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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, 2019

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

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

None

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

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

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 such files). Yes ☒ No ☐

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 ☒ 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, 2019, totaled approximately $39,767,025 based on the closing stock price as reported by the NASDAQ Global Select Market.

As of February 29, 2020, there were 10,648,947 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, 2019, are incorporated by reference into Part III of this report.	Part III - ITEMS 10, 11, 12, 13, 14

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Certification of Chief Executive Officer
Certification of Chief Financial Officer
Certification of Chief Executive Officer and Chief Financial Officer

FORWARD-LOOKING STATEMENTS

This Form 10-K contains “forward looking” statements that involve risks and uncertainties. These statements typically may be identified by the use of forward-looking words or phrases such as “may,” “believe,” “expect,” “forecast,” “intend,” “anticipate,” “predict,” “should,” “plan,” “likely,” “opportunity,” “estimated,” and “potential,” the negative use of these words or other similar words. All forward-looking statements included in this document are based on our current expectations, and we assume no obligation to update any such forward-looking statements. The Private Securities Litigation Reform Act of 1995 provides a “safe harbor” for such forward-looking statements. In order to comply with the terms of the safe harbor, we note that a variety of factors could cause actual results and experiences to differ materially from the anticipated results or other expectations expressed in such forward-looking statements. The risks and uncertainties that may affect the operations, performance, development, and results of our business include but are not limited to:

Risks and uncertainties related to our business:

- our ability to address our liquidity and capital resource needs, including our outstanding balance of $181.4 million of 4.5% Convertible Senior Notes due in May 2020 (the “Convertible Notes”);
- our history of losses and variable quarterly results;
- our ability to continue as a going concern;
- the volatility and liquidity of the financial markets;
- our expected future revenues, operations and expenditures;
- our ability to effectively manage expenses;
- 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;
- risks related to the failure to obtain or retain federal or state-controlled substances registrations and noncompliance with Drug Enforcement Administration (“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 demonstrate through clinical testing the quality, safety, and efficacy of our current and future investigational drug candidates or approved products;
- the timing of initiation and completion of clinical trials and submissions to U.S. and foreign authorities;
- compliance with post-marketing regulatory standards, post-marketing obligations or pharmacovigilance rules is not maintained;
- our ability to execute on our business strategy to enhance long-term stockholder value;
- our ability to identify and acquire cash flow generating assets and opportunities;
- our ability to successfully navigate recent changes to our Board of Directors and the senior management team;
- other factors that are described from time to time in our periodic filings with the Securities and Exchange Commission (the “SEC”) including those set forth in this filing as “Item 1A. Risk Factors;”

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

- our, or our current or potential partners’, ability to successfully commercialize Qsymia including risks and uncertainties related to expansion to direct to patient 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 sell through the Qsymia retail pharmacy network and the Qsymia Advantage program;
- the impact of promotional programs for Qsymia on our net product revenue and operating results in future periods;
- our ability to ensure that the entire supply chain for Qsymia timely, efficiently and consistently delivers Qsymia to our customers and partners;
- our ability to accurately forecast Qsymia demand;
- our ability to maintain the relationship with the sole manufacture for Qsymia;
- our, or our current or potential partners', ability to successfully seek and gain approval for Qsymia in territories outside the U.S.;
- our dialogue with certain Concerned Member States (as defined below) in Europe relating to the pending decentralized Marketing Authorization Application, the timing and scope of the assessment by such Concerned Member State health authorities of our Marketing Authorization Application, and ultimately the decision of such Concerned Member State health authorities on whether to grant Marketing Authorization for Qsymia in such EU countries;
- the timing of and costs associated with the 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 ("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 ("CVOT");
- the impact of the indicated uses and contraindications contained in the Qsymia label and the Risk Evaluation and Mitigation Strategy ("REMS") requirements;
- the impact of any possible future requirement to provide additional clinical data or further analysis of previously submitted clinical trial data;

Risks and uncertainties related to PANCREAZE (pancrelipase):

- risks and uncertainties related to the timing, strategy, tactics and success of the marketing and sales of PANCREAZE;
- our ability to successfully maintain and increase market share against current competing products and potential competitors that may develop alternative formulations of the drug;
- our ability to accurately forecast PANCREAZE demand;
- our ability to maintain the relationship with the sole manufacturer for PANCREAZE;
- our ability to maintain a satisfactory level of PANCREAZE inventory;
- the ability of our partners to maintain regulatory approvals to manufacture and adequately supply our products to meet demand;

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 commercial collaborators;
- our ability to find a new distribution partner or model for STENDRA in the United States, Canada, South America and India;
- 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 partner;

- Sanofi Chimie's ability to manufacture the avanafil active pharmaceutical ingredient and Sanofi Winthrop Industrie's ability to manufacture avanafil tablets; and
- the ability of our partners to maintain regulatory approvals to manufacture and adequately supply our products to meet demand.

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

PART I

Item 1. *Business*

Overview

VIVUS is a specialty pharmaceutical company with three approved therapies and one product candidate in clinical development. Qsymia® (phentermine and topiramate extended release) is approved by FDA for chronic weight management. We commercialize Qsymia in the U.S. through a specialty sales force supported by an internal commercial team and license the commercial rights to Qsymia in South Korea. In June 2018, we acquired the U.S. and Canadian commercial rights for PANCREAZE®/ PANCREASE® MT (pancrelipase), which is indicated for the treatment of exocrine pancreatic insufficiency ("EPI") due to cystic fibrosis or other conditions. We commercialize PANCREAZE in the U.S. through a specialty sales force supported by an internal commercial team. STENDRA® (avanafil) is approved by FDA for erectile dysfunction ("ED") and by the European Commission ("EC") under the trade name SPEDRA, for the treatment of ED in the EU. We license the commercial rights to STENDRA/SPEDRA in the U.S., EU and other countries.VI-0106 (tacrolimus) is in clinical development and is being studied in patients with pulmonary arterial hypertension ("PAH").

When reference is made to the "Company" or "VIVUS" in this filing, it refers to the Delaware corporation, or VIVUS, Inc., and, unless the context otherwise requires, its California predecessor, as well as all of its consolidated subsidiaries.

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.

Business Strategy

In April 2018, we added John Amos as our new Chief Executive Officer and a member of the VIVUS Board of Directors. With the addition of Mr. Amos, we announced a turnaround plan of building a portfolio of cash flow generating assets to leverage our expertise in commercializing specialty pharmaceutical assets. In June 2018, we completed the first acquisition under this strategy as we acquired all product rights for PANCREAZE® (pancrelipase) in the United States and PANCREASE MT in Canada for $135.0 million in cash from Janssen Pharmaceuticals. PANCREAZE/PANCREASE MT is a prescription medicine used to treat people who cannot digest food normally because their pancreas does not make enough enzymes due to cystic fibrosis or other conditions. We are supporting PANCREAZE in the U.S. market by leveraging our existing commercial infrastructure and 10 sales representatives in the U.S. focused on gastro-intestinal and cystic fibrosis physicians.

In June of 2018, we issued $110.0 million of 10.375% 2024 Notes ("2024 Notes") with affiliates of Athyrium Capital Management ("Athyrium"). Concurrent with the issuance of the 2024 Notes, we issued warrants to purchase 0.3 million shares of our common stock to the note holders. Additionally, concurrent with the issuance of the 2024 Notes, we repurchased Convertible Notes held by Athyrium, with a face value of $60.0 million, at a discount to par plus accrued interest. In October 2018, we settled a purchase of approximately $8.6 million outstanding principal amount of our Convertible Notes for approximately $7.1 million plus accrued interest. In September 2019, we repurchased $48.6 million aggregate principal amount of our 2024 Notes plus prepayment premiums of an aggregate of $6.4 million.

As of December 31, 2019, we had a total of $241.7 million of outstanding debt, $181.4 million of which is due in May 2020. We do not currently have sufficient cash and/or credit facilities in place to pay the debt due May 2020 and thus are actively pursuing funding, which may come through public or private debt or equity financings, collaborations or other available financing sources. Such funding 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 will not be able to continue our operations at our current level and may be required to relinquish rights to certain of our technologies, product candidates or products that we would otherwise seek to develop on our own. We might also be required to delay, reduce the scope of or eliminate one or more of our commercialization or development programs or obtain funds through collaborations with others that are on unfavorable terms or restructure VIVUS in other ways that may not be favorable. Even if adequate funds become available, we may need to raise additional funds in the near future to finance operations and pursue development and commercial opportunities.

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 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 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. In 2019, we introduced the Qsymia Advantage program to reach more of our intended patient population. The Qsymia Advantage program includes patient education resources and access to on-line or telephonic ordering, direct-to-patient home delivery and reduced pricing. In the fourth quarter of 2019, 31% of our scripts were issued through the Qsymia Advantage program. We believe we can increase Qsymia script volume through expansion of the Qsymia Advantage program.

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 (the “Alvogen License Agreement”) and a commercial supply agreement (the “Alvogen Supply Agreement”) with Alvogen Malta Operations (ROW) Ltd (“Alvogen”). Under the terms of the Alvogen License Agreement, Alvogen is 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 a payment of $2.5 million in September 2019 upon achieving marketing authorization. We are eligible to receive additional payments upon Alvogen achieving 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, we will supply product to Alvogen on an exclusive basis.

In October 2019, we announced that European regulatory agencies in Sweden, Denmark, Finland, Iceland, Norway, and Poland (the “Concerned Member States”) have accepted the Marketing Authorization Application (the “MAA”) for Qsymia on a decentralized basis, with Sweden acting as the lead (“Reference Member State”). Under the decentralized MAA procedure, the regulatory authorities in each of the Concerned Member States may, following the proposal by the Reference Member State, simultaneously grant Marketing Authorization for use of a product within their territory. Based on the decentralized MAA procedure timelines, we anticipate the completion of the MAA assessment in the second half of 2020.

In May 2019, we began enrollment in a Phase four clinical study designed to evaluate the safety and efficacy of Qsymia in obese adolescents between the ages of 12 and 17 years (NCT# 03922945). The Centers for Disease Control and Prevention estimates that nearly 21 percent of adolescents ages 12 to 19 years are obese. A study conducted by the World Health Organization found that obesity in children ages five to 19 years has risen ten-fold in the past four decades and estimates that more children globally will be overweight rather than underweight by 2022. The Phase 4 post-marketing study, which the U.S. Food and Drug Administration (FDA) required as part of the approval of Qsymia in 2012, is expected to enroll 200 patients at approximately 25 clinical sites in the United States. The primary endpoint of the randomized, double blind, placebo-controlled, parallel-design study is the mean percentage change in body-mass index (BMI) in patients randomized 1:2:1 to daily mid- or top-dose Qsymia compared with placebo over 56 weeks of treatment. Participants will also be instructed to follow a reduced-calorie diet and to implement a family-based lifestyle modification program that includes physical activity, behavioral change and family support. Safety and tolerability of Qsymia will also be assessed.

PANCREAZE/PANCREASE MT

In June 2018, we acquired the commercial rights to PANCREAZE and PANCREASE MT in the U.S. and Canada. Prior to the acquisition, PANCREAZE/PANCREASE MT had been commercialized by Janssen. In connection with the acquisition of PANCREAZE/PANCREASE MT, we and Janssen also entered into transition services agreements pursuant to which Janssen and a Canadian affiliate of Janssen provided certain transition services to us in the U.S. and Canada as we transitioned to full control over the PANCREAZE/PANCREASE MT supply chain. In the first quarter of 2019, we relaunched PANCREAZE in the U.S. by leveraging our existing commercial infrastructure and expanding it to include 10 additional contract sales representatives in the U.S. focused on gastro-intestinal and cystic fibrosis physicians. We also introduced the PANCREAZE Advantage program, which is intended to enhance patient access and improve the patient experience with patient and physician educational materials, a patient support program, and patient and payment assistance. We transitioned to direct sales in Canada in the third quarter of 2019. We have also prioritized supply chain improvement, working capital management and moving PANCREAZE/PANCREASE MT back into the view of the medical community. In February 2020, FDA approved the supplemental New Drug Application for an improved formulation of PANCREAZE that extends the shelf life to 36 months across all PANCREAZE dosages.

Approved in 2010, PANCREAZE is a pancreatic enzyme preparation consisting of pancrelipase, an extract derived from porcine pancreatic glands, as well as other enzyme classes, including porcine-derived lipases, proteases and amylases. PANCREAZE is specifically indicated for the treatment of exocrine pancreatic insufficiency (“EPI”). EPI is a condition that results from a deficiency in the production and/or secretion of pancreatic enzymes. It is associated with cystic fibrosis, chronic pancreatitis, pancreatic cancer and other conditions, and affects approximately 85 percent of cystic fibrosis patients. There is no cure for EPI and pancreatic enzyme replacement therapy is the primary treatment for the condition.

STENDRA/SPEDRA

STENDRA is an oral phosphodiesterase type 5 (“PDE5”) inhibitor that we have licensed from Mitsubishi Tanabe Pharma Corporation (“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.

The Menarini Group, through its subsidiary Berlin Chemie AG (“Menarini”), is our exclusive licensee for the commercialization and promotion of SPEDRA for the treatment of ED in over 40 countries, including the EU Member States. In addition, Menarini licensed rights directly from MTPC to commercialize avanafil in certain Asian territories. We receive royalties from Menarini based on SPEDRA net sales and are entitled to receive future milestone payments based on certain net sales targets. 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.

Metuchen Pharmaceuticals LLC (“Metuchen”) is our exclusive licensee for the development, commercialization and promotion of STENDRA in the United States, Canada, South America and India. Metuchen reimburses us for payments made to cover royalty and milestone obligations to MTPC, but otherwise owes us no future royalties. Metuchen obtains STENDRA exclusively from us. On September 30, 2019, Metuchen provided a written notice of termination of our supply agreement with them effective September 30, 2021.

We are currently in discussions with potential collaboration partners to develop, market and sell STENDRA/SPEDRA for territories in which we do not currently have a commercial collaboration, including Africa, the Middle East, Turkey, Russia, Mexico and Central America.

Product Development Pipeline and Life Cycle Management

VI-0106 - 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 endothelial 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, all of which have been shown to effectively dilate arterioles in the pulmonary circulation, to reduce symptoms and improve quality of life. While currently approved products treat the symptoms of PAH, they do little to address the pathologic cell proliferation that is the underlying cause of the disease. We believe that tacrolimus can be used to enhance bone morphogenetic protein receptor type 2 (“BMPR2”) signaling. BMPR2 signaling has been shown to be reduced in PAH patients, and this reduction in signaling is an important factor leading to cell proliferation within the pulmonary arteries. By restoring BMPR2 signaling, tacrolimus 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 acquired the exclusive, worldwide rights for the development and commercialization of BMPR2 activators for the treatment of PAH and related vascular diseases from Selten Pharma, Inc. (“Selten”). Selten assigned to us its license to a group of patents owned by the Board of Trustees of the Leland Stanford Junior University (“Stanford”) which cover uses of tacrolimus and ascomycin to treat PAH. 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 VI-0106, 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 3 and 4 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 U.S. and the EU on the basis of a scientific opinion adopted by the Committee for Orphan Medicinal Products of 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, if approved, for commercial use. If we are successful in our development efforts, we anticipate filing an IND with FDA and completing the development of our proprietary formulation of tacrolimus in the second half of 2020. We are currently seeking alternatives for financing the development of tacrolimus.

Qsymia for Additional Indications

We are currently considering further development of Qsymia for the treatment of various diseases, including pre-diabetes, obstructive sleep apnea, nonalcoholic steatohepatitis (“NASH”) and bariatric surgery.

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 ("MAA") denied in 2014	
		South Korea Commercially available	South Korea commercial rights licensed to Alvogen
Qsymia	Pre-diabetes	Phase 2 study completed Phase 3-ready	Worldwide rights available
Qsymia	Obstructive Sleep Apnea	Phase 2 study completed	Worldwide rights available
Qsymia	NASH	Preclinical	Worldwide rights available
Qsymia	Bariatric surgery	Preclinical	Worldwide rights available
PANCREAZE	EPI	*United States* Commercially available	U.S. and Canadian rights available
		Canada Commercially 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
VI-0106 (tacrolimus)	PAH	Phase 2a study completed IND to be filed in 2020	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 ("NIH") losing just 10% of body weight may help obese patients reduce the risk of developing other weight-related medical conditions, while making a meaningful difference in health and well-being.

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

Qsymia was approved with a REMS with a goal of informing prescribers and patients of reproductive potential regarding an increased risk of orofacial clefts in infants exposed to Qsymia during the first trimester of pregnancy, the importance of pregnancy prevention for females of reproductive potential receiving Qsymia and the need to discontinue Qsymia immediately if pregnancy occurs. The Qsymia REMS program includes a medication guide, patient brochure, healthcare provider training, distribution through certified home delivery and retail pharmacies, an implementation system and a time-table for assessments.

Upon receiving approval to market Qsymia, FDA required that we perform additional studies of Qsymia including a CVOT. To date, there have been no indications throughout the Qsymia clinical development program nor post-marketing experience of any increase in adverse cardiovascular ("CV") events associated with Qsymia. 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 and are currently in discussions with FDA regarding an ambulatory blood pressure study which we believe will provide additional relevant data. We have submitted information from the retrospective observational 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.

In October 2019, we announced that European regulatory agencies in Sweden, Denmark, Finland, Iceland, Norway, and Poland (the "Concerned Member States") have accepted the Marketing Authorization Application (the "MAA") for Qsymia on a decentralized basis, with Sweden acting as the lead ("Reference Member State"). Under the decentralized MAA procedure, the regulatory authorities in each of the Concerned Member States may, following the proposal of the Reference Member State, simultaneously grant Marketing Authorization for use of a product within those specific countries. Based on the decentralized MAA procedure timelines, we anticipate the completion of the MAA assessment in the second half of 2020.

In December 2019, we announced the results of a pharmacokinetic and pharmacodynamic study demonstrating that Qsymia capsules CIV has favorable pharmacokinetic, efficacy, and safety/tolerability profiles when used for eight

weeks to treat adolescents with obesity. The study was conducted in order to establish dosing levels for the ongoing Phase 4 post-marketing study of Qsymia in obese adolescents. The results have been published online in Diabetes, Obesity and Metabolism. This randomized, double blind, placebo-controlled, study was conducted at four U.S. sites and enrolled 42 participants ages 12-17 years with a BMI greater than or equal to the 95th percentile for age and sex. The study consisted of a 14-day (maximum) screening period followed by a 56-day treatment period. Eligible participants were randomly assigned in a 1:1:1 ratio to placebo, mid-dose Qsymia or top-dose Qsymia. Within each active treatment arm, doses were titrated at two-week intervals starting with low dose Qsymia and increasing until the randomized dose was achieved. Participants assigned to placebo underwent a sham titration to ensure that both participants and site personnel remained blinded to treatment assignment. The primary objective of the study was to describe the pharmacokinetic profiles of Qsymia after administration in adolescents with obesity.

In May 2019, we initiated a Phase 4 post-marketing study, which FDA required as part of the approval of Qsymia in 2012. The study is expected to enroll 200 participants at approximately 25 clinical sites in the United States. The primary endpoint of the randomized, double blind, placebo-controlled, parallel-design study is the mean percentage change in BMI in patients randomized 1:2:1 to daily mid- or top-dose Qsymia compared with placebo over 56 weeks of treatment. Participants will also be instructed to follow a reduced-calorie diet and to implement a family-based lifestyle modification program that includes physical activity, behavioral change and family support. Safety and tolerability of Qsymia will also be assessed. As of February 29, 2020, enrollment in the study is complete.

We have granted an exclusive license to Alvogen to commercialize and promote Qsymia for the treatment of obesity in South Korea. Alvogen has received marketing authorization in South Korea and launched commercial activities.

Foreign regulatory approvals, including EC marketing authorization to market Qsymia/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.

In June 2017, we entered into a settlement agreement with Actavis Laboratories FL, Inc., Actavis, Inc., and Actavis PLC, collectively referred to as Actavis, and in August 2017, we 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 agreement with DRL will permit DRL to begin selling a generic version of Qsymia on June 1, 2025, or earlier under certain circumstances.

PANCREAZE/PANCREASE MT for the Treatment of Exocrine Pancreatic Insufficiency

The pancreas produces enzymes to help with the digestion of food. EPI is a condition that results from a deficiency in the production and/or secretion of pancreatic enzymes. Due to a lack of these enzymes, people with EPI cannot properly digest the nutrients in food such as fats, proteins, and carbohydrates. EPI is associated with acute or chronic pancreatitis, which constitutes approximately 51% of the EPI market, cystic fibrosis, which constitutes approximately 20% of the EPI market and pancreatic cancer, which constitutes approximately 11% of the EPI market. There is no cure for EPI and pancreatic enzyme replacement therapy is the primary treatment for the condition.

Approved in 2010, PANCREAZE is a pancreatic enzyme preparation consisting of pancrelipase, an extract derived from porcine pancreatic glands, as well as other enzyme classes, including porcine-derived lipases, proteases and amylases. PANCREAZE is specifically indicated for the treatment of EPI.

From its approval through June 2018, PANCREAZE was commercialized by Janssen. In June 2018, we acquired the commercial rights to PANCREAZE and PANCREASE MT in the U.S. and Canada, respectively. In connection with the acquisition of PANCREAZE, we and Janssen also entered into transition services agreements pursuant to which Janssen and a Canadian affiliate of Janssen will provide certain transition services to us in the U.S. and Canada as we transitioned to full control over the PANCREAZE supply chain. The transition in the U.S. occurred in the first quarter of 2019. We commercialize PANCREAZE in the U.S. by leveraging our existing commercial infrastructure and expanding it to include 10 additional contract sales representatives in the U.S. focused on gastro-intestinal and cystic fibrosis physicians.

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 an sNDA for STENDRA. STENDRA is 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 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 Member States, 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. On September 30, 2019, Metuchen provided a written notice of termination of the Metuchen Supply Agreement effective September 30, 2021. 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 Africa, the Middle East, Turkey, Russia, 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.

VI-0106 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 endothelial 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 1, 2, 3, or 4, with the most impaired patients being class 4.

The symptoms of PAH are non-specific and thus are unfortunately most frequently diagnosed when patients have reached an advanced stage of the disease. Early symptoms may include shortness of breath during routine activity, fatigue, chest pain, racing heartbeat, pain in upper right side of abdomen, and decreased appetite. As PAH progresses and worsens, symptoms may include feeling light-headed (especially during physical activity), fainting, swelling in the ankles or legs, and bluish lips or skin. At its worse point, the patient develops right heart failure and is routinely hospitalized to manage their progressing disease which may ultimately lead to death. Currently, lung transplantation is the only option for patients who are not responsive to medical therapy.

The current medical therapies for PAH involve endothelin receptor antagonists (“ERA”) phosphodiesterase-5 (“PDE5”) inhibitors, prostacyclin analogues, selective IP receptor agonists, and soluble guanylate cyclase (“sGC”) stimulators, all of which have been shown to effectively dilate arterioles in the pulmonary circulation, to reduce symptoms and improve quality of life. While currently approved products treat the symptoms of PAH, they do little to address the pathologic cell proliferation that is the underlying cause of the 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 (“BMPR2”) signaling is an important factor for the inhibition of 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 in the U.S. An Orphan Drug Designation can provide benefits to us, such as: tax credits on clinical research, simplification of administrative procedures (reduction of the waiting period and reduction of the amount of registration fees), and marketing exclusivity of seven years after the marketing approval is granted for the approved orphan indication.

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

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

We have also assumed full responsibility for the development and commercialization of the licensed compounds for the treatment of PAH and related vascular diseases. 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 3 and 4 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 and expect to file an IND in the second half of 2020.

Tacrolimus for the treatment of PAH has received Orphan Drug Designation from FDA in the U.S. and the EC in the EU on the basis of a scientific opinion adopted by the Committee for Orphan Medicinal Products of 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, if approved, for commercial use. If we are successful in our development efforts, we anticipate filing an IND with FDA and completing the development of our proprietary formulation of tacrolimus in the second half of 2020.

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

Typically, human clinical trials are conducted in three phases that may overlap. In Phase 1, clinical trials are conducted with a small number of patients to determine the early safety profile and pharmacology of the new therapy. In Phase 2, clinical trials are conducted with groups of patients afflicted with a specific disease or medical condition in order to determine preliminary efficacy, optimal dosages and expanded evidence of safety. In Phase 3, large-scale, multicenter clinical trials are conducted with patients afflicted with a target disease or medical condition in order to provide substantial evidence of efficacy and safety required by FDA and others.

The results of the pre-clinical and clinical testing, together with chemistry and manufacturing information, are submitted to FDA in the form of a New Drug Application ("NDA") for a pharmaceutical product in order to obtain approval to commence commercial sales. In responding to an NDA, FDA may grant marketing approval or may request additional information or further research or studies 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 ("PDUFA") for a product containing a new molecular entity ("NME"), FDA has approximately twelve months in which to complete its initial review of a standard NDA and respond to the applicant, approximately eight months for a priority NDA, approximately ten months to review a non-NME standard NDA and six months for a non-NME 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 not be approved 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 based on new information regarding the safety or efficacy of the product or if compliance with post-marketing regulatory obligations is not maintained. 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, 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, are required 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 ("cGMP") regulations. Compliance with cGMP includes adhering to requirements relating to organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, and records and reports. Failure to comply with the statutory and regulatory requirements subjects the manufacturer to possible legal or regulatory action, such as suspension of manufacturing, seizure of product or voluntary recall of a product.

FDA imposes a number of complex regulations on entities that advertise and promote pharmaceuticals, which include, among other things, standards and regulations relating to direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities, and promotional activities involving the Internet. A product cannot be commercially promoted before it is approved. After approval, product promotion can include only those claims relating to safety and effectiveness that are consistent with the labeling approved by FDA. FDA has very broad enforcement authority. Failure to abide by these regulations can result in adverse publicity, and/or enforcement actions, including the issuance of a warning letter directing the entity to correct deviations from FDA standards, and state and federal civil and criminal investigations and prosecutions. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes drug products.

Companies that manufacture or distribute drug products or that hold approved NDAs must comply with other regulatory requirements, including submitting annual reports, reporting information about adverse drug experiences, and maintaining certain records. In addition, we are subject to various laws and regulations regarding the use and disposal of hazardous or potentially hazardous substances in connection with our manufacture and research. In each of these areas, as noted above, the government has broad regulatory and enforcement powers, including the ability to levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products, and withdraw approvals, any one or more of which could have a material adverse effect upon us.

Other Government Regulations

In addition to laws and regulations enforced by FDA, we are also subject to regulation under NIH guidelines as well as under the Controlled Substances Act ("CSA") and implementing regulations from the Drug Enforcement Administration ("DEA"), the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and other present and potential future federal, state or local laws and regulations, as our research and development may involve the controlled use of hazardous materials, chemicals, viruses and various radioactive compounds. As a Schedule IV controlled substance under the CSA, Qsymia is subject to DEA and state regulations relating to controlled substances including security requirements, record-keeping and certain reporting obligations as well as 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 and EU Good Laboratory Practice ("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 ("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. Although Directive 2001/20/EC has sought to harmonize the EU clinical trials regulatory framework, setting out common rules for the control and authorization of clinical trials in the EU, the EU Member States have transposed and applied the provisions of the Directive in a manner that is not always uniform. This has led to variations in the rules governing the conduct of clinical trials in the individual EU Member States. The EU legislator adopted Regulation (EU) No 536/2014 (the "Clinical Trials Regulation") in 2014. The new EU Clinical Trials Regulation, which will replace the EU Clinical Trials Directive, introduces a complete overhaul of the existing regulation of clinical trials for medicinal products in the EU, including a new coordinated procedure for authorization of clinical trials that is reminiscent of the mutual recognition procedure for marketing authorization of medicinal products, and increased obligations on sponsors to publish clinical trial results. The Clinical Trials Regulation is expected to start to apply in 2020. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

To obtain marketing authorization for 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 ("PIP") approved by the Paediatric Committee ("PDCO") of the EMA. Alternatively, confirmation that we have been granted a waiver or deferral from the conduct of these studies by the PDCO must be provided.

Medicinal products are authorized in the EU in one of two ways, either by the competent authorities of the EU Member States through the decentralized procedure, mutual recognition procedure or national procedure (single EU Member State), or through the centralized procedure by the European Commission following a positive opinion by the Committee for Medicinal Products for Human Use ("CHMP") of 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 and three of the four European Free Trade Association ("EFTA") countries (Iceland, Liechtenstein and Norway). The centralized procedure is compulsory for medicinal products produced by certain biotechnological processes, advanced therapy medicinal products, 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 containing a new active substance that is not yet authorized in the EEA or for products that constitute a significant therapeutic, scientific or technical innovation or for which grant of centralized marketing authorization is in the interest of patients in the EU. Accelerated assessment 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, particularly from a point of therapeutic innovation." 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 Heads of Medicines Agencies' Co-ordination group for Mutual recognition and Decentralised procedures – human ("CMDh") for review. This review, which may also be escalated to the CHMP in case of disagreement in CMDh would result in a decision by the European Commission. This decision is binding on all EU Member States. In accordance with the mutual recognition procedure, the company applies for national marketing authorization in one EU Member State. The mutual recognition procedure allows companies that have a medicinal product already authorized in one EU Member State to apply for this authorization to be recognized by the competent authorities in other EU Member States. The national marketing authorization procedure is founded on the same basic EU regulatory process as the other marketing authorization procedures discussed in this Section. The national marketing authorization procedure, which is increasingly rare, permits a company to submit an application to the competent authority of a single EU Member State and, if successful, to obtain a marketing authorization that is valid only in this EU Member State.

The maximum timeframe for the evaluation of a marketing authorization application in the EU is 210 days. This period does not include clock stops during which applicants respond to questions from the competent authority. The initial marketing authorization granted in the EU is valid for five years. The authorization may be renewed and remain valid for an unlimited period unless the national competent authority or the European Commission decides on justified grounds to proceed with one additional five-year renewal period. The renewal of a marketing authorization is subject to a re-evaluation of the risk-benefit balance of the product by the national competent authorities or the EMA.

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.

Similar 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 requiring marketing authorization holders to conduct pharmacovigilance activities, and to assess and monitor the safety of medicinal products. We cannot guarantee that we or Menarini, as the marketing authorization holder for SPEDRA in the EU, 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.

Various requirements apply to the manufacturing and placing on the EU market of medicinal products. Manufacture of medicinal products in the EU requires a manufacturing authorization. The manufacturing authorization holder must comply with requirements set out in the applicable EU laws, regulations and guidance. These requirements include compliance with EU cGMP standards when manufacturing medicinal products and APIs. These obligations extend to the manufacture of APIs outside of the EU for import into the EU. Similarly, the distribution of medicinal products into and within the EU is subject to compliance with the applicable EU laws, regulations and guidelines, including the requirement to hold appropriate authorizations for distribution granted by the competent authorities of the EU Member States. Marketing authorization holders may be subject to civil, criminal or administrative sanctions,

including suspension of manufacturing authorization, in case of non-compliance with the EU or EU Member States' requirements applicable to the manufacturing of medicinal products.

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

Failure to comply with the EU Member State laws implementing the Community Code on medicinal products, and EU rules governing the promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices, with the EU Member State laws that apply to the promotion of medicinal products, statutory health insurance, bribery and anti-corruption or with other applicable regulatory requirements can result in enforcement action by the EU Member State authorities, which may include any of the following: fines, imprisonment, orders forfeiting products or prohibiting or suspending their supply to the market, or requiring the manufacturer to issue public warnings, or to conduct a product recall.

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

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

United States Healthcare Reform

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively referred to in this report as the "Affordable Care Act," was adopted in the United States. This law has substantially changed the way healthcare is financed by both governmental and private insurers and has significantly impacted the pharmaceutical industry. The Affordable Care Act contains a number of provisions that may materially affect our business and operations, including those governing enrollment in federal healthcare programs, reimbursement changes, rules regarding prescription drug benefits under the health insurance exchanges, expansion of the 340B drug pricing program, and fraud and abuse and enforcement. These changes have impacted and will continue to impact existing government healthcare programs and have resulted 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. The Affordable Care Act also made changes to the 340B drug pricing program, which are described below under the heading "Coverage and Reimbursement." 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 at 100 percent 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 ("CMS"), the federal agency that administers Medicare and the Medicaid Drug Rebate program, issued final regulations that became effective on April 1, 2016 to implement the changes to the Medicaid Drug Rebate program under the Affordable Care Act. In addition, the Affordable Care Act requires pharmaceutical manufacturers of branded prescription drugs to pay an annual, nondeductible branded prescription drug fee to the federal government beginning in 2011, apportioned among these entities according to their market share in certain government healthcare programs, although this fee does not apply to sales of certain products approved exclusively for orphan indications. Each individual pharmaceutical manufacturer pays a prorated share of the branded prescription drug fee of $2.8 billion in 2019 and thereafter, 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 most Medicare Part D prescription drug plans, commonly referred to as the "donut hole," manufacturers were required to provide a 50 percent discount on branded prescription drugs dispensed to beneficiaries during their "donut hole" period as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D. The Bipartisan Budget Act of 2018 ("BBA") increased such manufacturer point-of-sale discounts to 70 percent effective as of January 1, 2019. We currently have limited coverage under Medicare Part D for our drugs, but coverage could increase in the future.

