with the Company's executive officers and other employees regarding certain of the Company's business and activities and Executive will be responsible for and undertake special projects, in any case as assigned by the Company in its sole discretion to Executive from time to time, for a period of one (1) year following the Separation Date. In this regard, Executive acknowledges that during the first three (3) months of the term of this Agreement, it is likely that he will be requested to consult on ***. Although *** is expected to require substantial time and effort of Executive, neither the Company nor Executive expects the time and effort of Executive to remain at such levels on a sustained basis over the remaining term of this Agreement. Executive further acknowledges that the consultation is to be performed from Executive's home and, upon reasonable advanced notice, the Company's office in California, but that the consultation also may require Executive to travel from time to time.

(b) From and after the Separation Date, Executive shall be an independent contractor of the Company, and this Agreement shall not be construed to create any association, partnership, joint

venture, employee or agency relationship between Executive and the Company for any purpose. After the Separation Date, Executive shall have no authority to bind the Company or its affiliates, and Executive shall not attempt to obligate or bind the Company or any of its affiliates in any way without the Company's prior approval. All documents, including but not limited to contracts, agreements, letters of intent, employment agreements and leases, that purport to bind or obligate the Company or any of its affiliates in any respect must be signed by the appropriate representative(s) of the Company.

(c) The Company will provide Executive with support services in its California office for the consulting period following the Separation Date to the extent determined necessary and reasonable by the Company. During the consulting period, Executive may be engaged or employed in any other business, trade, profession or other activity which does not place Executive in a conflict of interest with the Company; provided, that, during the consulting period, Executive shall not be engaged in any business activities that do or may compete with the business of the Company, without the Company's prior written consent to be given or withheld in its sole discretion.

(d) As compensation for Executive's consultation, Executive shall continue to be a Service Provider as defined in the Company's 2010 Equity Incentive Plan (the "**Plan**") and the Equity Awards will continue vesting in accordance with the Plan until the Consultation Termination Date (as defined below) ("**Consulting Fee**"). Executive acknowledges and agrees that the Consulting Fee does not constitute compensation for Executive's time worked and services rendered through the Separation Date, but rather constitutes consideration for Executive's agreement to provide consulting services to the Company on an "as needed" basis and as an independent consultant for the one (1) year period following the Separation Date, and that such consideration is above and beyond any wages, salary or other sums to which Executive is entitled from the Company under the terms of his employment with the Company or under any other contract or law. Executive shall be responsible for costs or expenses incurred by Executive in connection with the performance of the consulting services, and in no event shall the Company reimburse Executive for any such costs or expenses, except that the Company will reimburse Executive for travel-related expenses when the Company requests that Executive travel in order to provide the consulting services, and the Company pre-approves any such expenses.

(e) The Plan and the Notice of Grant for each Stock Option (as defined below) shall hereby be amended such that each such Stock Option shall be exercisable until the earlier of the Term/Expiration Date specified in each such Notice of Grant or such date as the Stock Option is terminated in accordance with the Plan; provided, however, that any portion of a Stock Option that vests during the period beginning with the Separation Date of this Agreement and ending on such date as the Bring Down Release is delivered by Executive and becomes effective (the "**Bring Down Date**") may not be exercised until after the Bring Down Date.

(f) For purposes of the Agreement, the Equity Awards shall mean the Stock Options and the RSUs set forth below, as of the Separation Date.

STOCK OPTIONS

Grant No.	Grant Date	Plan/Type	Shares	Vested	Unvested	Termination
00003582	09/03/2013	2010/ISO	31,004	31,004	0	09/03/2020
00003583	09/03/2013	2010/NQ	968,996	968,996	0	09/03/2020
00003981	01/23/2015	2010/NQ	542,508	421,854	120,654	01/23/2022
00004089	01/22/2016	2010/NQ	1,000,000	479,166	520,834	01/22/2023
00004190	01/27/2017	2010/NQ	1,000,000	0	1,000,000	01/27/2024
0003975	01/23/2015	2010/ISO	86,092	36,500	49,592	01/23/2022

RSUs

Grant No.	Grant Date	Plan/Type	Shares	Vested	Unvested
00003968	01/23/2015	2010/RSU	66,000	45,375	20,625
00004002	07/31/2015	2010/RSU	117,000	117,000	0
00004183	09/26/2016	2010/RSU	300,000	262,500	37,500
00004258	01/27/2017	2010/RSU	150,000	0	150,000

(g) The Company is and shall be, the sole and exclusive owner of all right, title and interest throughout the world in and to all the results and proceeds of the consulting services performed under this Agreement (the "**Deliverables**"), including all patents, copyrights, trademarks, trade secrets and other intellectual property rights (collectively "**Intellectual Property Rights**").

(h) The Company may terminate the consulting services provided under this Agreement upon written notice to Executive if the Company determines that Executive is not willing, available or able to provide the required consulting services after reasonable attempts by the Company to obtain such consulting services from Executive. The Company may also terminate this Agreement upon written notice to Executive for any reason after July 31, 2018. The consulting relationship will terminate, unless mutually renewed by both the Executive and the Company in writing, on the one (1) year anniversary of the Separation Date. In the event of termination pursuant to this Section 5(h) ("**Consultation Termination Date**"), Executive shall be a Service Provider under the Plan and the Equity Awards shall continue to vest through the date of termination of the consulting relationship.

(i) Executive agrees to execute a second release, in the form attached to this Agreement as Exhibit A (the "**Bring Down Release**"), on or within five (5) days of the Consultation

Termination Date, which Bring Down Release shall cover the period from the date of execution of this Agreement through the Consultation Termination Date.

6. Deferred Compensation. Notwithstanding anything in this Agreement to the contrary, if (i) on the date of Executive's "separation from service" within the meaning of Section 409A of the Internal Revenue Code of 1986, as amended (the "**Code**," and such separation, a "**Separation from Service**"), any of the Company's stock is publicly traded on an established securities market or otherwise (within the meaning of Section 409A(a)(2)(B)(i) of the Code), (ii) Executive is determined to be a "specified employee" within the meaning of Section 409A(a)(2)(B) of the Code, (iii) the payments or benefits provided to Executive from the Company on account of Executive's Separation from Service, to the extent such payments or benefit (after taking into account all exclusions applicable to such payments or benefits under Section 409A of the Code) is properly treated as "deferred compensation" subject to Section 409A and (iv) such delay is required to avoid the imposition of the tax set forth in Section 409A(a)(1) of the Code, as a result of such Separation from Service, Executive would receive any payment that, absent the application of this Section 8, would be subject to interest and additional tax imposed pursuant to Section 409A(a) of the Code as a result of the application of Section 409A(a)(2)(B)(i) of the Code, then no such payment shall be payable prior to the date that is the first business day after the earliest of (A) six (6) months after Executive's termination date, (B) Executive's death or (C) such other date as will cause such payment not to be subject to such interest and additional tax (with a catch-up payment equal to the sum of all amounts that have been delayed to be made as of the date of the initial payment).

7. General Release. Except for any rights granted under this Agreement, Executive, for himself, and for his heirs, assigns, executors and administrators, hereby releases, remises and forever discharges the Company, its parents, subsidiaries, affiliates, divisions, predecessors, successors, assigns, and their directors, officers, partners, attorneys, shareholders, administrators, employees, agents, representatives, employment benefit plans, plan administrators, fiduciaries, trustees, insurers and re-insurers, and all of their predecessors, successors and assigns, (collectively, the "**Releasees**"), of and from all claims, causes of action, covenants, contracts, agreements, promises, damages, disputes, demands, and all other manner of actions whatsoever, in law or in equity, that Executive ever had, may have had, now has, or that his heirs, assigns, executors or administrators hereinafter can, shall or may have, whether known or unknown, asserted or unasserted, suspected or unsuspected in connection with Executive's employment or the termination of that employment, or any act or omission with respect to Executive's employment which has occurred at any time up to and including the date of the execution of this Release (the "**Released Claims**").

(a) Released Claims. The Released Claims released include, but are not limited to, any claims for monetary damages; any claims related to Executive's employment with the Company or the termination thereof; any claims to severance or similar benefits; any claims to expenses, attorneys' fees or other indemnities ; any claims based on actions or failure to act on or before the date of this Agreement; any claims for other personal remedies or damages sought in any legal proceeding or charge filed with any court or federal, state or local agency either by one (1) or by a person claiming to act on Executive's behalf or in Executive's interest. Executive understands that the Released Claims might have arisen under many different local, state and federal statutes, regulations, case law and/or common law doctrines. Executive

hereby specifically, but without limitation, agrees to release all of the Releasees from any and all claims under the following:

i. Antidiscrimination laws, such as Title VII of the Civil Rights Act of 1964, as amended, and Executive Order 11246 (which prohibit discrimination based on race, color, national origin, religion, or sex); Section 1981 of the Civil Rights Act of 1866 (which prohibits discrimination based on race or color); the Americans with Disabilities Act and Sections 503 and 504 of the Rehabilitation Act of 1973 (which prohibit discrimination based upon disability); the Age Discrimination in Employment Act, as amended, 29 U.S.C. Section 621 *et seq*. (which prohibits discrimination on the basis of age); the Equal Pay Act (which prohibits paying men and women unequal pay for equal work); the California Fair Employment and Housing Act, California Government Code Section 12900 *et seq*. (which prohibits discrimination based on protected characteristics including race, color, religion, sex, gender, gender expression, gender identity, sexual orientation, marital status, national origin, language restrictions, ancestry, physical or mental disability, medical condition, age, military or veteran status, and denial of leave); the California Equal Pay Law (which prohibits paying an employee at a rate less than another employee of a different sex, race, or ethnicity for substantially similar work), California Labor Code Section 1197.5; the Unruh Civil Rights Act, California Civil Code Section 51 *et seq*. (which prohibits discrimination based on age, sex, race, color, religion, ancestry, national origin, disability, medical condition, marital status, or sexual orientation); New Jersey Law Against Discrimination, N.J.S.A. § 10:5-1 *et seq*.; or any other local, state or federal statute, regulation, common law or decision concerning discrimination, harassment, or retaliation on these or any other grounds or otherwise governing the employment relationship.

ii. Other employment laws, such as the federal Worker Adjustment and Retraining Notification Act of 1988 and the California Worker Adjustment and Retraining Notification Act, California Labor Code Sections 1400 *et seq*. (known as WARN laws, which require that advance notice be given of certain workforce reductions); the Executive Retirement Income Security Act of 1974 (which, among other things, protects employee benefits); the Fair Labor Standards Act of 1938 (which regulates wage and hour matters); the Family and Medical Leave Act of 1993 (which requires employers to provide leaves of absence under certain circumstances); the California Labor Code (which regulates employment and wage and hour matters); the California Family Rights Act of 1993, California Government Code Section 12945.1 *et seq*. (which requires employers to provide leaves of absence under certain circumstances); New Jersey Family Leave Act, N.J.S.A. § 34:11B-1 *et seq*.; Conscientious Employee Protection Act (C.E.P.A.), N.J.S.A. §§ 34:19-1 *et seq*.; New Jersey Wage Laws, N.J.S.A. § 34:11 *et seq*.; and any other federal, state, or local statute, regulation, common law or decision relating to employment, such as veterans' reemployment rights laws or any other aspect of employment.

iii. Other laws of general application, such as any federal, state, or local law enforcing express or implied employment or other contracts or covenants; any other federal, state or local laws providing relief for alleged wrongful discharge, physical or personal injury, breach of contract, emotional distress, fraud, negligent misrepresentation, defamation, invasion of privacy, violation of public policy and similar or related claims; common law claims under any tort, contract or other theory now or hereafter recognized, and any other federal, state, or local statute, regulation, common law or decision otherwise regulating employment.

