# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

	Form 10-K
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ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d	OF THE SECURITIES EXCHANGE ACT OF 1934 cal year ended December 31, 2016 or
☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR	15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
	period from to
	uission file number: 001-36075
Exp	ke Pharma, Inc.
	REFILETING, THE.  Registrant as Specified in its Charter)
 Delaware	20-8447886
(State or Other Jurisdiction of	(I.R.S. Employer
Incorporation or Organization)	Identification No.)
420 Stevens Avenue, Suite 370	00000
Solana Beach, California (Address of Principal Executive Offices)	92075 (Zip Code)
(Address of Finespar Executive States)	858-345-1494
	Telephone Number, Including Area Code) red pursuant to Section 12(b) of the Act:
Title of Each Class	Name of Each Exchange on Which Registered
Common Stock, par value \$0.0001 per share	The NASDAQ Capital Market
Securiues registe	red 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 pursual	
Indicate by check mark whether the registrant: (1) has filed all reports require	red to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 ports), and (2) has been subject to such filing requirements for the past 90 days. Yes $\boxtimes$ No $\square$
·	nd posted on its corporate Web site, if any, every Interactive Data File required to be submitted and the preceding 12 months (or for such shorter period that the registrant was required to submit and post
Indicate by check mark if disclosure of delinquent filers pursuant to Item 40 knowledge, in definitive proxy or information statements incorporated by referen	5 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's nce in Part III of this Form 10-K or any amendment to this Form 10-K. $\Box$
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 1	accelerated filer, a non-accelerated filer or a smaller reporting company. See definitions of "large 2b-2 of the Exchange Act. (Check one):
Large accelerated filer	Accelerated filer $\Box$
Non-accelerated filer	Smaller reporting company
Indicate by check mark whether the registrant is a shell company (as defined	l in Rule 12b-2 of the Securities Exchange Act of 1934). Yes □ No ⊠
50 0	filiates of the registrant as of the last business day of the registrant's most recently completed second registrant's common stock on the NASDAQ Capital Market of \$6.85 per share.
The number of outstanding shares of the registrant's common stock, par value	ue \$0.0001 per share, as of March 10, 2017 was 15,388,325.
DOCUMENTS	INCORPORATED BY REFERENCE
	curities and Exchange Commission pursuant to Regulation 14A in connection with the registrant's 2017 of, are incorporated by reference into Part III of this Form 10-K. Such proxy statement will be filed with and of the registrant's fiscal year ended December 31, 2016.

# EVOKE PHARMA, INC.

# FORM 10-K — ANNUAL REPORT

# For the Fiscal Year Ended December 31, 2016

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#### PART I

#### **Forward-Looking Statements and Market Data**

This Annual Report on Form 10-K contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. All statements other than statements of historical facts contained in this Annual Report on Form 10-K, including statements regarding our future results of operations and financial position, business strategy, prospective products, product approvals, regulatory developments, research and development costs, timing and likelihood of success, plans and objectives of management for future operations, and future results of current and anticipated products are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statement. The forward-looking statements are contained principally in the sections entitled "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business." In some cases, you can identify forwardlooking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these terms or other similar expressions. Although we believe the expectations reflected in these forward-looking statements are reasonable, such statements are inherently subject to risk and we can give no assurances that our expectations will prove to be correct. Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements, which speak only as of the date of this Annual Report on Form 10-K. You should read this Annual Report on Form 10-K completely. As a result of many factors, including without limitation those set forth under "Risk Factors" under Item 1A of this Part I below, and elsewhere in this Annual Report on Form 10-K, our actual results may differ materially from those anticipated in these forward-looking statements. Except as required by applicable law, we undertake no obligation to update these forward-looking statements to reflect events or circumstances after the date of this report or to reflect actual outcomes. For all forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

This Annual Report on Form 10-K also contains estimates, projections and other information concerning our industry, our business, and the markets for Gimoti™ (formerly known as EVK-001), including data regarding the estimated size of those markets, their projected growth rates, the incidence of certain medical conditions, statements that certain drugs or classes of drugs are the most widely prescribed in the United States or other markets, the perceptions and preferences of patients and physicians regarding certain therapies and other prescription, prescriber and patient data, as well as data regarding market research, estimates and forecasts prepared by our management. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources

We use our registered trademarks, EVOKE PHARMA and Gimoti, in this Annual Report on Form 10-K. This Annual Report on Form 10-K also includes trademarks, tradenames and service marks that are the property of other organizations. Solely for convenience, trademarks and tradenames referred to in this Annual Report on Form 10-K appear without the ® and TM symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or that the applicable owner will not assert its rights, to these trademarks and tradenames.