Certain provisions of the Affordable Care Act have been subject to judicial challenges as well as efforts to repeal or replace them or to alter their interpretation and implementation. For example, the Tax Cuts and Jobs Act enacted on December 22, 2017 (the "Tax Act") 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," effective January 1, 2019. Certain ACA-mandated fees have been repealed as part of the 2020 federal spending package, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share (referred to as the health insurance provider fee) and the medical device excise tax on non-exempt medical devices. Additional legislative changes, regulatory changes, and judicial challenges related to the Affordable Care Act remain possible. It is unclear how the Affordable Care Act and its implementation, as well as efforts to repeal or replace, or invalidate, the Affordable Care Act, or portions thereof, will affect our business. It is possible 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.

Some states have elected not to expand their Medicaid programs by raising the income limit to 133% of the federal poverty level as permitted under the Affordable Care Act. For each state that does not choose to expand its Medicaid program, there may be fewer insured patients overall, which could impact our sales, business and financial condition.

Coverage and Reimbursement

In both U.S. and foreign markets, our ability to commercialize our products successfully and to attract commercialization partners for our products, depends in significant part on the availability of adequate financial coverage and reimbursement from third-party payors, including, in the United States, governmental payors such as Medicare and Medicaid, as well as managed care organizations, private health insurers and other organizations. Third-party payors decide which drugs they will pay for and establish reimbursement and co-pay levels. Third-party payors are increasingly challenging the prices charged for medicines and examining their cost-effectiveness, in addition to their safety and efficacy. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the

cost-effectiveness of our products. Even with studies, our products may be considered less safe, less effective or less cost-effective than existing products, and third-party payors may not provide coverage and reimbursement for our product candidates, in whole or in part.

Political, economic and regulatory influences are subjecting the healthcare industry in the United States to fundamental changes. There have been, and we expect there will continue to be, legislative and regulatory proposals to change the healthcare system in ways that could impact our ability to sell our products profitably. We anticipate that the United States Congress, state legislatures and the private sector will continue to consider and may adopt healthcare policies intended to curb rising healthcare costs. These cost-containment measures include: controls on government funded reimbursement for drugs; new or increased requirements to pay prescription drug rebates to government healthcare programs; controls on healthcare providers; challenges to the pricing of drugs or limits or prohibitions on reimbursement for specific products through other means; requirements to try less expensive products or generics before a more expensive branded product; changes in drug importation laws; expansion of use of managed care systems in which healthcare providers contract to provide comprehensive healthcare for a fixed cost per person; and public funding for cost-effectiveness research, which may be used by government and private third-party payors to make coverage and payment decisions. Further, federal budgetary concerns could result in the implementation of significant federal spending cuts, including cuts in Medicare and other health related spending in the near-term. For example, beginning April 1, 2013, Medicare payments for all items and services, including drugs and biologics, were reduced by 2% under the sequestration (i.e., automatic spending reductions) required by the Budget Control Act of 2011, as amended by the American Taxpayer Relief Act of 2012. Subsequent legislation extended the 2% reduction, on average, to 2029. 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 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 program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B 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 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 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.

The Health Resources and Services Administration ("HRSA"), which administers the 340B program, issued a final regulation regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities, which became effective on January 1, 2019.

It is currently unclear how HRSA will apply its enforcement authority under the regulation. 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. HRSA also implemented a reporting requirement pursuant to which we are required to report the 340B ceiling prices for our covered outpatient drugs to HRSA on a quarterly basis. In addition, legislation may be introduced that, if passed, would further expand the 340B program to additional covered entities or would require participating manufacturers to agree to provide 340B discounted pricing on drugs used in the inpatient setting.

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

We are liable for errors associated with our submission of pricing data. Civil monetary penalties can be applied if we are found to have charged 340B covered entities more than the statutorily mandated ceiling price. 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 significant civil monetary penalties 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 significant civil monetary penalty 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.

CMS and the Office of the Inspector General have pursued manufacturers that were alleged to have failed 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 (“VA”) Federal Supply Schedule (“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 (“FCP”). The FCP is based on the non-federal average manufacturer price (“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. 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 ("HTAs") that compare the cost-effectiveness of our products to other available therapies. 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. 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 (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.

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. A negative HTA by a leading and recognized HTA body concerning one of our medicinal products could not only undermine our ability to obtain reimbursement for such product not only in the EU Member State in which the negative assessment was issued, but also in other EU Member States. For example, EU Member States that have not yet developed HTA mechanisms could rely to some extent on the HTA performed in countries with a developed HTA framework, such as France, Germany or Sweden, when adopting decisions concerning the pricing and reimbursement of a specific medicinal product.

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 establishes 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.

On January 31, 2018, the European Commission adopted a proposal for a regulation on HTA. This legislative proposal is intended to boost cooperation among EU Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at the EU level for joint clinical assessments in these areas. The proposal provides that EU Member States will be able to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU Member States will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technology, and making decisions on pricing and reimbursement. The European Commission has stated that the role of the draft HTA regulation is not to influence pricing and reimbursement decisions in the individual EU Member States. However, this consequence cannot be excluded. The related legislative process is currently ongoing, with EU member states currently divided on the proposal.

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 healthcare 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. Moreover, the anti-kickback statute is subject to evolving interpretation and there are no safe harbors for many common practices, including patient or product support programs, educational and research grants, or charitable donations. In October 2019, the federal government published a proposed regulation creating new safe harbors for, among other things, certain value-based arrangements and patient engagement tools, and that modifies and clarifies the scope of existing safe harbors for warranties and personal service agreements. The impact of the proposed regulation on our current or contemplated operations is not clear even if the proposed regulation is finalized. 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. Actions under the False Claims Act may be brought by the U.S. Attorney General or as a qui tam action by

a private individual in the name of the 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. False Claims Act liability is potentially significant in the healthcare industry because the statute provides for treble damages and mandatory penalties per false or fraudulent claim or statement. Because of the potential for large monetary exposure, healthcare and pharmaceutical companies often resolve allegations without admissions of liability for significant and material amounts. 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 ("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 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. In addition, the California Consumer Privacy Act ("CCPA") was signed into law on June 28, 2018 and largely took effect January 1, 2020. The law contains new disclosure obligations for businesses that collect personal information about California residents and affords those individuals new rights relating to their personal information that may affect our ability to use personal information. The CCPA has substantial penalties for non-compliance, and we continue to assess its impact on our business. Similarly, there are a number of legislative proposals at both the federal and state level that could impose new privacy and security-related obligations or limitations in areas affecting our business. 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 General Data Protection Regulation ("GDPR"), an EU-wide regulation that became fully enforceable on May 25, 2018, replacing the EU Data Protection Directive, imposes strict obligations and restrictions on the ability to collect, analyze or otherwise use, and transfer personal data, including health data from clinical trials and adverse event reporting. The GDPR imposes restrictions on the processing (e.g., collection, use, disclosure) of personal data. These obligations and restrictions concern, in particular, the consent of the individuals to whom the personal data relate, the information provided to the individuals prior to processing their personal data, the transfer of personal data out of the EEA or Switzerland, including to the United States, notification of data processing obligations to the competent national data protection authorities, security

breach notifications, security and confidentiality of the personal data, as well as substantial potential fines for breaches of the data protection obligations. Failure to comply with the requirements of the GDPR and the related national data protection laws of the EU Member States may result in substantial fines and administrative penalties. Compliance with GDPR 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 healthcare providers in the states. Other states prohibit providing meals to prescribers or other marketing-related activities and restrict the ability of manufacturers to offer co-pay support to patients for certain prescription drugs. Some states require the posting of information relating to clinical studies and their outcomes. Some states and cities require identification or licensing of sales representatives. In addition, some states 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 of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children’s Health Insurance Program to report annually to the Centers for Medicare and Medicaid Services within the U.S. Department of Health and Human Services (“CMS”) information related payments and other transfers of value, directly or indirectly, to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report information regarding payments and transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives; and
- the federal Foreign Corrupt Practices Act of 1977 and other similar anti-bribery laws in other jurisdictions prohibit companies and their intermediaries from providing money or anything of value to officials of foreign governments, candidates for foreign political office, or public 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. and foreign regulators, with more frequent and aggressive investigations and enforcement proceedings by both the Department of Justice and the U.S. Securities and Exchange Commission. A determination that our operations or activities are not, or were not, in compliance with United States or foreign laws or regulations could result in the imposition of substantial fines, interruptions of business, loss of supplier, vendor or other third-party relationships, termination of necessary licenses and permits, and other legal or equitable sanctions. Other internal or government investigations or legal or regulatory proceedings, including lawsuits brought by private litigants, may also follow as a consequence.

If our operations are found to be in violation of any of the laws or regulations described above or any other governmental regulations that apply to us, we may be subject to significant civil, criminal and administrative mandatory 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.

Data protection authorities from the different EU Member States may interpret the GDPR and applicable related national laws differently and impose requirements additional to those provided in the GDPR. In addition, guidance on implementation and compliance practices may be updated or otherwise revised, which adds to the complexity of processing personal data in the EU. When processing personal data of subjects in the EU, we must comply with the applicable data protection laws. In particular, when we rely on third party service providers processing personal data of subjects in the EU we must enter into suitable agreements with these providers and receive sufficient guarantees that the providers meet the requirements of the applicable data protection laws, particularly the GDPR which imposes specific and relevant obligations.

Although there are legal mechanisms to allow for the transfer of personal data from the EEA to the US, a decision of the European Court of Justice in the Schrems case (Case C-362/14 Maximillian Schrems v. Data Protection Commissioner) that invalidated the safe harbor framework has increased uncertainty around compliance with EU privacy law requirements. As a result of the decision, it was no longer possible to rely on the safe harbor certification as a legal basis for the transfer of personal data from the EU to entities in the US. On February 29, 2016, however, the European Commission announced an agreement with the United States Department of Commerce ("DOC") to replace the invalidated Safe Harbor framework with a new EU-US "Privacy Shield." On July 12, 2016, the European Commission adopted a decision on the adequacy of the protection provided by the Privacy Shield. The Privacy Shield is intended to address the requirements set out by the European Court of Justice in its ruling by imposing more stringent obligations on companies, providing stronger monitoring and enforcement by the DOC and Federal Trade Commission, and making commitments on the part of public authorities regarding access to information. US companies have been able to certify to the US Department of Commerce their compliance with the privacy principles of the Privacy Shield since August 1, 2016.

On September 16, 2016, an Irish privacy advocacy group brought an action for annulment of the EC decision on the adequacy of the Privacy Shield before the European Court of Justice (Case T-670/16). In October 2016, a further action for annulment was brought by three French digital rights advocacy groups (Case T-738/16). Case T-670/16 was declared inadmissible. Case T-738/16 is still pending before the European Court of Justice. The United States was admitted as an intervener in the action on September 4, 2018. If the European Court of Justice invalidates the Privacy Shield, it will no longer be possible to rely on the Privacy Shield certification to support transfer of personal data from the EU to entities in the US. Adherence to the Privacy Shield is not, however, mandatory. US-based companies are permitted to rely either on their adherence to the Privacy Shield or on the other authorized means and procedures to transfer personal data provided by the GDPR. If we or our vendors fail to comply with applicable data privacy laws, or if the legal mechanisms we or our vendors rely upon to allow for the transfer of personal data from the EEA or Switzerland to the US (or other countries not considered by the European Commission to provide an adequate level of data protection) are not considered adequate, we could be subject to government enforcement actions and significant penalties against us, and our business could be adversely impacted if our ability to transfer personal data outside of the EEA or Switzerland is restricted, which could adversely impact our operating results.

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. 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 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.

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

In July 2013, we entered into a license and commercialization agreement (the “Menarini License Agreement”) and a supply agreement (the “Menarini Supply Agreement”) with the Menarini Group through its subsidiary Berlin Chemie AG (“Menarini”).

Under the terms of the Menarini License Agreement, Menarini received an exclusive license to commercialize and promote SPEDRA for the treatment of ED in over 40 countries, including the EU Member States, plus Australia and New Zealand. Additionally, we transferred to Menarini ownership of the marketing authorization for SPEDRA in the EU for the treatment of ED, which was granted by the EC in June 2013. 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, 2019. 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. Under the terms of the Menarini Supply Agreement, Menarini has the right to manufacture SPEDRA independently, provided that it continues to satisfy certain minimum purchase obligations to the Company. Following the expiration of the Menarini Supply Agreement, Menarini would be responsible for its own supply of SPEDRA. Either party may terminate the Menarini Supply Agreement for the other party’s uncured material breach or bankruptcy, or upon the termination of the Menarini License Agreement.

In May 2019, we entered into Amendment No. 1 to the License and Commercialization Agreement and Commercial Supply Agreement with Menarini effective as of January 1, 2019, pursuant to which certain amendments were made to the Menarini License Agreement and the Menarini Supply Agreement, which include: (i) under the Menarini License Agreement, Menarini’s exclusive license to commercialize and promote avanafil for the treatment of ED will be limited to over 40 European countries and no longer includes Australia and New Zealand; (ii) under the Menarini License Agreement, the timing requirements of the product launches by Menarini have been adjusted; (iii) under the Menarini License Agreement, the milestone payments have been adjusted to reflect the removal of Australia and New Zealand and will continue to be non-refundable and non-creditable, with one exception added for certain costs and expenses incurred by Menarini for development work related to an avanafil development opportunity in the Menarini territory (“Menarini Development”); (iv) under the Menarini License Agreement, the royalties on avanafil sales payable by Menarini to us were adjusted to allow Menarini to recoup certain Menarini Development costs and expenses but only as to sales of the Menarini Development product unless the Menarini Development product is commercialized by the Company or its sublicensees outside the Menarini territory; (v) under the Menarini Supply Agreement, the minimum

purchase obligations for Menarini were modified and extended, including the ability of Menarini to satisfy its minimum purchase obligations with the purchase of avanafil active pharmaceutical ingredient ("API") and the addition of minimum purchase obligations for the calendar years for the extended term; and (vi) under the Menarini Supply Agreement, the term will be extended to December 31, 2023, unless otherwise agreed by the parties in writing. We and Menarini have entered into standalone agreements relating to Australia and New Zealand, including a license with royalties and milestone payments and a supply 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. Under the Sanofi License Agreement, we received payments of $10.0 million relating to license and milestone payments. In March 2017, we and Sanofi entered into the Termination, Rights Reversion and Transition Services Agreement (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.

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 December 7, 2018, we entered into an amendment to the Commercial Supply Agreement with Sanofi Chimie, pursuant to which certain amendments were made to the Commercial Supply Agreement, which include: (i) beginning January 1, 2019, Sanofi Chimie manufactures and supplies API for avanafil on an exclusive basis in all countries where we have the right to sell avanafil; (ii) beginning January 1, 2019, the yearly minimum quantities of API that we must purchase from Sanofi Chimie were adjusted, as well as adjustments to the associated pricing and payment terms; and (iii) with the initial five year term of the Commercial Supply Agreement expiring on December 31, 2018, we and Sanofi Chimie have agreed to extend the term of the Commercial Supply Agreement until December 31, 2023 unless either party makes a timely election to terminate the agreement and that thereafter the Commercial Supply Agreement will auto-renew for successive one year terms unless either party makes a timely election not to renew.

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 May 2019, we entered into Amendment N°1 to the Manufacturing and Supply Agreement with Sanofi Winthrop Industrie effective as of March 18, 2019, pursuant to which certain amendments were made to the Manufacturing and Supply Agreement, which include: (i) Sanofi Winthrop Industrie will manufacture and supply the tablets for the Company's drug avanafil on an exclusive basis in all countries where the Company or its sublicensees and/or Menarini have the right to sell avanafil; (ii) the yearly minimum quantities of tablets that the Company must purchase from Sanofi Winthrop Industrie and the price of such tablets were adjusted; and (iii) with the initial term of the Manufacturing and Supply Agreement expiring on January 16, 2021, the Company and Sanofi Winthrop Industrie have agreed to extend the term of the Manufacturing and Supply Agreement until December 31, 2023 unless either party makes a timely election to terminate the agreement and that thereafter the Manufacturing and Supply Agreement will auto-renew for successive one year terms unless either party makes a timely election not to renew.

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 reimburses us for payments made to cover royalty and milestone obligations to MTPC during the term of the license agreement but otherwise owes us no future royalties. On September 30, 2019, Metuchen provided a written notice of termination of the Metuchen Supply Agreement effective September 30, 2021.

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 (the "Alvogen License Agreement") and a commercial supply agreement (the "Alvogen Supply Agreement") with Alvogen Malta Operations (ROW) Ltd, which was subsequently assigned to Alvogen South Korea ("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 commercial launch and Alvogen 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 supply product to Alvogen.

Other

In October 2001, we entered into an assignment agreement (the "Assignment Agreement") with Thomas Najarian, M.D. for a combination of pharmaceutical agents for the treatment of obesity and other disorders (the "Combination Therapy") that became the focus of our development program for Qsymia. The Combination Therapy and all related patent applications (the "Combination Therapy Patents") were transferred to us with worldwide rights to

develop and commercialize the Combination Therapy and exploit the Combination Therapy 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 the Combination Therapy Patents until the last-to-expire of the assigned Combination Therapy Patents. To the extent that we decide not to commercially exploit the Combination Therapy Patents, the Assignment Agreement will terminate and the Combination Therapy and the Combination Therapy Patents will be assigned back to Dr. Najarian. From 2006 through November 2013, Dr. Najarian served as a Principal Scientist for the Company on a part time basis. Dr. Najarian 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. 16/732,544	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. 16/220,269	Pending
U.S. Patent Publication No. 2016/0250180 A1 16/220,276	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
TACROLIMUS	
U.S. Patent No. 9,474,745	Expiring 04/30/2032
U.S. Patent Application No. 16/198,242	Pending
PCT/US16/12694	Pending
PCT/US16/30737	Pending
PCT/US16/47148	Pending

* These expiration dates are based on the number of days of patent term adjustment (“PTA”) calculated by the U.S. Patent and Trademark Office (“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 ("EEA") under the Decentralized, Mutual Recognition or national 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, an applicant for a marketing authorization for a generic or biosimilar medicinal product is not permitted to cross refer to the preclinical and clinical trial data relating to the reference product. Even if the generic or biosimilar 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, PANCREAZE/PANCREASE MT and STENDRA/SPEDRA, 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 and PANCREAZE/PANCREASE MT product capsules and the STENDRA/SPEDRA 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, PANCREAZE/PANCREASE MT and STENDRA/SPEDRA and our clinical supplies. However, if we are unable to obtain a sufficient supply of Qsymia, PANCREAZE/PANCREASE MT or STENDRA/SPEDRA 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/SPEDRA for territories in which we do not have a commercial collaboration or our clinical trials may be delayed.

Catalent Pharma Solutions, LLC ("Catalent") manufactures our clinical and commercial supplies for Qsymia.

Nordmark Arzneimittel GmbH & Co. KG ("Nordmark") is the Company's sole source of clinical and commercial supplies for PANCREAZE/PANCREASE MT.

On July 31, 2013, we entered into a Commercial Supply Agreement with Sanofi Chimie, a wholly owned subsidiary of Sanofi, pursuant to which Sanofi Chimie manufactures and supplies the API for STENDRA. On November 18, 2013, we entered into a Manufacturing and Supply Agreement with Sanofi Winthrop Industrie, a wholly owned subsidiary of Sanofi, pursuant to which Sanofi Winthrop Industrie manufactures and supplies the tablets for avanafil.

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

We attempt to prevent disruption of supplies through supply agreements, purchase orders, appropriate forecasting, maintaining stock levels and other strategies. In the event we are unable to manufacture our products, either directly or indirectly through others or on commercially acceptable terms, if at all, we may not be able to commercialize

our products as planned. Although we are taking these actions to avoid a disruption in supply, we cannot provide assurance that we may not experience a disruption in the future.

Marketing and Sales

We commercialize Qsymia and PANCREAZE in the U.S. primarily through a 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. In 2019, we introduced the Qsymia Advantage program to reach more of our intended patient population. The Qsymia Advantage program includes patient education resources and access to a home delivery in addition to new pricing. We launched PANCREAZE in the U.S. in February of 2019, which included 10 contract sales representatives and additional marketing and promotional activities. We transitioned to direct sales of PANCREASE MT in Canada in the third quarter of 2019.

Product Distribution and REMS

We rely on Cardinal Health 105, Inc. (“Cardinal Health”) a third-party distribution and supply-chain management company, to warehouse Qsymia and PANCREAZE and distribute them to the certified home delivery pharmacies and wholesalers that then distribute our products 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. We have also teamed with MedVantx Pharmacy Services to provide direct-to-patient distribution of Qsymia.

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

Qsymia for the treatment of chronic weight management competes with several approved anti-obesity drugs including, Xenical® (orlistat), marketed by Roche; alli®, the over-the-counter version of orlistat, marketed by GlaxoSmithKline; Contrave® (naltrexone/bupropion), owned by Currax Pharmaceuticals, LLC; and Saxenda® (liraglutide), marketed by Novo Nordisk A/S. Qsymia also competes with generic phentermine.

Agents 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) and Ozempic® (semiglutide) 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.

In addition, there are other investigational drug candidates in clinical trials. For example, Rhythm Pharmaceuticals, Inc. ("Rhythm") is currently in Phase 2 and Phase 3 clinical trials for various applications of setmelanotide, a small peptide melanocortin 4 receptor ("MC4R") agonist, for the treatment of obesity in individuals with certain genetic deficiencies. 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 single-agent generic drugs 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 drugs in the U.S. or the importation of the generic drugs 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, we entered into a settlement agreement with Actavis Laboratories FL, Inc., Actavis, Inc., and Actavis PLC, collectively referred to as "Actavis," and in August 2017, we 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 agreement 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 ("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.

PANCREAZE

PANCREAZE for the treatment of pancreatic insufficiency competes with Creon®, marketed by AbbVie, Inc., Zenpep®, recently acquired by Nestlé, Pertzye®, marketed by Digestive Care, Inc., and UltresaTM, marketed by Aptalis Phama US, Inc.

STENDRA/SPEDRA

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 ("ODT")), co-promoted by GlaxoSmithKline plc and Merck & Co., Inc. Additionally, generic formulations of sildenafil citrate, vardenafil and tadalafil are currently available on the market and, 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.

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 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 10 years' market exclusivity. During this 10-year period no generic or biosimilar 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.

Employees

As of February 29, 2020, we had 59 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.

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 (the "Exchange Act"), 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 by visiting the SEC's Internet site at http://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 (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 Convertible Notes, with a face value of $181.4 million, are due in May 2020. We do not have sufficient financial resources or cash flows from our business to pay our substantial debt when due. If we are unable to pay our debt, we may be required to sell assets, restructure our debt or obtain additional debt or equity capital on terms that may be onerous or highly dilutive. Accordingly, our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern.

Our Convertible Notes, with a face value of $181.4 million, are due in May 2020. We do not have sufficient financial resources or cash flows from our business to pay our substantial debt. If we are unable to pay our debt, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional debt or equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the condition of the capital markets and our financial condition at such time. We may not be able to undertake any of these alternatives or engage in these activities on desirable terms, which could result in a default on our debt obligations.

Our consolidated financial statements for the year ended December 31, 2019 included in this report have been prepared assuming that we will continue as a going concern and do not include any adjustments that might result from the outcome of this uncertainty. Our independent registered public accounting firm's audit report on our consolidated financial statements includes an explanatory paragraph stating that there is substantial doubt about our ability to continue as a going concern. As a result of the substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding to us on commercially reasonable terms or at all. If we cannot continue as a viable entity, our security holders may lose some or all of their investment in our Company.

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

Our success will depend on our ability and that of our current or future collaborators to effectively and profitably commercialize Qsymia, PANCREAZE 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 Qsymia in the EU;
- manage our alliances with MTPC, Menarini, Metuchen and Alvogen to help ensure the commercial success of avanafil and the efficiency of our supply chain with Sanofi;
- 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 prescriber 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 ("REMS") any future changes to the REMS, and any other requirements established by FDA in the future;
- efficiently conduct the post-marketing studies required by FDA;
- effectively and efficiently manage our sales force and commercial team for the promotion of Qsymia and PANCREAZE;
- effectively increase the level of revenue for PANCREAZE;
- maintain a good relationship with the manufacturer of PANCREAZE;
- ensure a sufficient level of PANCREAZE inventory;
- ensure that the active pharmaceutical ingredients ("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;
- comply with other healthcare regulatory requirements;
- comply with state and federal controlled substances requirements; and
- maintain and defend our patents, if challenged.

If we are unable to successfully produce and commercialize Qsymia, PANCREAZE and/or 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 have had changes to our Board of Directors and to our management team which may cause disruption in our business, which disruption could have a materially adverse effect on our results of operations.

In 2018, former executives of Willow Biopharma Inc. joined our management team, including John Amos as our Chief Executive Officer, M. Scott Oehrlein as our Chief Operations Officer and Kenneth Suh as our President. On October 2, 2019, we and Messrs. Suh and Oehrlein agreed that they would leave the Company, effective October 31, 2019. Their responsibilities were assumed by current employees. On October 28, 2019, Eric W. Roberts and Allan L. Shaw notified us of their decision to resign from our Board of Directors, effective immediately. If we are unable to successfully navigate recent changes to our Board of Directors and senior management, our business could be harmed.

We may not be able to successfully develop, launch and commercialize VI-0106 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 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 VI-0106;
- 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 current Good Manufacturing Practices ("cGMP");
- establish and effectively manage a supply chain for tacrolimus and future development programs to ensure that the API and the finished products are manufactured in sufficient quantities and in compliance with regulatory requirements and with acceptable quality and pricing in order to meet commercial demand;
- effectively determine and manage the appropriate commercialization strategy;
- manage costs;
- achieve market acceptance by patients, the medical community and third-party payors and generate product sales;
- effectively compete with other therapies;
- maintain a continued acceptable safety profile for tacrolimus following approval;
- comply with healthcare regulatory requirements; and
- maintain and defend our patents, if challenged.

If we are unable to successfully develop, produce, 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 2018, we initiated a business turnaround plan. 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, 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 and fulfill their contractual obligations, including satisfying their minimum purchase requirements;
- 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 or between our collaborators and our suppliers or former 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 or breach the collaborative arrangement, which could negatively impact the continued commercialization of our drug products. For example, in September 2016, Auxilium terminated its agreement with us to commercialize STENDRA in the U.S. and Canada and, in March 2017, Sanofi terminated its agreement with us to commercialize STENDRA/SPEDRA in Africa, the Middle East, Turkey, and the CIS, including Russia.

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

If any of our collaboration partners fail to successfully commercialize Qsymia or STENDRA/SPEDRA or fulfill their contractual obligations, 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 ("NOLs") to reduce income in prior tax years and limiting the utilization of NOLs generated after December 31, 2017,

which could affect the timing of our ability to utilize NOLs, and (ii) limiting the amount of business interest expenses that can be deducted.

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. Also, on an interim basis, we have agreements with affiliates of Janssen for the commercialization of PANCREASE MT in Canada. 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. Such adjustments or restatements may materially and negatively affect our financial position and results of operations.

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 Qsymia and 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 Qsymia and STENDRA/SPEDRA in territories that are not covered by our current commercial collaboration agreements. For example, Qsymia is currently licensed for sale only in the U.S. and we have a commercialization agreement to market Qsymia in South Korea. STENDRA/SPEDRA is currently not marketed in Africa, the Middle East, Turkey, the CIS, Mexico and Central America. We may be unable to enter into agreements with third parties for Qsymia or STENDRA/SPEDRA for these territories on favorable terms or at all, which could delay, impair, or preclude our ability to commercialize Qsymia and STENDRA/SPEDRA in these territories.

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

In order to market products in many foreign jurisdictions, we, or our partners, must obtain separate regulatory approvals. Approval by FDA in the U.S. does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries. For example, while our drug STENDRA/SPEDRA has been approved in both the U.S. and the EU, our drug Qsymia has been approved in the U.S. but 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 Qsymia would not have been indicated. We intend to seek approval for Qsymia in the EU and also 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, having relied in large part on third parties to lead any such interactions, and the approval procedures vary among countries and can involve additional clinical 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.

Our worldwide operations and sales and the markets in which we operate are subject to public health risks, which could have a material adverse effect on us.

Public health issues, including any possible pandemic such as the coronavirus principally emanating from China at the beginning of 2020, or the outbreak of other contagious diseases such as avian influenza, measles or Ebola, whether in the United States or other countries and regions in which we operate, sell our products or are seeking regulatory approval, could cause damage or disruption to the Company or our partners, suppliers and customers, or could create political or economic instability, any of which could harm our financial condition and operating results. Regions around the world, including China, South Korea, Japan, and countries in the EU, have reported significant effects of the spread of the coronavirus as of March 2020. Related disruption and public health risks could materially adversely affect our business, including:

- in the EU, royalties received on sales of STENDRA/SPEDRA under our license agreement with Menarini, the production of the API and tablets for our drug avanafil by Sanofi Chimie and Sanofi Winthrop Industrie and the production of our drug PANCREAZE/PANCREASE MT by Nordmark; and
- in South Korea, royalties received on sales of Qsymia under the Alvogen License Agreement.

We have significant inventories on hand, and, in 2015, we recorded inventory impairment and commitment fees totaling $29.5 million, primarily to write off excess inventory related to Qsymia.

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

the product. The current FDA-approved commercial product shelf life for Qsymia is 36 months. STENDRA is approved in the U.S. and SPEDRA is approved in the EU for 48 months of commercial product shelf life.

Our write-down for excess and obsolete inventory is subjective and requires forecasting of the future market demand for our products. Forecasting demand for Qsymia, a drug in the obesity market in which there had been no new FDA-approved medications in over a decade prior to 2012, and for which reimbursement from third-party payors had previously been non-existent, has been difficult. PANCREAZE has a short shelf life and forecasting both the amounts and the timing of demand for PANCREAZE is difficult. Forecasting demand for STENDRA/SPEDRA, a drug that has a limited sales history and is in a crowded and competitive market, including significant new generic competitors 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, if any significant unanticipated changes in future product demand or market conditions occur or if our collaborators fail to satisfy their minimum purchase obligations. 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. (“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. Our distribution network also includes MedVantx Pharmacy Services, a home delivery pharmacy. 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 (“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 maintain or enter into agreements with suppliers or our suppliers fail to supply us with the APIs for our products, bulk products or finished products or if we rely on single-source suppliers, we may experience delays in commercializing our products.

We purchase all supplies related to PANCREAZE from a single manufacturer. 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 maintaining or entering into supply agreements on reasonable terms or at all or that we or our suppliers will be able to obtain or maintain the necessary regulatory approvals or state and federal controlled substances registrations for current or potential future suppliers in a timely manner or at all.

We anticipate that we will continue to rely on single-source suppliers for PANCREAZE, phentermine and topiramate for the foreseeable future. Any production shortfall on the part of our suppliers that impairs the supply of phentermine, topiramate or PANCREAZE 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 or PANCREAZE, 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 U.S. 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 U.S. 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 from Sanofi Chimie or tablets from Sanofi Winthrop Industrie or if our collaborators fail to satisfy their minimum purchase obligations, 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, PANCREAZE 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, PANCREAZE 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 acquired the rights to PANCREAZE from Janssen. 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, Janssen 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 and increase market acceptance and generate revenues will be subject to a variety of risks, many of which are out of our control.

Qsymia, PANCREAZE and STENDRA/SPEDRA may not gain or increase 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, including our Qsymia Advantage program;
- our ability to obtain marketing authorization by the EC for Qsymia in the EU;
- contraindications for Qsymia and STENDRA/SPEDRA;
- our ability to increase market acceptance for and use of PANCREAZE;
- 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 subject to additional REMS restrictions or 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 ("CVOT"). We estimate the cost of a CVOT as currently designed to be between $180.0 million and $220.0 million incurred over a period of approximately five years. We have held several meetings with FDA to discuss alternative strategies for obtaining cardiovascular ("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 Qsymia for treatment of obesity in accordance with the EU centralized marketing authorization procedure. We received feedback in 2014 from the EMA and the various competent authorities of the EU Member States. We worked with cardiovascular and epidemiology experts in exploring alternate solutions to demonstrate the long-term cardiovascular safety of Qsymia. After reviewing a summary of Phase 3 data relevant to CV risk and post-marketing safety data, the cardiology experts noted that they believe there was an absence of an overt CV risk signal and indicated that they did not believe a randomized placebo-controlled CVOT would provide additional information regarding the CV risk of Qsymia. The epidemiology experts maintained that a well-conducted retrospective observational study could provide data to further inform on potential CV risk. We worked with the expert group to develop a protocol and conduct a retrospective observational study. We have submitted information from the retrospective observational 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 that provides FDA with additional CV safety data. 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 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 regulatory obligations, 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 or other development activities for Qsymia, PANCREAZE and STENDRA, obtain regulatory approval for our future investigational drug candidates, successfully commercialize our approved drugs or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on commercially reasonable terms, or at all.