(a) Participation in Agency Proceedings. Nothing in this Agreement shall prevent Executive from filing a charge (including a challenge to the validity of this Agreement) with the Equal Employment Opportunity Commission (the "**EEOC**"), the National Labor Relations Board (the "NLRB"), the California Department of Fair Employment and Housing (the "**DFEH**"), or other similar state or local agencies, or from participating in any investigation or proceeding conducted by the EEOC, the NLRB, the DFEH or similar state or local agencies. However, by entering into this Agreement, Executive understands and agrees that he is waiving any and all rights to recover any monetary relief or other personal relief as a result of any such EEOC, NLRB, DFEH or similar state or local agency proceedings, including any subsequent legal action.

(b) Claims Not Released. The Released Claims do not include claims by Executive for: (1) unemployment insurance; (2) worker's compensation benefits; (3) state disability compensation; (4) Accrued Amounts ; (5) any rights for indemnification or contribution under the Company's certificate of incorporation or by-laws, the laws of the state of incorporation or any rights to insurance coverage under any applicable directors' and officers' liability insurance policy and (6) any other rights that cannot by law be released by private agreement.

(c) Waiver of Rights under California Civil Code Section 1542. Executive further acknowledges that he has read Section 1542 of the Civil Code of the State of California, which provides as follows:

> **A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS WHICH THE CREDITOR DOES NOT KNOW OR SUSPECT TO EXIST IN HIS OR HER FAVOR AT THE TIME OF EXECUTING THE RELEASE, WHICH IF KNOWN BY HIM OR HER MUST HAVE MATERIALLY AFFECTED HIS OR HER SETTLEMENT WITH THE DEBTOR.**

Executive understands that Section 1542 gives his the right not to release existing claims of which he is not now aware, unless he voluntarily chooses to waive this right. **Even though Executive is aware of this right, Executive nevertheless hereby voluntarily waives the right described in Section 1542, and elects to assume all risks for claims that now exist in his favor, *known or unknown*, arising from the subject matter of the Release.**

Executive acknowledges that different or additional facts may be discovered in addition to what he now knows or believes to be true with respect to the matters released in this Agreement, and Executive agrees that this Agreement will be and remain in effect in all respects as a complete and final release of the matters released, notwithstanding any such different or additional facts. Executive represents and warrants that he has not previously filed or joined in any claims that are released in this Agreement and that he has not given or sold any portion of any claims released herein to anyone else, and that he will indemnify and hold harmless the persons and entities released in this Agreement from all liabilities, claims, demands, costs, expenses and/or attorneys' fees incurred as a result of any such prior assignment or transfer.

8. Non-Disclosure of This Agreement. Executive agrees that from and after the date of the receipt of this Agreement, he will not, directly or indirectly, provide to any person or entity any information concerning or relating to the negotiation of this Agreement or its terms and conditions, except: (i) to the extent specifically required by law or legal process or as authorized in writing by the Company; (ii) to his tax advisors as may be necessary for the preparation of tax returns or other reports required by law; (iii) to his attorneys as may be necessary to secure advice concerning this Agreement; or (iv) to members of his immediate family. Executive agrees that prior to disclosing such information under parts (ii), (iii), or (iv), he will inform the recipients that they are bound by the limitations of this section. Subsequent disclosure by any such recipients will be deemed to be a disclosure by Executive in breach of this Agreement.

9. Obligations Regarding Confidential Information. Executive hereby reaffirms his existing obligations, to the fullest extent permitted by law, under the Confidential Information, Invention Assignment, and Arbitration Agreement that he signed with the Company or its affiliates on or about August 30, 2013 (the "Confidentiality Agreement"). Executive understands that his obligations under the Confidentiality Agreement survive his employment with the Company as provided in that agreement.

10. Return of Information and Property. Executive hereby covenants and agrees that Executive shall promptly return all documents (whether in hard copy or electronic format), keys, credit cards, data devices, computer equipment, Company products, keycards, account information, and all other items which are the property of the Company and/or which contain confidential information. Executive agrees to work in cooperation with the Company's IT Department to delete all Company confidential information and Company contacts from his/his personal laptop computer, cellular phone and iPad. If Executive fails to return any company property, the Company will deduct from the Severance an amount equal to the value of non-returned property.

11. Non-disparagement. Executive agrees that he will not make to any person or entity any false, disparaging, or derogatory comments about the Company, its business affairs, its products, its employees, clients, contractors, agents, or any of the other Releasees as defined in Section 5. The Company agrees to instruct the Company's officers not to make any disparaging statements about Executive to any third party, whether inside or outside the Company.

12. Communication with Government Agencies. Notwithstanding anything to the contrary herein, Executive understands that nothing in this Agreement restricts or prohibits Executive from initiating communications directly with, responding to any inquiries from, providing testimony before, providing confidential information to, reporting possible violations of law or regulation to, or from filing a claim or assisting with an investigation directly with a self-regulatory authority or a government agency or entity (collectively, "Government Agencies"), or from making other disclosures that are protected under the whistleblower provisions of state or federal law or regulation, and Executive does not need the Company's prior authorization to engage in such conduct. This Agreement does not limit Executive's right to receive an award for information provided to Government Agencies.

13. General. This Agreement and the Confidentiality Agreement contain the entire understanding and agreement between the parties relating to the subject matter of this Agreement, and may not be altered or amended except by an instrument in writing signed by both parties. Executive has not

relied upon any representation or statement outside this Agreement with regard to the subject matter, basis or effect of this Agreement. This Agreement shall be governed, construed, and enforced by the internal laws of the State of New Jersey, without regard to the choice of law rules of any jurisdiction. To the extent any lawsuit is permitted under this Agreement, the Executive hereby expressly consents to the personal and exclusive jurisdiction and venue of the state and federal courts located in New Jersey for any lawsuit filed against the Executive by the Company. The language of all parts of this Agreement will in all cases be construed as a whole, according to the language's fair meaning, and not strictly for or against any of the parties. This Agreement will be binding upon and inure to the benefit of the parties and their respective representatives, successors and permitted assigns. Neither the waiver by either party of a breach of or default under any of the provisions of the Agreement, nor the failure of such party, on one (1) or more occasions, to enforce any of the provisions of the Agreement or to exercise any right or privilege hereunder will thereafter be construed as a waiver of any subsequent breach or default of a similar nature, or as a waiver of any provisions, rights or privileges hereunder. The parties agree to take or cause to be taken such further actions as may be necessary or as may be reasonably requested in order to fully effectuate the purposes, terms, and conditions of this Agreement. This Agreement and the rights and obligations of the parties hereunder may not be assigned by Executive without the prior written consent of the Company, but may be assigned by the Company without Executive's permission or consent. If any one (1) or more of the provisions of this Agreement, or any part thereof, will be held to be invalid, illegal or unenforceable, the validity, legality and enforceability of the remainder of this Agreement will not in any way be affected or impaired thereby. This Agreement may be signed in one (1) or more counterparts, each of which will be deemed an original, and all of which together will constitute one (1) instrument.

14. Arbitration and Equitable Relief.

(a) Intent of Agreement. The Company and the Executive agree and intend for this Agreement to govern the resolution of all disputes, claims and other matters that arise out of or concerning our relationship, whether related to Executive's employment with the Company or not. The Company and the Executive (collectively, the "Parties") shall resolve all such matters in accordance with the provisions of this Agreement.

(b) Mandatory Arbitration. The Parties agree that all claims, complaints, controversies, grievances, or disputes (collectively, "**claims**") that arise out of or relate in any way to the Parties' relationship, whether based on contract, tort, statutory, or any other legal theory, shall be submitted to mandatory, binding arbitration in New Jersey before a neutral arbitrator who is licensed to practice law in the state in which the arbitration is convened (the "**Arbitrator**"). The arbitration shall be governed by the Federal Arbitration Act, 9 U.S.C. Section 1 *et seq*, as amended, and shall be administered by the Judicial Arbitration & Mediation Services, Inc. ("**JAMS**"), in accordance with pursuant to its then-current Employment Arbitration Rules & Procedures (the "**JAMS Rules**"). A copy of the Employment Arbitration Rules & Procedures is attached hereto as Exhibit B. The Rules are also available online at http://www.jamsadr.com/rules-employment-arbitration/. The Parties or their representatives may also call JAMS at 800.352.5267 if they have questions about the arbitration process. If the JAMS Rules are inconsistent with the terms of this Agreement, the terms of this Agreement shall govern.

(c) Covered Claims. This Agreement covers all claims under federal, state or local law arising out of or relating to Executive's application for employment with the Company, any offer of employment made by the Company, Executive's employment by the Company, the breach of any employment agreement, the termination of Executive's employment with the Company, or any other aspect of Executive's employment relationship with the Company, claims that the Executive may have against the Company or against its officers, directors, supervisors, managers, employees, or agents in their capacity as such, and claims that the Company may have against Executive. The claims covered by this Agreement (the "**Covered Claims**") include, but are not limited to, claims for breach of any contract or covenant (express or implied), tort claims, claims for wrongful termination (constructive or actual) in violation of public policy, claims for discrimination or harassment (including, but not limited to, harassment or discrimination based on race, sex, gender, religion, national origin, age, marital status, medical condition, psychological condition, mental condition, disability, sexual orientation, or any other characteristic protected by law), claims for violation of any federal, state, or other governmental law, statute, regulation, or ordinance, including, but not limited to, all claims arising under Title VII of the Civil Rights Act, the Age Discrimination in Employment Act, the Americans With Disabilities Act, the California Fair Employment and Housing Act, the Consolidated Omnibus Budget Reconciliation Act of 1985, and Employee Retirement Income Security Act. The Parties specifically agree that the Covered Claims include claims under the Fair Labor Standards Act, the California Labor Code, and other federal, state, or local laws governing wages, hours and working conditions, including, but not limited to, claims for overtime, unpaid wages, and meal period and rest break violations.