Unless the context requires otherwise, references in this Annual Report on Form 10-K to "Evoke," "we," "us" and "our" refer to Evoke Pharma, Inc.

#### Item 1. Business

# Overview

We are a specialty pharmaceutical company focused primarily on the development of drugs to treat gastrointestinal, or GI, disorders and diseases. We are developing Gimoti, an investigational metoclopramide nasal spray for the relief of symptoms associated with acute and recurrent diabetic gastroparesis in women. Diabetic gastroparesis is a GI disorder afflicting millions of patients worldwide in which the stomach takes too long to empty its contents resulting in serious digestive system symptoms and other complications. Metoclopramide is the only product currently approved in the United States to treat the symptoms associated with acute and recurrent diabetic gastroparesis, and is currently available only in oral tablet and injection dose forms. Gimoti is a novel formulation of this drug, designed to provide systemic delivery of metoclopramide through nasal spray administration.

Gastroparesis is a condition of delayed gastric emptying in the absence of mechanical obstruction. In patients with gastroparesis, food remains in the stomach for a longer time than normal, leading to a variety of GI symptoms and systemic metabolic complications. Gastroparesis typically occurs in individuals with diabetes, but is also observed in patients with prior gastric surgery, a preceding infectious illness, pseudo-obstruction, collagen vascular disorders and anorexia nervosa. In some patients with gastroparesis, no cause

can be identified, which is referred to as idiopathic gastroparesis. According to the American Motility Society Task Force on Gastroparesis, the prevalence of gastroparesis is estimated to be up to 4% of the United States population. Signs and symptoms of gastroparesis may include nausea, early satiety, bloating, prolonged fullness, upper abdominal pain, vomiting and retching. Patients may experience any combination of signs and symptoms with varying degrees of severity.

Patients with diabetic gastroparesis may experience impaired glucose control due to unpredictable gastric emptying and altered absorption of orally administered hypoglycemic drugs, which may affect the severity of their signs and symptoms. Severe signs and symptoms may cause complications such as malnutrition, esophagitis, and Mallory-Weiss tears. Gastroparesis adversely affects the lives of patients with the disease, resulting in decreased social interaction, poor work functionality, and the development of anxiety and/or depression.

We believe nasal spray administration has the potential to provide our target population of female diabetic gastroparesis patients with a preferred treatment option over the tablet formulation for several important reasons: (1) unlike metoclopramide tablets which may have erratic absorption due to gastroparesis itself, Gimoti is designed to bypass the digestive system to allow for more predictable drug absorption, even when patients are vomiting; (2) the absorption of Gimoti occurs across the thin mucosa in the nasal cavity to allow for rapid and predictable drug administration through the nasal route for patients with delayed gastric emptying and during episodes of vomiting; and (3) for gastroparesis patients experiencing nausea, a nasal spray may be better tolerated than an oral medication.

We have evaluated Gimoti in a multicenter, randomized, double-blind, placebo-controlled parallel group, dose-ranging Phase 2b clinical trial in 287 male and female subjects with diabetic gastroparesis where two doses of Gimoti were observed to be effective in improving the most prevalent and clinically relevant symptoms associated with gastroparesis in women while exhibiting a favorable safety profile. Subjects received either Gimoti or placebo four times daily for 28 days.

In July 2016, we announced results from a Phase 3 clinical trial of Gimoti in female patients with symptoms associated with acute and recurrent diabetic gastroparesis. This Phase 3 clinical trial was a multicenter, randomized, double-blind, placebo-controlled, parallel group clinical trial to evaluate the efficacy, safety and population pharmacokinetics, or PK, of Gimoti in adult female patients with diabetic gastroparesis. Subjects received either Gimoti or placebo four times daily for 28 days. The primary endpoint was the change in symptoms from the baseline period to Week 4 as measured using a proprietary Patient Reported Outcome, or PRO, instrument. On a daily basis, subjects reported the frequency and severity of their gastroparesis signs and symptoms using a telephone diary. The subjects' daily symptom scores were the basis for calculating their weekly scores using the PRO instrument.