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

Although Qsymia is a once-a-day, proprietary extended-release formulation, both of the approved APIs (phentermine and topiramate) that are combined to produce Qsymia are commercially available as drug products at

prices that together are lower than the price at which we sell Qsymia. In addition, the distribution and sale of these drug products is not limited under a REMS program, as is the case with Qsymia. Further, the individual drugs contained in the Qsymia formulation are available in retail pharmacies. We cannot be sure that physicians will view Qsymia as sufficiently superior to a treatment regimen of Qsymia's individual APIs to justify the significantly higher cost for Qsymia, and they may prescribe the individual generic drugs already approved and marketed by other companies instead of our combination drug. Although our U.S. and European patents contain composition, product formulation and method-of-use claims that we believe protect Qsymia, these patents may be ineffective or impractical to prevent physicians from prescribing, or pharmacists from dispensing, the individual generic constituents marketed by other companies instead of our combination drug. Phentermine and topiramate are currently available in generic form, although the doses used in Qsymia are currently not available. In the third quarter of 2013, Supernus Pharmaceuticals, Inc. launched Trokendi XR™ and in the second quarter of 2014, Upsher-Smith Laboratories, Inc. launched Qudexy™. Both products provide an extended-release formulation of the generic drug topiramate that is indicated for certain types of seizures and migraines. Topiramate is not approved for obesity treatment, and phentermine is only approved for short-term treatment of obesity. However, because the price of Qsymia is significantly higher than the prices of the individual components as marketed by other companies, physicians may have a greater incentive to write prescriptions for the individual components outside of their approved indication, instead of for our combination drug, and this may limit how we price or market Qsymia. Similar concerns could also limit the reimbursement amounts private health insurers or government agencies in the U.S. are prepared to pay for Qsymia, which could also limit market and patient acceptance of our drug and could negatively impact our revenues.

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

Once an applicant receives authorization to market a medicinal product in an EU Member State, through any application route, the applicant is required to engage in pricing discussions and negotiations with a separate pricing authority in that country. The legislators, policymakers and healthcare insurance funds in the EU Member States continue to propose and implement cost-containing measures to keep healthcare costs down, due in part to the attention being paid to healthcare cost containment and other austerity measures in the EU. Certain of these changes could impose limitations on the prices pharmaceutical companies are able to charge for their products. The amounts of reimbursement available from governmental agencies or third-party payors for these products may increase the tax obligations on pharmaceutical companies such as ours, or may facilitate the introduction of generic competition with respect to our products. Furthermore, an increasing number of EU Member States and other foreign countries use prices for medicinal products established in other countries as "reference prices" to help determine the price of the product in their own territory. Consequently, a downward trend in the price of medicinal products in some countries could contribute to similar downward trends elsewhere. 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. For more information concerning pricing and reimbursement of medicinal products in the EU and, in particular, the impact of HTA, please refer to Item 1, "Business – Coverage and Reimbursement."

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

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

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

Although we have obtained product liability insurance coverage for Qsymia, we may be unable to maintain this product liability coverage for Qsymia or any other of our approved drugs in amounts or scope sufficient to provide us with adequate coverage against all potential risks. A product liability claim in excess of, or excluded from, our insurance coverage would have to be paid out of cash reserves and could have a material adverse effect upon our business, financial condition and results of operations. Product liability insurance is expensive even with large self-insured retentions or deductibles, difficult to maintain, and current or increased coverage may not be available on acceptable terms, if at all.

In addition, we develop, test, and manufacture through third parties, approved drugs and future investigational drug candidates that are used by humans. We face an inherent risk of product liability exposure related to the testing of our approved drugs and investigational drug candidates in clinical trials. An individual may bring a liability claim against us if one of our approved drugs or future investigational drug candidates causes, or merely appears to have caused, an injury.

If we cannot successfully defend ourselves against a product liability claim, whether involving Qsymia, PANCREAZE, 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 ED. 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 Xenical® (orlistat), marketed by Roche; alli®, the over-the-counter version of orlistat, marketed by GlaxoSmithKline; Contrave® (naltrexone/bupropion), Nalpropion Pharmaceuticals, 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 other investigational drug candidates in 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, we entered into a settlement agreement with Actavis Laboratories FL, Inc., Actavis, Inc., and Actavis PLC, collectively referred to as "Actavis," and in August 2017, we 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 agreement 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 ("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 or FDA may permit 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.

PANCREAZE for the treatment of pancreatic insufficiency competes with Creon®, marketed by AbbVie, Inc., Zenpep®, recently acquired by Nestlé, Pertzye®, marketed by Digestive Care, Inc., and Ultresa™, marketed by Aptalis Phama US, Inc.

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 ("ODT")), co-promoted by GlaxoSmithKline plc and Merck & Co., Inc. Additionally, generic formulations of sildenafil citrate, vardenafil and tadalafil are currently available on the market and, 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.

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. 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 (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. Also, on June 8, 2018, we closed on the acquisition of PANCREAZE from Janssen, pursuant to which we acquired the rights to PANCREAZE and PANCREASE MT in the U.S. and Canada. Further potential transactions we may consider include a variety of different business arrangements, including strategic partnerships, joint ventures, spin-offs, restructurings, divestitures, business combinations and investments. In addition, another entity may pursue us as an acquisition target. Any such transactions may require us to incur non-recurring or other charges, may increase our near- and long-term expenditures and may pose significant integration challenges, require additional expertise or disrupt our management or business, any of which could harm our operations and financial results.

As part of an effort to enter into significant transactions, we conduct business, legal and financial due diligence with the goal of identifying and evaluating material risks involved in the transaction. Despite our efforts, we ultimately may be unsuccessful in ascertaining or evaluating all such risks and, as a result, might not realize the expected benefits of

the transaction. If we fail to realize the expected benefits from any transaction we may consummate, whether as a result of unidentified risks, integration difficulties, regulatory setbacks or other events, our business, results of operations and financial condition could be adversely affected.

Our failure to successfully identify, acquire, develop and market additional investigational drug candidates or approved drugs would impair our ability to grow.

As part of our growth strategy, we may acquire, in-license, develop and/or market additional products and investigational drug candidates. Most recently, on June 8, 2018, we closed on the acquisition of PANCREAZE from Janssen, pursuant to which we acquired the rights to PANCREAZE and PANCREASE MT in the U.S. and Canada. Also, on January 6, 2017, we entered into a Patent Assignment Agreement with Selten, whereby we received exclusive, worldwide rights for the development and commercialization of tacrolimus for the treatment of PAH and related vascular diseases. Because our internal research capabilities are limited, we may be dependent upon pharmaceutical and biotechnology companies, academic scientists and other researchers to sell or license products or technology to us. The success of this strategy depends partly upon our ability to identify, select and acquire promising pharmaceutical investigational drug candidates and products.

The process of proposing, negotiating and implementing a license or acquisition of an investigational drug candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing and sales resources, may compete with us for the license or acquisition of investigational drug candidates and approved products. We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional investigational drug candidates on terms that we find acceptable, or at all.

In addition, future acquisitions may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management’s time and attention to develop acquired products or technologies;
- incurrence of substantial debt or dilutive issuances of securities to pay for acquisitions;
- higher than expected acquisition, integration and maintenance costs;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- inability to retain key employees of any acquired businesses.

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

If we fail to retain our key personnel and hire, train and retain qualified employees, we may not be able to compete effectively, which could result in reduced revenues or delays in the development of our investigational drug candidates or commercialization of our approved drugs.

Our success is highly dependent upon the skills of a limited number of key management personnel. To reach our business objectives, we will need to retain and hire qualified personnel in the areas of manufacturing, commercial operations, research and development, regulatory and legal affairs, business development, clinical trial design, execution and analysis, and pre-clinical testing. There can be no assurance that we will be able to retain or hire such personnel, as we must compete with other companies, academic institutions, government entities and other agencies. The loss of any of our key personnel or the failure to attract or retain necessary new employees could have an adverse effect on our research programs, investigational drug candidate development, approved drug commercialization efforts and business operations.

We rely on third parties and collaborative partners to manufacture sufficient quantities of compounds within product specifications as required by regulatory agencies for use in our pre-clinical and clinical trials and commercial operations and an interruption to this service may harm our business.

We do not have the ability to manufacture the materials we use in our pre-clinical and clinical trials and commercial operations. Rather, we rely on various third parties to manufacture these materials and there may be long lead times to obtain materials. There can be no assurance that we will be able to identify, contract with, qualify and obtain prior regulatory approval for additional sources of clinical materials. If interruptions in this supply occur for any reason, including a decision by the third parties to discontinue manufacturing, technical difficulties, labor disputes, natural or other disasters, or a failure of the third parties to follow regulations, we may not be able to obtain regulatory approvals for our investigational drug candidates and may not be able to successfully commercialize these investigational drug candidates or our approved drugs.

Our third-party manufacturers and collaborative partners may encounter delays and problems in manufacturing our approved drugs or investigational drug candidates for a variety of reasons, including accidents during operation, failure of equipment, delays in receiving materials, natural or other disasters, political or governmental changes, or other factors inherent in operating complex manufacturing facilities. Supply-chain management is difficult. Commercially available starting materials, reagents, excipients, and other materials may become scarce, more expensive to procure, or not meet quality standards, and we may not be able to obtain favorable terms in agreements with subcontractors. Our third-party manufacturers may not be able to operate manufacturing facilities in a cost-effective manner or in a time frame that is consistent with our expected future manufacturing needs. If our third-party manufacturers, cease or interrupt production or if our third-party manufacturers and other service providers fail to supply materials, products or services to us for any reason, such interruption could delay progress on our programs, or interrupt the commercial supply, with the potential for additional costs and lost revenues. If this were to occur, we may also need to seek alternative means to fulfill our manufacturing needs.

For example, Catalent Pharma Solutions, LLC (“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 PANCREAZE, Nordmark is our sole source of clinical and commercial supplies. Nordmark has significant experience in manufacturing; however, there is no assurance that they will continue to be successful in supplying PANCREAZE in the future or if we will be able to continue our relationship with Nordmark on favorable terms to us for any future formulations and quantities.

For avanafil, Sanofi Chimie manufactures and supplies the API for avanafil on an exclusive basis in the United States and other territories and on a semi-exclusive basis in Europe, including the EU, Latin America and other

territories. Sanofi Winthrop Industrie manufactures and supplies the avanafil tablets for STENDRA and SPEDRA on an exclusive basis in the United States and other territories and on a semi-exclusive basis in Europe, including the EU, Latin America and other territories. Sanofi is responsible for all aspects of manufacture, including obtaining the starting materials for the production of API. If Sanofi is unable to manufacture the API or tablets in sufficient quantities to meet projected demand, future sales could be adversely affected, which in turn could have a detrimental impact on our financial results, our license, commercialization, and supply agreements with our collaboration partners, and our ability to enter into a collaboration agreement for the commercialization in other territories.

Any failure of current or future manufacturing sites, including those of Sanofi Chimie and Sanofi Winthrop Industrie, to receive or maintain approval from FDA or foreign authorities, obtain and maintain ongoing FDA or foreign regulatory compliance, or manufacture avanafil API or tablets in expected quantities could have a detrimental impact on our ability to commercialize STENDRA under our agreements with Menarini and Metuchen and our ability to enter into a collaboration agreement for the commercialization of STENDRA in our other territories not covered by our agreements with Menarini and Metuchen.

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

We seek to maintain the confidential nature of our confidential information through contractual provisions in our agreements with third parties, including our agreements with clinical research organizations (“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. Additionally, we launched the VIVUS Healthcare Platform in 2019, which will provide current and potential customers with an integrated online approach to weight management. We have also launched the Qsymia Advantage program and the PANCREAZE Advantage program.

The collection and use of personal health data and other personal data in the EU is governed by the General Data Protection Regulation (“GDPR”) which became applicable on May 25, 2018, replacing the EU Data Protection Directive. The GDPR imposes strict obligations and restrictions on the ability to collect, analyze or otherwise use, and transfer personal data, including health data from clinical trials and adverse event reporting and substantial fines and other administrative penalties. Ongoing compliance with the GDPR may be onerous and increase our cost of doing business. For more information concerning the data protection requirements in the EU and the EU Member States and the rules governing the transfer of personal data to the U.S., please refer to Item 1, “Business – Fraud and Abuse and Privacy and Data Security Laws and Regulations.”

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 healthcare 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. Moreover, the anti-kickback statute is subject to evolving interpretation and there are no safe harbors for many common practices, including patient or product support programs, educational and research grants, or charitable donations. 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. Actions under the False Claims Act may be brought by the U.S. Attorney General or as a qui tam action by a private individual in the name of the 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. False Claims Act liability is potentially significant in the healthcare industry because the statute provides for treble damages and mandatory penalties per false or fraudulent claim or statement. Because of the potential for large monetary exposure, healthcare and pharmaceutical companies often resolve allegations without admissions of liability for significant and material amounts. 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 ("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. The GDPR, for example, is an EU-wide regulation that imposes restrictions on the processing (e.g., collection, use, disclosure) of personal data and that also imposes strict restrictions on the transfer of personal data out of the EU to the U.S. 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 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. For example, the California Consumer Privacy Act ("CCPA"), which largely took effect January 1, 2020, contains new disclosure obligations for businesses that collect personal information about California residents and affords those individuals new rights relating to their personal information that may affect our ability to use personal information. 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 healthcare providers in the states. Other states prohibit providing meals to prescribers or other marketing-related activities and restrict the ability of manufacturers to offer co-pay support to patients for certain prescription drugs. Some states require the posting of information relating to clinical studies and their outcomes. Some states and cities require identification or licensing of sales representatives. 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, some states 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 of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to the Centers for Medicare and Medicaid Services ("CMS") within the U.S. Department of Health and Human Services information related payments and other transfers of value, directly or indirectly, to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report information regarding payments and transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives; and

- the federal Foreign Corrupt Practices Act of 1977 and other similar anti-bribery laws in other jurisdictions prohibit companies and their intermediaries from providing money or anything of value to officials of foreign governments, candidates for foreign political office, or public 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. and foreign 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.

State and federal regulatory and enforcement agencies continue to actively investigate violations of healthcare laws and regulations, and the U.S. Congress continues to strengthen the arsenal of enforcement tools. Most recently, the Bipartisan Budget Act of 2018 increased the criminal and civil penalties that can be imposed for violating certain federal

healthcare laws, including the federal healthcare Anti-Kickback Statute. 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 (i.e., loss of coverage for products), and the curtailment or restructuring of our operations including by entering into a Corporate Integrity Agreement with the U.S. Department of Health and Human Services Office of Inspector General. 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 to, use, disclosure of, acquisition of, or the prevention of access to, confidential information (including but not limited to trade secrets or other intellectual property, proprietary business information and personal information), and could result in financial, legal, business and reputational harm to us. For example, any such event that leads to unauthorized access, use or disclosure of personal information, including personal information regarding patients or employees, could harm our reputation, require us to comply with federal and/or state breach notification laws and foreign law equivalents, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information. Security breaches and other inappropriate access to, or interference with our information technology systems that access or maintain confidential information, 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, PANCREAZE and STENDRA are subject to these regulations. Failure by us or any of our collaborators 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 or limit our ability to commercialize our drugs.

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

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

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

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

All of those involved in the preparation of a therapeutic drug for clinical trials or commercial sale, including our existing supply contract manufacturers, and clinical trial investigators, are subject to extensive regulation. Components of a finished drug product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with current 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. (“PCI”) for Qsymia packaging services. We rely on Nordmark to supply PANCREAZE. 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 at 100 percent of the average manufacturer price. In addition, the Affordable Care Act and subsequent legislation changed the definition of average manufacturer price. Finally, the Affordable Care Act requires pharmaceutical manufacturers of branded prescription drugs to pay a branded prescription drug fee to the federal government beginning in 2011. Each individual pharmaceutical manufacturer pays a prorated share of the branded prescription drug fee of $2.8 billion in 2019 and thereafter, 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 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 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 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 Health Resources and Services Administration ("HRSA"), which administers the 340B program, issued a final regulation regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities, which became effective on January 1, 2019. It is currently unclear how HRSA will apply its enforcement authority under the regulation. 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. HRSA also implemented a 340B ceiling price reporting requirement pursuant to which we are required to report the 340B ceiling prices for our covered outpatient drugs to HRSA on a quarterly basis. In addition, legislation may be introduced that, if passed, would further expand the 340B program to additional covered entities or would require participating manufacturers to agree to provide 340B discounted pricing on drugs used in the inpatient setting.

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

We are liable for errors associated with our submission of pricing data. Civil monetary penalties can be applied if we are found to have charged 340B covered entities more than the statutorily mandated ceiling price. 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 significant civil monetary penalties 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 significant civil monetary penalty 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.

CMS and the Office of the Inspector General have pursued manufacturers that were alleged to have failed 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 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 include measures that limit or prohibit payments for some medical treatments or subject the pricing of drugs to government control and regulations changing the rebates we are required to provide, and proposals that would do so. 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 2029. These cuts reduce reimbursement payments related to our products, which could potentially negatively impact our revenue.

In March 2010, the President signed 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.
- 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 at 100 percent of the average manufacturer price.
- Effective in January 2011, pharmaceutical companies were required to provide a 50 percent discount on branded prescription drugs dispensed to beneficiaries during their Medicare Part D coverage gap period or "donut hole," which is a coverage gap that currently exists in the Medicare Part D prescription drug program. The BBA increased such manufacturer point-of-sale discounts to 70% effective as of January 1, 2019. We currently have limited 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 an annual, nondeductible, branded prescription drug fee to the federal government, which is apportioned among pharmaceutical manufacturers according to their market share in certain government healthcare programs, although this fee does not apply to sales of certain products approved exclusively for orphan indications. Each individual pharmaceutical manufacturer pays a prorated share of the branded prescription drug fee of $2.8 billion in 2019 and thereafter, 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 revenue.

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.

Certain provisions of the Affordable Care Act have been subject to judicial challenges as well as efforts to repeal or replace them or to alter their interpretation or implementation. 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, effective January 1, 2019. Additional legislative changes, regulatory changes, and judicial challenges related to 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.

There can be no assurance that future healthcare legislation or other changes in the administration or interpretation of government healthcare or third-party reimbursement programs will not have a material adverse effect on us. Healthcare reform is also under consideration in other countries where we intend to market Qsymia.

We expect to experience pricing and reimbursement pressures in connection with the sale of Qsymia, STENDRA and our investigational drug candidates, if approved, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative and regulatory actions. 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 ED 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. 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. For more information concerning pricing and reimbursement of medicinal products in the EU and, in particular, the impact of HTA, please refer to Item 1, “Business – Coverage and Reimbursement.”

Setbacks and consolidation in the pharmaceutical and biotechnology industries, and our, or our collaborators’, inability to obtain third-party coverage and adequate reimbursement, could make partnering more difficult and diminish our revenues.

Setbacks in the pharmaceutical and biotechnology industries, such as those caused by safety concerns relating to high-profile drugs like Avandia®, Vioxx® and Celebrex®, or investigational drug candidates, as well as competition from generic drugs, litigation, and industry consolidation, may have an adverse effect on us. For example, pharmaceutical companies may be less willing to enter into new collaborations or continue existing collaborations if they are integrating a new operation as a result of a merger or acquisition or if their therapeutic areas of focus change following a merger. Moreover, our and our collaborators’ ability to commercialize any of our approved drugs or future investigational drug candidates will depend in part on government regulation and the availability of coverage and adequate reimbursement from third-party payors, including private health insurers and government payors, such as the Medicaid and Medicare programs, increases in government-run, single-payor health insurance plans and compulsory licenses of drugs. Government and third-party payors are increasingly attempting to contain healthcare costs by limiting coverage and reimbursement levels for new drugs. Given the continuing discussion regarding the cost of healthcare, managed care, universal healthcare coverage and other healthcare issues, we cannot predict with certainty what additional healthcare initiatives, if any, will be implemented or the effect any future legislation or regulation will have on our business. These efforts may limit our commercial opportunities by reducing the amount a potential collaborator is willing to pay to license our programs or investigational drug candidates in the future due to a reduction in the potential revenues from drug sales. Adoption of legislation and regulations could limit pricing approvals for, and reimbursement of, drugs. A government or third-party payor decision not to approve pricing for, or provide adequate coverage and reimbursements of, our drugs could limit market acceptance of these drugs.

Our business and operations would suffer in the event of system failures.

Despite the implementation of security measures, our internal computer systems and those of our contract sales organization ("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.

Additionally, we sell Qsymia through MedVantx Pharmacy Services ("MedVantx"), a home delivery pharmacy. System failures by MedVantx could have a significant adverse impact on our ability to fulfill prescriptions transmitted to MedVantx.

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.

Brexit may harm our ability to market our products, to do business, increase our costs and negatively affect our stock price.

Worldwide economic conditions remain uncertain due to various developments including the decision by the United Kingdom ("UK") to initiate the formal procedure of withdrawal from the EU (often referred to as "Brexit"), current economic challenges in Asia and other disruptions to global and regional economies and markets.

Brexit has created significant uncertainty about the future relationship between the UK and the EU, including with respect to the laws and regulations that will apply as the UK determines which EU laws to replace or replicate in the event of a withdrawal. From a regulatory perspective, the UK's withdrawal from the EU could give rise to significant complexity and risks.

The UK officially left the EU on January 31, 2020. There will be a transitional period until December 31, 2020 during which the EU and the UK will seek to negotiate new trade agreements. In light of the fact that a significant portion of the regulatory framework in the UK is derived from EU laws, Brexit (in any form) could materially impact the EU and UK regulatory regime governing development, manufacture, importation, approval and commercialization of our product candidates in the UK or the EU. For example, there is a strong risk that the scope of a marketing authorization for a medicinal product granted by the European Commission or by the competent authorities of EU member states will not encompass the UK. In these circumstances, a separate authorization granted by the UK competent authorities will be required to place medicinal products on the UK market. In addition, our ability to rely on UK manufacturing sites to

supply medicinal products intended for the EU market will depend on the terms of the UK's withdrawal from the EU and, potentially, on the ability to obtain relevant exemptions under EU law to supply the EU market with medicinal products manufactured at UK-certified sites. There is also a risk that if batch release and quality control testing sites for our products are located only in the UK, manufacturers will be required to use sites in other EU member states to manufacture products for supply to the EU market. Any or all of these changes, if they occur, could increase our costs and otherwise adversely affect our business. In addition, currency exchange rates for the British Pound and the Euro with respect to each other and to the U.S. dollar have already been, and may continue to be, negatively affected by Brexit, which could cause volatility in our quarterly financial results.

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. For example, we have limited patent coverage for PANCREAZE, which would not protect us should others develop alternative formulations of the drug. These companies would then be able to develop, manufacture and sell products that compete directly with our products. In that case, our revenues and operating results could decline.

Other entities may also challenge the validity or enforceability of our patents and patent applications in litigation or administrative proceedings. The sponsor of a generic application seeking to rely on one of our approved drug products as the reference listed drug must make one of several certifications regarding each listed patent. A “Paragraph III” certification is the sponsor’s statement that it will wait for the patent to expire before obtaining approval for its product. A “Paragraph IV” certification is a challenge to the patent; it is an assertion that the patent does not block approval of the later product, either because the patent is invalid or unenforceable or because the patent, even if valid, is not infringed by the new product. Once FDA accepts for filing a generic application containing a Paragraph IV certification, the applicant must within 20 days provide notice to the reference listed drug (“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 submitted by generic drug companies asserting that generic forms of our approved therapies 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 ("FDCA") which renders it susceptible to potential competition from generic manufacturers via the ANDA approval process. The FDCA 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 certain Paragraph IV certification notices and have entered into settlement agreements with those who have submitted those notices. The settlement agreement with Actavis Laboratories FL, Inc., Actavis, Inc., and Actavis PLC, collectively referred to as "Actavis," will permit Actavis to begin selling a generic version of Qsymia on December 1, 2024, or earlier under certain circumstances. The settlement with Dr. Reddy's Laboratories, S.A. and Dr. Reddy's Laboratories, Inc., collectively referred to as "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 or any of our other approved therapies is introduced, these therapies would become subject to increased competition and our revenue would be adversely affected.

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

Our commercial success also depends, in part, upon our ability to develop future investigational drug candidates, market and sell approved drugs and conduct our other research, development and commercialization activities without infringing or misappropriating the patents and other proprietary rights of others. There are many patents and patent applications owned by others that could be relevant to our business. For example, there are numerous U.S. and foreign issued patents and pending patent applications owned by others that are related to the therapeutic areas in which we have approved drugs or future investigational drug candidates as well as the therapeutic targets to which these drugs and candidates are directed. There are also numerous issued patents and patent applications covering chemical compounds or synthetic processes that may be necessary or useful to use in our research, development, manufacturing or commercialization activities. Because patent applications can take many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that our approved drugs, future investigational drug candidates or technologies may infringe. There also may be existing patents, of which we are not aware, that our approved drugs, investigational drug candidates or technologies may infringe. Further, it is not always

clear to industry participants, including us, which patents cover various types of products or methods. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. We cannot assure you that others holding any of these patents or patent applications will not assert infringement claims against us for damages or seek to enjoin our activities. If we are sued for patent infringement, we would need to demonstrate that our products or methods do not infringe the patent claims of the relevant patent and/or that the patent claims are invalid or unenforceable, and we may not be able to do this.

There can be no assurance that approved drugs or future investigational drug candidates do not or will not infringe on the patents or proprietary rights of others. In addition, third parties may already own or may obtain patents in the future and claim that use of our technologies infringes these patents.

If a person or entity files a legal action or administrative action against us, or our collaborators, claiming that our drug discovery, development, manufacturing or commercialization activities infringe a patent owned by the person or entity, we could incur substantial costs and diversion of the time and attention of management and technical personnel in defending ourselves against any such claims. Furthermore, parties making claims against us may be able to obtain injunctive or other equitable relief that could effectively block our ability to further develop, commercialize and sell any current or future approved drugs, and such claims could result in the award of substantial damages against us. In the event of a successful claim of infringement against us, we may be required to pay damages and obtain one or more licenses from third parties. We may not be able to obtain these licenses at a reasonable cost, if at all. In that case, we could encounter delays in product introductions while we attempt to develop alternative investigational drug candidates or be required to cease commercializing any affected current or future approved drugs and our operating results would be harmed.

Furthermore, because of the substantial amount of pre-trial document and witness discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the trading price of our common stock.

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

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

Even if international patent applications ultimately issue or receive approval, it is likely that the scope of protection provided by such patents will be different from, and possibly less than, the scope provided by our corresponding U.S. patents. The success of our international market opportunity is dependent upon the enforcement of patent rights in various other countries. A number of countries in which we have filed or intend to file patent applications have a history of weak enforcement and/or compulsory licensing of intellectual property rights. Moreover, the legal systems of certain countries, particularly certain developing countries, do not favor the aggressive enforcement of patents and other intellectual property protection, particularly those relating to biotechnology and/or pharmaceuticals, which make it difficult for us to stop the infringement of our patents. Even if we have patents issued in these jurisdictions, there can be no assurance that our patent rights will be sufficient to prevent generic competition or unauthorized use.

Attempting to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

Risks Relating to our Financial Position and Need for Financing

We will require additional capital for our debt servicing requirements and future operating plans, and we may not be able to secure the requisite additional funding on acceptable terms, or at all, which would not allow us to continue our operations at current levels or continue as a going concern and may force us to delay, reduce or eliminate commercialization or development efforts.

Our Convertible Notes, with a face value of $181.4 million, are due in May 2020. We will require additional funding prior to May 2020 to service our existing debt, including the maturity of our Convertible Notes, to fund our operations and to pursue development and commercial opportunities. We do not currently have sufficient cash and/or credit facilities in place to pay the debt due May 2020, and we are actively pursuing funding, which may come through public or private debt or equity financings, collaborations or other available financing sources. Such funding 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 will not be able to continue our operations at our current level, or at all, and we may be required to relinquish rights to certain of our technologies, product candidates or products that we would otherwise seek to develop on our own. We might also be required to delay, reduce the scope of or eliminate one or more of our commercialization or development programs or obtain funds through collaborations with others that are on unfavorable terms or restructure the Company in other ways that may not be favorable. Even if adequate funds become available, we may need to raise additional funds in the near future to finance our operations and pursue development and commercial opportunities.

Our independent registered public accounting firm's audit report on our consolidated financial statements includes an explanatory paragraph stating that there is substantial doubt about our ability to continue as a going concern. If we cannot continue as a viable entity, our security holders may lose some or all of their investment in our Company.

Our future capital requirements will depend upon numerous factors, including:

- our ability to secure financing in order to repay our Convertible Notes at maturity in May 2020;
- our ability to expand the use of Qsymia and PANCREAZE;
- the costs to commercialize PANCREAZE;
- our ability to obtain marketing authorization by the EC for Qsymia in the EU and other territories;
- 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 produce and 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 costs associated with obtaining, developing and marketing any new development assets;
- the scope, timing, costs and results of pre-clinical, clinical and retrospective observational studies and trials;
- the cost of access to electronic records and databases that allow for retrospective observational studies;
- patient recruitment and enrollment in future clinical trials;
- the costs involved in seeking regulatory approvals for future drug candidates;
- the costs involved in filing and pursuing patent applications, defending and enforcing patent claims;
- the establishment of collaborations, sublicenses and strategic alliances and the related costs, including milestone payments;

- the cost of manufacturing and commercialization activities and arrangements;
- the level of resources devoted to our future sales and marketing capabilities;
- the cost, timing and outcome of litigation, if any;
- the impact of healthcare reform, if any, imposed by the federal government; and
- the activities of competitors.

Future capital requirements will also depend on the extent to which we acquire or invest in additional businesses, products and technologies. On January 6, 2017, we entered into a Patent Assignment Agreement with Selten whereby we received exclusive, worldwide rights for the development and commercialization of BMPR2 activators for the treatment of PAH and related vascular diseases. We paid Selten an upfront payment of $1.0 million, and we will pay additional milestone payments based on global development status and future sales milestones, as well as tiered royalty payments on future sales of these compounds. The total potential milestone payments are $39.6 million.

To obtain additional capital when needed, we will evaluate alternative financing sources, including, but not limited to, the issuance of equity or debt securities, corporate alliances, joint ventures and licensing agreements. However, there can be no assurance that funding will be available on favorable terms, if at all. We are continually evaluating our existing portfolio and we may choose to divest, sell or spin-off one or more of our drugs and/or investigational drug candidates at any time. We cannot assure you that our drugs will generate revenues sufficient to enable us to earn a profit. If we are unable to obtain additional capital, management may be required to explore alternatives to reduce cash used by operating activities, including the termination of research and development efforts that may appear to be promising to us, the sale of certain assets and the reduction in overall operating activities. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate one or more of our development programs or our commercialization efforts.

Raising additional funds by issuing securities will cause dilution to existing stockholders and raising funds through lending and licensing arrangements may restrict our operations or require us to relinquish proprietary rights.

To the extent that we raise additional capital by issuing equity securities, our existing stockholders' ownership will be diluted. We have financed our operations, and we expect to continue to finance our operations, primarily by issuing equity and debt securities. Moreover, any issuances by us of equity securities may be at or below the prevailing market price of our common stock and in any event may have a dilutive impact on your ownership interest, which could cause the market price of our common stock to decline. To raise additional capital, we may choose to issue additional securities at any time and at any price.

As of December 31, 2019, we have $181.4 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 1,683,000 shares of our common stock under certain circumstances prior to maturity at a conversion rate of 6.73038 shares per $1,000 principal amount of Convertible Notes, which represents a conversion price of approximately $148.58 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.

In April 2018, we entered into an agreement for the 2024 Notes with Athyrium Capital Management, LP ("Athyrium"). $110.0 million of the 2024 Notes were drawn down in June 2018, with the remaining $10.0 million available for drawing upon meeting certain conditions. Payments on the 2024 Notes bear interest at 10.375% and are interest-only for the first 36 months; thereafter the notes will be repaid in 36 equal monthly payments. Concurrently, we repurchased Convertible Notes held by Athyrium, with a face value of $60.0 million, for $51.0 million. In October 2018, we settled a purchase of approximately $8.6 million outstanding principal amount of our Convertible Notes for approximately $7.1 million plus accrued interest. In September 2019, we repurchased $48.6 aggregate principal amount of the 2024 Notes plus prepayment premiums. We continue our evaluation of alternatives for addressing our remaining $181.4 million of Convertible Notes.

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 (the "BioPharma Agreement") with BioPharma Secured Investments III Holdings Cayman LP ("BioPharma") which provides for the purchase of a debt-like instrument. Under the BioPharma Agreement, we may not (i) incur indebtedness greater than a specified amount, (ii) pay a dividend or other cash distribution on our capital stock, unless we have cash and cash equivalents in excess of a specified amount, (iii) amend or restate our certificate of incorporation or bylaws unless such amendments or restatements do not affect BioPharma's interests under the BioPharma Agreement, (iv) encumber the collateral, or (v) abandon certain patent rights, in each case without the consent of BioPharma. Any future debt financing we enter into may involve similar or more onerous covenants that restrict our operations.

If we raise additional capital through collaboration, licensing or other similar arrangements, it may be necessary to relinquish potentially valuable rights to our drugs or future investigational drug candidates, potential products or proprietary technologies, or grant licenses on terms that are not favorable to us. If adequate funds are not available, our ability to achieve profitability or to respond to competitive pressures would be significantly limited and we may be required to delay, significantly curtail or eliminate the commercialization of one or more of our approved drugs or the development of one or more of our future investigational drug candidates.

The investment of our cash balance and our available-for-sale securities are subject to risks that may cause losses and affect the liquidity of these investments.

At December 31, 2019, we had $32.6 million in cash and cash equivalents, and had no available-for-sale securities. While our excess cash balances are typically 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. To the extent we determine to invest any excess funds in debt securities with maturities greater than money market securities, those investments may be subject to the loss of principal if interest rates change and we are required to liquidate the position prior to maturity. If we invest in corporate debt securities, we are also subject to credit risk and the loss of principal if credit ratings change. Further, institutional money market funds are required by rules of the SEC to mark their portfolio to market and are no longer permitted to issue and redeem shares at a constant net asset value, typically $1 per share.