(d) Claims Not Covered. Claims for workers' compensation, unemployment compensation benefits, claims as a stockholder or any other claims that, as a matter of law, the Parties cannot agree to arbitrate are not subject to, and are excluded from, this Agreement. Nothing in this Agreement shall be interpreted prohibit or preclude the filing of complaints with the California Department of Fair Employment and Housing, the Equal Employment Opportunity Commission, or the National Labor Relations Board.

(e) Waiver of Class Action and Collective Action Claims. Except as otherwise required by law, the Parties expressly intend and agree that: (a) class action and collective action procedures shall neither be asserted nor apply in any arbitration conducted pursuant to this Agreement; (b) each Party will not assert class or collective action claims against the other in arbitration or otherwise; and (c) the Parties shall only submit their own, individual claims in arbitration and will not seek to represent the interests of any other person.

(f) Waiver of Trial By Jury. THE EXECUTIVE UNDERSTANDS AND FULLY AGREES THAT BY ENTERING INTO THIS AGREEMENT, BOTH THE COMPANY AND THE EXECUTIVE ARE GIVING UP THEIR CONSTITUTIONAL RIGHT TO HAVE A TRIAL BY JURY, AND ARE GIVING UP THEIR NORMAL RIGHTS OF APPEAL FOLLOWING THE RENDERING OF A DECISION, EXCEPT AS THE FEDERAL ARBITRATION ACT AND APPLICABLE FEDERAL LAW ALLOW FOR JUDICIAL REVIEW OF ARBITRATION PROCEEDINGS.

(g) Claims Procedure. Arbitration shall be initiated pursuant to this Agreement upon written notice of either Party. The aggrieved Party shall give written notice of any claim to the other Party

by certified or registered mail, return receipt requested. The Executive agrees to mail written notice of all claims to the Company's General Counsel at 900 E. Hamilton Avenue, Suite 550, Campbell, CA 95008 ("**Notice Address**"). The Company agrees to mail written notice of all claims to Executive's last known address on file with the Company. The written notice shall identify and describe the nature of all claims asserted and the facts upon which such claims are based. Written notice of arbitration shall be initiated within the statute of limitations and other time limitations applicable to the claim(s) asserted.

(h) Arbitrator Selection. The Arbitrator shall be selected as provided in the JAMS Rules.

(i) Discovery. The JAMS Rules regarding discovery shall apply to any arbitration conducted under this Agreement. The Arbitrator shall decide all discovery disputes.

(j) Substantive Law. The Arbitrator shall apply the substantive law (and the law of remedies, if applicable) of the state in which the claim arose, or federal law, or both, as applicable to the claim(s) asserted. The Federal Rules of Evidence shall apply. The Arbitrator, and not any federal, state, or local court or agency, shall have exclusive authority to resolve any dispute relating to the interpretation, applicability, or enforceability of this Agreement. The Arbitrator shall conduct and preside over an arbitration hearing of reasonable length, to be determined by the Arbitrator. The Arbitrator shall provide the Parties with a written decision explaining his or her findings and conclusions. The Arbitrator's decision shall be final and binding upon the Parties.

(k) Motions. The Arbitrator shall have jurisdiction to hear and decide prehearing disputes and is authorized to hold prehearing conferences by telephone or in person as the Arbitrator deems necessary. The Arbitrator shall have the authority to set deadlines for completion of discovery and the filing of dispositive motions, and to set briefing schedules for any motions. The Arbitrator shall have the authority to adjudicate any cause of action, claim, or defense, including entire claims, pursuant to a motion for summary adjudication and/or summary judgment, and, in deciding such motions, shall apply applicable substantive state or federal law.

(l) Compelling Arbitration/Enforcing Award. Either Party may bring an action in court to compel arbitration under this Agreement and to confirm, vacate or enforce an arbitration award. Each Party shall bear its own attorney fees and costs and other expenses of such action.

(m) Arbitration Fees and Costs. The Company shall be responsible for all costs unique to the arbitration process. Each Party shall pay its own costs and attorneys' fees, if any; provided, however, if the Arbitrator determines that the Executive's position was asserted in good faith with a reasonable basis, the Company shall pay the Executive's reasonable attorneys' fees and costs. Under no circumstances shall the Executive be responsible for the Company's attorneys' fees.

(n) Term of Agreement. This Agreement shall survive the termination of Executive's employment. It may only be revoked or modified in a writing that specifically states the intent to revoke or modify the Agreement and that is signed by both Executive and the Chairman of the Board.

(o) Severability. If any provision of this Agreement is adjudged to be void or otherwise unenforceable, in whole or in part, the void or unenforceable provision shall be severed and such adjudication shall not affect the validity of the remainder of this Agreement.

(p) Voluntary Agreement. By executing this Agreement, the Parties represent that they have been given the opportunity to fully review, comprehend and negotiate the terms of this Agreement. The Parties understand the terms of this Agreement, and freely and voluntarily sign it.

15. No Admission; Attorneys' Fees. The parties agree that nothing contained in this Agreement will constitute or be treated as an admission of liability or wrongdoing by either of them. In any action to enforce the terms of this Agreement, the prevailing party will be entitled to recover its costs and expenses, including reasonable attorneys' fees.

16. ADEA Acknowledgment/Time Periods. With respect to the General Release in Section 5 hereof, Executive agrees and understands that by signing this Agreement, he is specifically releasing all claims under the Age Discrimination in Employment Act, as amended, 29 U.S.C. Section 621 *et seq*. Executive acknowledges that he has carefully read and understands this Agreement in its entirety, and executes it voluntarily and without coercion.

(a) Consideration Period. Executive further acknowledges that he is hereby being advised in writing to consult with a competent, independent attorney of his or her choice, at his or her own expense, regarding the legal effect of this Agreement before signing it, and that he is being given a period of twenty-one (21) days within which to consider and execute this Agreement, unless he voluntarily chooses to execute this Agreement before the end of the twenty-one (21) day period.

(b) Revocation Period. Executive understands that he has seven (7) days following his execution of this Agreement to revoke it in writing, and that this Agreement is not effective or enforceable until after this seven (7) day period has expired without revocation. For a revocation to be effective, written notice must be received by the Chief Financial Officer of the Company at 900 E. Hamilton Avenue, Suite 550, Campbell, CA 95008, by no later than 9:00 a.m. on the eighth (8th) calendar day after the date by which Executive has signed this Agreement ("**Revocation Deadline**").

17. Execution. Executive agrees that he will not sign and execute this Agreement before his Separation Date. Executive understands and agrees that this Agreement shall be null and void and have no legal or binding effect whatsoever if: (1) Executive signs but then timely revokes the Agreement or (2) the Agreement is not signed by Executive on or before the twenty-first (21st) day after Executive receives it. This Agreement is only effective upon the receipt by the Company of this Agreement, duly executed by Executive and without revocation by the Executive of the Agreement by the Revocation Deadline ("**Effective Date**").

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the undersigned, intending to be bound hereby, have agreed to the terms and conditions of this Agreement as of the date first set forth below.

EXECUTIVE:

/s/ Seth H.Z. Fischer
Name: Seth H.Z. Fischer

Date: 12/26/2017

VIVUS, INC.

By: /s/ Mark Oki

Name: Mark Oki

Title: Chief Financial Officer

Date: 26 Dec 2017

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ELECTION TO EXECUTE PRIOR TO EXPIRATION
OF 21-DAY CONSIDERATION PERIOD

I, Seth H.Z. Fischer, understand that I have twenty-one (21) days within which to consider and execute the attached Confidential Separation Agreement and General Release. However, after having an opportunity to consult counsel, I have freely and voluntarily elected to execute the Confidential Separation Agreement and General Release before such twenty-one (21) day period has expired.

Date Executive Signature

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EXHIBIT A

BRING DOWN RELEASE

Pursuant to Section 5(h) of the [DATE] Confidential Separation, General Release and Post-Separation Consulting Agreement (the "Agreement") entered into between entered into between Seth H.Z. Fischer ("Executive") and VIVUS, Inc. (the "Company"), Executive and the Company agree as follows:

1. Defined Terms. Defined terms used but not defined in this Bring Down Release shall have the meanings given such terms in the Agreement.

2. Acknowledgement. Executive acknowledges and agrees that, other than the payments described in Section 5 of the Agreement, he has been fully paid any and all compensation due and owing to her, including all wages, salary, commissions, bonuses, incentive payments, consultant fees, profit-sharing payments, expense reimbursements, leave or other benefits, up to and through the Consulting Termination Date or otherwise. Executive further agrees that the Severance Benefits referred to in Section 4 of the Agreement is not compensation for Executive's services rendered through the Separation Date or Consulting Termination Date, but rather constitutes consideration for the promises contained in the Agreement, and is above and beyond any wages, compensation, or salary or other sums to which he is entitled from the Company under the terms of his employment or consulting relationship with the Company or under any other contract or law.

