VIVUS INC
Form 10-K
March 14, 2018
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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	The NASDAQ Global Select Market
(Title of class)	
Preferred Share Purchase Rights	
(Title of class)	

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

None

Indicate by check mark if the registrant is a well known seasoned issuer, as defined in Rule 405 of the Securities

Act. Yes 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 wo 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;

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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.

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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.

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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.

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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.

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Products and Development Programs

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

Drug	Indication	Status	Commercial rights
Qsymia	Obesity	United States Commercially available	Worldwide rights available, except for South Korea
		EU Marketing Authorization Application, or MAA, denied in 2014	
		South Korea Not yet commercially available	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	Worldwide license from MTPC (excluding certain Asian markets). U.S., Canada, South America and India commercial rights licensed to Metuchen
		EU Commercially available	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,

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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

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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.

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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

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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.

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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.

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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

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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

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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

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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

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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

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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

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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

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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

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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.

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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.

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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.

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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

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*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

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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)

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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.

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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.

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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;

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- 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.

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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.

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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.

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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

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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.

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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;

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- 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

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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

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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

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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

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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

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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.

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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

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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.

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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.

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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

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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

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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.

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

All of those involved in the preparation of a therapeutic drug for clinical trials or commercial sale, including our existing supply contract manufacturers, and clinical trial investigators, are subject to extensive regulation. Components of a finished drug product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with current Good Manufacturing Practices, or cGMP. These regulations govern quality control of the manufacturing processes and documentation policies and procedures, and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Our facilities and quality systems and the facilities and quality systems of our third-party contractors must be inspected routinely for compliance. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulation occurs independent of such an inspection or audit, we or 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

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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

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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

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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.

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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

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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

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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

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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

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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.

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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.

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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.

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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.

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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.

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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

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· 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;

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- 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

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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,

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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.

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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.

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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.

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Item 6. Selected Financial Data

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

Selected Financial Data

(In thousands, except per share 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

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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.

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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.

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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

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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.

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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

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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

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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,

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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

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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.

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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.

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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.

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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

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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

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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.

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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.

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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.

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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.

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Item 8. Financial Statements and Supplementary Data

VIVUS, INC.

1.Index to Consolidated Financial Statements

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

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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.

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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

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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.

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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.

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VIVUS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)

(In thousands)

	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated 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.

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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.

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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.

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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.

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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

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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.

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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

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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

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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

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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):

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	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.

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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		