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 and to file a petition for certiorari in the Supreme Court has now expired and the matter is concluded.

We have an accumulated deficit of $912.0 million as of December 31, 2019, and we may continue to incur substantial operating losses for the future.

We have generated a cumulative net loss of $912.0 million for the period from our inception through December 31, 2019, 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, 2019, we had approximately $648.5 million and $278.2 million of total federal and state net operating loss ("NOL") carryforwards, respectively, with which to offset our future taxable income. 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 ("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 our formation, due to the significant complexity and cost associated with the study. We have completed studies through December 31, 2016 and concluded no adjustments were required. If we have experienced a change of control at any time since our formation, our NOL carryforwards and tax credits may not be available, or their utilization could be subject to an annual limitation under Section 382. A full valuation allowance has been provided against our NOL carryforwards, and if an adjustment is required, this adjustment would be offset by an adjustment to the valuation allowance. Accordingly, there would be no impact on the consolidated balance sheet or statement of operations.

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

We are subject to income taxes and other taxes in both the U.S. and the foreign jurisdictions in which we currently operate or have historically operated. The determination of our worldwide provision for income taxes and

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

Risks Relating to an Investment in our Common Stock

Our stock price has been and may continue to be volatile.

The market price of our common stock has been volatile and is likely to continue to be so. The market price of our common stock may fluctuate due to factors including, but not limited to:

- our ability to meet the expectations of investors related to the production and commercialization of Qsymia, PANCREAZE 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 Qsymia 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;
- trading activity by highly technical investors utilizing sophisticated algorithms and high frequency trading;
- investment activities employed by short sellers of our common stock;

- developments or disputes concerning patents or other proprietary rights;
- reports of prescription data by us or from independent third parties for our products;
- licensing, product, patent or securities litigation; and
- public concern as to the safety or efficacy of our drugs or future investigational drug candidates developed by us.

These factors and fluctuations, as well as political and other market conditions, may adversely affect the market price of our common stock. Additionally, volatility or a lack of positive performance in our stock price may adversely affect our ability to retain or recruit key employees, all of whom have been or will be granted equity awards as an important part of their compensation packages.

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

Our operating results will likely fluctuate from fiscal quarter to fiscal quarter, and from year to year, and are difficult to predict. Product sales of Qsymia may never increase or become profitable. We may be unsuccessful in properly integrating and profitably marketing PANCREAZE. 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.

It is likely that in some future period or periods our operating results will be below the expectations of securities analysts or investors. If one or more of the analysts who cover us downgrade our stock, or if our results of operations do not meet their expectations, the trading price of our stock could decline. In addition, the trading market for our common stock is influenced by the research and reports that industry or securities analysts publish about us or our business. If one or more of these analysts cease coverage of our Company or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

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 December 30, 2019, our Board of Directors adopted a new stockholder rights plan to replace the Company's stockholder rights plan that expired in accordance with its terms on November 9, 2019. Under the new rights plan, we issued a dividend of one right for each share of our common stock held by stockholders of record as of the close of

business on January 13, 2020. The new rights plan is designed to protect stockholder value by mitigating the likelihood of an "ownership change" that would result in significant limitations to our ability to use our net operating losses or other tax attributes to offset future income. The new rights plan is similar to rights plans adopted by other public companies with significant net operating loss carryforwards

The new rights plan provides, subject to certain exceptions that if any person or group acquires 4.9% or more of the Company's 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 the Company's outstanding common stock as of the date of the new rights plan will trigger a dilutive event only if they acquire an additional 1% of the outstanding shares of our common stock.

The new rights plan will continue in effect until December 30, 2022, unless earlier terminated or the rights are earlier exchanged or redeemed by our Board of Directors. We expect to submit the new rights plan to a vote at our 2020 annual meeting of stockholders. If stockholders do not approve the plan at the 2020 annual meeting, it will expire at the close of business on the following day.

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

- authorize the issuance of preferred stock by the Board without prior stockholder approval, commonly referred to as "blank check" preferred stock, with rights senior to those of common stock;
- prohibit stockholder action 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 the 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 governing 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, and may delay, deter or prevent a tender offer or takeover attempt that a stockholder might consider in its best interest.

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 (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***

We are not aware of any asserted or unasserted claims against us where we believe that an unfavorable resolution would have an adverse material impact on our operations or financial position.

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

None.

PART II

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

VIVUS's common stock trades publicly on the Nasdaq Global Select Market under the symbol "VVUS." As of February 29, 2020, there were 10,648,947 shares of outstanding common stock that were held by 1,438 stockholders of record and no outstanding shares of preferred stock. On February 29, 2020, the last reported sales price of our common stock on the Nasdaq Global Select Market was $1.81 per share.

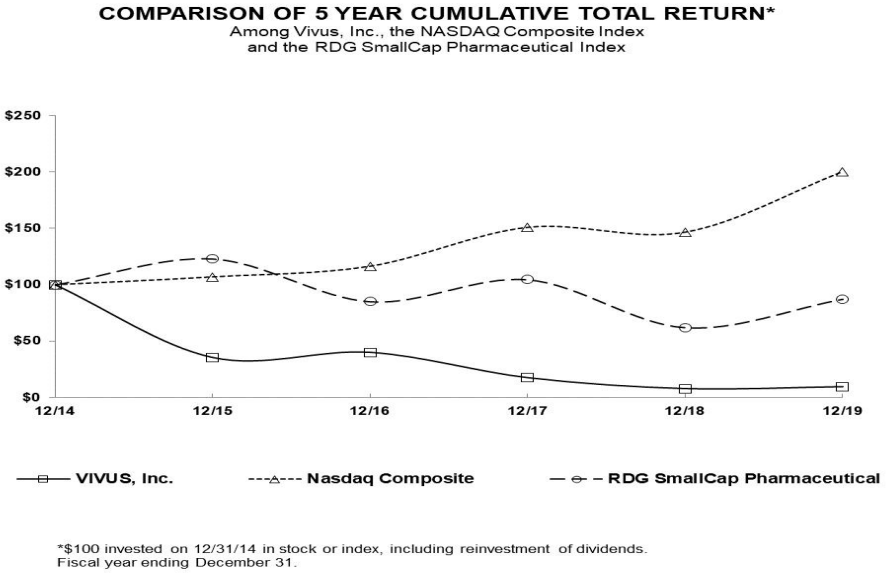
Dividends

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 and applicable contractual restrictions.

Stock Performance Graph

The following graph shows a comparison of total stockholder return for holders of our common stock from December 31, 2014 through December 31, 2019 compared with the Nasdaq Composite Index and the RDG SmallCap Pharmaceutical Index. Total stockholder return assumes $100 invested at the beginning of the period in our common stock, the stock represented in the Nasdaq Composite Index and the stock represented by the RDG SmallCap Pharmaceutical Index, respectively. This graph is presented pursuant to SEC rules. We believe that while total stockholder return can be an important indicator of corporate performance, the stock prices of small cap pharmaceutical stocks like VIVUS are subject to a number of market-related factors other than company performance, such as competitive announcements, mergers and acquisitions in the industry, the general state of the economy, and the performance of other medical technology stocks.

COMPARISON OF 5-YEAR CUMULATIVE TOTAL RETURN*
Among VIVUS, Inc., the Nasdaq Composite Index, and the RDG SmallCap Pharmaceutical Index



* $100 invested on 12/31/2014 in stock or index, including reinvestment of dividends. Fiscal year ending December 31.

Item 6. ***Selected Financial Data***

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

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

Selected Annual Financial Data

	Year Ended December 31,				
	2019	2018	2017	2016	2015
Income Statement Data:					
Total revenue	$ 69,760	$ 65,062	$ 65,373	$ 124,258	$ 95,430
Total operating expenses	$ 80,729	$ 68,541	$ 62,580	$ 68,573	$ 155,707
Income (loss) from operations	$ (10,969)	$ (3,479)	$ 2,793	$ 55,685	$ (60,277)
Net (loss) income	$ (31,503)	$ (36,950)	$ (30,511)	$ 23,302	$ (93,107)
Basic net (loss) income per share	$ (2.96)	$ (3.48)	$ (2.89)	$ 2.23	$ (8.96)
Diluted net (loss) income per share	$ (2.96)	$ (3.48)	$ (2.89)	$ 2.22	$ (8.96)
Balance Sheet Data:					
Working capital	$ (128,346)	$ 124,327	$ 224,643	$ 255,159	$ 214,143
Total assets	$ 218,308	$ 302,147	$ 264,968	$ 305,776	$ 277,202
Long-term debt	$ 241,727	$ 294,446	$ 235,683	$ 241,318	$ 231,390
Accumulated deficit	$ (912,008)	$ (880,515)	$ (843,565)	$ (813,054)	$ (836,356)
Stockholders' (deficit) equity	$ (69,224)	$ (40,023)	$ (9,338)	$ 18,185	$ (7,085)

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, 2019, 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.

Reverse Stock Split

On September 10, 2018, we effected a one-for-10 reverse stock split of our common stock. As a result of the reverse stock split, every 10 shares of our pre-reverse split common stock issued and outstanding was combined and converted into one issued and outstanding share of post-reverse split common stock without any change in the par value of the shares. Accordingly, an amount equal to the par value of the decreased shares resulting from the reverse stock split was reclassified from "Common stock" to "Additional paid-in capital." No fractional shares were issued as a result of the reverse stock split; any fractional shares that would have resulted were rounded up to the nearest whole share. Proportionate voting rights and other rights of stockholders were not affected by the reverse stock split, other than as a result of the rounding up of potential fractional shares. All stock options, warrants and restricted stock units outstanding and common stock reserved for issuance under our equity incentive plans immediately prior to the reverse stock split were adjusted by dividing the number of affected shares of common stock by 10 and, where applicable, multiplying the exercise price by 10. All share and per share amounts related to common stock, stock options, warrants and restricted stock units have been restated for all periods to give retroactive effect to the reverse stock split.

Overview

VIVUS is a specialty pharmaceutical company with three approved therapies and one product candidate in clinical development. Qsymia® (phentermine and topiramate extended release) is approved by FDA for chronic weight management. In June 2018, we acquired the U.S. and Canadian commercial rights for PANCREAZE®/PANCREASE® MT (pancrelipase), which is indicated for the treatment of exocrine pancreatic insufficiency ("EPI") due to cystic fibrosis or other conditions. STENDRA® (avanafil) is approved by FDA for erectile dysfunction ("ED") and by the EC under the trade name SPEDRA, for the treatment of ED in the EU. VI-0106 (tacrolimus) is in clinical development and is being studied in patients with pulmonary arterial hypertension ("PAH").

Business Strategy

In April 2018, we added John Amos as our new Chief Executive Officer and a member of the VIVUS Board of Directors. With the addition of Mr. Amos, we announced a turnaround plan of building a portfolio of cash flow generating assets to leverage our expertise in commercializing specialty pharmaceutical assets. In June 2018, we completed the first acquisition under this strategy as we acquired all product rights for PANCREAZE (pancrelipase) in the United States and PANCREASE MT in Canada for $135.0 million in cash from Janssen Pharmaceuticals. PANCREAZE/PANCREASE MT is a prescription medicine used to treat people who cannot digest food normally because their pancreas does not make enough enzymes due to cystic fibrosis or other conditions. We are supporting PANCREAZE in the U.S. market by leveraging our existing commercial infrastructure and 10 sales representatives in the U.S. focused on gastro-intestinal and cystic fibrosis physicians.

In June of 2018, we issued $110.0 million of 10.375% 2024 Notes ("2024 Notes") with affiliates of Athyrium Capital Management ("Athyrium"). Concurrent with the issuance of the 2024 Notes, we issued warrants to purchase 0.3 million shares of our common stock to the note holders. Additionally, concurrent with the issuance of the 2024 Notes, we repurchased Convertible Notes held by Athyrium, with a face value of $60.0 million, at a discount to par plus accrued interest. In October 2018, we settled a purchase of approximately $8.6 million outstanding principal amount of our Convertible Notes for approximately $7.1 million plus accrued interest. In September 2019, we repurchased $48.6 million aggregate principal amount of our 2024 Notes plus prepayment premiums of an aggregate of $6.4 million.

As of December 31, 2019, we had a total of $241.7 million of outstanding debt, $181.4 million of which is due in May 2020. We do not currently have sufficient cash and/or credit facilities in place to address the debt due May 2020 and thus are actively pursuing funding, which may come through public or private debt or equity financings, collaborations or other available financing sources. Such funding 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 will not be able to continue our operations at our current level and may be required to relinquish rights to certain of our technologies, product candidates or products that we would otherwise seek to develop on our own. We might also be required to delay, reduce the scope of or eliminate one or more of our commercialization or development programs or obtain funds through collaborations with others that are on unfavorable terms or restructure VIVUS in other ways that may not be favorable. Even if adequate funds become available, we may need to raise additional funds in the near future to finance operations and pursue development and commercial opportunities.

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 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 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. In 2019, we introduced the Qsymia Advantage program to reach more of our intended patient population. The Qsymia Advantage program includes patient education resources and access to a home delivery in addition to new pricing.

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 (the "Alvogen License Agreement") and a commercial supply agreement (the "Alvogen Supply Agreement") with Alvogen Malta Operations (ROW) Ltd ("Alvogen"). Under the terms of the Alvogen License Agreement, Alvogen is 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 a payment of $2.5 million in September 2019 upon achieving marketing authorization. We are eligible to receive additional payments upon Alvogen achieving 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, we will supply product to Alvogen on an exclusive basis.

In October 2019, we announced that European regulatory agencies in Sweden, Denmark, Finland, Iceland, Norway, and Poland (the "Concerned Member States") have accepted the Marketing Authorization Application (the "MAA") for Qsymia on a decentralized basis, with Sweden acting as the lead. Under the decentralized MAA procedure, the regulatory authorities in each of the Concerned Member States may simultaneously provide Marketing Authorization for use of a product within those specific countries. Based on the decentralized MAA procedure timelines, we anticipate the completion of the MAA assessment in the second half of 2020.

In December 2019, we announced the results of a pharmacokinetic and pharmacodynamic study demonstrating that Qsymia capsules CIV has favorable pharmacokinetic, efficacy, and safety/tolerability profiles when used for eight weeks to treat adolescents with obesity. The study was conducted in order to establish dosing levels for the ongoing Phase 4 post-marketing study of Qsymia in obese adolescents. The primary objective of the study was to describe the pharmacokinetic profiles of Qsymia after administration in adolescents with obesity.

PANCREAZE/PANCREASE MT

In June 2018, we acquired the commercial rights to PANCREAZE and PANCREASE MT in the U.S. and Canada. Prior to the acquisition, PANCREAZE/PANCREASE MT had been commercialized by Janssen. In connection with the acquisition of PANCREAZE/PANCREASE MT, we and Janssen also entered into transition services agreements pursuant to which Janssen and a Canadian affiliate of Janssen provided certain transition services to us in the U.S. and Canada as we transitioned to full control over the PANCREAZE/PANCREASE MT supply chain, which was completed in the first quarter of 2019. In the first quarter of 2019, we relaunched PANCREAZE in the U.S. by leveraging our existing commercial infrastructure and expanding it to include 10 additional contract sales representatives in the U.S. focused on gastro-intestinal and cystic fibrosis physicians. We also introduced the PANCREAZE Advantage program, which is intended to enhance patient access and improve the patient experience with patient and physician educational materials, a patient support program, and patient and payment assistance. We transitioned to direct sales in Canada in the third quarter of 2019. We have also prioritized supply chain improvement, working capital management and moving PANCREAZE/PANCREASE MT back into the view of the medical community. In February 2020, FDA approved the supplemental New Drug Application for an improved formulation of PANCREAZE that extends the shelf life to 36 months across all PANCREAZE dosages.

Approved in 2010, PANCREAZE/PANCREASE MT is a pancreatic enzyme preparation consisting of pancrelipase, an extract derived from porcine pancreatic glands, as well as other enzyme classes, including porcine-derived lipases, proteases and amylases. PANCREAZE/PANCREASE MT is specifically indicated for the treatment of exocrine pancreatic insufficiency ("EPI"). EPI is a condition that results from a deficiency in the production and/or secretion of pancreatic enzymes. It is associated with cystic fibrosis, chronic pancreatitis, pancreatic cancer and other conditions, and affects approximately 85 percent of cystic fibrosis patients. There is no cure for EPI and pancreatic enzyme replacement therapy is the primary treatment for the condition.

STENDRA/SPEDRA

STENDRA is an oral phosphodiesterase type 5 ("PDE5") inhibitor that we have licensed from Mitsubishi Tanabe Pharma Corporation ("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.

The Menarini Group, through its subsidiary Berlin Chemie AG (“Menarini”), is our exclusive licensee for the commercialization and promotion of SPEDRA for the treatment of ED in over 40 countries, including the EU Member States. In addition, Menarini licensed rights directly from MTPC to commercialize avanafil in certain Asian territories. We receive royalties from Menarini based on SPEDRA net sales and are entitled to receive future milestone payments based on certain net sales targets. 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.

Metuchen Pharmaceuticals LLC (“Metuchen”) is our exclusive licensee for the development, commercialization and promotion of STENDRA in the United States, Canada, South America and India. Metuchen reimburses us for payments made to cover royalty and milestone obligations to MTPC, but otherwise owes us no future royalties. Metuchen obtains STENDRA exclusively from us. On September 30, 2019, Metuchen provided a written notice of termination of our supply agreement with them effective September 30, 2021.

We are currently in discussions with potential collaboration partners to develop, market and sell STENDRA/SPEDRA for territories in which we do not currently have a commercial collaboration, including Africa, the Middle East, Turkey, Russia, Mexico and Central America.

Product Development Pipeline and Life Cycle Management

VI-0106 - 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 current medical therapies for PAH involve endothelin receptor antagonists, PDE5 inhibitors, prostacyclin analogues, selective prostaglandin I2 receptor agonists, and soluble guanate cyclase stimulators, all of which have been shown to effectively dilate arterioles in the pulmonary circulation, to reduce symptoms and improve quality of life. While currently approved products treat the symptoms of PAH, they do little to address the pathologic cell proliferation that is the underlying cause of the disease. We believe that tacrolimus can be used to enhance bone morphogenetic protein receptor type 2 (“BMPR2”) signaling. BMPR2 signaling has been shown to be reduced in PAH patients, and this reduction in signaling is an important factor leading to cell proliferation within the pulmonary arteries. By restoring BMPR2 signaling, tacrolimus 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 acquired the exclusive, worldwide rights for the development and commercialization of BMPR2 activators for the treatment of PAH and related vascular diseases from Selten Pharma, Inc. (“Selten”). Selten assigned to us its license to a group of patents owned by the Board of Trustees of the Leland Stanford Junior University (“Stanford”) which cover uses of tacrolimus and ascomycin to treat PAH. 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 VI-0106, 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 3 and 4 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 U.S. and the EU on the basis of a scientific opinion adopted by the Committee for Orphan Medicinal Products of 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, if approved, for commercial use. If we are successful in our development efforts, we anticipate filing an IND with FDA and completing the development of our proprietary formulation of tacrolimus in the second half of 2020. We are currently seeking alternatives for financing the development of tacrolimus.

Qsymia for Additional Indications

We are currently considering further development of Qsymia for the treatment of various diseases, including obstructive sleep apnea and nonalcoholic steatohepatitis ("NASH").

NOL Rights Plan

On December 30, 2019, our Board of Directors adopted a new stockholder rights plan to replace the Company's stockholder rights plan that expired on November 9, 2019. Under the new rights plan, we issued a dividend of one right for each share of our common stock held by stockholders of record as of the close of business on January 13, 2020. The new rights plan is designed to protect stockholder value by mitigating the likelihood of an "ownership change" that would result in significant limitations to our ability to use our net operating losses or other tax attributes to offset future income. The new rights plan is similar to rights plans adopted by other public companies with significant net operating loss carryforwards

The new rights plan provides, subject to certain exceptions, that if any person or group acquires 4.9% or more of the Company's 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 the Company's outstanding common stock as of the date of the new rights plan will trigger a dilutive event only if they acquire an additional 1% of the outstanding shares of VIVUS common stock.

The new rights plan will continue in effect until December 30, 2022, unless earlier terminated or the rights are earlier exchanged or redeemed by the Board of Directors. We expect to submit the new rights plan to a vote at our 2020 annual meeting of stockholders. If stockholders do not approve the plan at the 2020 annual meeting, it will expire at the close of business on the following day.

Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues, expenses and related disclosures. On an ongoing basis, we evaluate our estimates, including those related to available-for-sale securities, research and development expenses, income taxes, inventories, revenues, including revenues from multiple-element arrangements, contingencies and litigation and share-based compensation. We base our estimates on historical experience, information received from third parties and on various market specific and other relevant assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ significantly from these estimates under different assumptions or conditions. Our significant accounting policies are more fully described in Note 1 to our Consolidated Financial Statements included elsewhere in this report.

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

Revenue Recognition

For all revenue transactions, we evaluate our contracts with our customers to determine revenue recognition using the following five-step model:

1) We identify the contract(s) with a customer;
2) We identify the performance obligations in the contract;
3) We determine the transaction price;
4) We allocate the transaction price to the identified performance obligations; and
5) We recognize revenue when (or as) the entity satisfies a performance obligation.

Product Revenue

Product revenue is recognized at the time of shipment at which time we have satisfied our performance obligation. Product revenue is recognized net of consideration paid to our 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 a reserve for estimated product returns, certain prompt pay discounts and allowances offered to our customers, program rebates and chargebacks. These product revenue allowances are recognized as a reduction of revenue at the date at which the related revenue is recognized. We also offer discount programs to patients. Calculating certain of these items involves estimates and judgments based on sales or invoice data, contractual terms, utilization rates, new information regarding changes in these programs' regulations and guidelines that would impact the amount of the actual rebates or chargebacks. We review the adequacy of product revenue allowances on a quarterly basis. Amounts accrued for product revenue allowances are adjusted when trends or significant events indicate that adjustment is appropriate and to reflect actual experience. See Note 9 to our consolidated financial statements for product reserve balances.

Change in Accounting Estimate in 2017

We ship units of Qsymia through a distribution network that includes certified retail pharmacies. We began shipping Qsymia in September 2012, and we grant rights to our 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 we had no previous experience in selling Qsymia and given the lengthy return period, we were not initially able to reliably estimate expected returns of Qsymia at the time of shipment, which was required by the accounting literature at the time, and we therefore recognized revenue when units were dispensed to patients through prescriptions, at which point the product was not subject to return, or when the expiration period had ended.

Beginning in the first quarter of 2017, with 48 months of returns experience, we believed that we had sufficient data and experience from selling Qsymia to reliably estimate expected returns. Therefore, beginning in the first quarter of 2017, under the then relevant accounting literature, we began recognizing revenue from the sales of Qsymia upon shipment and recording reserves for expected returns, discounts and fees at the time of shipment.

In accordance with this change in accounting estimate, in the first quarter of 2017 we 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. We 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 $0.57 per share in 2017.

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

	Product Returns	Discount Programs	Wholesaler/ Pharmacy Fees	Cash Discounts	Rebates/ Chargebacks	Total
Balance at January 1, 2017	$ —	$ (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*	(11,428)	(13,908)	(6,937)	(1,327)	(6,001)	(39,601)
Payments	4,404	15,991	7,017	1,370	1,317	30,099
Balance at December 31, 2018	(14,878)	(2,301)	(1,003)	(152)	(4,968)	(23,302)
Current provision related to sales made during current period*	(11,787)	(11,726)	(9,510)	(1,966)	(9,719)	(44,708)
Payments	11,791	11,537	9,122	1,866	11,905	46,221
Balance at December 31, 2019	$ (14,874)	$ (2,490)	$ (1,391)	$ (252)	$ (2,782)	$ (21,789)

* Current provision related to sales made during current period includes $44.4 million, $39.1 million and $38.7 million for product revenue allowances related to revenue recognized during the years ended December 31, 2019, 2018 and 2017, 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 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. We recognize supply revenue at the time of shipment and, in the unusual case where the product does not meet contractually specified product dating criteria at the time of shipment to the partner, we record a reserve for estimated product returns. There are no such reserves as of December 31, 2019.

License and Milestone Revenue

License and milestone revenues related to arrangements, usually license and/or supply agreements, entered into by us are recognized by following the five-step process outlined above. The allocation and timing of recognition of such revenue will be determined by that process and the amounts recognized and the timing of that recognition may not exactly follow the wording of the agreement as the amount allocated following the accounting analysis of the agreement may differ and the timing of recognition of a significant performance obligation may predate the contractual date.

Royalty Revenue

We rely on data provided by our collaboration partners in determining our contractually based royalty revenue. Such data includes accounting estimates and reports for various discounts and allowances, including product returns. We record royalty revenues based on the best data available and make any adjustments to such revenues as such information becomes available.

Inventories

Inventories are valued at the lower of cost or net realizable value. 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 (“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.

Research and Development Expenses

Research and development ("R&D") expenses include license fees, related compensation, consultants' fees, facilities costs, administrative expenses related to R&D activities and clinical trial costs incurred by clinical research organizations or CROs, and research institutions under agreements that are generally cancelable, among other related R&D costs. We also record accruals for estimated ongoing clinical trial costs. Clinical trial costs represent costs incurred by CRO and clinical sites and include advertising for clinical trials and patient recruitment costs. These costs are recorded as a component of R&D expenses and are expensed as incurred. Under our agreements, progress payments are typically made to investigators, clinical sites and CROs. We analyze the progress of the clinical trials, including levels of patient enrollment, invoices received and contracted costs when evaluating the adequacy of accrued liabilities. Significant judgments and estimates must be made and used in determining the accrued balance in any accounting period. Actual results could differ from those estimates under different assumptions. Revisions are charged to expense in the period in which the facts that give rise to the revision become known.

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

Share-Based Payments

Compensation expense is recognized for share-based payments, including stock options, restricted stock units and shares issued under the employee stock purchase plan, using a fair value based method. We estimate the fair value of share based payment awards on the date of the grant using the Black Scholes option pricing model, which requires us to estimate the expected term of the award, the expected volatility, the risk-free interest rate and the expected dividends. The expected term, which represents the period of time that options granted are expected to be outstanding, is derived by analyzing the historical experience of similar awards, giving consideration to the contractual terms of the share based awards, vesting schedules and expectations of future employee behavior. Expected volatilities are estimated using the historical share price performance over the expected term of the option, which are adjusted as necessary for any other factors which may reasonably affect the volatility of VIVUS's stock in the future. The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of the grant for the expected term of the award. We do not anticipate paying any dividends in the near future. We develop pre-vesting forfeiture assumptions based on an analysis of historical data.

Share-based compensation expense is allocated among cost of goods sold, research and development and selling, general and administrative expenses, or included in the inventory carrying value and absorbed into inventory, based on the function of the related employee.

Fair Value Measurements

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Three levels of inputs are used to measure fair value. The three levels are as follows: Level 1, defined as observable inputs such as quoted market prices in active markets; Level 2, defined as inputs other than the quoted prices in active markets that are either directly or indirectly observable; and Level 3, defined as significant unobservable inputs in which little or no market data exists.

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

Our convertible notes contain a conversion option that is classified as equity. We determined the fair value of the liability component of the debt instrument and allocated the excess amount of $95.3 million from the initial proceeds to the conversion option in additional paid-in capital. The fair value of the debt component was determined by estimating a risk adjusted interest rate, or market yield, at the time of issuance for similar notes that do not include the conversion feature. This excess is reported as a debt discount and is amortized as non-cash interest expense, using the effective-interest method, over the expected life of the convertible notes. The convertible notes are recorded in the balance sheet as a component of long-term debt.

Issuance costs related to the conversion feature of the convertible notes were charged to additional paid in capital. The portion of the issuance costs related to the debt component is being amortized and recorded as additional interest expense over the expected life of the convertible notes. In connection with the issuance of the convertible notes, we 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 was no allowance for doubtful accounts at December 31, 2019 or 2018.

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, 2019, it was considered more likely than not that our deferred tax assets would not be realized. However, should there be a change in our ability to recover its deferred tax assets, we would recognize a benefit to our tax provision in the period in which we determine that it is more likely than not that we will recover its deferred tax assets.

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

Contingencies and Litigation

We are periodically involved in disputes and litigation related to a variety of matters. When it is probable that we will experience a loss, and that loss is quantifiable, we record appropriate reserves. We record legal fees and costs as an expense when incurred.

RESULTS OF OPERATIONS

Revenues

(in thousands, except for percentages)	Years Ended December 31, 2019	2018	2017	Increase/(Decrease) 2019 vs 2018	2018 vs 2017
Qsymia—Net product revenue	$ 37,750	$ 40,558	$ 44,983	(7)%	(10)%
PANCREAZE/PANCREASE MT—Net product revenue	21,299	16,226	—	31 %	N/A
License and milestone revenue	2,500	—	7,500	N/A	(100)%
Qsymia—Supply revenue	1,186	—	—	N/A	N/A
STENDRA/SPEDRA—Supply revenue	3,448	4,863	10,407	(29)%	(53)%
STENDRA/SPEDRA—Royalty revenue	2,020	2,307	2,483	(12)%	(7)%
PANCREASE MT—Royalty revenue	1,557	1,108	—	41 %	N/A
Total revenue	$ 69,760	$ 65,062	$ 65,373	7 %	(0)%

Net product revenue

In the first quarter of 2017, we began recognizing revenue from the sales of Qsymia upon shipment and recording reserves for expected returns, discounts and fees at the time of shipment. Revenue for 2017 includes gross Qsymia product revenue of $17.9 million and net Qsymia product revenue of $7.3 million related to shipments which had previously been deferred. Excluding this one-time adjustment, Qsymia net product revenue for 2017 was $37.6 million.

The following table reconciles gross Qsymia product revenue to net Qsymia product revenue (in thousands):

	Year Ended December 31, 2019	2018	2017
Gross Qsymia product revenue	$ 63,197	$ 66,513	$ 85,044
Returns & allowances	(1,082)	(2,967)	(9,251)
Discount programs	(15,849)	(13,703)	(20,129)
Wholesaler/Pharmacy fees	(6,063)	(6,704)	(7,728)
Cash discounts	(1,062)	(1,327)	(1,697)
Rebates/Chargebacks	(1,391)	(1,254)	(1,256)
Net Qsymia product revenue	$ 37,750	$ 40,558	$ 44,983

The following table reconciles gross PANCREAZE/PANCREASE MT product revenue to net PANCREAZE/PANCREASE MT product revenue (in thousands):

	Year Ended December 31,		
	2019	2018	2017
Gross PANCREAZE/PANCREASE MT product revenue	$ 45,231	$ 30,717	$ —
Returns & allowances	(10,704)	(8,460)	—
Discount programs	(23)	—	—
Wholesaler/Pharmacy fees	(3,974)	(381)	—
Cash discounts	(903)	(604)	—
Rebates/Chargebacks	(8,328)	(5,046)	—
Net PANCREAZE/PANCREASE MT product revenue	$ 21,299	$ 16,226	$ —

Prescriptions are as follows:

	Year Ended December 31,		
	2019	2018	2017
Qsymia units shipped (in thousands)	331	349	441
Qsymia prescriptions dispensed (in thousands)	337	360	395
PANCREAZE/PANCREASE MT units shipped (in thousands)	115	73	—

Units shipped represent our direct shipments into the sales channel. We expect net Qsymia product revenue in 2020 to be consistent with or increase from 2019 levels due to new marketing and distribution efforts. We anticipate that future PANCREAZE/PANCREASE MT product revenue will increase from 2019 levels but will fluctuate from period to period based on our wholesalers' management of the supply chain and the impact of our relaunch efforts. Also, we anticipate that future PANCREAZE/PANCREASE MT net product revenue will continue to be negatively impacted by potential future promotional strategies, including coupon programs.

License and milestone revenue

License and milestone revenue for 2019 related to contractual payments due to us upon Alvogen receiving marketing authorization in South Korea. 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 for commercial rights to Qsymia in South Korea.

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.

Supply revenue

We supply Qsymia and STENDRA/SPEDRA to our collaboration 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. 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

We record royalty revenue related to sales of STENDRA/SPEDRA and Canadian sales of PANCREASE MT based on reports provided by our partners. Upon taking over operations for Canadian sales for PANCREASE MT, including ownership of the Canadian inventory in the third quarter of 2019, net sales of PANCREASE MT began to be recorded as net product revenue with costs recorded as cost of goods sold. We expect STENDRA/SPEDRA royalty revenue in 2019 to remain relatively consistent with current levels.