3. General Release. Except for any rights granted under the Agreement and this Bring Down Release, Executive, for himself, and for Executive's heirs, assigns, executors and administrators, hereby releases, remises and forever discharges the Company and its parents, subsidiaries, affiliates, and divisions, and each of their respective directors, officers, partners, attorneys, shareholders, administrators, employees, agents, representatives, employment benefit plans, plan administrators, fiduciaries, trustees, insurers and re-insurers, agents, and all of their predecessors, successors and assigns (collectively, the "**Releasees**") of and from all claims, causes of action, covenants, contracts, agreements, promises, damages, disputes, demands, and all other manner of actions whatsoever, in law or in equity, that Executive ever had, may have had, now has, or that Executive's heirs, assigns, executors or administrators hereinafter can, shall or may have, whether known or unknown, asserted or unasserted, suspected or unsuspected, as a result of or related to Executive's employment or consulting relationship with the Company, the termination of that employment or consulting relationship, or any act or omission which has occurred at any time up to and including the date of the execution of this Bring Down Release (the "**Released Claims**").

a) Released Claims. The Released Claims released include, but are not limited to, any claims for monetary damages; any claims for wages or compensation allegedly owed to Executive; any claims related to Executive's employment or consulting relationship with the Company or the termination thereof; any claims to severance or similar benefits; any claims to expenses, attorneys' fees or other indemnities; any claims based on any actions or failures to act that occurred on or before the date of this Bring Down Release; and any claims for other personal remedies or damages sought in any legal proceeding or charge filed with any court or federal, state or local agency either by Executive or by any person claiming to act on Executive's behalf or in Executive's interest. Executive understands that the Released Claims

may have arisen under different local, state and federal statutes, regulations, or common law doctrines. Executive hereby specifically, but without limitation, agrees to release all Releasees from any and all claims under each of the following laws:

i. Antidiscrimination laws, such as Title VII of the Civil Rights Act of 1964, as amended, and Executive Order 11246 (which prohibit discrimination based on race, color, national origin, religion, or sex); Section 1981 of the Civil Rights Act of 1866 (which prohibits discrimination based on race or color); the Age Discrimination in Employment Act of 1967 (which prohibits discrimination based upon age); the Americans with Disabilities Act and Sections 503 and 504 of the Rehabilitation Act of 1973 (which prohibit discrimination based upon disability); the Equal Pay Act (which prohibits paying men and women unequal pay for equal work); the California Fair Employment and Housing Act, California Government Code Section 12900 et seq. (which prohibits discrimination based on protected characteristics including race, color, religion, sex, gender, sexual orientation, marital status, national origin, language restrictions, ancestry, physical or mental disability, medical condition, age, and denial of leave); the California Equal Pay Law (which prohibits paying an employee at a rate less than another employee of a different sex, race, or ethnicity for substantially similar work), California Labor Code Section 1197.5; the Unruh Civil Rights Act, California Civil Code Section 51 et seq. (which prohibits discrimination based on age, sex, race, color, religion, ancestry, national origin, disability, medical condition, marital status, or sexual orientation); New Jersey Law Against Discrimination, N.J.S.A. § 10:5-1 *et seq*.; or any other local, state or federal statute, regulation, common law or decision concerning discrimination, harassment, or retaliation on these or any other grounds or otherwise governing the employment relationship.

ii. Other employment laws, such as the federal Worker Adjustment and Retraining Notification Act of 1988 and the California Worker Adjustment and Retraining Notification Act, California Labor Code Sections 1400 et seq. (known as WARN laws, which require advance notice of certain workforce reductions); the Executive Retirement Income Security Act of 1974 (which, among other things, protects employee benefits); the Fair Labor Standards Act of 1938 (which regulates wage and hour matters); the Family and Medical Leave Act of 1993 (which requires employers to provide leaves of absence under certain circumstances); the California Labor Code (which regulates employment and wage and hour matters, including but not limited to misclassification claims); the California Family Rights Act of 1993, California Government Code Section 12945.1 et seq. (which requires employers to provide leaves of absence under certain circumstances); New Jersey Family Leave Act, N.J.S.A. § 34:11B-1 *et seq*.; Conscientious Employee Protection Act (C.E.P.A.), N.J.S.A. §§ 34:19-1 *et seq*.; New Jersey Wage Laws, N.J.S.A. § 34:11 *et seq*.; and any other federal, state, or local statute, regulation, common law or decision relating to employment, reemployment rights, leaves of absence or any other aspect of employment.

iii. Other laws of general application, such as federal, state, or local laws enforcing express or implied employment agreements or other contracts or covenants, or addressing breaches of such agreements, contracts or covenants; federal, state or local laws providing relief for alleged wrongful discharge or termination, physical or personal injury, emotional distress, fraud, intentional or negligent misrepresentation, defamation, invasion of privacy, violation of public policy or similar claims; common law claims under any tort, contract or other theory now or hereafter recognized, and any other federal, state, or local statute, regulation, common law doctrine, or decision regulating or regarding employment.

a) Participation in Agency Proceedings. Nothing in this Bring Down Release shall prevent Executive from filing a charge (including a challenge to the validity of this Bring Down Release) with the Equal Employment Opportunity Commission (the "**EEOC**"), the National Labor Relations Board (the "**NLRB**"), the California Department of Fair Employment and Housing (the "DFEH"), or other similar federal, state or local agency, or from participating in any investigation or proceeding conducted by the EEOC, the NLRB, the DFEH or similar federal, state or local agencies. However, by entering into this Bring Down Release, Executive understands and agrees that Executive is waiving any and all rights to recover any monetary relief or other personal relief as a result of any such EEOC, NLRB, DFEH or similar federal, state or local agency proceeding, including any subsequent legal action.

b) Claims Not Released. The Released Claims do not include claims by Executive for unemployment insurance benefits, workers' compensation benefits, previously vested benefits under any Company-sponsored benefits plan or any other rights that cannot by law be released by private agreement.

c) Waiver of Rights under California Civil Code Section 1542. Executive further acknowledges that he has read Section 1542 of the Civil Code of the State of California, which provides as follows:

> **A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS WHICH THE CREDITOR DOES NOT KNOW OR SUSPECT TO EXIST IN HIS OR HER FAVOR AT THE TIME OF EXECUTING THE RELEASE, WHICH IF KNOWN BY HIM OR HER MUST HAVE MATERIALLY AFFECTED HIS OR HER SETTLEMENT WITH THE DEBTOR.**

Executive understands that Section 1542 gives him the right not to release existing claims of which Executive is not now aware, unless he voluntarily chooses to waive this right. **Even though Executive is aware of this right, he nevertheless hereby voluntarily waives the right described in Section 1542 and any other statutes of similar effect, and elects to assume all risks for claims that now exist in Executive's favor, *known or unknown*, arising from the subject matter of the Release.** Executive acknowledges that different or additional facts may be discovered in addition to what Executive now knows or believes to be true with respect to the matters released in this Bring Down Release, and Executive agrees that this Bring Down Release will be and remain in effect in all respects as a complete and final release of the matters released, notwithstanding any such different or additional facts. EXCEPT AS OUTLINED ABOVE, THIS MEANS THAT, BY SIGNING THIS BRING DOWN RELEASE, EXECUTIVE WILL WAIVE ANY RIGHT HE MAY HAVE HAD TO PURSUE OR BRING A LAWSUIT OR MAKE ANY LEGAL CLAIM AGAINST COMPANY OR THE SEPARATION DATE RELEASEES INCLUDING, BUT NOT LIMITED TO, CLAIMS THAT IN ANY WAY ARISE FROM OR RELATE TO EXECUTIVE'S EMPLOYMENT OR CONSULTING RELATIONSHIP WITH THE COMPANY OR THE TERMINATION OF THAT EMPLOYMENT OR CONSULTING RELATIONSHIPO, UP TO AND INCLUDING THE DATE OF THE EXECUTION OF THIS BRING DOWN RELEASE. EXECUTIVE AGREES NOT TO PURSUE OR BRING ANY SUCH LAWSUIT OR LEGAL CLAIM SEEKING MONETARY OR OTHER RELIEF.

IN WITNESS WHEREOF, the undersigned has executed this Bring Down Release as of the Consultation Termination Date.

[DO NOT SIGN UNTIL LAST DAY OF CONSULTING RELATIONSHIP]

Date Executive Signature

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EXHIBIT B

Employment Arbitration Rules & Procedures

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JAMS
Employment Arbitration Rules & Procedures
Effective July 1, 2014

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JAMS EMPLOYMENT ARBITRATION RULES & PROCEDURES

JAMS provides arbitration and mediation services worldwide. We resolve some of the world's largest, most complex and contentious disputes, utilizing JAMS Rules & Procedures as well as the rules of other domestic and international arbitral institutions.

JAMS arbitrators and mediators are full-time neutrals who come from the ranks of retired state and federal judges and prominent attorneys. These highly trained, experienced ADR professionals are dedicated to the highest ethical standards of conduct.

Parties wishing to write a pre-dispute JAMS arbitration clause into their agreement should review the sample arbitration clauses on page 4. These clauses may be modified to tailor the arbitration process to meet the parties' individual needs.

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Administrative Fees

For two-party matters, JAMS charges a $1,200 Filing Fee, to be paid by the party initiating the Arbitration. For matters involving three or more parties, the Filing Fee is $2,000. A Case Management Fee of 12% will be assessed against all Professional Fees, including time spent for hearings, pre- and post-hearing reading and research and award preparation.

JAMS neutrals set their own hourly, partial and full-day rates. For information on individual neutrals' rates and the administrative fees, please contact JAMS at 800.352.5267. The fee structure is subject to change.

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Sample Clauses for Use in Employment Dispute Resolution Programs and Contracts

The following are basic sample clauses providing for mediation or arbitration in an employment contract. A variety of issues may affect the enforceability or effectiveness of these sample clauses; therefore, it is recommended that you review applicable law in your jurisdiction and consult experienced counsel for advice. The information contained herein should not be considered legal advice or legal opinion. For information about setting a case, call your local JAMS office at 800.352.5267.

Sample Clause for Mediation Only

Any controversy, dispute or claim arising out of or relating to this [contract] or breach thereof shall first be settled through good-faith negotiation [OR company employment program] [other]. If the dispute cannot be settled through negotiation [OR company employment program] [other], the parties agree to attempt in good faith to settle the dispute by mediation administered by JAMS.

Sample Clause for Mediation and Arbitration

Any controversy, dispute or claim arising out of or relating to this [contract] or breach thereof shall first be settled through good-faith negotiation [OR company employment program] [other]. If the dispute cannot be settled through negotiation [OR company employment program] [other], the parties agree to attempt in good faith to settle the dispute by mediation administered by JAMS. If the parties are unsuccessful at resolving the dispute through mediation, the parties agree to [binding] arbitration administered by JAMS pursuant to its Employment Arbitration Rules & Procedures and subject to JAMS Policy on Employment Arbitration Minimum Standards of Procedural Fairness. Judgment on the Award may be entered in any court having jurisdiction.

All of the JAMS Rules, including the Employment Arbitration Rules set forth below, can be accessed at the JAMS website: **www.jamsadr.com/rules-clauses**.

JAMS EMPLOYMENT ARBITRATION RULES & PROCEDURES

Rule 1. Scope of Rules

(a) The JAMS Employment Arbitration Rules and Procedures ("Rules") govern binding Arbitrations of disputes or claims that are administered by JAMS and in which the Parties agree to use these Rules or, in the absence of such agreement, the disputes or claims are employment-related, unless other Rules are prescribed.

(b) The Parties shall be deemed to have made these Rules a part of their Arbitration agreement ("Agreement") whenever they have provided for Arbitration by JAMS under its Employment Rules or for Arbitration by JAMS without specifying any particular JAMS Rules and the disputes or claims meet the criteria of the first paragraph of this Rule.

(c) The authority and duties of JAMS as prescribed in the Agreement of the Parties and in these Rules shall be carried out by the JAMS National Arbitration Committee ("NAC") or the office of JAMS General Counsel or their designees.