Cost of goods sold and Amortization of intangible assets

	Year Ended December 31, 2019							
(In thousands, except percentages)	**Qsymia**		**PANCREAZE/ PANCREASE MT**		**STENDRA/ SPEDRA**		**Total**	
Net product revenue	$ 37,750		$ 21,299		$ —		$ 59,049	
Supply revenue	1,186		—		3,448		4,634	
Total product and supply revenue	38,936	100%	$ 21,299	100%	$ 3,448	100%	$ 63,683	100%
Cost of goods sold (excluding amortization)	5,775	15%	$ 6,460	30%	$ 3,436	100%	$ 15,671	25%
Amortization of intangible assets	362	1%	14,190	67%	—	0%	14,552	23%
Total cost of goods sold	6,137	16%	$ 20,650	97%	$ 3,436	100%	$ 30,223	47%
Product and supply gross margins	$ 32,799	84%	$ 649	3%	$ 12	0%	$ 33,460	53%

	Year Ended December 31, 2018							
	Qsymia		**PANCREAZE/ PANCREASE MT**		**STENDRA/ SPEDRA**		**Total**	
Net product revenue	$ 40,558		$ 16,226		$ —		$ 56,784	
Supply revenue	—		—		4,863		4,863	
Total product and supply revenue	$ 40,558	100%	$ 16,226	100%	$ 4,863	100%	$ 61,647	100%
Cost of goods sold (excluding amortization)	$ 4,693	12%	$ 5,156	32%	$ 4,764	98%	$ 14,613	24%
Amortization of intangible assets	$ 363	1%	$ 8,277	51%	$ —	0%	$ 8,640	14%
Total cost of goods sold	$ 5,056	12%	$ 13,433	83%	$ 4,764	98%	$ 23,253	38%
Product and supply gross margins	$ 35,502	88%	$ 2,793	17%	$ 99	2%	$ 38,394	62%

	Year Ended December 31, 2017							
	Qsymia		**PANCREAZE/ PANCREASE MT**		**STENDRA/ SPEDRA**		**Total**	
Net product revenue	$ 44,983		$ —		$ —		$ 44,983	
Supply revenue	—		—		10,407		10,407	
Total product and supply revenue	$ 44,983	100%	$ —		$ 10,407	100%	$ 55,390	100%
Cost of goods sold (excluding amortization)	$ 6,993	16%	$ —		$ 9,650	93%	$ 16,643	30%
Amortization of intangible assets	$ 544	1%	$ —		$ —	0%	$ 544	1%
Total cost of goods sold	$ 7,537	17%	$ —		$ 9,650	93%	$ 17,187	31%
Product and supply gross margins	$ 37,446	83%	$ —		$ 757	7%	$ 38,203	69%

Cost of goods sold for Qsymia 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 PANCREAZE/PANCREASE MT includes third party contract manufacturing costs, amortization of the PANCREAZE/PANCREASE MT license, service fees, royalties, insurance, and overhead costs. Cost of goods sold for STENDRA/SPEDRA shipped to our commercialization partners includes the inventory costs of API and tableting. Fluctuations in the cost of goods sold as a percentage of net product and supply revenue over the periods was primarily due to the sales mix among Qsymia, STENDRA/SPEDRA and PANCREAZE/PANCREASE MT.

Selling, general and administrative

(In thousands, except percentages)	Years Ended December 31, 2019	2018	2017	Increase/(Decrease) 2019 vs 2018	2018 vs 2017
Selling and marketing	$ 17,968	$ 13,970	$ 16,638	29 %	(16)%
General and administrative	22,071	23,971	23,492	(8)%	2 %
Total selling, general and administrative expenses	$ 40,039	$ 37,941	$ 40,130	6 %	(5)%

The increase in selling and marketing expenses in 2019 compared to 2018 was due primarily to commercialization efforts for PANCREAZE, including additions to our sales force to support the relaunch in the first quarter of 2019 and related promotional activities. The decrease in selling and marketing expenses in 2018 compared to 2017 was due primarily to the reduction of the size of our sales force in 2017 and cost saving efforts to reduce marketing programs, partially offset by the addition of PANCREAZE marketing expenses. Selling and marketing expenses for our current products are expected to remain stable in future quarters.

The decrease in general and administrative expenses in 2019 compared to 2018 and the increase in 2018 compared to 2017 was due primarily to approximately $2.0 million in one-time expenses related to the PANCREAZE and Willow Biopharma acquisitions in 2018. In addition, we had reductions in legal spending due to the settlement of our Qsymia litigation in 2017, partially offsetting the one-time expenses in 2018. We expect general and administrative expenses to fluctuate significantly on a quarterly basis due to the timing of activities within our business development and financing activities.

Research and development

Drug Indication/Description (In thousands, except percentages)	Years Ended December 31, 2019	2018	2017	Increase/(Decrease) 2019 vs 2018	2018 vs 2017
Qsymia	$ 2,678	$ 1,120	$ 31	139 %	3,513 %
STENDRA/SPEDRA	282	172	127	64 %	35 %
PANCREAZE/PANCREASE MT	3,753	878	—	327 %	N/A
VI-0106	247	1,999	2,189	(88)%	(9)%
Share-based compensation	207	312	345	(34)%	(10)%
Overhead costs*	3,300	2,866	2,571	15 %	11 %
Total research and development expenses	$ 10,467	$ 7,347	$ 5,263	42 %	40 %

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

The increase in total research and development expenses in 2019 as compared to 2018 was primarily due to increased spending related to post marketing requirements assumed as part of the acquisition of PANCREAZE.PANCREASE MT in June 2018, in addition to spending on our Qsymia adolescent safety and efficacy study (OB-403) as we enrolled our first patients across multiple sites and started monitoring visits. Our spending to develop VI-0106 for the treatment of PAH experienced a decrease due to the timing of development activities.

The increase in total research and development expenses in 2018 as compared to 2017 was primarily due to increased spending for Qsymia post-marketing requirements and spending for PANCREAZE product improvements.

We expect research and development expenses will vary based on enrollment of the OB-0403 clinical trial and development efforts related to our VI-0106 product candidate.

Interest and other expense, net

Interest expense, net consists primarily of interest expense and the amortization of issuance costs from our Convertible Notes and 2024 Notes and the amortization of the debt discount on the Convertible Notes. Other expense and income were not significant. Interest expense for 2019 included prepayment premiums of $6.4 million related to the repurchase of $48.6 million aggregate principal amount of our 2024 Notes. Exclusive of those payments, the decrease in 2019 is due to the paydown of debt in 2018 and the loss of its associated discounts, partially offset by the additional debt issued in June 2018. We expect interest and other expense (income) for 2020 exclusive of any possible refinancing of our convertible debt to remain consistent with levels at the end of 2019.

Provision for (Benefit from) income taxes

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, 2019. We will continue to assess such evidence on a quarterly basis in 2020 to determine whether we will need to reverse all or a portion of the valuation allowance.

LIQUIDITY AND CAPITAL RESOURCES

Cash. Cash, cash equivalents and available-for-sale securities totaled $32.6 million at December 31, 2019, as compared to $111.2 million at December 31, 2018. The decrease was primarily due to the $55.0 million payment to repurchase $48.6 million aggregate principal amount of debt, plus prepayment premiums, net cash used for operating activities and other debt servicing during the period.

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. From time to time, the Company may also invest its cash to retire or purchase its outstanding debt, make asset acquisitions, conduct research and development or expand the Company. 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' deficit.

Accounts Receivable. We extend credit to our customers for product sales resulting in accounts receivable. Customer accounts are monitored for past due amounts. Past due accounts receivable, determined to be uncollectible, are written off against the allowance for doubtful accounts. Allowances for doubtful accounts are estimated based upon past due amounts, historical losses and existing economic factors, and are adjusted periodically. Historically, we have had no significant uncollectable accounts receivable. We offer cash discounts to our customers, generally 2% of the sales price as an incentive for prompt payment.

Accounts receivable (net of allowance for doubtful accounts and cash discounts) at December 31, 2019, was $22.3 million, as compared to $25.6 million at December 31, 2018. As of February 29, 2020, we had collected 62% of the accounts receivable outstanding at December 31, 2019.

Liabilities. Total liabilities were $287.5 million at December 31, 2019, compared to $342.2 million at December 31, 2018. The decrease in total liabilities was primarily due to the repayment of certain existing debt. Additional changes in total liabilities were due to timing differences in our various liability accounts.

Summary Cash Flows

	Years Ended December 31,		
	2019	2018	2017
Cash provided by (used for):	(in thousands)		
Operating activities	$ (30,474)	$ (23,607)	$ (16,364)
Investing activities	81,569	(56,150)	24,012
Financing activities	(48,821)	43,776	(26,039)

Operating Activities. Cash used for operating activities in 2019 resulted from our net loss as adjusted for non-cash items, in addition to the increase in inventories and decreases in accounts payable and deferred revenue, partially offset by decreases in accounts receivable and prepaid expenses and an increase in accrued liabilities. Cash used for operating activities in 2018 primarily consisted of our operating losses, adjusted for non-cash items, in addition to increases in accounts receivable and inventory due to the addition of PANCREAZE, partially offset by an increase in accrued and other liabilities, primarily due to product reserves for PANCREAZE. Cash used for operating activities in 2017 primarily consisted of our operating losses adjusted for non-cash items, in addition to increases in accounts receivable and inventory and a decrease in our deferred revenue balances due to our switch to the sell-in model for Qsymia product revenue. These were partially offset by increases in accounts payable and accrued liability balances, mostly due to timing.

Investing Activities. Cash provided by investing activities in 2019 resulted primarily from sales and maturities of our investment securities used for the paydown of a portion of our debt and for operating uses. Cash used for investing activities in 2018 primarily related to cash paid for the acquisition of the PANCREAZE license, partially offset by net proceeds from sales and maturities of our investment securities. Cash provided by or used for investing activities in 2017 primarily related to the net maturities of investment securities.

Financing Activities. Cash used by financing activities in 2019 were primarily due to the repayment of $48.6 million of our Senior Secured Notes due 2024, in addition to principal payments on financing leases, partially offset by proceeds from our employee stock purchase plan. Cash provided by financing activities in 2018 resulted from the net proceeds of $108.0 million from the issuance of our Senior Secured Notes due 2024, partially offset by the use of a total of $58.1 million to repurchase a combined total of $68.6 million of face value of our Convertible Notes and the repayment of $6.2 million of our Senior Secured Notes due 2018. Cash used in financing activities for 2017 consisted primarily of our repayments of $26.1 million under our Senior Secured Notes due 2018.

We do not currently have sufficient cash and/or credit facilities in place to pay the debt due May 1, 2020 and thus are actively pursuing funding, which may come through public or private debt or equity financings, collaborations or other available financing sources. Such funding 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 will not be able to continue our operations at our current level and may be required to relinquish rights to certain of our technologies, product candidates or products that we would otherwise seek to develop on our own. We might also be required to delay, reduce the scope of or eliminate one or more of our commercialization or development programs or obtain funds through collaborations with others that are on unfavorable terms or restructure VIVUS in other ways that may not be favorable. Even if adequate funds become available, we may need to raise additional funds in the near future to finance operations and pursue development and commercial opportunities.

Our consolidated financial statements have been prepared assuming that we will continue as a going concern. Our coming debt maturities as well as our negative cash flow from operations and accumulated deficit raise substantial doubt about our ability to continue as a going concern. Our consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Contractual Obligations

The following table summarizes our contractual obligations at December 31, 2019, 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, 2019. The amounts below

do not include contingent milestone payments or royalties, and assume the agreements and commitments will run through the end of terms, as such no early termination fees or penalties are included herein:

Contractual obligations	Payments Due by Period				
	Total	2020	2021 - 2023	2024 - 2025	Thereafter
	(in thousands)				
Operating leases	$ 1,513	$ 834	$ 679	$ —	$ —
Purchase obligations	134,328	16,219	47,287	22,908	47,914
Notes payable	242,778	181,426	51,898	9,454	—
Interest payable	23,635	10,901	12,366	368	—
Total contractual obligations	$ 402,254	$ 209,380	$ 112,230	$ 32,730	$ 47,914

Operating Leases

We have a lease of 13,981 square feet of office space at 900 East Hamilton Avenue, Campbell, California (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. On December 7, 2018, we entered into an amendment to the Commercial Supply Agreement with Sanofi Chimie, pursuant to which certain amendments were made to the Commercial Supply Agreement, which include: (i) beginning January 1, 2019, Sanofi Chimie will manufacture and supply API for avanafil on an exclusive basis in all countries where we have the right to sell avanafil; (ii) beginning January 1, 2019, the yearly minimum quantities of API that we must purchase from Sanofi Chimie will be adjusted, as well as adjustments to the associated pricing and payment terms; and (iii) with the initial five year term of the Commercial Supply Agreement expiring on December 31, 2018, we and Sanofi Chimie have agreed to extend the term of the Commercial Supply Agreement until December 31, 2023 unless either party makes a timely election to terminate the agreement and that thereafter the Commercial Supply Agreement will auto-renew for successive one year terms unless either party makes a timely election not to renew. We have minimum purchase commitments with Sanofi to purchase API materials and tablets through 2023. Our minimum purchase commitments with Sanofi totaled approximately $18.9 million as of December 31, 2019. PANCREAZE is currently manufactured by Nordmark. Our minimum purchase commitments to Nordmark totaled approximately $113.0 million at December 31, 2019. Our minimum purchase commitments for Qsymia totaled approximately $1.6 million at December 31, 2019.

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 (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. 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 $148.58 per share. In 2018, we repurchased a total of $68.6 million of face value of the Convertible notes for a total of $58.1 million in cash.

Senior Secured Notes Due 2024

In June 2018, we entered into an indenture (the "Indenture") with U.S. Bank National Association as trustee and collateral agent regarding the purchase agreement entered into with affiliates of Athyrium Capital Management (collectively, the "Purchasers") for the issuance and sale of (i) $110.0 million of 10.375% senior secured notes due 2024 (the "Notes"), (ii) up to an additional $10.0 million of 10.375% senior secured notes due 2024 to be issued subsequently at our option within 12 months of the Notes issue date, subject to certain conditions, and (iii) a warrant for 330,000 shares issued concurrently with the issuance of the Notes. The Notes were issued at a purchase price equal to 99% of the principal amount. The Notes contain customary representations, warranties, covenants, conditions and indemnities. Payments on the Notes are interest-only for the first 3 months; thereafter, the Notes will be repaid in 36 equal monthly payments. In September 2019, the Company repurchased $48.6 million aggregate principal amount of the 2024 Notes plus prepayment premiums of an aggregate of $6.4 million.

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. The MTPC agreement contains a number of milestone payments to be made by us based on various triggering events.

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

The term of the MTPC agreement is based on a country-by-country and on a product-by-product basis. The term shall continue until the later of 10 years after the date of the first sale for a particular product or the expiration of the last-to-expire patents within the MTPC patents covering such product in such country.

In 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 Member States, Latin

America and other territories. On December 7, 2018, we entered into an amendment to the Commercial Supply Agreement with Sanofi Chimie, pursuant to which certain amendments were made to the Commercial Supply Agreement, which include: (i) beginning January 1, 2019, Sanofi Chimie will manufacture and supply API for avanafil on an exclusive basis in all countries where we have the right to sell avanafil; (ii) beginning January 1, 2019, the yearly minimum quantities of API that we must purchase from Sanofi Chimie will be adjusted, as well as adjustments to the associated pricing and payment terms; and (iii) with the initial five year term of the Commercial Supply Agreement expiring on December 31, 2018, we and Sanofi Chimie have agreed to extend the term of the Commercial Supply Agreement until December 31, 2023 unless either party makes a timely election to terminate the agreement and that thereafter the Commercial Supply Agreement will auto-renew for successive one year terms unless either party makes a timely election not to renew.

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 May 2019, we entered into Amendment N°1 to the Manufacturing and Supply Agreement with Sanofi Winthrop Industrie effective as of March 18, 2019, pursuant to which certain amendments were made to the Manufacturing and Supply Agreement, which include: (i) Sanofi Winthrop Industrie will manufacture and supply the tablets for our drug avanafil on an exclusive basis in all countries where we or our sublicensees and/or Menarini have the right to sell avanafil; (ii) the yearly minimum quantities of tablets that we must purchase from Sanofi Winthrop Industrie and the price of such tablets were adjusted; and (iii) with the initial term of the Manufacturing and Supply Agreement expiring on January 16, 2021, we and Sanofi Winthrop Industrie have agreed to extend the term of the Manufacturing and Supply Agreement until December 31, 2023 unless either party makes a timely election to terminate the agreement and that thereafter the Manufacturing and Supply Agreement will auto-renew for successive one year terms unless either party makes a timely election not to renew.

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 an amendment to our agreement with MTPC which, among other things, changes the definition of net sales used to calculate royalties owed by us to MTPC.

Other

In October 2001, we entered into the Assignment Agreement with Thomas Najarian, M.D., for the Combination Therapy, that has since been the focus of our investigational drug candidate development program for Qsymia for the treatment of obesity, obstructive sleep apnea and diabetes. The Combination Therapy and all the related Patents were transferred to us with worldwide rights to develop and commercialize the Combination Therapy and exploit the Patents. The Assignment Agreement requires us to pay royalties on worldwide net sales of a product for the treatment of obesity that is based upon the Combination Therapy and the Patents until the last-to-expire of the assigned Patents. To the extent that we decide not to commercially exploit the Patents, the Assignment Agreement will terminate, and the Combination Therapy and Patents will be assigned back to Dr. Najarian.

Off-Balance Sheet Arrangements

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

Indemnifications

In the normal course of business, we provide indemnifications of varying scope to certain customers against claims of intellectual property infringement made by third parties arising from the use of its products and to its clinical

research organizations and investigator sites against liabilities incurred in connection with any third-party claim arising from the work performed on behalf of the Company, among others. Historically, costs related to these indemnification provisions have not been significant and we are unable to estimate the maximum potential impact of these indemnification provisions on our future results of operations.

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

Recent Accounting Pronouncements

The information on recent account pronouncements is 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 and applicable contractual restrictions.

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 and cash equivalents as of December 31, 2019 consisted of cash deposits and money market funds. Our cash, cash equivalents and available-for-sale securities as of December 31, 2018 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, when we have cash to invest, 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. We had no available-for-sale securities at December 31, 2019. In general, money market funds are not subject to market risk because the interest paid on such funds fluctuates with the prevailing interest rate.

A portion of our operations consist of revenues from outside of the United States, some of which are denominated in Euros and Canadian Dollars, and, as such, we have foreign currency exchange exposure for these revenues and associated accounts receivable. Future fluctuations in the Euro and Canadian Dollar exchange rates may impact our revenues and cash flows.

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

VIVUS, INC.

1. Index to Consolidated Financial Statements

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

Report of Independent Registered Public Accounting Firm	95
Consolidated Balance Sheets as of December 31, 2019 and 2018	96
Consolidated Statements of Operations for the years ended December 31, 2019, 2018 and 2017	97
Consolidated Statements of Comprehensive Loss for the years ended December 31, 2019, 2018 and 2017	97
Consolidated Statements of Stockholders' Deficit for the years ended December 31, 2019, 2018 and 2017	98
Consolidated Statements of Cash Flows for the years ended December 31, 2019, 2018 and 2017	99
Notes to Consolidated Financial Statements	100
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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, 2019 and 2018, the related consolidated statements of operations, comprehensive loss, stockholders' deficit, and cash flows for each of the three years in the period ended December 31, 2019, 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, 2019 and 2018, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2019, in conformity with accounting principles generally accepted in the United States of America.

Going Concern Uncertainty

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. At December 31, 2019, the Company has cash and cash equivalents of $32.6 million and a total of $241.7 million in debt, $181.4 million of which is due May 2020. The Company also has recurring negative cash flows from operations and an accumulated deficit. All of these matters raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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 Public Company Accounting Oversight Board (United States) ("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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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 3, 2020
We have served as the Company's auditor since 2005.

VIVUS, INC.

CONSOLIDATED BALANCE SHEETS

(In thousands, except par value)

	December 31, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 32,649	$ 30,411
Available-for-sale securities	—	80,838
Accounts receivable, net	22,338	25,608
Inventories, net	33,679	23,132
Prepaid expenses and other current assets	8,134	7,538
Total current assets	96,800	167,527
Fixed assets, net	233	341
Right-of-use assets	1,135	—
Intangible and other non-current assets	120,140	134,279
Total assets	$ 218,308	$ 302,147
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 7,726	$ 8,921
Accrued and other liabilities	32,398	33,044
Deferred revenue	1,249	1,235
Current portion of lease liability	767	—
Current portion of long-term debt	183,006	—
Total current liabilities	225,146	43,200
Long-term debt	58,721	294,446
Deferred revenue, net of current portion	3,063	4,290
Lease liability, net of current portion	602	—
Non-current accrued and other liabilities	—	234
Total liabilities	287,532	342,170
Commitments and contingencies		
Stockholders' deficit:		
Preferred stock; $.001 par value; 5,000 shares authorized; no shares issued and outstanding at December 31, 2019 and 2018	—	—
Common stock; $.001 par value; 200,000 shares authorized; 10,649 and 10,636 shares issued and outstanding at December 31, 2019 and 2018, respectively	11	11
Additional paid-in capital	842,808	840,751
Accumulated other comprehensive loss	(35)	(270)
Accumulated deficit	(912,008)	(880,515)
Total stockholders' deficit	(69,224)	(40,023)
Total liabilities and stockholders' deficit	$ 218,308	$ 302,147

See accompanying notes to consolidated financial statements.

VIVUS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share data)

	Year Ended December 31,		
	2019	2018	2017
Revenue:			
Net product revenue	$ 59,049	$ 56,784	$ 44,983
License and milestone revenue	2,500	—	7,500
Supply revenue	4,634	4,863	10,407
Royalty revenue	3,577	3,415	2,483
Total revenue	69,760	65,062	65,373
Operating expenses:			
Cost of goods sold (excluding amortization)	15,671	14,613	16,643
Amortization of intangible assets	14,552	8,640	544
Sales and marketing	17,968	13,970	16,638
General and administrative	22,071	23,971	23,492
Research and development	10,467	7,347	5,263
Total operating expenses	80,729	68,541	62,580
(Loss) Income from operations	(10,969)	(3,479)	2,793
Interest and other expense:			
Interest expense	20,728	33,876	33,231
Gain on extinguishment of debt	—	(1,427)	—
Other (income) expense, net	(215)	970	71
Interest and other expense, net	20,513	33,419	33,302
Loss before income taxes	(31,482)	(36,898)	(30,509)
Provision for income taxes	21	52	2
Net loss	$ (31,503)	$ (36,950)	$ (30,511)
Basic and diluted net loss per share:	$ (2.96)	$ (3.48)	$ (2.89)
Shares used in per share computation:			
Basic and diluted	10,641	10,621	10,574

VIVUS, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS INCOME

(In thousands)

	Year Ended December 31,		
	2019	2018	2017
Net loss	$ (31,503)	$ (36,950)	$ (30,511)
Unrealized gain on securities, net of taxes	271	338	8
Translation adjustment	(36)	—	—
Comprehensive loss	$ (31,268)	$ (36,612)	$ (30,503)

See accompanying notes to consolidated financial statements.

VIVUS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' DEFICIT

(In thousands)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Amount				
Balances, December 31, 2016	10,483	$ 10	$ 831,845	$ (616)	$ (813,054)	$ 18,185
Sale of common stock through employee stock purchase plan	5	—	38	—	—	38
Vesting of restricted stock units	115	1	(1)	—	—	—
Share-based compensation expense	—	—	2,942	—	—	2,942
Net unrealized gain on securities	—	—	—	8	—	8
Net loss	—	—	—	—	(30,511)	(30,511)
Balances, December 31, 2017	10,603	11	834,824	(608)	(843,565)	(9,338)
Sale of common stock through employee stock purchase plan	11	—	41	—	—	41
Exercise of common stock options for cash	10	—	78	—	—	78
Vesting of restricted stock units	12	—	—	—	—	—
Share-based compensation expense	—	—	3,285	—	—	3,285
Warrants issued for acquisition of PANCREAZE	—	—	828	—	—	828
Warrants issued in association with the issuance of debt	—	—	1,695	—	—	1,695
Net unrealized gain on securities	—	—	—	338	—	338
Net loss	—	—	—	—	(36,950)	(36,950)
Balances, December 31, 2018	10,636	11	840,751	(270)	(880,515)	(40,023)
Sale of common stock through employee stock purchase plan	12	—	31	—	—	31
Vesting of restricted stock units	1	—	—	—	—	—
Share-based compensation expense	—	—	2,026	—	—	2,026
Translation adjustment	—	—	—	(36)	—	(36)
Net unrealized gain on securities	—	—	—	271	—	271
Cumulative effect of accounting change	—	—	—	—	10	10
Net loss	—	—	—	—	(31,503)	(31,503)
Balances, December 31, 2019	10,649	$ 11	$ 842,808	$ (35)	$ (912,008)	$ (69,224)

See accompanying notes to consolidated financial statements.

VIVUS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Year Ended December 31,		
	2019	2018	2017
Operating activities:			
Net loss	$ (31,503)	$ (36,950)	$ (30,511)
Adjustments to reconcile net loss to net cash used for operating activities:			
Depreciation and amortization	14,702	8,875	811
Amortization of debt issuance costs and discounts	(4,070)	18,228	20,442
Amortization of discount or premium on available-for-sale securities	(502)	559	768
Share-based compensation expense	2,026	3,285	2,942
Gain on extinguishment of debt	—	(1,427)	—
Changes in assets and liabilities:			
Accounts receivable	2,857	(13,421)	(2,709)
Inventories	(12,623)	(5,849)	(1,526)
Prepaid expenses and other assets	(201)	(370)	1,069
Accounts payable	(1,195)	(1,151)	5,365
Accrued and other liabilities	1,248	5,838	5,859
Deferred revenue	(1,213)	(1,224)	(18,874)
Net cash used for operating activities	(30,474)	(23,607)	(16,364)
Investing activities:			
Fixed asset purchases	(42)	(34)	(21)
Acquisition of PANCREAZE license	—	(135,000)	—
Purchases of available-for-sale securities	(16,879)	(41,506)	(31,097)
Proceeds from maturity of available-for-sale securities	42,087	58,101	37,470
Proceeds from sales of available-for-sale securities	56,403	62,289	17,660
Net cash provided by (used for) investing activities	81,569	(56,150)	24,012
Financing activities:			
Net proceeds from debt issuance	—	107,991	—
Repayments of notes payable	(48,649)	(64,334)	(26,077)
Principal payments of financing leases	(203)	—	—
Net proceeds from exercise of common stock options	—	78	—
Sale of common stock through employee stock purchase plan	31	41	38
Net cash (used for) provided by financing activities	(48,821)	43,776	(26,039)
Effect of exchange rates on cash and cash equivalents	(36)	—	—
Net increase (decrease) in cash and cash equivalents	2,238	(35,981)	(18,391)
Cash and cash equivalents:			
Beginning of year	30,411	66,392	84,783
End of year	$ 32,649	$ 30,411	$ 66,392
Supplemental cash flow disclosure:			
Interest paid	$ 18,315	$ 18,445	$ 15,350
Income taxes paid	$ 46	$ 60	$ 47
Non-cash investing activities:			
Unrealized gain on securities	$ 271	$ 338	$ 8

See accompanying notes to consolidated financial statements.

VIVUS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1. Business and Significant Accounting Policies

Business

VIVUS is a specialty pharmaceutical company with three approved therapies (Qsymia®, PANCREAZE®/PANCREASE® MT and STENDRA®/SPEDRA) and one product candidate in active clinical development (VI-0106). Qsymia (phentermine and topiramate extended release) is approved by the U.S. Food and Drug Administration ("FDA") for chronic weight management. In June 2018, the Company acquired the U.S. and Canadian commercial rights for PANCREAZE/PANCREASE MT (pancrelipase), which is indicated for the treatment of exocrine pancreatic insufficiency due to cystic fibrosis or other conditions. STENDRA (avanafil) is approved by FDA for erectile dysfunction ("ED"), and by the European Commission ("EC") under the trade name SPEDRA, for the treatment of ED. The Company commercializes Qsymia and PANCREAZE in the U.S. through a specialty sales force supported by an internal commercial team. The Company licenses the commercial rights to STENDRA/SPEDRA in the U.S., EU and other countries. VI-0106 (tacrolimus) is in active clinical development and is being studied in patients with pulmonary arterial hypertension ("PAH").

When reference is made to the "Company" or "VIVUS" in these footnotes, it refers to the Delaware corporation, or VIVUS, Inc., and, unless the context otherwise requires, its California predecessor, as well as all of its consolidated subsidiaries.

Liquidity and Ability to Continue as a Going Concern

At December 31, 2019, the Company's accumulated deficit was approximately $912.0 million and its cash and cash equivalents were $32.6 million. As of December 31, 2019, the Company had a total of $241.7 million in debt, $181.4 million of which is due May 2020. See Note 13 for additional information regarding the Company's debt.

The Company does not currently have sufficient cash and/or credit facilities in place to pay the debt due May 2020 and is actively pursuing funding, which may come through public or private debt or equity financings, collaborations, sale of assets or other available financing sources. Such funding 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 will not be able to continue its operations at its current level and may be required to relinquish rights to certain of its technologies, product candidates or products that it would otherwise seek to develop on its own. It might also 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 restructure the Company in other ways that may not be favorable. Even if adequate funds become available, the Company may need to raise additional funds in the near future to finance operations and pursue development and commercial opportunities.

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern. The Company's coming debt maturities as well as its negative cash flow from operations and accumulated deficit raise substantial doubt about its ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Management has evaluated all events and transactions that occurred after December 31, 2019, through the date these consolidated financial statements were issued. 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.

Reverse Stock Split

On September 10, 2018, the Company effected a one-for-10 reverse stock split of its common stock. As a result of the reverse stock split, every 10 shares of the Company's pre-reverse split common stock issued and outstanding was combined and converted into one issued and outstanding share of post-reverse split common stock without any change in the par value of the shares. Accordingly, an amount equal to the par value of the decreased shares resulting from the reverse stock split was reclassified from "Common stock" to "Additional paid-in capital." No fractional shares were issued as a result of the reverse stock split; any fractional shares that would have resulted were rounded up to the nearest whole share. Proportionate voting rights and other rights of stockholders were not affected by the reverse stock split, other than as a result of the rounding up of potential fractional shares. All stock options, warrants and restricted stock units outstanding and common stock reserved for issuance under the Company's equity incentive plans immediately prior to the reverse stock split were adjusted by dividing the number of affected shares of common stock by 10 and, where applicable, multiplying the exercise price by 10. All share and per share amounts related to common stock, stock options, warrants and restricted stock units have been restated for all periods to give retroactive effect to the reverse stock split.

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 the recognition of revenue and related reserves, 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, 2019 and 2018, all cash equivalents were invested in money market funds or U.S. Treasury securities. These investments are recorded at fair value. See Note 3.

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.

Debt 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. See Note 3.

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. See Note 13.

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, 2019 or 2018. The allowance for cash discounts is $252,000 and $152,000 at December 31, 2019 and 2018, respectively.

Inventories

Inventories are valued at the lower of cost or net realizable value. 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 ("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.

Property and Equipment

Property and equipment is stated at cost and includes computers and software, furniture and fixtures, leasehold improvements and manufacturing equipment. Depreciation is computed using the straight-line method over the estimated useful lives of two to seven years for computers and software, furniture and fixtures and manufacturing equipment. Leasehold improvements are amortized using the straight-line method over the shorter of the remaining lease term or the estimated useful lives. Expenditures for repairs and maintenance, which do not extend the useful life of the property and equipment, are expensed as incurred. Gains and losses associated with dispositions are reflected as a non-operating gain or loss in the accompanying consolidated statements of operations.

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

Debt Issuance Costs

Debt issuance costs, which are presented in the consolidated 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

See Note 2.

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.

Research and Development Expenses

Research and development ("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 of $1.9 million, $2.1 million and $3.2 million in 2019, 2018 and 2017, respectively.

Share-Based Compensation

Compensation expense is recognized for share-based payments, including stock options, restricted stock units and shares issued under the employee stock purchase plan, using a fair-value based method. The Company estimates the fair value of share-based payment awards on the date of the grant using the Black-Scholes option-pricing model, which requires the Company to estimate the expected term of the award, the expected volatility, the risk-free interest rate and the expected dividends. The expected term, which represents the period of time that options granted are expected to be outstanding, is derived by analyzing the historical experience of similar awards, giving consideration to the contractual terms of the share-based awards, vesting schedules and expectations of future employee behavior. Expected volatilities are estimated using the historical share price performance over the expected term of the option, which are adjusted as necessary for any other factors which may reasonably affect the volatility of VIVUS's stock in the future. The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of the grant for the expected term of the award. The Company does not anticipate paying any dividends in the near future. The Company develops pre-vesting forfeiture assumptions based on an analysis of historical data and expected future activity.

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 by considering 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. Realization of deferred tax assets by the Company is dependent upon the amount and timing of the generation of future taxable income, if any. As a result of the Company's analysis of all available evidence, both positive and negative, as of December 31, 2019, it was considered more likely than not that the Company's deferred tax assets would not be realized. As a result, the Company's net deferred tax assets have been fully offset by a valuation allowance. 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 will continue to analyze the evidence each quarter during 2020 to determine whether it becomes more likely than not that all or a portion of its deferred tax assets are realizable.

The Company recognizes interest and penalties accrued on any unrecognized tax benefits as a component of its provision for income taxes. See Note 18.

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. See Note 8.

Net Loss Per Share

The Company computes basic net loss per share applicable to common stockholders based on the weighted average number of common shares outstanding during the period. Diluted net 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 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 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 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 loss per share (in thousands, except per share amounts):

	2019	2018	2017
Net loss	$ (31,503)	$ (36,950)	$ (30,511)
Basic and Diluted:			
Weighted-average shares outstanding	10,641	10,621	10,574
Basic and diluted net loss per share	$ (2.96)	$ (3.48)	$ (2.89)

For the years ended December 31, 2019, 2018, and 2017, potentially dilutive outstanding stock options and RSUs of 2,847,000, 2,168,000 and 1,350,000, respectively, were not included in the computation of diluted net loss per share because the effect would have been anti-dilutive.

Recent Accounting Pronouncement Adopted

In February 2016, the Financial Accounting Standards Board ("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 requires lessees to recognize on the balance sheet the assets and liabilities for the rights and obligations created by those leases. The Company adopted this standard on January 1, 2019 using the modified retrospective transition method, and as a result did not adjust comparative periods. The Company has one large operating lease for its

corporate headquarters and several smaller leases, including financing leases for its automobile fleet and copiers. See Note 14.

Recent Accounting Pronouncements Not Yet Adopted

In June 2016, the FASB issued Accounting Standards Update 2016-13, *Measurement of Credit Losses on Financial Instruments*, which requires credit losses on most financial assets measured at amortized cost and certain other instruments to be measured using an expected credit loss model, referred to as the current expected credit loss (CECL) model. Under this model, entities will estimate credit losses over the entire contractual term of the instrument. The standard is effective for the Company beginning January 1, 2023. The Company does not expect the adoption of this standard to have a material impact on its consolidated financial statements.

In August 2018, the FASB issued Accounting Standards Update 2018-13, *Fair Value Measurement* (Topic 820): *Disclosure Framework-Changes to the Disclosure Requirements for Fair Value Measurement*, which adds disclosure requirements to Topic 820 for the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements. This standard is effective for fiscal years beginning after December 31, 2019 and early adoption is permitted. The Company is evaluating the provisions of this guidance, but currently does not expect it to have a material impact on its consolidated financial statements.

Note 2. Revenue

On January 1, 2018, the Company adopted Accounting Standards Update No. 2014-09, *Revenue from Contracts with Customers* ("Topic 606"). Topic 606 supersedes the revenue recognition requirements in Topic 605 *Revenue Recognition* ("Topic 605") and requires entities to recognize revenue when control of the promised goods or services is transferred to customers at an amount that reflects the consideration to which the entity expects to be entitled to in exchange for those goods or services.

The Company adopted Topic 606 as of January 1, 2018 using the modified retrospective transition method applied to those contracts which were not completed as of January 1, 2018. Results for reporting periods beginning on or after January 1, 2018 are presented under Topic 606, while prior period amounts are not adjusted and continue to be reported in accordance with our historic accounting under Topic 605. Due in large part to the change in accounting estimate made by the Company in the first quarter of 2017, revenue amounts as reported for the year ended December 31, 2017 under Topic 605 are approximately the same as they would have been under Topic 606, and the Company did not have or record a cumulative impact of adopting Topic 606 as of January 1, 2018.

Revenue Recognition

For all revenue transactions, the Company evaluates its contracts with its customers to determine revenue recognition using the following five-step model:

1) The Company identifies the contract(s) with a customer;
2) The Company identifies the performance obligations in the contract;
3) The Company determines the transaction price;
4) The Company allocates the transaction price to the identified performance obligations; and
5) The Company recognizes revenue when (or as) the entity satisfies a performance obligation.

Product Revenue

Product revenue is recognized at the time of shipment at which time the Company has satisfied its performance obligation. 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 a reserve for estimated product returns, 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 date at which the related revenue is recognized. 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. See Note 9 for product reserve balances.

Change in Accounting Estimate in 2017

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, which was required by the accounting literature at the time, and therefore recognized revenue when units were dispensed to patients through prescriptions, at which point the product was not subject to return, or when the expiration period had ended.

Beginning in the first quarter of 2017, with 48 months of returns experience, the Company believed that it had sufficient data and experience from selling Qsymia to reliably estimate expected returns. Therefore, beginning in the first quarter of 2017, under the then relevant accounting literature, the Company began recognizing revenue from the sales of Qsymia upon shipment and recording reserves for expected returns, discounts and fees 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 $0.57 per share for the year ended December 31, 2017.

Supply Revenue

The Company produces STENDRA/SPEDRA through a contract manufacturing partner and then sells it to the Company's 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. The Company recognizes supply revenue at the time of shipment and, in the unusual case where the product does not meet contractually-specified product dating criteria at the time of shipment to the partner, the Company records a reserve for estimated product returns. There are no such reserves as of December 31, 2019.

License and Milestone Revenue

License and milestone revenues related to arrangements, usually license and/or supply agreements, entered into by the Company are recognized by following the five-step process outlined above. The allocation and timing of recognition of such revenue will be determined by that process and the amounts recognized and the timing of that recognition may not exactly follow the wording of the agreement as the amount allocated following the accounting analysis of the agreement may differ and the timing of recognition of a significant performance obligation may predate the contractual date.

Royalty Revenue

The Company relies on data provided by its collaboration partner in determining its contractually-based royalty revenue. Such data includes accounting estimates and reports for various discounts and allowances, including product

returns. The Company records royalty revenues based on the best data available and makes any adjustments to such revenues as such information becomes available.

Segment and Geographic Information

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

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

Revenue disaggregated by revenue source and by geographic region was as follows (in thousands):

	Years Ended December 31,		
	2019		
	U.S.	ROW	Total
Qsymia—Net product revenue	$ 37,750	$ —	$ 37,750
Qsymia—License revenue	—	2,500	2,500
Qsymia—Supply revenue	—	1,186	1,186
PANCREAZE - Net product revenue	20,302	997	21,299
PANCREAZE - Royalty revenue	—	1,557	1,557
STENDRA/SPEDRA—Supply revenue	—	3,448	3,448
STENDRA/SPEDRA—Royalty revenue	—	2,020	2,020
Total revenue	$ 58,052	$ 11,708 (1)	$ 69,760

	2018		
	U.S.	ROW	Total
Qsymia—Net product revenue	$ 40,558	$ —	$ 40,558
PANCREAZE - Net product revenue	16,226	—	16,226
PANCREAZE - Royalty revenue	—	1,108	1,108
STENDRA/SPEDRA—Supply revenue	1,646	3,217	4,863
STENDRA/SPEDRA—Royalty revenue	—	2,307	2,307
Total revenue	$ 58,430	$ 6,632 (2)	$ 65,062

	2017		
	U.S.	ROW	Total
Qsymia—Net product revenue	$ 44,983	$ —	$ 44,983
Qsymia—License revenue	5,000	2,500	7,500
STENDRA/SPEDRA—Supply revenue	5,909	4,498	10,407
STENDRA/SPEDRA—Royalty revenue	—	2,483	2,483
Total revenue	$ 55,892	$ 9,481 (3)	$ 65,373

(1) $5.5 million of which was attributable to Germany, $3.7 million of which was attributable to South Korea and $2.5 million of which was attributable to Canada.

(2) $5.5 million of which was attributable to Germany and $1.1 million of which was attributable to Canada.

(3) $7.0 million of which was attributable to Germany and $2.5 million of which was attributable to South Korea.

Revenue and cost of goods sold by source was as follows (in thousands):

	Year Ended December 31, 2019			
	Qsymia	PANCREAZE	STENDRA/ SPEDRA	Total
Net product revenue	$ 37,750	$ 21,299	$ —	$ 59,049
License	2,500	—	—	2,500
Supply revenue	1,186	—	3,448	4,634
Royalty revenue	—	1,557	2,020	3,577
Total revenue	$ 41,436	$ 22,856	$ 5,468	$ 69,760
Cost of goods sold (excluding amortization)	$ 5,775	$ 6,460	$ 3,436	$ 15,671
Amortization of intangible assets	$ 362	$ 14,190	$ —	$ 14,552

	2018			
	Qsymia	PANCREAZE	STENDRA/ SPEDRA	Total
Net product revenue	$ 40,558	$ 16,226	$ —	$ 56,784
Supply revenue	—	—	4,863	4,863
Royalty revenue	—	1,108	2,307	3,415
Total revenue	$ 40,558	$ 17,334	$ 7,170	$ 65,062
Cost of goods sold (excluding amortization)	$ 4,693	$ 5,156	$ 4,764	$ 14,613
Amortization of intangible assets	$ 363	8,277	$ —	$ 8,640

	2017			
	Qsymia	PANCREAZE	STENDRA/ SPEDRA	Total
Net product revenue	$ 44,983	$ —	$ —	$ 44,983
License	7,500	—	—	7,500
Supply revenue	—	—	10,407	10,407
Royalty revenue	—	—	2,483	2,483
Total revenue	$ 52,483	$ —	$ 12,890	$ 65,373
Cost of goods sold (excluding amortization)	$ 6,993	$ —	$ 9,650	$ 16,643
Amortization of intangible assets	$ 544	—	$ —	$ 544

Major customers

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

	2019	2018	2017
Amerisource Bergen	30 %	34 %	32 %
McKesson	29 %	30 %	37 %
Cardinal Health, Inc.	26 %	28 %	29 %

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

	2019	2018
Cardinal Health, Inc.	41 %	29 %
Amerisource Bergen	26 %	20 %
McKesson	24 %	5 %
Johnson & Johnson	— %	40 %

Major suppliers

The Company does not have any manufacturing facilities and intends to continue to rely on third parties for the supply of the starting materials, API and tablets. Catalent Pharma Solutions, LLC ("Catalent") is the Company's sole source of clinical and commercial supplies for Qsymia. Nordmark Arzneimittel GmbH & Co. KG ("Nordmark") is the Company's sole source of clinical and commercial supplies for PANCREAZE. Sanofi Chimie manufactures and supplies the API for our drug avanafil on an exclusive basis in the United States and other territories and on a semi-exclusive basis in Europe, including the EU Member States, 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 Member States, Latin America and other territories. Third-party manufacturers may not be able to meet the Company's needs with respect to timing, quantity or quality.

During the years ended December 31, 2019, 2018 and 2017, the Company incurred expenses for work performed by a third-party clinical research organization that accounted for 31%, 30% and 0%, respectively, of total research and development expenses.

Note 3. 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, 2019			
Cash and cash equivalents	**Amortized Cost**	**Gross Unrealized Gains**	**Gross Unrealized Losses**	**Estimated Fair Value**
Cash and money market funds	$ 32,649	$ —	$ —	$ 32,649

	As of December 31, 2018			
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	$ 30,411	$ —	$ —	$ 30,411
U.S. Treasury securities	42,261	34	(111)	42,184
Corporate debt securities	38,848	9	(203)	38,654
Total	111,520	43	(314)	111,249
Less amounts classified as cash and cash equivalents	(30,411)	—	—	(30,411)
Total available-for-sale securities	$ 81,109	$ 43	$ (314)	$ 80,838

As of December 31, 2019, the Company had no available-for-sale securities. As of December 31, 2018, the Company's available for sale securities were viewed by the Company as available to support current operations and even those securities with maturities beyond 12 months were classified as current assets. Due to their short-term maturities, the Company believes that the fair value of its bank deposits, accounts payable and accrued expenses approximate their carrying value.

Fair Value Measurements

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

- Level 1 — Quoted prices in active markets for identical assets or liabilities.
- Level 2 — Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that

are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

- Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

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

	As of December 31, 2019			
	Level 1	Level 2	Level 3	Total
Cash and money market funds	$ 32,649	$ —	$ —	$ 32,649

	As of December 31, 2018			
	Level 1	Level 2	Level 3	Total
Cash and money market funds	$ 30,411	$ —	$ —	$ 30,411
U.S. Treasury securities	42,184	—	—	42,184
Corporate debt securities	—	38,654	—	38,654
Total	$ 72,595	$ 38,654	$ —	$ 111,249

Note 4. Accounts Receivable

Accounts receivable consist of the following (in thousands):

	Balance as of	
	December 31, 2019	December 31, 2018
Qsymia	$ 15,423	$ 13,987
PANCREAZE	6,380	10,213
STENDRA/SPEDRA	787	1,560
	22,590	25,760
Allowance for cash discounts	(252)	(152)
Net	$ 22,338	$ 25,608

Note 5. Inventories

Inventories consist of the following (in thousands):

	Balance as of	
	December 31, 2019	December 31, 2018
Raw materials	$ 26,313	$ 17,813
Work-in-process	2,908	1,719
Finished goods	4,458	3,600
Inventories, net	$ 33,679	$ 23,132

Raw materials inventories consist primarily of the API for Qsymia and STENDRA/SPEDRA.

Note 6. Prepaid Expenses and Other Current Assets

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

	Balance as of	
	December 31, 2019	December 31, 2018
Prepaid insurance	$ 2,029	$ 1,451
Prepaid sales and marketing expenses	1,806	1,525
Taxes receivable	1,196	779
Other prepaid expenses and assets	3,103	3,783
Total	$ 8,134	$ 7,538

The amounts included in prepaid expenses and other current assets consist primarily of prepayments for future services, miscellaneous non-trade receivables, prepaid interest and interest income receivable. These costs have been deferred as prepaid expenses and other current assets on the consolidated balance sheets and will be either (i) charged to expense accordingly when the related prepaid services are rendered to the Company, or (ii) converted to cash when the receivable is collected by the Company.

Note 7. Property and Equipment

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

	Balance as of	
	December 31, 2019	December 31, 2018
Computers and software	$ 2,041	$ 1,999
Furniture and fixtures	185	185
Manufacturing equipment	213	213
Leasehold improvements	513	513
	2,952	2,910
Accumulated depreciation	(2,719)	(2,569)
Property and equipment, net	$ 233	$ 341

Note 8. Intangible and Other Non-Current Assets

Intangible and other non-current assets consist of the following (in thousands):

	December 31, 2019			December 31, 2018		
	Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization	Net
PANCREAZE license (1)	$ 141,895	$ (22,467)	$ 119,428	$ 141,895	$ (8,277)	$ 133,618
Janssen patents (2)	3,050	(2,959)	91	3,050	(2,597)	453
Long-term receivables (3)	413	—	413	—	—	—
Other non-current assets (4)	208	—	208	208	—	208
Total	$ 145,566	$ (25,426)	$ 120,140	$ 145,153	$ (10,874)	$ 134,279

(1) In June 2018, the Company acquired the rights to license PANCREAZE in the U.S. and Canada, as described further in Note 12. The rights are being amortized over their estimated useful life of 10 years using the straight-line method.

(2) In September 2014, the Company acquired certain patents relating to Qsymia from Janssen Pharmaceuticals, approximately $3.1 million of which was recorded as an intangible asset. The patents are being amortized over their estimated useful life of 5.5 years using the straight-line method.

(3) Long-term receivables consist of amounts not expected to be collected within a year of the balance sheet date.

(4) Other non-current assets primarily consist of real estate deposits.

Amortization of intangible assets was $14.6 million, $8.6 million and $0.5 million for the years ended December 31, 2019, 2018 and 2017, respectively. Future expected amortization expenses for intangible assets as of December 31, 2019 are as follows (in thousands):

2020	$ 14,280
2021	14,190
2022	14,189
2023	14,190
2024	14,189
Thereafter	48,481
Total	$ 119,519

Note 9. Accrued and Other Liabilities

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

	Balance as of	
	December 31, 2019	December 31, 2018
Reserve for product returns (see Note 2)	$ 14,874	$ 14,878
Product-related accruals (see Note 2)	6,663	8,272
Accrued manufacturing costs	3,105	4,313
Accrued employee compensation and benefits	2,777	2,591
Accrued interest on debt (see Note 13)	1,351	—
Other accrued liabilities	3,628	2,990
Total	$ 32,398	$ 33,044

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

Note 10. Non-Current Accrued and Other Liabilities

There were no non-current accrued and other liabilities at December 31, 2019. Non-current accrued and other liabilities were $0.2 million at December 31, 2018, and were primarily comprised of deferred rent and costs associated with the exit of certain operating leases and security deposits relating to the sublease agreements. See Note 14.

Note 11. Deferred Revenue

Deferred revenue relates to a prepayment for future royalties on sales of SPEDRA. In 2019 and 2018, the Company recorded $1.2 million of revenues which had been deferred as of December 31, 2018 and 2017, respectively. These amounts were applied against the prepayment for future royalties.

Note 12. License, Commercialization and Supply Agreements

MTPC

In January 2001, the Company entered into an exclusive development, license and clinical trial and commercial supply agreement with Tanabe Seiyaku Co., Ltd., now Mitsubishi Tanabe Pharma Corporation ("MTPC"), for the development and commercialization of avanafil. Under the terms of the agreement, MTPC agreed to grant an exclusive license to the Company for products containing avanafil outside of Japan, North Korea, South Korea, China, Taiwan, Singapore, Indonesia, Malaysia, Thailand, Vietnam and the Philippines. The Company agreed to grant MTPC an exclusive, royalty free license within those countries for oral products that we develop containing avanafil. The MTPC agreement contains a number of milestone payments to be made by us based on various triggering events. The term of the MTPC agreement is based on a country by country and on a product by product basis. In August 2012, the Company entered into an amendment to the agreement with MTPC that permitted the Company to manufacture the API and tablets for STENDRA/SPEDRA by itself or through third parties. In 2015, the Company transferred the manufacturing of the API and tablets for STENDRA/SPEDRA to Sanofi. The Company maintains royalty obligations to MTPC which have been passed through to our commercialization partners.

Menarini

In July 2013, the Company entered into a license and commercialization agreement (the "Menarini License Agreement") and a supply agreement (the "Menarini Supply Agreement") with the Menarini Group through its subsidiary Berlin Chemie AG ("Menarini"). Under the terms of the Menarini License Agreement, Menarini received an exclusive license to commercialize and promote SPEDRA for the treatment of ED in over 40 countries, including the EU Member States, plus Australia and New Zealand. Additionally, the Company transferred to Menarini ownership of the marketing authorization for SPEDRA in the EU for the treatment of ED, which was granted by the EC in June 2013. Under the Menarini License Agreement, the Company has and is entitled to receive milestone payments based on certain net sales targets, plus royalties on SPEDRA sales. Under the terms of the Menarini Supply Agreement, the Company supplied Menarini with SPEDRA drug product until December 31, 2018. Under the Menarini Supply Agreement, Menarini also has the right to manufacture SPEDRA independently, provided that it continues to satisfy certain minimum purchase obligations to the Company. Following the expiration of the Menarini Supply Agreement, Menarini would be responsible for its own supply of SPEDRA. Either party may terminate the Menarini Supply Agreement for the other party's uncured material breach or bankruptcy, or upon the termination of the Menarini License Agreement.

In May 2019, the Company entered into Amendment No. 1 to the License and Commercialization Agreement and Commercial Supply Agreement with Menarini effective as of January 1, 2019, pursuant to which certain amendments were made to the Menarini License Agreement and the Menarini Supply Agreement, which include: (i) under the Menarini License Agreement, Menarini's exclusive license to commercialize and promote the Company's drug avanafil for the treatment of ED will be limited to over 40 European countries and will no longer include Australia and New Zealand; (ii) under the Menarini License Agreement, the timing requirements of the product launches by Menarini have been adjusted; (iii) under the Menarini License Agreement, the milestone payments have been adjusted to reflect the removal of Australia and New Zealand and will continue to be non-refundable and non-creditable, with one exception added for certain costs and expenses incurred by Menarini for development work related to an avanafil development opportunity in the Menarini territory ("Menarini Development"); (iv) under the Menarini License Agreement, the royalties on avanafil sales payable by Menarini to the Company will be adjusted to allow Menarini to recoup certain Menarini Development costs and expenses but only as to sales of the Menarini Development product unless the Menarini Development product is commercialized by the Company or its sublicensees outside the Menarini territory; (v) under the Menarini Supply Agreement, the minimum purchase obligations for Menarini will be modified and extended, including the ability of Menarini to satisfy its minimum purchase obligations with the purchase of avanafil API and the addition of minimum purchase obligations for the calendar years for the extended term; and (vi) under the Menarini Supply Agreement, the term will be extended to December 31, 2023, unless otherwise agreed by the parties in writing. The Company and Menarini have entered into standalone agreements relating to Australia and New Zealand, including a license with royalties and milestone payments and a supply agreement.

Sanofi

In July 2013, the Company entered into a Commercial Supply Agreement with Sanofi Chimie to manufacture and supply the API for avanafil on an exclusive basis in the United States and other territories and on a semi-exclusive basis in Europe, including the EU Member States, Latin America and other territories. In December 2018, the Company entered into an amendment to the Commercial Supply Agreement with Sanofi Chimie, pursuant to which certain amendments were made to the Commercial Supply Agreement, which include: (i) beginning January 1, 2019, Sanofi Chimie will manufacture and supply API for avanafil on an exclusive basis in all countries where the Company has the right to sell avanafil; (ii) beginning January 1, 2019, the yearly minimum quantities of API that the Company must purchase from Sanofi Chimie will be adjusted, as well as adjustments to the associated pricing and payment terms; and (iii) with the initial five year term of the Commercial Supply Agreement expiring on December 31, 2018, the Company and Sanofi Chimie have agreed to extend the term of the Commercial Supply Agreement until December 31, 2023 unless either party makes a timely election to terminate the agreement and that thereafter the Commercial Supply Agreement will auto-renew for successive one year terms unless either party makes a timely election not to renew.

In November 2013, the Company entered into a Manufacturing and Supply Agreement with Sanofi Winthrop Industrie to manufacture and supply the avanafil tablets on an exclusive basis in the United States and other territories and on a semi exclusive basis in Europe, including the EU Member States, Latin America and other territories. The Company has minimum annual purchase commitments under these agreements for at least the initial five-year term. In May 2019, the Company entered into Amendment N°1 to the Manufacturing and Supply Agreement with Sanofi Winthrop Industrie effective as of March 18, 2019, pursuant to which certain amendments were made to the Manufacturing and Supply Agreement, which include: (i) Sanofi Winthrop Industrie will manufacture and supply the tablets for the Company's drug avanafil on an exclusive basis in all countries where the Company or its sublicensees and/or Menarini have the right to sell avanafil; (ii) the yearly minimum quantities of tablets that the Company must purchase from Sanofi Winthrop Industrie and the price of such tablets will be adjusted; and (iii) with the initial term of the Manufacturing and Supply Agreement expiring on January 16, 2021, the Company and Sanofi Winthrop Industrie have agreed to extend the term of the Manufacturing and Supply Agreement until December 31, 2023 unless either party makes a timely election to terminate the agreement and that thereafter the Manufacturing and Supply Agreement will auto-renew for successive one year terms unless either party makes a timely election not to renew.

Metuchen

In September 2016, the Company entered into a license and commercialization agreement (the "Metuchen License Agreement") and a commercial supply agreement (the "Metuchen Supply Agreement") with Metuchen Pharmaceuticals LLC ("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 (the "Metuchen Territory") effective October 1, 2016. The Company and Metuchen have agreed not to develop, commercialize, or in-license any other product that operates as a PDE-5 inhibitor in the Metuchen Territory for a limited time period, subject to certain exceptions. The Metuchen License Agreement will terminate upon the expiration of the last-to-expire payment obligations under the Metuchen License Agreement; upon expiration of the term of the Metuchen License Agreement, the exclusive license granted under the Metuchen License Agreement shall become fully paid-up, royalty-free, perpetual and irrevocable as to the Company but not certain trademark royalties due to MTPC.

Metuchen will obtain STENDRA exclusively from the Company for a mutually agreed term pursuant to the Metuchen Supply Agreement. Metuchen may elect to transfer the control of the supply chain for STENDRA for the Metuchen Territory to itself or its designee by assigning to Metuchen the Company's agreements with the contract manufacturer. For 2016 and each subsequent calendar year during the term of the Metuchen Supply Agreement, if Metuchen fails to purchase an agreed minimum purchase amount of STENDRA from the Company, it will reimburse the Company for the shortfall as it relates to the Company's out of pocket costs to acquire the API needed to manufacture the agreed upon minimum purchase amount of STENDRA. Upon the termination of the Metuchen Supply Agreement (other than by Metuchen for the Company's uncured material breach or upon completion of the transfer of the control of the supply chain), Metuchen's agreed minimum purchase amount of STENDRA from the Company shall accelerate for the entire then current initial term or renewal term, as applicable. The initial term under the Metuchen Supply Agreement will be for a period of five years, with automatic renewal for successive two-year periods unless either party provides a termination notice to the other party at least two years in advance of the expiration of the then current term. On

September 30, 2019, Metuchen provided a written notice of termination of the Metuchen Supply Agreement effective September 30, 2021.

Alvogen

In September 2017, the Company entered into a license and commercialization agreement (the "Alvogen License Agreement") and a commercial supply agreement (the "Alvogen Supply Agreement") with Alvogen Malta Operations (ROW) Ltd ("Alvogen") which was subsequently assigned to Alvogen South Korea. Under the terms of the Alvogen License Agreement, Alvogen will be solely responsible for obtaining and maintaining regulatory approvals for all sales and marketing activities for Qsymia in South Korea. The Company received an upfront payment of $2.5 million in September 2017, which was recorded in license and milestone revenue in the third quarter of 2017, and $2.5 million in the third quarter of 2019 upon Alvogen receiving marketing authorization. The Company is eligible to receive additional payments upon commercial launch and reaching a sales milestone. Additionally, the Company will receive a royalty on Alvogen's Qsymia net sales in South Korea. Under the Alvogen Supply Agreement, the Company will supply product to Alvogen on an exclusive basis.

PANCREAZE

In June 2018, the Company closed on an Asset Purchase Agreement (the "PANCREAZE Purchase Agreement") with Janssen Pharmaceuticals, Inc. ("Janssen") pursuant to which the Company acquired the rights to PANCREAZE and PANCREASE MT in the U.S. and Canada and certain existing inventory for a purchase price of $135.0 million in cash.

The Company also acquired all of the outstanding shares of Willow Biopharma Inc. ("Willow"). Willow had no significant assets at the time of acquisition. The Company issued fully-exercisable warrants to the former owners of Willow, including John Amos, M. Scott Oehrlein and Kenneth Suh, the Company's current Chief Executive Officer, former Chief Operations Officer and former President, respectively, for the purchase of 357,000 shares of the Company's common stock at an exercise price of $3.70 per share and agreed to assume certain of Willow's liabilities. The amounts paid to the former owners were accounted for as a fee for the acquisition of PANCREAZE.

As all the PANCREAZE assets acquired were a part of one product line, the PANCREAZE Purchase Agreement was accounted for as an asset acquisition, with an intangible asset of $141.9 million for the PANCREAZE license recorded on the consolidated balance sheet, which was comprised of the purchase price of $135.0 million, the fair value of the warrants issued of $0.8 million, the value of liabilities assumed of $0.4 million, the value of the Willow liabilities assumed of $1.5 million and accruals for estimated destruction of future unsalable inventory of $6.3 million, less the net value of PANCREAZE inventory acquired of $2.1 million. The fair value of the warrants issued was recorded in additional paid-in capital and was estimated using the Black-Scholes option pricing model, using a term of 7.0 years, an estimated volatility of 61.6%, a risk-free interest rate of 2.91% and an expected dividend yield of 0%. The intangible asset is being amortized over an expected useful life of 10 years, which corresponds with the expiration of certain significant patent rights related to PANCREAZE.

In connection with the PANCREAZE Purchase Agreement, the Company and Janssen also entered into transition services agreements pursuant to which Janssen and a Canadian affiliate of Janssen provided certain transition services to the Company in the U.S. and Canada as the Company transitioned to full control over the PANCREAZE supply chain. The Company and Johnson & Johnson Health Care Systems Inc., a New Jersey corporation and an affiliate of Janssen, also entered into a Long-Term Collaboration Agreement pursuant to which they will cooperate in the reporting and certification of pricing and sales data and the payment of rebates and discounts under certain governmental programs. These agreements terminated in the third quarter of 2019.

In conjunction with the PANCREAZE Purchase Agreement, Janssen assigned to the Company the Amended and Restated Know-How License and Supply Agreement (the "Nordmark Supply Agreement") effective as of November 7, 2017 by and between Nordmark Arzneimittel GmbH & Co. KG ("Nordmark") and Janssen. In order to extend the term of the Nordmark Supply Agreement and ensure a stable and predictable price of the Product, the Company entered into the First Amendment to the Supply Agreement on June 26, 2019 (the "Amended Nordmark Supply Agreement"). The material terms of the Amended Nordmark Supply Agreement are: (i) the Company shall purchase certain minimum order quantities at the applicable supply prices for the calendar years under the Amended Nordmark Supply Agreement; (ii) in exchange for Nordmark's obligations under the Amended Nordmark Supply Agreement, the Company shall pay

an annual fee to Nordmark; (iii) Nordmark and the Company have agreed to undertake joint efforts to develop new formulations of PANCREAZE; (iv) the term of the Amended Nordmark Supply Agreement begins on June 26, 2019 and will continue through December 31, 2029, unless earlier terminated and may be renewed for additional five year periods unless earlier terminated; and (v) Nordmark shall have the option to terminate the Amended Nordmark Supply Agreement upon certain circumstances related to the launch date in the United States if the Company assigns any or all of its rights under the Amended Nordmark Supply Agreement to certain parties and/or enters into a transaction or series of transactions resulting in a Change of Control, as defined in the Amended Nordmark Supply Agreement.

Note 13. Long-Term Debt

The Company's indebtedness consists of the following (in thousands):

	Balance as of	
	December 31, 2019	December 31, 2018
Convertible senior notes due 2020	$ 181,426	$ 181,426
Unamortized discount and debt issuance costs	1,580	6,358
Convertible senior notes due 2020, net	183,006	187,784
2024 Notes	61,351	110,000
Unamortized premium and debt issuance costs, net	(2,630)	(3,338)
2024 Notes, net	58,721	106,662
Total debt	241,727	294,446
Less current portion	183,006	—
Total long-term debt	$ 58,721	$ 294,446

Convertible Senior Notes Due 2020

In May 2013, the Company closed offerings of $250.0 million in 4.5% Convertible Senior Notes due May 2020 (the "Convertible Notes"). The Convertible Notes are governed by an indenture, dated May 2013 between the Company and Deutsche Bank National Trust Company, as trustee. Total net proceeds from the Convertible Notes were approximately $241.8 million. The Convertible Notes are convertible at a conversion rate of approximately $148.58 per share at the option of the holders. Subject to certain limitations, the Company will settle conversions of the Convertible Notes by paying or delivering, as the case may be, cash, shares of its common stock or a combination of cash and shares of our common stock, at the Company's election. Interest payments are made quarterly. In June 2018, the Company repurchased $60.0 million of face value of the Convertible Notes for $51.0 million in cash plus accrued but unpaid interest using funds received from the issuance of the Company's Senior Secured Notes Due 2024. The gain was accounted for as a debt modification with the gain applied to the modified debt. In October 2018, the Company repurchased $8.6 million of face value of the Convertible Notes for $7.1 million in cash plus accrued but unpaid interest. The gain on this repurchase of $1.4 million was accounted for as an extinguishment of debt and recorded on the income statement.

Senior Secured Notes Due 2024

In June 2018, the Company entered into an indenture (the "Indenture") with U.S. Bank National Association as trustee and collateral agent regarding the purchase agreement entered into with affiliates of Athyrium Capital Management (collectively, the "Purchasers") for the issuance and sale of (i) $110.0 million of 10.375% senior secured notes due 2024 (the "2024 Notes"), (ii) up to an additional $10.0 million of 10.375% senior secured notes due 2024 to be issued subsequently at the Company's option within 12 months of the issue date of the 2024 Notes, subject to certain conditions, and (iii) a warrant for 330,000 shares issued concurrently with the issuance of the 2024 Notes. The 2024 Notes were issued at a purchase price equal to 99% of the principal amount and contain customary representations, warranties, covenants, conditions and indemnities.

The Company used the net proceeds from the issuance of the 2024 Notes to pay (i) certain fees, costs and expenses relating to the issuance and sale of the 2024 Notes, (ii) to finance a portion of the acquisition of PANCREAZE and (iii) to repurchase $60.0 million of the Company's outstanding Convertible Notes from the Purchasers or their affiliates for a purchase price of $51.0 million (plus accrued but unpaid interest to the repurchase date). The fair value of the warrant issued was estimated using the Black-Scholes option pricing model, using a term of 6.0 years, an estimated volatility of 62.7%, a risk-free interest rate of 2.83% and an expected dividend yield of 0%. The Indenture has an effective interest rate of 11.3% and includes customary covenants and events of default, including covenants that, among other things, restrict the incurrence of future indebtedness, the granting of liens, the making of investments, distributions or dividends, and the Company's ability to merge, consolidate or sell assets, in each case subject to certain exceptions. In addition, the Indenture includes certain financial maintenance covenants related to minimum cash balances and minimum quarterly net revenues related to PANCREAZE.

As of June 30, 2019, the Company was not in compliance with a covenant in the Indenture related to PANCREAZE net revenues. The Company subsequently received a waiver from the consenting noteholders with respect to any potential event of default or default that may have resulted from such covenant non-compliance. In September 2019, the Company entered into a second supplemental indenture (the "Second Supplemental Indenture") which amended the Indenture to (i) revise the compliance dates for minimum quarterly PANCREAZE net sales, (ii) reduce the minimum unrestricted cash equivalents, and (iii) effect the pledge of material intellectual property related to Qsymia® and PANCREAZE®. The Second Supplemental Indenture was entered into in satisfaction of the conditions set forth in the waiver of default obtained in connection with the Indenture. As of December 31, 2019, the Company was in compliance with the covenants in the Indenture as modified by the Second Supplemental Indenture.

In September 2019, the Company repurchased $48.6 million aggregate principal amount of the 2024 Notes plus prepayment premiums of an aggregate of $6.4 million. The prepayment premiums were recorded as interest expense. There was no gain or loss on the transaction.