(d) JAMS may, in its discretion, assign the administration of an Arbitration to any of its Resolution Centers.

(e) The term "Party" as used in these Rules includes Parties to the Arbitration and their counsel or representatives.

(f) "Electronic filing" (e-file) means the electronic transmission of documents to and from JAMS and other Parties for the purpose of filing via the Internet. "Electronic service" (e-service) means the electronic transmission of documents via JAMS Electronic Filing System to a party, attorney or representative under these Rules.

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Rule 2. Party Self-Determination

(a) The Parties may agree on any procedures not specified herein or in lieu of these Rules that are consistent with the applicable law and JAMS policies (including, without limitation, the JAMS Policy on Employment Arbitration Minimum Standards of Procedural Fairness and Rules 15(i), 30 and 31). The Parties shall promptly notify JAMS of any such Party-agreed procedures and shall confirm such procedures in writing. The Party-agreed procedures shall be enforceable as if contained in these Rules.

(b) When an Arbitration Agreement provides that the Arbitration will be non-administered or administered by an entity other than JAMS and/or conducted in accordance with rules other than JAMS Rules, the Parties may subsequently agree to modify that Agreement to provide that the Arbitration will be administered by JAMS and/or conducted in accordance with JAMS Rules.

Rule 3. Amendment of Rules

JAMS may amend these Rules without notice. The Rules in effect on the date of the commencement of an Arbitration (as defined in Rule 5) shall apply to that Arbitration, unless the Parties have agreed upon another version of the Rules.

Rule 4. Conflict with Law

If any of these Rules, or modification of these Rules agreed to by the Parties, is determined to be in conflict with a provision of applicable law, the provision of law will govern over the Rule in conflict, and no other Rule will be affected.

Rule 5. Commencing an Arbitration

(a) The Arbitration is deemed commenced when JAMS issues a Commencement Letter based upon the existence of one of the following:

(i) A post-dispute Arbitration Agreement fully executed by all Parties specifying JAMS administration or use of any JAMS Rules; or

(ii) A pre-dispute written contractual provision requiring the Parties to arbitrate the employment dispute or claim and specifying JAMS administration or use of any JAMS Rules or that the Parties agree shall be administered by JAMS; or

(iii) A written confirmation of an oral agreement of all Parties to participate in an Arbitration administered by JAMS or conducted pursuant to any JAMS Rules; or

(iv) The Respondent's failure to timely object to JAMS administration; or
(v) A copy of a court order compelling Arbitration at JAMS.

(b) The issuance of the Commencement Letter confirms that requirements for commencement have been met, that JAMS has received all payments required under the applicable fee schedule and that the Claimant has provided JAMS with contact information for all Parties along with evidence that the Demand for Arbitration has been served on all Parties.

(c) If a Party that is obligated to arbitrate in accordance with subparagraph (a) of this Rule fails to agree to participate in the Arbitration process, JAMS shall confirm in writing that Party's failure to respond or participate, and, pursuant to Rule 19, the Arbitrator, once appointed, shall schedule, and provide appropriate notice of, a Hearing or other opportunity for the Party demanding the Arbitration to demonstrate its entitlement to relief.

(d) The date of commencement of the Arbitration is the date of the Commencement Letter but is not intended to be applicable to any legal requirements such as the statute of limitations, any contractual limitations period or claims notice requirements. The term "commencement," as used in this Rule, is intended only to pertain to the operation of this and other Rules (such as Rule 3, 13(a), 17(a), 31(a)).

Rule 6. Preliminary and Administrative Matters

(a) JAMS may convene, or the Parties may request, administrative conferences to discuss any procedural matter relating to the administration of the Arbitration.

(b) If no Arbitrator has yet been appointed, at the request of a Party and in the absence of Party agreement, JAMS may determine the location of the Hearing, subject to Arbitrator review. In determining the location of the Hearing, such factors as the subject matter of the dispute, the convenience of the Parties and witnesses, and the relative resources of the Parties shall be considered, but in no event will the Hearing be scheduled in a location that precludes attendance by the Employee.

(c) If, at any time, any Party has failed to pay fees or expenses in full, JAMS may order the suspension or termina-

tion of the proceedings. JAMS may so inform the Parties in order that one of them may advance the required payment. If one Party advances the payment owed by a non-paying Party, the Arbitration shall proceed, and the Arbitrator may allocate the non-paying Party's share of such costs, in accordance with Rules 24(f) and 31(c). An administrative suspension shall toll any other time limits contained in these Rules or the Parties' Agreement.

(d) JAMS does not maintain an official record of documents filed in the Arbitration. If the Parties wish to have any documents returned to them, they must advise JAMS in writing within thirty (30) calendar days of the conclusion of the Arbitration. If special arrangements are required regarding file maintenance or document retention, they must be agreed to in writing, and JAMS reserves the right to impose an additional fee for such special arrangements. Documents that are submitted for e-filing are retained for thirty (30) calendar days following the conclusion of the Arbitration.

(e) Unless the Parties' Agreement or applicable law provides otherwise, JAMS, if it determines that the Arbitrations so filed have common issues of fact or law, may consolidate Arbitrations in the following instances:

(i) If a Party files more than one Arbitration with JAMS, JAMS may consolidate the Arbitrations into a single Arbitration.

(ii) Where a Demand or Demands for Arbitration is or are submitted naming Parties already involved in another Arbitration or Arbitrations pending under these Rules, JAMS may decide that the new case or cases shall be consolidated into one or more of the pending proceedings and referred to one of the Arbitrators or panels of Arbitrators already appointed.

(iii) Where a Demand or Demands for Arbitration is or are submitted naming parties that are not identical to the Parties in the existing Arbitration or Arbitrations, JAMS may decide that the new case or cases shall be consolidated into one or more of the pending proceedings and referred to one of the Arbitrators or panels of Arbitrators already appointed.

When rendering its decision, JAMS will take into account all circumstances, including the links between the cases and the progress already made in the existing Arbitrations.

Unless applicable law provides otherwise, where JAMS decides to consolidate a proceeding into a pending Arbitration, the Parties to the consolidated case or cases will be deemed to have waived their right to designate an Arbitrator as well as any contractual provision with respect to the site of the Arbitration.

(f) Where a third party seeks to participate in an Arbitration already pending under these Rules or where a Party to an Arbitration under these Rules seeks to compel a third party to participate in a pending Arbitration, the Arbitrator shall determine such request, taking into account all circumstances he or she deems relevant and applicable.

Rule 7. Number and Neutrality of Arbitrators; Appointment and Authority of Chairperson

(a) The Arbitration shall be conducted by one neutral Arbitrator, unless all Parties agree otherwise. In these Rules, the term "Arbitrator" shall mean, as the context requires, the Arbitrator or the panel of Arbitrators in a tripartite Arbitration.

(b) In cases involving more than one Arbitrator, the Parties shall agree on, or, in the absence of agreement, JAMS shall designate, the Chairperson of the Arbitration Panel. If the Parties and the Arbitrators agree, a single member of the Arbitration Panel may, acting alone, decide discovery and procedural matters, including the conduct of hearings to receive documents and testimony from third parties who have been subpoenaed to produce documents.

(c) Where the Parties have agreed that each Party is to name one Arbitrator, the Arbitrators so named shall be neutral and independent of the appointing Party, unless the Parties have agreed that they shall be non-neutral.

Rule 8. Service

(a) The Arbitrator may at any time require electronic filing and service of documents in an Arbitration. If an Arbitrator requires electronic filing, the Parties shall maintain and regularly monitor a valid, usable and live email address for the receipt of all documents filed through JAMS Electronic Filing System. Any document filed electronically shall be considered as filed with JAMS when the transmission to JAMS Electronic Filing System is complete. Any document e-filed by 11:59 p.m. (of the sender's time zone) shall be deemed filed on that date. Upon completion of filing, JAMS

Electronic Filing System shall issue a confirmation receipt that includes the date and time of receipt. The confirmation receipt shall serve as proof of filing.

(b) Every document fi with JAMS Electronic Filing System shall be deemed to have been signed by the Arbitrator, Case Manager, attorney or declarant who submits the document to JAMS Electronic Filing System, and shall bear the typed name, address and telephone number of a signing attorney. Documents containing signatures of third parties (i.e., unopposed motions, affidavits, stipulations, etc.) may also be filed electronically by indicating that the original signatures are maintained by the filing Party in paper format.

(c) Delivery of e-service documents through JAMS Electronic Filing System to other registered users shall be considered as valid and effective service and shall have the same legal effect as an original paper document. Recipients of e-service documents shall access their documents through JAMS Electronic Filing System. E-service shall be deemed complete when the Party initiating e-service completes the transmission of the electronic document(s) to JAMS Electronic Filing System for e-filing and/or e-service. Upon actual or constructive receipt of the electronic document(s) by the Party to be served, a Certificate of Electronic Service shall be issued by JAMS Electronic Filing System to the Party initiating e-service, and that Certificate shall serve as proof of service. Any Party who ignores or attempts to refuse e-service shall be deemed to have received the electronic document(s) 72 hours following the transmission of the electronic document(s) to JAMS Electronic Filing System.

(d) If an electronic filing or service does not occur because of (1) an error in the transmission of the document to JAMS Electronic Filing System or served Party which was unknown to the sending Party; (2) a failure to process the electronic document when received by JAMS Electronic Filing System;
(3) the Party was erroneously excluded from the service list; or (4) other technical problems experienced by the filer, the Arbitrator or JAMS may, for good cause shown, permit the document to be filed *nunc pro tunc* to the date it was first attempted to be sent electronically. Or, in the case of service, the Party shall, absent extraordinary circumstances, be entitled to an order extending the date for any response or the period within which any right, duty or other act must be performed.

(e) For documents that are not filed electronically, service by a Party under these Rules is effected by providing one signed copy of the document to each Party and two copies in the case of a sole Arbitrator and four copies in the case of a tripartite panel to JAMS. Service may be made by hand-delivery, overnight delivery service or U.S. mail. Service by any of these means is considered effective upon the date of deposit of the document.

(f) In computing any period of time prescribed or allowed by these Rules for a Party to do some act within a prescribed period after the service of a notice or other paper on the Party and the notice or paper is served on the Party only by U.S. mail, three (3) calendar days shall be added to the prescribed period.

Rule 9. Notice of Claims

(a) Each Party shall afford all other Parties reasonable and timely notice of its claims, affirmative defenses or counterclaims. Any such notice shall include a short statement of its factual basis. No claim, remedy, counterclaim, or affirmative defense will be considered by the Arbitrator in the absence of such prior notice to the other Parties, unless the Arbitrator determines that no Party has been unfairly prejudiced by such lack of formal notice or all Parties agree that such consideration is appropriate notwithstanding the lack of prior notice.