Future estimated payments on all of the Company's indebtedness as of December 31, 2019 are as follows (in thousands):

2020	$ 192,327
2021	20,152
2022	23,034
2023	21,076
2024	9,822
	$ 266,411

Note 14. Leases

The Company adopted Accounting Standards Update 2016-02, Leases (Topic 842) on January 1, 2019 using the modified retrospective transition method, and as a result did not adjust comparative periods. The Company has a large operating lease for its corporate headquarters and several smaller leases, including financing leases for its automobile fleet and copiers. At the time of adoption, the Company recorded the following amounts (in thousands):

	Right-of-Use Asset	Current Portion of Lease Liability	Lease Liability, Net of Current Portion	Current Portion of Deferred Rent	Deferred Rent, Net of Current Portion	Accumulated Deficit
Operating leases	$ 1,201	$ 512	$ 1,017	$ (94)	$ (234)	$ —
Financing leases	329	131	188	—	—	10
Total	$ 1,530	$ 643	$ 1,205	$ (94)	$ (234)	$ 10

The Company's leases have remaining lease terms ranging from less than 1 year up to 2.6 years, some of which include options to extend the leases for up to 2 years.

The components of lease expense were as follows (in thousands):

	Year Ended December 31, 2019
Operating lease cost	$ 521
Finance lease cost:	
Amortization of right-of-use assets	$ 211
Interest on lease liabilities	11
Total finance lease cost	$ 222

Supplemental balance sheet information related to leases was as follows:

	Balance as of December 31, 2019
Right-of-use assets:	
Operating leases	$ 781
Financing leases	354
Total right-of-use assets	$ 1,135
Current portion of lease liability:	
Operating leases	$ 551
Financing leases	216
Total current portion of lease liability	$ 767
Lease liability, net of current portion	
Operating leases	$ 466
Financing leases	136
Total lease liability, net of current portion	$ 602

The weighted average remaining lease term as of December 31, 2019 was 1.7 years for operating leases and 1.7 years for financing leases. The weighted average discount rate as of December 31, 2019 was 7.8% for operating leases and 2.9% for financing leases.

Future payments of lease liabilities are as follows:

	Operating Leases	Finance Leases
2020	$ 610	$ 224
2021	482	117
2022	-	21
Total lease payments	1,092	362
Less imputed interest	(75)	(10)
Total	$ 1,017	$ 352

Note 15. Stockholders' Equity

Common Stock

The Company is authorized to issue 200,000,000 shares of common stock with a par value of $0.001 per share. As of December 31, 2019 and 2018, there were 10,649,000 and 10,636,000 shares, respectively, issued and outstanding.

Reverse Stock Split

On September 10, 2018, the Company effected a one-for-10 reverse stock split of its common stock. As a result of the reverse stock split, every 10 shares of the Company's pre-reverse split common stock issued and outstanding was combined and converted into one issued and outstanding share of post-reverse split common stock without any change in the par value of the shares. Accordingly, an amount equal to the par value of the decreased shares resulting from the reverse stock split was reclassified from "Common stock" to "Additional paid-in capital." No fractional shares were issued as a result of the reverse stock split; any fractional shares that would have resulted were rounded up to the nearest whole share. Proportionate voting rights and other rights of stockholders were not affected by the reverse stock split, other than as a result of the rounding up of potential fractional shares. All stock options, warrants and restricted stock units outstanding and common stock reserved for issuance under the Company's equity incentive plans immediately prior to the reverse stock split were adjusted by dividing the number of affected shares of common stock by 10 and, where applicable, multiplying the exercise price by 10. All share and per share amounts related to common stock, stock options, warrants and restricted stock units have been restated for all periods to give retroactive effect to the reverse stock split.

Preferred Stock

The Company is authorized to issue 5,000,000 shares of undesignated preferred stock with a par value of $0.001 per share. As of December 31, 2019 and 2018, there were no preferred shares issued or outstanding. The Company may issue shares of preferred stock in the future, without stockholder approval, upon such terms as the Company's management and Board of Directors may determine.

Stockholder Rights Plan

On December 30, 2019, the Company's Board of Directors adopted a Preferred Stock Rights Agreement (the "New Rights Plan") to replace the Company's stockholder rights plan that expired in accordance with its terms on November 9, 2019. Under the New Rights Plan, the Company issued a dividend of one right for each share of its common stock held by stockholders of record as of the close of business on January 13, 2020. Each right would initially entitle the holder to purchase one one-thousandth of a share of the Company's Series A Participating Preferred Stock for a purchase price of $12.68 (subject to adjustment). Under certain circumstances set forth in the New Rights Plan, the Company may suspend the exercisability of the rights.

The New Rights Plan is designed to protect stockholder value by mitigating the likelihood of an "ownership change" that would result in significant limitations to our ability to use our net operating losses or other tax attributes to offset future income. The New Rights Plan is similar to rights plans adopted by other public companies with significant net operating loss carryforwards

The New Rights Plan provides, subject to certain exceptions that if any person or group acquires 4.9% or more of the Company's 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 the Company's outstanding common stock as of the date of the new rights plan will trigger a dilutive event only if they acquire an additional 1% of the outstanding shares of VIVUS common stock.

The New Rights Plan will continue in effect until December 30, 2022, unless earlier terminated or the rights are earlier exchanged or redeemed by the Board of Directors. The Company expects to submit the New Rights Plan to a vote at the 2020 annual meeting of stockholders. If stockholders do not approve the plan at the 2020 annual meeting, it will expire at the close of business on the following day.

Note 16. Stock Option and Purchase Plans

Stock Option Plans

In July 2018, the Company's Board of Directors terminated the 2010 Equity Incentive Plan (the "2010 Plan") and adopted and approved a new 2018 Equity Incentive Plan (the "2018 Plan") which was approved by the Company's stockholders at the 2018 Annual Meeting of Shareholders. The 2010 Plan continues to govern awards previously granted

under it and the 2001 Stock Option Plan continues to govern awards previously granted under it. The 2018 Plan provides for the grant of stock options, stock appreciation rights, restricted stock awards, restricted stock units, performance shares and performance units to individuals who perform services to the Company. The 2018 Plan will be administered by the Board of Directors, or a committee of individuals appointed by the Board of Directors, including the Compensation Committee of the Board of Directors. The maximum term of an option will be specified in the award agreement, provided that the term will be no more than 10 years, and provided further that an incentive stock option granted to a ten percent stockholder must have a term not exceeding 5 years.

The 2018 Plan's original share reserve was 150,000 shares, plus any shares reserved but not issued pursuant to awards under the 2010 Plan as of the date of stockholder approval of the 2018 Plan, or 603,375 shares, plus any shares subject to outstanding awards under the 2010 Plan and 2001 Stock Option Plan that expire or otherwise terminate without having been exercised in full, or are forfeited to or repurchased by the Company, up to a maximum of 1,881,449 shares (which was the number of shares subject to outstanding options under the 2010 Plan and 2001 Stock Option Plan as of the date of stockholder approval).

In April 2018, the Company's Board of Directors adopted the VIVUS, Inc. 2018 Inducement Equity Incentive Plan (the "Inducement Plan") and reserved 502,000 shares of the Company's common stock for issuance pursuant to equity awards granted under the Inducement Plan. The Inducement Plan was adopted without stockholder approval pursuant to Rule 5635(c)(4) and Rule 5635(c)(3) of the Nasdaq Listing Rules. The Inducement Plan provides for the grant of equity-based awards, including options, stock appreciation rights, restricted stock, restricted stock units, performance units and performance shares. In accordance with Rule 5635(c)(4) and Rule 5635(c)(3) of the Nasdaq Listing Rules, awards under the Inducement Plan may only be made to individuals not previously employees of the Company (or following such individuals' bona fide period of non-employment with the Company), as an inducement material to the individuals' entry into employment with the Company.

Restricted Stock Units

A summary of restricted stock unit award activity is as follows:

	Number of Restricted Stock Units	Weighted Average Grant Date Fair Value
Restricted stock units outstanding, January 1, 2017	53,843	$ 18.99
Granted	45,000	11.73
Vested	(62,192)	14.79
Forfeited	(7,518)	14.99
Restricted stock units outstanding, December 31, 2017	29,133	17.78
Vested	(19,185)	19.82
Forfeited	(8,903)	12.05
Restricted stock units outstanding, December 31, 2018	1,045	29.08
Vested	(957)	27.40
Restricted stock units outstanding, December 31, 2019	88	$ 47.33

Stock Options

A summary of stock option award activity for all plans is as follows:

	Years Ended December 31,					
	2019		2018		2017	
	Number of Shares	Weighted-Average Exercise Price	Number of Shares	Weighted-Average Exercise Price	Number of Shares	Weighted-Average Exercise Price
Options outstanding at beginning of year	2,441,062	$ 20.92	1,422,581	$ 34.12	954,724	$ 46.23
Granted	492,660	$ 4.08	1,157,668	$ 3.95	518,484	$ 10.60
Exercised	—	$ —	(10,029)	$ 6.99	—	$ —
Cancelled	(186,479)	$ 5.73	(129,158)	$ 15.27	(50,627)	$ 21.66
Options outstanding at end of year	2,747,243	$ 18.93	2,441,062	$ 20.92	1,422,581	$ 34.12
Options exercisable at end of year	1,862,669	$ 25.70	1,124,744	$ 39.25	653,183	$ 60.72
Weighted average grant-date fair value of options granted during the year		$ 2.32		$ 1.90		$ 4.95

At December 31, 2019, stock options outstanding and exercisable were as follows:

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number Outstanding at December 31, 2019	Weighted-Average Remaining Contractual Life	Weighted-Average Exercise Price	Number Exercisable December 31, 2019	Weighted-Average Exercise Price
$ 2.81 — $ 3.70	663,700	4.19 years	$ 3.66	400,240	$ 3.65
$ 3.90 — $ 4.05	669,560	5.19 years	$ 4.03	183,902	$ 4.02
$ 4.07 — $ 10.60	603,297	3.34 years	$ 9.17	550,556	$ 9.51
$ 11.20 — $ 27.40	557,930	3.39 years	$ 15.83	475,215	$ 16.63
$ 27.90 — $ 257.40	252,756	1.36 years	$ 128.69	252,756	$ 128.69
$ 2.81 — $ 257.40	2,747,243	3.82 years	$ 18.93	1,862,669	$ 25.70

The aggregate intrinsic value of outstanding options as of December 31, 2019 was $0. At December 31, 2019, the Company had 997,075 shares available for grant.

Valuation Assumptions for Options

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

	2019	2018	2017
Expected life (in years)	4.70	4.50	4.27
Volatility	68.5 %	57.7 %	57.0 %
Risk-free interest rate	2.57 %	2.70 %	1.80 %
Dividend yield	—	—	—

Employee Stock Purchase Plan

The Company has reserved a total of 600,000 shares for issuance under the 1994 Employee Stock Purchase Plan (the “ESPP”). Under the ESPP, eligible employees may authorize payroll deductions of up to 10% of their base compensation (as defined) to purchase up to 1,000 shares per offering period of common stock at a price equal to 85% of the lower of the fair market value as of the beginning or the end of each six-month offering period.

As of December 31, 2019, 201,673 shares have been issued to employees, and there are 398,327 shares available for issuance under the ESPP. The weighted average fair value of shares issued under the ESPP in 2019, 2018 and 2017 was $1.16, $1.63 and $2.28 per share, respectively.

Valuation Assumptions for ESPP Shares

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

	2019	2018	2017
Expected life (in years)	0.5	0.5	0.5
Volatility	64.4 %	91.5 %	47.4 %
Risk-free interest rate	2.0 %	2.4 %	1.2 %
Dividend yield	—	—	—

Share-Based Compensation Expense

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

	2019	2018	2017
Cost of goods sold	$ 56	$ 66	$ 53
Selling and marketing	280	349	371
General and administrative	1,483	2,558	2,173
Research and development	207	312	345
Total share-based compensation expense	$ 2,026	$ 3,285	$ 2,942
Share-based compensation expense capitalized as part of the cost of inventory	$ 39	$ 26	$ 9

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

	2019	2018	2017
Restricted stock units	$ —	$ 249	$ 924
Stock options	2,007	3,007	2,002
Employee stock purchase plan	19	29	16
	$ 2,026	$ 3,285	$ 2,942

As of December 31, 2019, unrecognized estimated compensation expense totaled $3.0 million related to non-vested stock options and restricted stock units and $12,000 related to the ESPP. The weighted average remaining requisite service period for the non-vested stock options was 2.3 years and for the ESPP was less than 6 months.

Note 17. Commitments

Lease Commitments

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

lease term for two years at the fair market rental rate then prevailing as detailed in the Campbell Lease. Beginning in August 2018, we also rent a small office space in Morristown, New Jersey with a rental period through August 2020.

Future minimum lease payments under operating leases at December 31, 2019, were as follows (in thousands):

2020	$ 601
2021	482
	$ 1,083

Cardiovascular Outcomes Trial

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

Note 18. Income Taxes

The Company uses the liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and the tax bases of assets and liabilities and are measured using enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized. Deferred income taxes result from differences in the recognition of expenses for tax and financial reporting purposes, as well as operating loss and tax credit carryforwards. Significant components of the Company's deferred income tax assets as of December 31, 2019 and 2018, are as follows (in thousands):

	2019	2018
Deferred tax assets:		
Net operating loss carry forwards	$ 160,464	$ 152,172
Research and development credit carry forwards	16,859	16,721
Share-based compensation	5,113	5,086
Accruals and other	13,655	15,180
Depreciation	265	633
Deferred revenue	960	1,268
	197,316	191,060
Valuation allowance	(197,316)	(191,060)
Total	$ —	$ —

Realization of deferred tax assets by the Company is dependent upon the generation of future taxable income, if any, the amount and timing of which are uncertain. As a result of the Company's analysis of all available evidence, both positive and negative, as of December 31, 2019, it was considered more likely than not that the Company's deferred tax assets would not be realized. As a result, the Company's net deferred tax assets have been fully offset by a valuation allowance.

The net increase in the valuation allowance in 2019 was $6.3 million. The net increase in the valuation allowance in 2018 was $0.2 million. As of December 31, 2019, the Company had no significant deferred tax liabilities.

On December 22, 2017, the Tax Cuts and Jobs Act (the "Act") was signed into law. Among other changes is a permanent reduction in the federal corporate income tax rate from 35% to 21% effective January 1, 2018. As a result of the reduction in the corporate income tax rate, the Company revalued its net deferred tax asset at December 31, 2017. This resulted in a reduction in the value of our net deferred tax asset of approximately $98.4 million, which was entirely offset by the change in valuation allowance of $98.4 million due to the Company's full valuation allowance position.

The Act includes certain anti-deferral and anti-base erosion provisions, including a new minimum tax on global intangible low-taxed income (“GILTI”). The Act subjects the Company to current tax on GILTI of its controlled foreign corporations. Due to current year positive tested income for the Company's foreign subsidiaries, the Company was subject to GILTI. Therefore, the Company recognized a GILTI inclusion of $0.2 million for ended December 31, 2019. There is no tax expense impact related to GILTI inclusion.

As of December 31, 2019, the Company had approximately $648.5 million and $278.2 million of total federal and state net operating loss (“NOL”) carryforwards, respectively, with which to offset its future taxable income. The federal and state NOL carryforwards will begin expiring in 2028, unless previously utilized. Of the total federal NOL amount, the Company had $633.6 million of federal NOLs generated prior to tax years beginning in 2018 which may be used to offset 100% of the Company's federal taxable income (subject to the Section 382 limitation discussed below). Federal NOL carryforwards generated in tax years beginning in 2018 are not subject to expiration. Of the total federal NOL amount, the Company had $14.9 million of federal NOLs that arose in tax years beginning after 2017 which can be carried forward indefinitely against future income, but can only be used to offset a maximum of 80% of the Company’s federal taxable income in any year.

The Act expanded the scope of the $1.0 million deduction limitation and expanded the definition of a covered person under US Internal Revenue Code (“IRC”) Section 162(m) for tax years beginning after December 31, 2017. The Act repealed the performance-based exception; therefore, all compensation paid to a covered employee in excess of $1.0 million will be nondeductible, unless it is subject to the transition rule. The Act expanded the definition of a covered employee to include the CFO and to cover any individual who served as the CEO or CFO at any time during the tax year. The covered employee definition has been further expanded to provide that once an employee becomes a covered employee for any tax year beginning after December 31, 2016, the employee will remain a covered employee for all future tax years. The Company had approximately $0.0 million of officer compensation expense limited for the year ended December 31, 2019.

The Act revised the business interest expense limitation. For tax years beginning after December 31, 2017, IRC Section 163(j) limits the deduction for business interest to the sum of business interest income and 30 percent of adjusted taxable income without regard to business interest expense or income, and NOL deduction. Limited interest is carried forward indefinitely. In 2019, the Company’s interest limitation was $20.7 million. State conformity to this provision is applied on a jurisdiction-by-jurisdiction basis.

The Act extended and modified IRC Section 168(k) bonus depreciation provisions, allowing businesses to immediately deduct 100% of the cost of eligible property in the year it is placed in service through 2022. The amount of allowable bonus depreciation is then phased down over four years as follows: 80% will be allowed for property placed in service in 2023, 60% in 2024, 40% in 2025, and 20% in 2026. The Company has taken bonus depreciation of approximately $0.04 million in 2019. State conformity to this provision is applied on a jurisdiction-by-jurisdiction basis.

As of December 31, 2019, the Company has federal and state research credit carryforwards of approximately $12.9 million, and $5.2 million, respectively. The federal research credit carryforwards will begin expiring in 2020, unless previously utilized. The state research credit carryforwards do not expire.

Utilization of the Company’s NOL and tax credit carryforwards (“Tax Attributes”) may be subject to substantial annual limitations provided by the U.S. Internal Revenue Code and similar state provisions to the extent certain ownership changes are deemed to occur. Such an annual limitation could result in the expiration of the Tax Attributes before utilization. The Tax Attributes reflected above have not been reduced by any limitations. To the extent it is determined upon completion of the analysis that such limitations do apply, the Company will adjust the Tax Attributes accordingly. The Company faces the risk that its ability to use its Tax Attributes will be substantially restricted if it undergoes an ownership change, as defined in Section 382 of the U.S. Internal Revenue Code (“Section 382”).

An ownership change under Section 382 would occur if 5-percent shareholders, within the meaning of Section 382, collectively increased their ownership in the Company by more than 50 percentage points over a rolling three-year period. The Company has completed studies through December 31, 2016, and concluded that no adjustments were required. If the Company has experienced a change of control at any time since its formation, its NOL carryforwards and tax credits may not be available, or their utilization could be subject to an annual limitation under Section 382. A full valuation allowance has been provided against the Company's NOL carryforwards, and if an adjustment is required, this adjustment would be offset by an adjustment to the valuation allowance. Accordingly, there would be no impact on the consolidated financial statements.

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

	2019	2018	2017
Income (loss) before income taxes:			
Domestic	$ (31,643)	$ (36,800)	$ (30,371)
International	161	(98)	(138)
Income (loss) before taxes	$ (31,482)	$ (36,898)	$ (30,509)

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

	2019	2018	2017
Current:			
Federal	$ —	$ —	$ —
State	21	57	2
Foreign	—	(5)	—
Total current provision (benefit) for income taxes	$ 21	$ 52	$ 2
Deferred:			
Federal	$ —	$ —	$ —
State	—	—	—
Foreign	—	—	—
Total deferred provision for income taxes	$ —	$ —	$ —
Total provision (benefit) for income taxes from continuing operations	$ 21	$ 52	$ 2

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

	2019	2018	2017
Tax at U.S. federal statutory rate	21 %	21 %	35 %
State income taxes, net of federal tax effect	1	2	1
Change in valuation allowance	(23)	(2)	310
Permanent items	—	(21)	(24)
Tax credits	1	—	1
Tax Cuts and Jobs Act impact	—	—	(323)
Effective tax rate	— %	— %	— %

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

	2019	2018	2017
Unrecognized tax benefits as of January 1	$ 91	$ 110	$ 65
Gross increase/(decrease) for tax positions of prior years	3	(33)	—
Gross increase/(decrease) for tax positions of current year	93	14	45
Unrecognized tax benefits balance at December 31	$ 187	$ 91	$ 110

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

	2019	2018
Total unrecognized tax benefits	$ 187	$ 91
Amounts netted against deferred tax assets	(187)	(91)
Unrecognized tax benefits recorded on consolidated balance sheets	$ —	$ —

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

The Company files income tax returns in the United States, Canada, and the Netherlands. The federal and state income tax returns are open under the statute of limitations subject to tax examinations for the tax years ended December 31, 2015 through December 31, 2018. To the extent the Company has tax attribute carryforwards, the tax years in which the attribute was generated may still be adjusted upon examination by the IRS or state tax authorities to the extent utilized in a future period. In Canada, the Canadian Revenue Agency may reassess an income tax within three years of the original notice of assessment. For the Netherlands, the tax administration can impose an additional assessment within five years from the year in which the tax debt originated.

Note 19. 401(k) Plan

All of the Company's full-time employees are eligible to participate in the VIVUS 401(k) Plan. Employer-matching contributions for the years ended December 31, 2019, 2018 and 2017 were $256,000, $277,000 and $272,000, respectively.

Note 20. Legal Matters

The Company is not aware of any asserted or unasserted claims against it where it believes that an unfavorable resolution would have an adverse material impact on the operations or financial position of the Company.

Note 21. Selected Financial Data (Unaudited)

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

	Quarter Ended,			
	March 31	June 30	September 30	December 31
2019				
Total revenue	$ 16,146	$ 18,390	$ 17,970	$ 17,254
Total gross profit	11,838	14,013	14,954	13,284
Operating expenses	20,233	20,437	19,127	20,932
Net loss	(7,949)	(5,935)	(11,072)	(6,547)
Basic and diluted net loss per share	$ (0.75)	$ (0.56)	$ (1.04)	$ (0.61)
2018				
Total revenue	$ 11,900	$ 14,960	$ 18,088	$ 20,114
Total gross profit	9,270	11,674	14,604	14,901
Operating expenses	14,192	18,312	17,680	18,357
Net loss	(10,653)	(12,574)	(9,223)	(4,500)
Basic and diluted net loss per share	$ (1.00)	$ (1.18)	$ (0.87)	$ (0.42)

FINANCIAL STATEMENT SCHEDULE

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

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

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

	Balance at Beginning of Period	Charged to Operations*	Charges Utilized	Balance at End of Period
Allowance for Cash Discounts				
Fiscal year ended December 31, 2017	$ 213	$ 1,344	$ (1,362)	$ 195
Fiscal year ended December 31, 2018	$ 195	$ 1,346	$ (1,389)	$ 152
Fiscal year ended December 31, 2019	$ 152	$ 1,921	$ (1,821)	$ 252

* Amount charged to operations during fiscal years ended December 31, 2019, 2018 and 2017, includes $1,965,000, $1,327,000 and $1,697,000, respectively, for cash discount allowances related to revenue recognized during each fiscal year. The remaining amounts were recorded on the consolidated balance sheets as deferred revenue at the end of each period, respectively.

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

None.

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

Evaluation of Disclosure Controls and Procedures.

We maintain disclosure controls and procedures that are designed to provide reasonable assurance that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the timelines specified in the Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by Rule 13a-15(b) under the Exchange Act, the Company carried out an evaluation, under the supervision and with the participation of the Company's management, including the Company's Chief Executive Officer and the Company's Chief Financial Officer, of the effectiveness of the design and operation of the Company's disclosure controls and procedures as of the end of the year covered by this report. Based on the foregoing evaluation, our Chief Executive Officer and Chief Financial Officer concluded that the design and operation of our disclosure controls and procedures were effective at the reasonable assurance level as of such date.

Management's Annual Report on Internal Control Over Financial Reporting

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

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

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

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

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

Our management has used the framework set forth in the report entitled Internal Control—Integrated Framework published by the Committee of Sponsoring Organizations of the Treadway Commission (2013), known as the COSO Framework, to evaluate the effectiveness of the Company's internal control over financial reporting. Based on

this assessment, management has concluded that our internal control over financial reporting was effective as of December 31, 2019.

Changes in Internal Controls Over Financial Reporting

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

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

None.

PART III

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

The information required by this item is hereby incorporated by reference from the information under the captions "Election of Directors," "Corporate Governance—Board Committees," "Executive Officers" and "Delinquent Section 16(a) Reports" (as applicable) contained in the Company's definitive Proxy Statement, to be filed with the Securities and Exchange Commission no later than 120 days from the end of the Company's last fiscal year in connection with the solicitation of proxies for its 2020 Annual Meeting of Stockholders.

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

Item 11. *Executive Compensation*

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

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

Equity Compensation Plan Information

Information about our equity compensation plans that were approved by our stockholders as of December 31, 2019 was as follows:

Plan Category	Number of Shares to be issued Upon Exercise of Outstanding Options and Rights	Weighted Average Exercise Price of Outstanding Options	Number of Shares Remaining Available for Future Issuance(c)
Equity compensation plans approved by stockholders(a)	2,317,743	$ 21.76	1,395,402
Equity compensation plans not approved by stockholders(b)	429,500	3.70	—
Total	2,747,243	$ 18.93	1,395,402

(a) Consists of four plans: our 2001 Stock Option Plan, our 2010 Equity Incentive Plan, our 2018 Equity Incentive Plan and our 1994 Employee Stock Purchase Plan.

(b) Consists of our 2018 Inducement Equity Incentive Plan.

(c) Includes 997,075 shares for our 2018 Equity Incentive Plan and 398,327 shares for our 1994 Employee Stock Purchase Plan.

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

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

The information required by this item is incorporated by reference from the information under the caption "Certain Relationships and Related Transactions" and "Corporate Governance—Board Independence" in the Company's Proxy Statement referred to in Item 10 above.

Item 14. ***Principal Accounting Fees and Services***

The information required by this item is incorporated by reference from the information under the caption "Ratification of Appointment of Independent Registered Public Accounting Firm" in the Company's Proxy Statement referred to in Item 10 above.

PART IV

Item 15. ***Exhibits and Financial Statement Schedules***

(a) Documents filed as part of this report

1. Financial Statements

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

2. Financial Statement Schedules

Reference is made to the financial statement schedules included under Item 8 of Part II hereof. All other schedules are omitted because they are not applicable or the required information is shown in the financial statements or the notes thereto.

3. Exhibits

Refer to Item 15(b) immediately below.

(b) Exhibits

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

VIVUS, INC.
REPORT ON FORM 10-K FOR
THE YEAR ENDED DECEMBER 31, 2019
EXHIBIT INDEX

Exhibit Number	Description	Incorporation by reference		
		Exhibit	Form	Filing Date
2.1†	Asset Purchase Agreement between the Registrant and K-V Pharmaceutical Company dated as of March 30, 2007	2.1	Form 10-K for the fiscal year ended December 31, 2012 (001-33389)	February 26, 2013
2.2†	Asset Purchase Agreement dated October 1, 2010, between the Registrant, MEDA AB and Vivus Real Estate, LLC	2.2	Form 10-K/A for the fiscal year ended December 31, 2012 (001-33389)	June 12, 2013
2.3†	Asset Purchase Agreement between the Registrant and Janssen Pharmaceuticals, Inc. dated April 30, 2018	2.1	Form 10-Q for the fiscal quarter ended June 30, 2018 (001-33389)	August 7, 2018
3.1	Amended and Restated Certificate of Incorporation of the Registrant, as amended and restated through September 10, 2018	3.1	Form 8-K (001-33389)	September 10, 2018
3.2	Amended and Restated Bylaws of the Registrant, as further amended	3.2	Form 10-Q for the fiscal quarter ended June 30, 2018 (001-33389)	August 7, 2018
3.3	Amended and Restated Certificate of Designation of Rights, Preferences and Privileges of Series A Participating Preferred Stock of the Registrant	3.3	Form 8-A (001-33389)	March 28, 2007
4.1	Specimen Common Stock Certificate of the Registrant	4.1	Form 10-K/A for the fiscal year ended December 31, 1996 (001-33389)	April 16, 1997
4.2#	Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934			
4.3	Preferred Stock Rights Agreement, dated as of December 30, 2019, between the Registrant and Computershare Trust Company, N.A.	4.1	Form 8-K (001-33389)	December 31, 2019
4.4	Indenture dated as of May 21, 2013, by and between the Registrant and Deutsche Bank Trust Company Americas, as trustee	4.1	Form 8-K (001-33389)	May 21, 2013
4.5	Form of 4.50% Convertible Senior Note due May 1, 2020 (included in Exhibit 4.4)	4.2	Form 8-K (001-33389)	May 21, 2013
4.6	Indenture, dated as of June 8, 2018, among the Registrant, the other guarantors from time to time party thereto and U.S. Bank National Association, as trustee and collateral agent	4.1	Form 8-K (001-33389)	June 11, 2018

Exhibit Number	Description	Incorporation by reference		
		Exhibit	Form	Filing Date
4.7	First Supplemental Indenture, dated as of October 11, 2018, among the Registrant, as issuer and U.S. Bank National Association, as trustee and collateral agent	4.3	Form 8-K (001-33389)	October 17, 2018
4.8	Second Supplemental Indenture, dated as of September 30, 2019, among the Registrant, as issuer and U.S. Bank National Association, as trustee and collateral agent	4.2	Form 8-K (001-33389)	October 3, 2019
4.9	Form of 2024 Note (included in Exhibit 4.6)	4.2	Form 8-K (001-33389)	June 11, 2018
4.10	Warrant to Purchase Shares of Common Stock issued to Torreya Capital, LLC dated February 23, 2018	4.5	Form 10-Q for the fiscal quarter ended March 31, 2018 (001-33389)	May 8, 2018
4.11	Form of Athyrium Warrant, dated as of June 8, 2018	4.3	Form 8-K (001-33389)	June 11, 2018
4.12*	Form of Warrant to be issued by the Registrant to certain shareholders of Willow Biopharma Inc.	4.9	Form 10-Q for the fiscal quarter ended June 30, 2018 (001-33389)	August 7, 2018
10.1*	Form of Indemnification Agreement by and among the Registrant and the Officers of the Registrant	10.11	Form 8-B (001-33389)	June 25, 1996
10.2*	Form of Indemnification Agreement by and among the Registrant and the Directors of the Registrant	10.1	Form 8-K (001-33389)	August 12, 2014
10.3*	1994 Employee Stock Purchase Plan	4.2	Form S-8 (001-33389)	August 6, 2019
10.4*	2001 Stock Option Plan and Form of Agreement thereunder	10.44	Form S-8 (001-33389)	November 15, 2001
10.5*	2001 Stock Option Plan, as amended on July 12, 2006	10.1	Form 8-K (001-33389)	July 13, 2006
10.6*	Form of Notice of Grant and Restricted Stock Unit Agreement under the VIVUS, Inc. 2001 Stock Option Plan	10.2	Form 8-K (001-33389)	July 13, 2006
10.7*	2010 Equity Incentive Plan and Form of Agreement thereunder	10.7	Form 10-K for the fiscal year ended December 31, 2010 (001-33389)	March 1, 2011
10.8*	2010 Equity Incentive Plan	4.1	Form S-8 (001-33389)	December 15, 2017
10.9*	Stand-Alone Stock Option Agreement with Michael P. Miller dated as of April 30, 2010	10.1	Form 8-K (001-33389)	May 6, 2010
10.10*	2018 Inducement Equity Incentive Plan	4.1	Form S-8 (001-33389)	June 1, 2018
10.11*	Form of Agreement under the 2018 Inducement Equity Incentive Plan	10.4	Form 10-Q for the fiscal quarter ended June 30, 2018 (001-33389)	August 7, 2018
10.12*	2018 Equity Incentive Plan	4.1	Form S-8 (001-33389)	August 6, 2019

Exhibit Number	Description	Incorporation by reference		
		Exhibit	Form	Filing Date
10.13*	Form of Restricted Stock Units Agreement under the 2018 Equity Incentive Plan	10.2	Form 10-Q for the fiscal quarter ended September 30, 2018 (001-33389)	November 1, 2018
10.14*	Form of Stock Option Agreement under the 2018 Equity Incentive Plan	10.3	Form 10-Q for the fiscal quarter ended September 30, 2018 (001-33389)	November 1, 2018
10.15†	Agreement effective as of December 28, 2000, between the Registrant and Tanabe Seiyaku Co., Ltd.	10.15	Form 10-K for the fiscal year ended December 31, 2012 (001-33389)	February 26, 2013
10.16	Amendment No. 1 effective as of January 9, 2004, to the Agreement effective as of December 28, 2000, between the Registrant and Tanabe Seiyaku Co., Ltd.	10.42A	Form 10-Q for the fiscal quarter ended March 31, 2004 (001-33389)	May 7, 2004
10.17	Termination and Release executed by Tanabe Holding America, Inc. dated May 1, 2007	10.61	Form 8-K (001-33389)	May 4, 2007
10.18†	Second Amendment effective as of August 1, 2012, to the Agreement dated as of December 28, 2000, between the Registrant and Mitsubishi Tanabe Pharma Corporation (formerly Tanabe Seiyaku Co., Ltd.)	10.1	Form 8-K (001-33389)	August 10, 2012
10.19†	Third Amendment effective as of February 21, 2013, to the Agreement dated as of December 28, 2000, between the Registrant and Mitsubishi Tanabe Pharma Corporation (formerly Tanabe Seiyaku Co., Ltd.)	10.1	Form 8-K (001-33389)	February 25, 2013
10.20	Fourth Amendment to the Agreement dated as of December 28, 2000, between the Registrant and Mitsubishi Tanabe Pharma Corporation (formerly Tanabe Seiyaku Co., Ltd.), effective as of July 1, 2013	10.1	Form 8-K (001-33389)	July 29, 2013
10.21†	Settlement and Modification Agreement dated July 12, 2001, between ASIVI, LLC, AndroSolutions, Inc., Gary W. Neal and the Registrant	10.20	Form 10-K for the fiscal year ended December 31, 2012 (001-33389)	February 26, 2013
10.22†	Assignment Agreement between Thomas Najarian, M.D. and the Registrant dated October 16, 2001	10.79	Form 10-K for the fiscal year ended December 31, 2009 (001-33389)	March 10, 2010
10.23†	Master Services Agreement dated as of September 12, 2007, between the Registrant and Medpace, Inc.	10.2	Form 10-Q for the fiscal quarter ended March 31, 2013 (001-33389)	May 8, 2013

Exhibit Number	Description	Incorporation by reference		
		Exhibit	Form	Filing Date
10.24†	Exhibit A: Medpace Task Order Number: 06 dated as of December 15, 2008, pursuant to that certain Master Services Agreement, between the Registrant and Medpace, Inc., dated as of September 12, 2007	10.1	Form 8-K/A (001-33389)	July 15, 2009
10.25†	Commercial Manufacturing and Packaging Agreement by and between the Registrant and Catalent Pharma Solutions, LLC dated as of July 17, 2012	10.1	Form 8-K (001-33389)	July 23, 2012
10.26†	Purchase and Sale Agreement effective as of March 25, 2013, between the Registrant and BioPharma Secured Investments III Holdings Cayman LP	10.1	Form 10-Q for the fiscal quarter ended March 31, 2013 (001-33389)	May 8, 2013
10.27	Capped Call Confirmation dated May 15, 2013, by and between the Registrant and Deutsche Bank AG, London Branch	10.1	Form 8-K (001-33389)	May 16, 2013
10.28*	Form of Amended and Restated Change of Control and Severance Agreement	10.1	Form 8-K (001-33389)	July 5, 2013
10.29*	Form of Second Amended and Restated Change of Control and Severance Agreement	10.1	Form 8-K (001-33389)	June 24, 2015
10.30*	Form of Third Amended and Restated Change of Control and Severance Agreement	10.5	Form 10-Q for the fiscal quarter ended June 30, 2018 (001-33389)	August 7, 2018
10.31†	License and Commercialization Agreement dated July 5, 2013, between the Registrant and Berlin-Chemie AG	10.3	Form 10-Q for the fiscal quarter ended June 30, 2013 (001-33389)	August 8, 2013
10.32†	Commercial Supply Agreement dated as of July 5, 2013, between the Registrant and Berlin-Chemie AG	10.4	Form 10-Q for the fiscal quarter ended June 30, 2013 (001-33389)	August 8, 2013
10.33††	Amendment No. 1 to License and Commercialization Agreement and Commercial Supply Agreement dated May 21, 2019 between the Registrant and the Menarini Group through its subsidiary Berlin-Chemie AG	10.3	Form 10-Q (001-33389)	August 6, 2019
10.34	Agreement dated July 18, 2013, by and between the Registrant and First Manhattan Co.	10.1	Form 8-K (001-33389)	July 19, 2013
10.35*	Letter Agreement dated July 18, 2013, by and among the Registrant, First Manhattan Co. and Peter Y. Tam	10.1	Form 8-K (001-33389)	July 24, 2013
10.36*	Employment Agreement dated September 3, 2013, by and between the Registrant and Seth H. Z. Fischer	10.1	Form 8-K (001-33389)	September 4, 2013

Exhibit Number	Description	Incorporation by reference		
		Exhibit	Form	Filing Date
10.37*†	Confidential Separation, General Release and Post-Separation Consulting Agreement effective December 31, 2017, between the Registrant and Seth H. Z. Fischer	10.55	Form 10-K for the fiscal year ended December 31, 2017 (001-33389)	March 14, 2018
10.38†	License and Commercialization Agreement dated as of October 10, 2013, by and between the Registrant and Auxilium Pharmaceuticals, Inc.	10.9	Form 10-Q for the quarter ended September 30, 2013 (001-33389)	November 7, 2013
10.39†	Commercial Supply Agreement dated as of October 10, 2013, by and between the Registrant and Auxilium Pharmaceuticals, Inc.	10.10	Form 10-Q for the quarter ended September 30, 2013 (001-33389)	November 7, 2013
10.40	Letter Regarding Termination Notice dated December 30, 2015, from Auxilium Pharmaceuticals, Inc. and Endo Ventures Limited to the Registrant	10.53	Form 10-K for the fiscal year ended December 31, 2015 (001-33389)	March 9, 2016
10.41	Letter Regarding Termination Notice dated as of June 30, 2016, from Auxilium Pharmaceuticals, Inc. and Endo Ventures Limited to the Registrant	10.1	Form 10-Q for the fiscal quarter ended June 30, 2016 (001-33389)	August 4, 2016
10.42	Letter Regarding Termination Notice dated as of August 29, 2016, from Auxilium Pharmaceuticals, LLC and Endo Ventures Limited to the Registrant	10.1	Form 10-Q for the fiscal quarter ended September 30, 2016 (001-33389)	November 9, 2016
10.43*	Letter Agreement dated November 4, 2013, by and between the Registrant and Timothy E. Morris	10.1	Form 8-K (001-33389)	November 5, 2013
10.44†	Commercial Supply Agreement dated July 31, 2013, by and between the Registrant and Sanofi Chimie	10.8	Form 10-Q for the fiscal quarter ended June 30, 2013 (001-33389)	August 8, 2013
10.45†	Termination, Rights Reversion and Transition Services Agreement dated March 23, 2017, by and between the Registrant and Sanofi	10.3	Form 10-Q for the fiscal quarter ended March 31, 2017 (001-33389)	May 3, 2017
10.46†	Manufacturing and Supply Agreement dated November 18, 2013, by and between the Registrant and Sanofi Winthrop Industrie	10.45	Form 10-K for the fiscal year ended December 31, 2013 (001-33389)	February 28, 2014
10.47††	Amendment Nº1 to the Manufacturing and Supply Agreement dated May 22, 2019 between the Registrant and Sanofi Winthrop Industrie	10.2	Form 10-Q (001-33389)	August 6, 2019
10.48†	License and Commercialization Agreement dated December 11, 2013, by and between the Registrant and Sanofi	10.46	Form 10-K for the fiscal year ended December 31, 2013 (001-33389)	February 28, 2014

Exhibit Number	Description	Incorporation by reference		
		Exhibit	Form	Filing Date
10.49†	Supply Agreement effective as of December 11, 2013, by and between the Registrant and Sanofi Winthrop Industrie	10.47	Form 10-K for the fiscal year ended December 31, 2013 (001-33389)	February 28, 2014
10.50†	Patent Assignment Agreement, dated August 24, 2014, by and between the Registrant and Janssen Pharmaceuticals, Inc.	10.1	Form 10-Q for the fiscal quarter ended September 30, 2014 (001-33389)	November 5, 2014
10.51*	Letter Agreement dated April 13, 2015, by and between the Registrant and Guy P. Marsh	10.1	Form 10-Q for the fiscal quarter ended June 30, 2015 (001-33389)	August 3, 2015
10.52*	Letter Agreement dated July 20, 2015, by and between the Registrant and Wesley W. Day, Ph.D.	10.3	Form 10-Q for the fiscal quarter ended June 30, 2015 (001-33389)	August 3, 2015
10.53*	Letter Agreement dated August 17, 2015, by and between the Registrant and Svai S. Sanford	10.3	Form 10-Q for the fiscal quarter ended September 30, 2015 (001-33389)	November 4, 2015
10.54	Lease Agreement effective December 11, 2012, by and between the Registrant and SFERS Real Estate Corp. U.	10.34	Form 10-K for the fiscal year ended December 31, 2012 (001-33389)	February 26, 2013
10.55	First Amendment to Lease effective August 30, 2016, between the Registrant and MV Campus Owner, LLC, the successor in interest to SFERS Real Estate Corp. U.	10.2	Form 10-Q for the fiscal quarter ended September 30, 2016 (001-33389)	November 9, 2016
10.56	Office Lease effective September 2, 2016, between the Registrant and AG-SW Hamilton Plaza Owner, L.P.	10.3	Form 10-Q for the fiscal quarter ended September 30, 2016 (001-33389)	November 9, 2016
10.57†	License and Commercialization Agreement dated as of September 30, 2016, by and between the Registrant and Metuchen Pharmaceuticals LLC	10.4	Form 10-Q for the fiscal quarter ended September 30, 2016 (001-33389)	November 9, 2016
10.58†	Commercial Supply Agreement dated as of September 30, 2016, by and between the Registrant and Metuchen Pharmaceuticals LLC	10.5	Form 10-Q for the fiscal quarter ended September 30, 2016 (001-33389)	November 9, 2016
10.59†	Patent Assignment Agreement dated as of January 6, 2017, by and between the Registrant and Selten Pharma, Inc.	10.55	Form 10-K for the fiscal year ended December 31, 2016 (001-33389)	March 8, 2017
10.60†	License Assignment Agreement dated as of January 6, 2017, by and between the Registrant and Selten Pharma, Inc.	10.56	Form 10-K for the fiscal year ended December 31, 2016 (001-33389)	March 8, 2017
10.61†	Settlement Agreement dated June 29, 2017, by and between the Registrant and Actavis Laboratories FL, Inc.	10.1	Form 10-Q for the fiscal quarter ended June 30, 2017 (001-33389)	August 3, 2017

Exhibit Number	Description	Incorporation by reference		
		Exhibit	Form	Filing Date
10.62	Collateral Agreement, dated as of June 8, 2018, among the Registrant, the other guarantors from time to time party thereto and U.S. Bank National Association, as trustee and collateral agent	10.1	Form 8-K (001-33389)	June 11, 2018
10.63	Purchase Agreement between the Registrant and affiliates of Athyrium Capital Management dated April 30, 2018	10.3	Form 10-Q for the fiscal quarter ended June 30, 2018 (001-33389)	August 7, 2018
10.64†	Amendment Nº1 to Commercial Supply Agreement dated December 7, 2018 between Sanofi Chimie and the Registrant	10.62	Form 10-K for the fiscal year ended December 31, 2018 (001-33389)	February 26, 2019
10.65	Amendment No. 1 to Collateral Agreement dated as of July 6, 2018 between the Registrant and U.S. Bank National Association, as trustee and collateral agent	10.63	Form 10-K for the fiscal year ended December 31, 2018 (001-33389)	February 26, 2019
10.66	Amendment No. 2 to Collateral Agreement dated as of October 11, 2018 between the Registrant and U.S. Bank National Association, as trustee and collateral agent	10.64	Form 10-K for the fiscal year ended December 31, 2018 (001-33389)	February 26, 2019
10.67	Amendment No. 3 to Collateral Agreement dated as of December 7, 2018 between the Registrant and U.S. Bank National Association, as trustee and collateral agent	10.65	Form 10-K for the fiscal year ended December 31, 2018 (001-33389)	February 26, 2019
10.68	Amendment No. 4 to Collateral Agreement dated as of March 20, 2019 between the Registrant and U.S. Bank National Association, as trustee and collateral agent	10.1	Form 10-Q (001-33389)	April 30, 2019
10.69	Amendment No. 5 to Collateral Agreement dated as of June 5, 2019 between the Registrant and U.S. Bank National Association, as trustee and collateral agent	10.1	Form 10-Q (001-33389)	August 6, 2019
10.70††	Amended and Restated Know-How License and Supply Agreement dated November 3, 2017 between Janssen Pharmaceuticals, Inc. and Nordmark Arzneimittel GmbH & Co. KG	10.4	Form 10-Q (001-33389)	August 6, 2019
10.71††	First Amendment to the Amended and Restated Know-How License and Supply Agreement dated June 26, 2019 between the Registrant and Nordmark Arzneimittel GmbH & Co. KG	10.5	Form 10-Q (001-33389)	August 6, 2019
21.1#	List of Subsidiaries			
23.1#	Consent of Independent Registered Public Accounting Firm			
24.1	Power of Attorney (See signature page)			

Exhibit Number	Description	Incorporation by reference		
		Exhibit	Form	Filing Date
31.1#	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002			
31.2#	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002			
32.1+	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002			
101	The following materials from the Registrant's Annual Report on Form 10-K for the year ended December 31, 2019, formatted in Extensible Business Reporting Language (XBRL), include: (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Operations, (iii) the Consolidated Statements of Comprehensive (Loss) Income, (iv) the Consolidated Statements of Cash Flows, and (v) related notes			

† Confidential treatment granted.

†† Portions of this exhibit have been omitted pursuant to Item 601(b) of Regulation S-K.

* Indicates management contract or compensatory plan or arrangement.

Filed herewith.

+ Furnished herewith.

Item 16. ***Form 10-K Summary***

None.

SIGNATURES

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

VIVUS, INC.,
a Delaware Corporation

By: /s/ John P. Amos
John P. Amos
Chief Executive Officer
(Principal Executive Officer)

Date: March 3, 2020

POWER OF ATTORNEY

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

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

Signature	Title	Date
/s/ John P. Amos John P. Amos	Chief Executive Officer (Principal Executive Officer) and Director	March 3, 2020
/s/ David Y. Norton David Y. Norton	Chairman of the Board of Directors and Director	March 3, 2020
/s/ Mark K. Oki Mark K. Oki	Senior Vice President, Chief Financial Officer and Chief Accounting Officer (Principal Financial and Accounting Officer)	March 3, 2020
/s/ Karen Ferrell Karen Ferrell	Director	March 3, 2020
/s/ Edward A. Kangas Edward A. Kangas	Director	March 3, 2020
/s/ Thomas B. King Thomas B. King	Director	March 3, 2020
/s/ Jorge Plutzky, M.D. Jorge Plutzky, M.D.	Director	March 3, 2020
/s/ Herman Rosenman Herman Rosenman	Director	March 3, 2020

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

VIVUS, Inc. ("we," "our" or the "Company") has registered under Section 12 of the Securities Exchange Act of 1934, as amended, (1) common stock, $0.001 par value per share (the "common stock"), of the Company and (2) rights (the "Rights") to purchase specified units of the Series A Participating Preferred Stock, $0.001 par value per share, of the Company (the "Series A Participating Preferred Stock").

The following descriptions of our capital stock (including our common stock), the Rights and the Rights Agreement (as defined below) are summaries and are subject to, and are qualified in their entirety by reference to, the provisions of (1) our Amended and Restated Certificate of Incorporation (the "Certificate of Incorporation"), (2) our Amended and Restated Bylaws, as further amended (the "Bylaws"), (3) our Amended and Restated Certificate of Designation of Rights, Preferences and Privileges of Series A Participating Preferred Stock of the Company and (4) the Preferred Stock Rights Agreement, dated as of December 30, 2019, between the Company and Computershare Trust Company, N.A. (the "Rights Agreement"), copies of which are incorporated by reference as Exhibits 3.1, 3.2, 3.3 and 4.3, respectively, to our Annual Report on Form 10-K for the year ended December 31, 2019 of which this Exhibit 4.2 is a part.

Capital Stock

Our Certificate of Incorporation authorizes us to issue a total of 205,000,000 shares of capital stock, consisting of (1) 200,000,000 shares of common stock, and (2) 5,000,000 shares of preferred stock, $0.001 par value per share (the "preferred stock").

Common Stock

Voting Rights

The holders of shares of our common stock are entitled to one vote per share on all matters to be voted on by stockholders. Directors are elected by a plurality of the votes cast by stockholders present in person or represented by proxy at a meeting of the stockholders of the Company and entitled to vote on the election of directors. Except as otherwise provided by applicable law, our Certificate of Incorporation or our Bylaws, every matter other than the election of directors will be decided by the affirmative vote of a majority of the votes cast by stockholders present in person or represented by proxy at the meeting and entitled to vote on such matter. Except as otherwise provided in our Certificate of Incorporation or as required by applicable law, holders of shares of our common stock are not entitled to cumulate their votes in the election of directors or with respect to any matter submitted to a vote of the stockholders.

Dividends

The holders of our common stock are entitled to receive dividends declared by our Board of Directors (the "Board") out of funds legally available for the payment of dividends under Delaware law, subject to the rights, if any, of the holders of our preferred stock. In addition, our debt financing arrangements currently impose limitations, and debt financing or other contractual arrangements may in the future impose limitations, on our ability to pay dividends.

Liquidation

Upon any liquidation, dissolution or winding up of our business, the holders of common stock are entitled to share equally in all assets available for distribution after payment of all liabilities and provision for liquidation preference of shares of preferred stock then outstanding.

Rights and Preferences

The holders of our common stock have no preemptive rights and no rights to convert their common stock into any other securities. There are also no redemption or sinking fund provisions applicable to our common stock.

All outstanding shares of common stock are fully paid and nonassessable. In addition, see "Anti-Takeover Effects of Provisions of Our Certificate of Incorporation, Bylaws, Other Agreements and Delaware Law" below.

Listing

Our common stock is traded on The Nasdaq Global Select Market under the trading symbol "VVUS."

Preferred Stock

Our Board has the authority, without further action by our stockholders, to issue up to 5,000,000 shares of our preferred stock, each with a par value of $0.001 per share, in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting, or the designation of, such series, any or all of which may be greater than the rights of common stock. The issuance of our preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon our liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change in control of our Company or other corporate action.

Our Board has adopted the Amended and Restated Certificate of Designation of Rights, Preferences and Privileges of Series A Participating Preferred Stock of VIVUS, Inc. setting forth the rights, powers and preferences of our Series A Participating Preferred Stock, as described below. In addition, we have issued Rights to purchase specified units of Series A Participating Preferred Stock. For more information about the Rights, see "Rights to Purchase Series A Participating Preferred Stock."

In addition, see "Anti-Takeover Effects of Provisions of Our Certificate of Incorporation, Bylaws, Other Agreements and Delaware Law" below.

Series A Participating Preferred Stock

Amount

Under the Amended and Restated Certificate of Designation of Rights, Preferences and Privileges of Series A Participating Preferred Stock, we may issue 700,000 shares of Series A Participating Preferred Stock.

Ranking

The Series A Participating Preferred Stock will rank junior to all other series of the Company's preferred stock as to the payment of dividends and the distribution of assets, unless the terms of any such series provide otherwise.

Proportional Adjustment

In the event that the Company shall at any time after the issuance of any share or shares of Series A Participating Preferred Stock (i) declare any dividend on common stock payable in shares of common stock, (ii) subdivide the outstanding common stock or (iii) combine the outstanding common stock into a smaller number of shares, then in each such case the Company shall simultaneously effect a proportional adjustment to the number of outstanding shares of Series A Participating Preferred Stock.

Dividend Rights

Subject to the prior and superior right of the holders of any shares of any series of preferred stock ranking prior and superior to the shares of Series A Participating Preferred Stock with respect to dividends, the holders of shares of Series A Participating Preferred Stock will be entitled to receive when, as and if declared by the Board out of funds legally available for the purpose, quarterly dividends payable in cash on the last day of March, June, September and December in each year (referred to as a "Quarterly Dividend Payment Date"), commencing on the first Quarterly Dividend Payment Date after the first issuance of a share or fraction of a share of Series A Participating Preferred Stock, in an amount per share (rounded to the nearest cent) equal to 1,000 times the aggregate per share amount of all cash dividends, and 1,000 times the aggregate per share amount (payable in kind) of all non-cash dividends or other distributions other than a dividend payable in shares of common stock or a

subdivision of the outstanding shares of common stock (by reclassification or otherwise), declared on the common stock since the immediately preceding Quarterly Dividend Payment Date, or, with respect to the first Quarterly Dividend Payment Date, since the first issuance of any share or fraction of a share of Series A Participating Preferred Stock.

We will be required to declare a dividend or distribution on the Series A Participating Preferred Stock as provided in the preceding paragraph immediately after we declare a dividend or distribution on the common stock (other than a dividend payable in shares of common stock).

Dividends will begin to accrue on outstanding shares of Series A Participating Preferred Stock from the Quarterly Dividend Payment Date first following the date of issue of such shares of Series A Participating Preferred Stock, unless the date of issue of such shares is prior to the record date for the first Quarterly Dividend Payment Date, in which case dividends on such shares will begin to accrue from the date of issue of such shares, or unless the date of issue is a Quarterly Dividend Payment Date or is a date after the record date for the determination of holders of shares of Series A Participating Preferred Stock entitled to receive a quarterly dividend and before such Quarterly Dividend Payment Date, in either of which events such dividends will begin to accrue from such Quarterly Dividend Payment Date. Accrued but unpaid dividends will not bear interest. Dividends paid on the shares of Series A Participating Preferred Stock in an amount less than the total amount of such dividends at the time accrued and payable on such shares will be allocated pro rata on a share-by-share basis among all such shares at the time outstanding.

Voting Rights

Each share of Series A Participating Preferred Stock will entitle the holder thereof to 1,000 votes on all matters submitted to a vote of the stockholders of the Company. Except as otherwise provided herein or by law, the holders of shares of Series A Participating Preferred Stock and the holders of shares of common stock will vote together as one class on all matters submitted to a vote of stockholders of the Company.

Certain Restrictions on Dividends

Whenever quarterly dividends or other dividends or distributions payable on the Series A Participating Preferred Stock as described above are in arrears, the Company will be restricted in its ability to declare or pay dividends on, redeem or purchase or otherwise acquire for consideration, or make other distributions of shares of stock ranking junior to, or on parity with, the Series A Participating Preferred Stock (subject to specified exceptions for stock ranking on a parity with the Series A Participating Preferred Stock). In such event, the Company will also be restricted in its ability to purchase shares of Series A Participating Preferred Stock.

Distribution Upon Liquidation of Dissolution

Upon any liquidation, dissolution or winding up of the Company, the holders of shares of Series A Participating Preferred Stock will be entitled to receive an aggregate amount per share equal to 1,000 times the aggregate amount to be distributed per share to holders of shares of common stock plus an amount equal to any accrued and unpaid dividends on such shares of Series A Participating Preferred Stock.

Exchange Upon Consolidation or Merger

In the event Company enters into any consolidation, merger, combination or other transaction in which the shares of our common stock are exchanged for or changed into other stock or securities, cash and/or any other property, then the shares of Series A Participating Preferred Stock must at the same time be similarly exchanged or changed in an amount per share equal to 1,000 times the aggregate amount of stock, securities, cash and/or any other property (payable in kind), as the case may be, into which or for which each share of common stock is changed or exchanged.

Rights and Redemption

The shares of Series A Participating Preferred Stock will not be redeemable. There is also no sinking fund provision applicable to our Series A Participating Preferred Stock.

Amendments

Our Certificate of Incorporation may not be amended in any manner which would materially alter or change the powers, preference or special rights of the Series A Participating Preferred Stock so as to affect them adversely without the affirmative vote of the holders of a majority of the outstanding shares of Series A Participating Preferred Stock, voting separately as a series.

Rights to Purchase Series A Participating Preferred Stock

We are a party to the Rights Agreement, dated as of December 30, 2019, with Computershare Trust Company, N.A. On December 30, 2019, our Board authorized and declared a dividend distribution of one Right, initially representing the right to purchase one one-thousandth (0.001) of a share of our Series A Participating Preferred Stock, for each share of our common stock outstanding on January 13, 2020 to the stockholders of record at the close of business on that date. As of December 31, 2019, there were no Rights outstanding, and as of January 13, 2020, there were 10,648,947 Rights outstanding.

We expect to submit the Rights Agreement to a vote at our 2020 annual meeting of stockholders. If our stockholders do not approve the Rights Agreement at the 2020 annual meeting, it will expire at the close of business on the following day.

Exercise of Rights

Prior to the Distribution Date (as defined below), the Rights are not exercisable. On or after the Distribution Date, each Right would initially entitle the holder to purchase one one-thousandth (0.001) of a share of the Series A Participating Preferred Stock for a purchase price of $12.68 (subject to adjustment) (the "Purchase Price"). Under certain circumstances set forth in the Rights Agreement, the Company may suspend the exercisability of the Rights.

The "Distribution Date" means the earlier of (1) the close of business on the tenth business day after the Stock Acquisition Date (as defined below), or (2) the close of business on the tenth business day (or such later date as the Board determines prior to the time at which any person becomes an Acquiring Person) after the date that a tender or exchange offer by any person (other than any "Exempt Person" (as defined below)) is first published, sent or given within the meaning of applicable Securities and Exchange Commission rules, if on the completion of the tender or exchange offer, that person, or any affiliate or associate of that person, would become an Acquiring Person.

Definition of "Acquiring Person"

An "Acquiring Person" is a person (including a legal entity) or group that, together with affiliates and associates of such person or group, acquires beneficial ownership of 4.9% or more of the shares of common stock then outstanding, other than, generally: (A) the Company, its subsidiaries and their respective employee benefit plans or any person or entity organized, appointed or established by the Company for or pursuant to the terms of any such plan; (B) any stockholder that, as of the time of the first public announcement of approval of the Rights Agreement, beneficially owns 4.9% or more of the shares of common stock then outstanding, unless such person thereafter acquires an additional 1% of the outstanding shares of common stock, subject to certain exceptions (including pursuant to a dividend or distribution paid or made by the Company on the outstanding common stock or pursuant to a split or subdivision of the outstanding common stock); (C) a person who becomes an Acquiring Person solely as a result of the Company repurchasing shares of common stock or a stock dividend, stock split, reverse stock split or similar transaction effected by the Company (unless and until such person acquires additional shares, other than in certain specified exempt transactions); (D) certain stockholders who inadvertently or without knowledge of the terms of the Rights, becomes Acquiring Persons and who thereafter reduce the percentage of shares owned below 4.9%; (E) investment advisors to mutual funds, to the extent that such advisor does not hold and no single fund advised by such advisor holds 4.9% or more of the Company's outstanding common stock, and (F) any person whose beneficial ownership of common stock is determined by the Board not to be inconsistent with the purpose of the Rights Agreement.

For purposes of the Rights Agreement, "Exempt Person" generally means a person (including a legal entity) identified in clauses (A), (E) or (F) in the definition of "Acquiring Person" above.

Flip-In

In the event that any person or group becomes an Acquiring Person, each holder of a Right will thereafter have the right to receive, upon exercise, common stock (or, in certain circumstances, cash, property or other securities of the Company), having a value equal to two times the exercise price of the Right. The exercise price is the Purchase Price times the number of units associated with each Right (initially, one). Notwithstanding any of the foregoing, following the occurrence of an Acquiring Person becoming such, all Rights that are, or (under certain circumstances specified in the Rights Agreement) were, beneficially owned by any Acquiring Person or its affiliates and associates and certain transferees thereof will be null and void.

Exchange

At any time following the (1) first date on which there is a public announcement by the Company or an Acquiring Person that an Acquiring Person has become an Acquiring Person or (2) any earlier date on which at least a majority of our Board becomes aware of the existence of an Acquiring Person (the "Stock Acquisition Date") but before the time the Acquiring Person becomes the beneficial owner of 50% or more of the outstanding shares of common stock, the Board may, at its option, exchange the Rights (other than Rights owned by such person or group which have become void), in whole or in part, for common stock at an exchange ratio of one share of common stock per Right (subject to adjustment); provided, that no holder is entitled to receive pursuant to such exchange common stock that would result in a beneficial ownership of more than 4.9% of the common stock then outstanding.

Term and Expiration

The Rights and the Rights Agreement will expire on the earliest of (i) December 30, 2022, (ii) the time at which the Rights are redeemed or exchanged by our Board pursuant to the Rights Agreement, (iii) the repeal of Section 382 of the Internal Revenue Code of 1986, as amended, or any successor statute if the Board determines that the Rights Agreement is no longer necessary or desirable for the preservation of the Tax Benefits, (iv) the first business day following the date on which the Rights Agreement fails to be ratified by the our stockholders at our 2020 annual meeting, and (v) the beginning of a taxable year to which the Board determines that no Tax Benefits may be carried forward.

Redemption

At any time prior to such time as any person becomes an Acquiring Person, we may redeem the Rights in whole, but not in part, at a price of $0.0001 per Right. Immediately upon the action of the Board ordering redemption of the Rights, the Rights will terminate and the only right of the holders of Rights will be to receive the $0.0001 redemption price.

Anti-Dilution Provisions

The Purchase Price payable, and the number of units of Series A Participating Preferred Stock or other securities or property issuable, upon exercise of the Rights, are subject to adjustment from time to time to prevent dilution (i) in the event of a stock dividend on, or a subdivision, combination or reclassification of, the Series A Participating Preferred Stock, (ii) if holders of the Series A Participating Preferred Stock are granted certain rights or warrants to subscribe for Series A Participating Preferred Stock or convertible securities at less than the current market price of the Series A Participating Preferred Stock, or (iii) upon the distribution to holders of the Series A Participating Preferred Stock of evidences of indebtedness or assets (excluding regular quarterly cash dividends) or of subscription rights or warrants (other than those referred to above). Generally, no adjustments to the Purchase Price of less than 1% will be made.

Amendments

For so long as the Rights are then redeemable, any of the provisions of the Rights Agreement may be amended by the Board without the approval of any holders of the Rights. At any time when the Rights are not then redeemable, the provisions of the Rights Agreement may be amended by the Board to make changes which do not adversely affect the interests of holders of Rights, cause the Rights again to become redeemable or cause the Rights

Agreement to become otherwise amendable. In addition, the redemption price under the Rights Agreement may not be amended at any time.

Stockholder Rights

Until a Right is exercised, the holder thereof, as such, will have no rights as the Company's stockholder, including the right to vote or to receive dividends. Stockholder may, depending on circumstances, recognize taxable income in the event that the Rights become exercisable for our Series A Participating Preferred Stock (or other consideration) or in the event the Rights are redeemed.

Anti-Takeover Effects of Provisions of Our Certificate of Incorporation, Bylaws, Other Agreements and Delaware Law

Rights Plan

As described above, the Rights Agreement, also referred to as our rights plan, is designed to protect stockholder value by mitigating the likelihood of an "ownership change" that would result in significant limitations to our ability to use our net operating losses or other tax attributes to offset future income. The 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 rights plan will trigger a dilutive event only if they acquire an additional 1% of the outstanding shares of our common stock. For more information about the Rights and the Rights Agreement, see "Rights to Purchase Series A Participating Preferred Stock."

Provisions of Our Certificate of Incorporation and Bylaws; Delaware Anti-Takeover Statute

Some provisions of our Certificate of Incorporation and Bylaws could delay or prevent a change in control of our Company, including provisions which:

- 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 our common stock;
- prohibit stockholder action by written consent (as described below);
- 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 the General Corporation Law of the State of Delaware. 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 governing 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, and may delay, deter or prevent a tender offer or takeover attempt that a stockholder might consider in its best interest.

Elimination of Stockholder Action by Written Consent

Under our Certificate of Incorporation, no action may be taken by the stockholders of the Company except at an annual or special meeting of the stockholders called in accordance with the Bylaws, and no action may be taken by our stockholders by written consent.

Exhibit 21.1

LIST OF SUBSIDIARIES

The following is a list of subsidiaries of VIVUS, Inc.

1. Vivus Pharmaceuticals Limited (British Columbia), a wholly owned subsidiary of VIVUS, Inc.

2. VIVUS BV (Netherlands), a wholly owned subsidiary of VIVUS, Inc.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Forms S-8 (No. 333-57374, No. 333-73394, No. 333-104287, No. 333-107066, No. 333 142354, No. 333 150647, No. 333 157787, No. 333 164921, No. 333 168106, No. 333 175926, No. 333 199881, No. 333 215089, No. 333-222089, No. 333-225367, No. 333-227966 and No. 333-233053) and Form S-3 (No. 333 227353) of our report dated March 3, 2020 relating to the consolidated financial statements and financial statement schedule of VIVUS, Inc. (which report expresses an unqualified opinion and includes an explanatory paragraph related to substantial doubt about the Company's ability to continue as a going concern), which appears in this Annual Report on Form 10-K.

/s/ OUM & CO. LLP
San Francisco, California
March 3, 2020

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT

TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, John P. Amos, Chief Executive Officer, certify that:

1. I have reviewed this annual report on Form 10-K of VIVUS, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 3, 2020

By: /s/ John P. Amos
Name: John P. Amos
Title: *Chief Executive Officer*

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT

TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Mark K. Oki, Senior Vice President, Chief Financial Officer and Chief Accounting Officer, certify that:

1. I have reviewed this annual report on Form 10-K of VIVUS, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 3, 2020

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

Exhibit 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER

PURSUANT TO

18 U.S.C. SECTION 1350,

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, John P. Amos, Chief Executive Officer of VIVUS, Inc., certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report of VIVUS, Inc. on Form 10-K for the period ending December 31, 2019 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Annual Report on Form 10-K fairly presents, in all material respects, the financial condition and results of operations of VIVUS, Inc. This written statement is being furnished to the Securities and Exchange Commission as an exhibit to such Annual Report on Form 10-K. A signed original of this statement has been provided to VIVUS, Inc. and will be retained by VIVUS, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Date: March 3, 2020

By: /s/ John P. Amos
John P. Amos
Chief Executive Officer

I, Mark K. Oki, Senior Vice President, Chief Financial Officer and Chief Accounting Officer, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report of VIVUS, Inc. on Form 10-K for the period ending December 31, 2019 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Annual Report on Form 10-K fairly presents, in all material respects, the financial condition and results of operations of VIVUS, Inc. This written statement is being furnished to the Securities and Exchange Commission as an exhibit to such Annual Report on Form 10-K. A signed original of this statement has been provided to VIVUS, Inc. and will be retained by VIVUS, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Date: March 3, 2020

By: /s/ Mark K. Oki
Mark K. Oki
Senior Vice President, Chief Financial Officer and Chief Accounting Officer