(b) Claimant's notice of claims is the Demand for Arbitration referenced in Rule 5. It shall include a statement of the remedies sought. The Demand for Arbitration may attach and incorporate a copy of a Complaint previously filed with a court. In the latter case, Claimant may accompany the Complaint with a copy of any Answer to that Complaint filed by any Respondent.

(c) Within fourteen (14) calendar days of service of the notice of claim, a Respondent may submit to JAMS and serve on other Parties a response and a statement of any affirmative defenses, including jurisdictional challenges, or counterclaims it may have.

(d) Within fourteen (14) calendar days of service of a counterclaim, a Claimant may submit to JAMS and serve on other Parties a response to such counterclaim and any affirmative defenses, including jurisdictional challenges, it may have.

(e) Any claim or counterclaim to which no response has been served will be deemed denied.

(f) Jurisdictional challenges under Rule 11 shall be deemed waived, unless asserted in a response to a Demand or counterclaim or promptly thereafter, when circumstances first suggest an issue of arbitrability.

Rule 10. Changes of Claims

After the filing of a claim and before the Arbitrator is appointed, any Party may make a new or different claim against a Party or any third Party that is subject to Arbitration in the proceeding. Such claim shall be made in writing, filed with JAMS and served on the other Parties. Any response to the new claim shall be made within fourteen (14) calendar days after service of such claim. After the Arbitrator is appointed, no new or different claim may be submitted, except with the Arbitrator's approval. A Party may request a hearing on this issue. Each Party has the right to respond to any new or amended claim in accordance with Rule 9(c) or (d).

Rule 11. Interpretation of Rules and Jurisdictional Challenges

(a) Once appointed, the Arbitrator shall resolve disputes about the interpretation and applicability of these Rules and conduct of the Arbitration Hearing. The resolution of the issue by the Arbitrator shall be final.

(b) Jurisdictional and arbitrability disputes, including disputes over the formation, existence, validity, interpretation or scope of the agreement under which Arbitration is sought, and who are proper Parties to the Arbitration, shall be submitted to and ruled on by the Arbitrator. Unless the relevant law requires otherwise, the Arbitrator has the authority to determine jurisdiction and arbitrability issues as a preliminary matter.

(c) Disputes concerning the appointment of the Arbitrator shall be resolved by JAMS.

(d) The Arbitrator may, upon a showing of good cause or *sua sponte*, when necessary to facilitate the Arbitration, extend any deadlines established in these Rules, provided that the time for rendering the Award may only be altered in accordance with Rules 22(i) or 24.

Rule 12. Representation

(a) The Parties, whether natural persons or legal entities such as corporations, LLCs, or partnerships, may be represented by counsel or any other person of the Party's choice. Each Party shall give prompt written notice to the Case Manager and the other Parties of the name, address, telephone and fax numbers and email address of its representative. The representative of a Party may act on the Party's behalf in complying with these Rules.

(b) Changes in Representation. A Party shall give prompt written notice to the Case Manager and the other Parties of any change in its representation, including the name, address, telephone and fax numbers and email address of the new representative. Such notice shall state that the written consent of the former representative, if any, and of the new representative, has been obtained and shall state the effective date of the new representation.

Rule 13. Withdrawal from Arbitration

(a) No Party may terminate or withdraw from an Arbitration after the issuance of the Commencement Letter (see Rule 5), except by written agreement of all Parties to the Arbitration.

(b) A Party that asserts a claim or counterclaim may unilaterally withdraw that claim or counterclaim without prejudice by serving written notice on the other Parties and the Arbitrator. However, the opposing Parties may, within seven (7) calendar days of such notice, request that the Arbitrator condition the withdrawal upon such terms as he or she may direct.

Rule 14. *Ex Parte* Communications

(a) No Party may have any *ex parte* communication with a neutral Arbitrator, except as provided in section (b) of this Rule. The Arbitrator(s) may authorize any Party to communicate directly with the Arbitrator(s) by email or other written means as long as copies are simultaneously forwarded to the JAMS Case Manager and the other Parties.

(b) A Party may have *ex parte* communication with its appointed neutral or non-neutral Arbitrator as necessary to secure the Arbitrator's services and to assure the absence of conflicts, as well as in connection with the selection of the Chairperson of the arbitral panel.

(c) The Parties may agree to permit more extensive *ex parte* communication between a Party and a non-neutral Arbitrator. More extensive communications with a non-neutral Arbitrator may also be permitted by applicable law and rules of ethics.

Rule 15. Arbitrator Selection, Disclosures and Replacement

(a) Unless the Arbitrator has been previously selected by agreement of the Parties, JAMS may attempt to facilitate agreement among the Parties regarding selection of the Arbitrator.

(b) If the Parties do not agree on an Arbitrator, JAMS shall send the Parties a list of at least five (5) Arbitrator candidates in the case of a sole Arbitrator and ten (10) Arbitrator candidates in the case of a tripartite panel. JAMS shall also provide each Party with a brief description of the background and experience of each Arbitrator candidate. JAMS may replace any or all names on the list of Arbitrator candidates for reasonable cause at any time before the Parties have submitted their choice pursuant to subparagraph
(c) below.

(c) Within seven (7) calendar days of service by the Parties of the list of names, each Party may strike two (2) names in the case of a sole Arbitrator and three (3) names in the case of a tripartite panel, and shall rank the remaining Arbitrator candidates in order of preference. The remaining Arbitrator candidate with the highest composite ranking shall be appointed the Arbitrator. JAMS may grant a reasonable extension of the time to strike and rank the Arbitrator candidates to any Party without the consent of the other Parties.

(d) If this process does not yield an Arbitrator or a complete panel, JAMS shall designate the sole Arbitrator or as many members of the tripartite panel as are necessary to complete the panel.

(e) If a Party fails to respond to a list of Arbitrator candidates within seven (7) calendar days after its service, or fails to respond according to the instructions provided by JAMS, JAMS shall deem that Party to have accepted all of the Arbitrator candidates.

(f) Entities whose interests are not adverse with respect to the issues in dispute shall be treated as a single Party for purposes of the Arbitrator selection process. JAMS

shall determine whether the interests between entities are adverse for purposes of Arbitrator selection, considering such factors as whether the entities are represented by the same attorney and whether the entities are presenting joint or separate positions at the Arbitration.

(g) If, for any reason, the Arbitrator who is selected is unable to fulfill the Arbitrator's duties, a successor Arbitrator shall be chosen in accordance with this Rule. If a member of a panel of Arbitrators becomes unable to fulfill his or her duties after the beginning of a Hearing but before the issuance of an Award, a new Arbitrator will be chosen in accordance with this Rule, unless, in the case of a tripartite panel, the Parties agree to proceed with the remaining two Arbitrators. JAMS will make the final determination as to whether an Arbitrator is unable to fulfill his or her duties, and that decision shall be final.

(h) Any disclosures regarding the selected Arbitrator shall be made as required by law or within ten (10) calendar days from the date of appointment. Such disclosures may be provided in electronic format, provided that JAMS will produce a hard copy to any Party that requests it. The Parties and their representatives shall disclose to JAMS any circumstances likely to give rise to justifiable doubt as to the Arbitrator's impartiality or independence, including any bias or any financial or personal interest in the result of the Arbitration or any past or present relationship with the Parties and their representatives. The obligation of the Arbitrator, the Parties and their representatives to make all required disclosures continues throughout the Arbitration process.

(i) At any time during the Arbitration process, a Party may challenge the continued service of an Arbitrator for cause. The challenge must be based upon information that was not available to the Parties at the time the Arbitrator was selected. A challenge for cause must be in writing and exchanged with opposing Parties, who may respond within seven (7) days of service of the challenge. JAMS shall make the final determination as to such challenge. Such determination shall take into account the materiality of the facts and any prejudice to the Parties. That decision will be final.

(j) Where the Parties have agreed that a Party-appointed Arbitrator is to be non-neutral, that Party-appointed Arbitrator is not obliged to withdraw if requested to do so only by the party who did not appoint that Arbitrator.

Rule 16. Preliminary Conference

At the request of any Party or at the direction of the Arbitrator, a Preliminary Conference shall be conducted with the Parties or their counsel or representatives. The Preliminary Conference may address any or all of the following subjects:

(a) The exchange of information in accordance with Rule 17 or otherwise;

(b) The schedule for discovery as permitted by the Rules, as agreed by the Parties or as required or authorized by applicable law;

(c) The pleadings of the Parties and any agreement to clarify or narrow the issues or structure the Arbitration Hearing;

(d) The scheduling of the Hearing and any pre-Hearing exchanges of information, exhibits, motions or briefs;

(e) The attendance of witnesses as contemplated by Rule 21;

(f) The scheduling of any dispositive motion pursuant to Rule 18;

(g) The premarking of exhibits, preparation of joint exhibit lists and the resolution of the admissibility of exhibits;

(h) The form of the Award; and

(i) Such other matters as may be suggested by the Parties or the Arbitrator.

The Preliminary Conference may be conducted telephonically and may be resumed from time to time as warranted.

Rule 17. Exchange of Information

(a) The Parties shall cooperate in good faith in the voluntary and informal exchange of all non-privileged documents and other information (including electronically stored information ("ESI")) relevant to the dispute or claim immediately after commencement of the Arbitration. They shall complete an initial exchange of all relevant, nonprivileged documents, including, without limitation, copies of all documents in their possession or control on which they rely in support of their positions, names of individuals whom they may call as witnesses at the Arbitration Hearing

and names of all experts who may be called to testify at the Arbitration Hearing, together with each expert's report, which may be introduced at the Arbitration Hearing, within twenty-one (21) calendar days after all pleadings or notice of claims have been received. The Arbitrator may modify these obligations at the Preliminary Conference.

(b) Each Party may take at least one deposition of an opposing Party or an individual under the control of the opposing Party. The Parties shall attempt to agree on the number, time, location and duration of the deposition(s). Absent agreement, the Arbitrator shall determine these issues, including whether to grant a request for additional depositions, based upon the reasonable need for the requested information, the availability of other discovery and the burdensomeness of the request on the opposing Parties and witness.

(c) As they become aware of new documents or information, including experts who may be called upon to testify, all Parties continue to be obligated to provide relevant, nonprivileged documents, to supplement their identification of witnesses and experts and to honor any informal agreements or understandings between the Parties regarding documents or information to be exchanged. Documents that were not previously exchanged, or witnesses and experts that were not previously identified, may not be considered by the Arbitrator at the Hearing, unless agreed by the Parties or upon a showing of good cause.

(d) The Parties shall promptly notify JAMS when a dispute exists regarding discovery issues. A conference shall be arranged with the Arbitrator, either by telephone or in person, and the Arbitrator shall decide the dispute. With the written consent of all Parties, and in accordance with an agreed written procedure, the Arbitrator may appoint a special master to assist in resolving a discovery dispute.

Rule 18. Summary Disposition of a Claim or Issue

The Arbitrator may permit any Party to file a Motion for Summary Disposition of a particular claim or issue, either by agreement of all interested Parties or at the request of one Party, provided other interested Parties have reasonable notice to respond to the motion.

Rule 19. Scheduling and Location of Hearing

(a) The Arbitrator, after consulting with the Parties that have appeared, shall determine the date, time and location of the Hearing. The Arbitrator and the Parties shall attempt to schedule consecutive Hearing days if more than one day is necessary.

(b) If a Party has failed to participate in the Arbitration process, and the Arbitrator reasonably believes that the Party will not participate in the Hearing, the Arbitrator may set the Hearing without consulting with that Party. The non-participating Party shall be served with a Notice of Hearing at least thirty (30) calendar days prior to the scheduled date, unless the law of the relevant jurisdiction allows for, or the Parties have agreed to, shorter notice.

(c) The Arbitrator, in order to hear a third-party witness, or for the convenience of the Parties or the witnesses, may conduct the Hearing at any location. Any JAMS Resolution Center may be designated a Hearing location for purposes of the issuance of a subpoena or subpoena *duces tecum* to a third-party witness.

Rule 20. Pre-Hearing Submissions

(a) Except as set forth in any scheduling order that may be adopted, at least fourteen (14) calendar days before the Arbitration Hearing, the Parties shall file with JAMS and serve and exchange (1) a list of the witnesses they intend to call, including any experts; (2) a short description of the anticipated testimony of each such witness and an estimate of the length of the witness' direct testimony; and (3) a list of all exhibits intended to be used at the Hearing. The Parties should exchange with each other copies of any such exhibits to the extent that they have not been previously exchanged. The Parties should pre-mark exhibits and shall attempt to resolve any disputes regarding the admissibility of exhibits prior to the Hearing.

(b) The Arbitrator may require that each Party submit a concise written statement of position, including summaries of the facts and evidence a Party intends to present, discussion of the applicable law and the basis for the requested Award or denial of relief sought. The statements, which may be in the form of a letter, shall be filed with JAMS and served upon the other Parties at least seven (7) calendar days before the Hearing date. Rebuttal statements or other pre-Hearing written submissions may be permitted or required at the discretion of the Arbitrator.

Rule 21. Securing Witnesses and Documents for the Arbitration Hearing

At the written request of a Party, all other Parties shall produce for the Arbitration Hearing all specified witnesses in their employ or under their control without need of subpoena. The Arbitrator may issue subpoenas for the attendance of witnesses or the production of documents either prior to or at the Hearing pursuant to this Rule or Rule 19(c). The subpoena or subpoena *duces tecum* shall be issued in accordance with the applicable law. Pre-issued subpoenas may be used in jurisdictions that permit them. In the event a Party or a subpoenaed person objects to the production of a witness or other evidence, the Party or subpoenaed person may fi an objection with the Arbitrator, who shall promptly rule on the objection, weighing both the burden on the producing Party and witness and the need of the proponent for the witness or other evidence.

Rule 22. The Arbitration Hearing

(a) The Arbitrator will ordinarily conduct the Arbitration Hearing in the manner set forth in these Rules. The Arbitrator may vary these procedures if it is determined to be reasonable and appropriate to do so. It is expected that the Employee will attend the Arbitration Hearing, as will any other individual party with information about a significant issue.

(b) The Arbitrator shall determine the order of proof, which will generally be similar to that of a court trial.

(c) The Arbitrator shall require witnesses to testify under oath if requested by any Party, or otherwise at the discretion of the Arbitrator.

(d) Strict conformity to the rules of evidence is not required, except that the Arbitrator shall apply applicable law relating to privileges and work product. The Arbitrator shall consider evidence that he or she finds relevant and material to the dispute, giving the evidence such weight as is appropriate. The Arbitrator may be guided in that determination by principles contained in the Federal Rules of Evidence or any other applicable rules of evidence. The Arbitrator may limit testimony to exclude evidence that would be immaterial or unduly repetitive, provided that all Parties are afforded the opportunity to present material and relevant evidence.

(e) The Arbitrator shall receive and consider relevant deposition testimony recorded by transcript or videotape, provided that the other Parties have had the opportunity to attend and cross-examine. The Arbitrator may in his or her discretion consider witness affidavits or other recorded testimony even if the other Parties have not had the opportunity to cross-examine, but will give that evidence only such weight as he or she deems appropriate.

(f) The Parties will not offer as evidence, and the Arbitrator shall neither admit into the record nor consider, prior settlement offers by the Parties or statements or recommendations made by a mediator or other person in connection with efforts to resolve the dispute being arbitrated, except to the extent that applicable law permits the admission of such evidence.

(g) The Hearing, or any portion thereof, may be conducted telephonically or videographically with the agreement of the Parties or at the discretion of the Arbitrator.

(h) When the Arbitrator determines that all relevant and material evidence and arguments have been presented, and any interim or partial Awards have been issued, the Arbitrator shall declare the Hearing closed. The Arbitrator may defer the closing of the Hearing until a date determined by the Arbitrator, to permit the Parties to submit post-Hearing briefs, which may be in the form of a letter, and/or to make closing arguments. If post-Hearing briefs are to be submitted, or closing arguments are to be made, the Hearing shall be deemed closed upon receipt by the Arbitrator of such briefs or at the conclusion of such closing arguments, whichever is later.

(i) At any time before the Award is rendered, the Arbitrator may, *sua sponte* or on application of a Party for good cause shown, reopen the Hearing. If the Hearing is reopened, the time to render the Award shall be calculated from the date the reopened Hearing is declared closed by the Arbitrator.

(j) The Arbitrator may proceed with the Hearing in the absence of a Party that, after receiving notice of the Hearing pursuant to Rule 19, fails to attend. The Arbitrator may not render an Award solely on the basis of the default or absence of the Party, but shall require any Party seeking relief to submit such evidence as the Arbitrator may require for the rendering of an Award. If the Arbitrator reasonably believes that a Party will not attend the Hearing, the Arbitrator may schedule the Hearing as a telephonic Hearing and

may receive the evidence necessary to render an Award by affidavit. The notice of Hearing shall specify if it will be in person or telephonic.

(k) Any Party may arrange for a stenographic or other record to be made of the Hearing and shall inform the other Parties in advance of the Hearing.
(i) The requesting Party shall bear the cost of such stenographic record. If all other Parties agree to share the cost of the stenographic record, it shall be made available to the Arbitrator and may be used in the proceeding.
(ii) If there is no agreement to share the cost, the stenographic record may not be provided to the Arbitrator and may not be used in the proceeding, unless the Party arranging for the stenographic record agrees to provide access to the stenographic record either at no charge or on terms that are acceptable to the Parties and the reporting service.
(iii) If the Parties agree to the Optional Arbitration Appeal Procedure (see Rule 34), they shall, if possible, ensure that a stenographic or other record is made of the Hearing.
(iv) The Parties may agree that the cost of the stenographic record shall or shall not be allocated by the Arbitrator in the Award.

Rule 23. Waiver of Hearing

The Parties may agree to waive the oral Hearing and submit the dispute to the Arbitrator for an Award based on written submissions and other evidence as the Parties may agree.

Rule 24. Awards

(a) The Arbitrator shall render a Final Award or a Partial Final Award within thirty (30) calendar days after the date of the close of the Hearing, as defined in Rule 22(h) or (i), or, if a Hearing has been waived, within thirty (30) calendar days after the receipt by the Arbitrator of all materials specified by the Parties, except (1) by the agreement of the Parties; (2) upon good cause for an extension of time to render the Award; or (3) as provided in Rule 22(i). The Arbitrator shall provide the Final Award or the Partial Final Award to JAMS for issuance in accordance with this Rule.

(b) Where a panel of Arbitrators has heard the dispute, the decision and Award of a majority of the panel shall constitute the Arbitration Award.

(c) In determining the merits of the dispute, the Arbitrator shall be guided by the rules of law agreed upon by the Parties. In the absence of such agreement, the Arbitrator will be guided by the law or the rules of law that he or she deems to be most appropriate. The Arbitrator may grant any remedy or relief that is just and equitable and within the scope of the Parties' agreement, including, but not limited to, specific performance of a contract or any other equitable or legal remedy.

(d) In addition to a Final Award or Partial Final Award, the Arbitrator may make other decisions, including interim or partial rulings, orders and Awards.

(e) Interim Measures. The Arbitrator may grant whatever interim measures are deemed necessary, including injunctive relief and measures for the protection or conservation of property and disposition of disposable goods. Such interim measures may take the form of an interim or Partial Final Award, and the Arbitrator may require security for the costs of such measures. Any recourse by a Party to a court for interim or provisional relief shall not be deemed incompatible with the agreement to arbitrate or a waiver of the right to arbitrate.

(f) The Award of the Arbitrator may allocate Arbitration fees and Arbitrator compensation and expenses, unless such an allocation is expressly prohibited by the Parties' Agreement or by applicable law. (Such a prohibition may not limit the power of the Arbitrator to allocate Arbitration fees and Arbitrator compensation and expenses pursuant to Rule 31(c).)

(g) The Award of the Arbitrator may allocate attorneys' fees and expenses and interest (at such rate and from such date as the Arbitrator may deem appropriate) if provided by the Parties' Agreement or allowed by applicable law. When the Arbitrator is authorized to award attorneys' fees and must determine the reasonable amount of such fees, he or she may consider whether the failure of a Party to cooperate reasonably in the discovery process and/or comply with the Arbitrator's discovery orders caused delay to the proceeding or additional costs to the other Parties.

(h) The Award shall consist of a written statement signed by the Arbitrator regarding the disposition of each claim and the relief, if any, as to each claim. The Award shall also contain a concise written statement of the reasons for the Award, stating the essential findings and conclusions

on which the Award is based. The Parties may agree to any other form of Award, unless the Arbitration is based on an arbitration agreement that is required as a condition of employment.

(i) After the Award has been rendered, and provided the Parties have complied with Rule 31, the Award shall be issued by serving copies on the Parties. Service may be made by U.S. mail. It need not be sent certified or registered.

(j) Within seven (7) calendar days after service of a Partial Final Award or Final Award by JAMS, any Party may serve upon the other Parties and on JAMS a request that the Arbitrator correct any computational, typographical or other similar error in an Award (including the reallocation of fees pursuant to Rule 31 or on account of the effect of an offer to allow judgment), or the Arbitrator may *sua sponte* propose to correct such errors in an Award. A Party opposing such correction shall have seven (7) calendar days thereafter in which to file any objection. The Arbitrator may make any necessary and appropriate corrections to the Award within twenty-one (21) calendar days of receiving a request or fourteen (14) calendar days after his or her proposal to do so. The Arbitrator may extend the time within which to make corrections upon good cause. The corrected Award shall be served upon the Parties in the same manner as the Award.

(k) The Award is considered final, for purposes of either the Optional Arbitration Appeal Procedure pursuant to Rule 34 or a judicial proceeding to enforce, modify or vacate the Award pursuant to Rule 25, fourteen (14) calendar days after service is deemed effective if no request for a correction is made, or as of the effective date of service of a corrected Award.

Rule 25. Enforcement of the Award

Proceedings to enforce, confirm, modify or vacate an Award will be controlled by and conducted in conformity with the Federal Arbitration Act, 9 U.S.C. Sec 1, *et seq*., or applicable state law. The Parties to an Arbitration under these Rules shall be deemed to have consented that judgment upon the Award may be entered in any court having jurisdiction thereof.

Rule 26. Confidentiality and Privacy

(a) JAMS and the Arbitrator shall maintain the confidential nature of the Arbitration proceeding and the Award, includ-

ing the Hearing, except as necessary in connection with a judicial challenge to or enforcement of an Award, or unless otherwise required by law or judicial decision.

(b) The Arbitrator may issue orders to protect the confidentiality of proprietary information, trade secrets or other sensitive information.

(c) Subject to the discretion of the Arbitrator or agreement of the Parties, any person having a direct interest in the Arbitration may attend the Arbitration Hearing. The Arbitrator may exclude any non-Party from any part of a Hearing.

Rule 27. Waiver

(a) If a Party becomes aware of a violation of or failure to comply with these Rules and fails promptly to object in writing, the objection will be deemed waived, unless the Arbitrator determines that waiver will cause substantial injustice or hardship.

(b) If any Party becomes aware of information that could be the basis of a challenge for cause to the continued service of the Arbitrator, such challenge must be made promptly, in writing, to the Arbitrator or JAMS. Failure to do so shall constitute a waiver of any objection to continued service by the Arbitrator.

Rule 28. Settlement and Consent Award

(a) The Parties may agree, at any stage of the Arbitration process, to submit the case to JAMS for mediation. The JAMS mediator assigned to the case may not be the Arbitrator or a member of the Appeal Panel, unless the Parties so agree, pursuant to Rule 28(b).

(b) The Parties may agree to seek the assistance of the Arbitrator in reaching settlement. By their written agreement to submit the matter to the Arbitrator for settlement assistance, the Parties will be deemed to have agreed that the assistance of the Arbitrator in such settlement efforts will not disqualify the Arbitrator from continuing to serve as Arbitrator if settlement is not reached; nor shall such assistance be argued to a reviewing court as the basis for vacating or modifying an Award.

(c) If, at any stage of the Arbitration process, all Parties agree upon a settlement of the issues in dispute and request the Arbitrator to embody the agreement in a Consent Award, the Arbitrator shall comply with such request, unless the

Arbitrator believes the terms of the agreement are illegal or undermine the integrity of the Arbitration process. If the Arbitrator is concerned about the possible consequences of the proposed Consent Award, he or she shall inform the Parties of that concern and may request additional specific information from the Parties regarding the proposed Consent Award. The Arbitrator may refuse to enter the proposed Consent Award and may withdraw from the case.

Rule 29. Sanctions

The Arbitrator may order appropriate sanctions for failure of a Party to comply with its obligations under any of these Rules or with an order of the Arbitrator. These sanctions may include, but are not limited to, assessment of Arbitration fees and Arbitrator compensation and expenses; any other costs occasioned by the actionable conduct, including reasonable attorneys' fees; exclusion of certain evidence; drawing adverse inferences; or, in extreme cases, determining an issue or issues submitted to Arbitration adversely to the Party that has failed to comply.

Rule 30. Disqualification of the Arbitrator as a Witness or Party and Exclusion of Liability

(a) The Parties may not call the Arbitrator, the Case Manager or any other JAMS employee or agent as a witness or as an expert in any pending or subsequent litigation or other proceeding involving the Parties and relating to the dispute that is the subject of the Arbitration. The Arbitrator, Case Manager and other JAMS employees and agents are also incompetent to testify as witnesses or experts in any such proceeding.

(b) The Parties shall defend and/or pay the cost (including any attorneys' fees) of defending the Arbitrator, Case Manager and/or JAMS from any subpoenas from outside parties arising from the Arbitration.

(c) The Parties agree that neither the Arbitrator, nor the Case Manager, nor JAMS is a necessary Party in any litigation or other proceeding relating to the Arbitration or the subject matter of the Arbitration, and neither the Arbitrator, nor the Case Manager, nor JAMS, including its employees or agents, shall be liable to any Party for any act or omission in connection with any Arbitration conducted under these Rules, including, but not limited to, any disqualification of or recusal by the Arbitrator.

Rule 31. Fees

(a) Except as provided in paragraph (c) below, unless the Parties have agreed to a different allocation, each Party shall pay its *pro rata* share of JAMS fees and expenses as set forth in the JAMS fee schedule in effect at the time of the commencement of the Arbitration. To the extent possible, the allocation of such fees and expenses shall not be disclosed to the Arbitrator. JAMS' agreement to render services is jointly with the Party and the attorney or other representative of the Party in the Arbitration. The non-payment of fees may result in an administrative suspension of the case in accordance with Rule 6(c).

(b) JAMS requires that the Parties deposit the fees and expenses for the Arbitration from time to time during the course of the proceedings and prior to the Hearing. The Arbitrator may preclude a Party that has failed to deposit its *pro rata* or agreed-upon share of the fees and expenses from offering evidence of any affirmative claim at the Hearing.

(c) If an Arbitration is based on a clause or agreement that is required as a condition of employment, the only fee that an employee may be required to pay is the initial JAMS Case Management Fee. JAMS does not preclude an employee from contributing to administrative and Arbitrator fees and expenses. If an Arbitration is not based on a clause or agreement that is required as a condition of employment, the Parties are jointly and severally liable for the payment of JAMS Arbitration fees and Arbitrator compensation and expenses. In the event that one Party has paid more than its share of such fees, compensation and expenses, the Arbitrator may award against any other Party any such fees, compensation and expenses that such Party owes with respect to the Arbitration.

(d) Entities whose interests are not adverse with respect to the issues in dispute shall be treated as a single Party for purposes of JAMS' assessment of fees. JAMS shall determine whether the interests between entities are adverse for purpose of fees, considering such factors as whether the entities are represented by the same attorney and whether the entities are presenting joint or separate positions at the Arbitration.

Rule 32. Bracketed (or High-Low) Arbitration Option

(a) At any time before the issuance of the Arbitration Award, the Parties may agree, in writing, on minimum and maximum amounts of damages that may be awarded on each claim or on all claims in the aggregate. The Parties shall promptly notify JAMS and provide to JAMS a copy of their written agreement setting forth the agreed-upon minimum and maximum amounts.

(b) JAMS shall not inform the Arbitrator of the agreement to proceed with this option or of the agreed-upon minimum and maximum levels without the consent of the Parties.

(c) The Arbitrator shall render the Award in accordance with Rule 24.

(d) In the event that the Award of the Arbitrator is between the agreed-upon minimum and maximum amounts, the Award shall become final as is. In the event that the Award is below the agreed-upon minimum amount, the final Award issued shall be corrected to reflect the agreed-upon minimum amount. In the event that the Award is above the agreed-upon maximum amount, the final Award issued shall be corrected to reflect the agreed-upon maximum amount.

Rule 33. Final Offer (or Baseball) Arbitration Option

(a) Upon agreement of the Parties to use the option set forth in this Rule, at least seven (7) calendar days before the Arbitration Hearing, the Parties shall exchange and provide to JAMS written proposals for the amount of money damages they would offer or demand, as applicable, and that they believe to be appropriate based on the standard set forth in Rule 24(c). JAMS shall promptly provide copies of the Parties' proposals to the Arbitrator, unless the Parties agree that they should not be provided to the Arbitrator. At any time prior to the close of the Arbitration Hearing, the Parties may exchange revised written proposals or demands, which shall supersede all prior proposals. The revised written proposals shall be provided to JAMS, which shall promptly provide them to the Arbitrator, unless the Parties agree otherwise.

(b) If the Arbitrator has been informed of the written proposals, in rendering the Award, the Arbitrator shall choose between the Parties' last proposals, selecting the proposal

that the Arbitrator finds most reasonable and appropriate in light of the standard set forth in Rule 24(c). This provision modifies Rule 24(h) in that no written statement of reasons shall accompany the Award.

(c) If the Arbitrator has not been informed of the written proposals, the Arbitrator shall render the Award as if pursuant to Rule 24, except that the Award shall thereafter be corrected to conform to the closest of the last proposals and the closest of the last proposals will become the Award.

(d) Other than as provided herein, the provisions of Rule 24 shall be applicable.

Rule 34. Optional Arbitration Appeal Procedure

The Parties may agree at any time to the JAMS Optional Arbitration Appeal Procedure. All Parties must agree in writing for such procedures to be effective. Once a Party has agreed to the Optional Arbitration Appeal Procedure, it cannot unilaterally withdraw from it, unless it withdraws, pursuant to Rule 13, from the Arbitration.

***** 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, No. 333-215089 and No. 333-222089) and Form S-3 (No. 333-161948) of our reports dated March 13, 2018 relating to the consolidated financial statements and financial statement schedule of VIVUS, Inc. 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 13, 2018

Exhibit 31.1

CERTIFICATION OF INTERIM CHIEF EXECUTIVE OFFICER PURSUANT

TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Thomas B. King, Interim 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(s) 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(s) 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 13, 2018

By: /s/ Thomas B. King
Name: Thomas B. King
Title: *Interim 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(s) 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(s) 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 13, 2018

By: /s/ Mark K. Oki
Name: Mark K. Oki
Title: *Chief Financial Officer and Chief Accounting Officer*

Exhibit 32.1

CERTIFICATION OF INTERIM 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, Thomas B. King, Interim 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, 2017 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 13, 2018

By: /s/ Thomas B. King
Thomas B. King
Interim 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, 2017 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 13, 2018

By: /s/ Mark K. Oki
Mark K. Oki
Chief Financial Officer and Chief Accounting Officer