A total of 205 women (mean age 52.7 years, 88% with type 2 diabetes; 79% postmenopausal, 51% using insulin, mean duration of diabetes was 12.9 years and the mean baseline glycated hemoglobin (HbA1c) was 7.5%) were randomized and 93% completed the study. Other demographic and baseline characteristics were similar between treatment groups. The primary endpoint for the intent to treat, or ITT, population was not statistically significant (*p*=0.881), however, in exploratory analyses, a statistically significant treatment effect was seen at Weeks 1 to 3 for patients with higher baseline symptom scores (moderate to severe) in the ITT population (n=105) and for all four weeks for the per protocol population. The per protocol population included all randomized subjects who completed the 28-day treatment period, had no protocol violations or major protocol deviations, had at least 75% overall diary compliance (*i.e.*, 21 or more completed diaries) during the treatment period, and had a non-missing weekly mean daily value for the gastroparesis symptoms assessment, or GSA, total score for Week 4. Five or more daily GSA total scores must be available during a given week for the weekly mean to be non-missing. Statistically significant treatment effects were seen for nausea and upper abdominal pain for all four study weeks. Reports of treatment-emergent adverse events were similar in both groups (36% Gimoti and 35% placebo) and most were mild or moderate in severity. There were slightly more reports of nasal irritation in subjects receiving placebo than in subjects receiving Gimoti. These safety results were consistent with findings from previous Gimoti studies that showed the nasal formulation of metoclopramide has a favorable safety profile and was well-tolerated by healthy volunteers and patients with diabetic gastroparesis.

In September 2016, we announced the completion of a pre-New Drug Application, or NDA, meeting with the U.S. Food and Drug Administration, or FDA. The purpose of the meeting was to discuss a proposed NDA and to confirm various regulatory, chemistry, manufacturing, and control, or CMC, and non-clinical requirements for our potential NDA submission for Gimoti. At the pre-NDA meeting, the FDA reviewed a portion of our data package being prepared for the NDA submission. Based on the review, discussion, and minutes received, we believe that the available data would be sufficient for submission of those portions of an NDA utilizing the 505(b)(2) pathway, with acceptance of the final NDA subject to the FDA's review of the complete package.

In December 2016, we announced the completion of a second pre-NDA meeting with FDA, in which FDA agreed that a comparative exposure PK trial was acceptable as a basis for submission of a Gimoti NDA. The comparative exposure PK trial will serve as a portion of the full 505(b)(2) data package to include prior efficacy and safety data developed by us and FDA's prior findings of safety and efficacy for the Listed Drug, Reglan Tablets. We expect to begin and complete the comparative exposure PK trial in the second half of 2017, followed by a potential NDA submission in late 2017 or early 2018.

In February 2017, we announced that we received a letter from the FDA exempting Gimoti from a Human Factors, or HF, Validation study requirement prior to submission of the NDA. In February 2016, FDA published new guidance entitled "Applying Human Factors and Usability Engineering to Medical Devices," which requires drug products classified as a drug/device combination, such as Gimoti, undergo evaluation that may require an HF Validation study as described in FDA's Guidance.

To comply with this new FDA Guidance, we evaluated the need for an HF Validation study and submitted an HF assessment report to FDA for Gimoti using a Failure Mode and Effects Analysis risk analysis taking into account the intended uses, users, use environments, product-user interface, and associated medical factors. In their written response, FDA stated we had adequately considered the risks associated with the proposed Gimoti nasal spray and determined that an HF Validation study is not needed at this time. The favorable FDA response helps reduce potential risks and saves additional resources in the development process, including NDA preparation.

In 2014, we also completed a thorough ECG (QT/QTc) study and reported positive results in December 2014. Prolongation of the QT interval may increase the risk for cardiac arrhythmias. Data from the thorough ECG (QT/QTc) trial met the pre-specified primary endpoint, demonstrating that Gimoti, at therapeutic and supratherapeutic doses, did not prolong the QT/QTc interval in healthy subjects.

We have also conducted a companion clinical trial with Gimoti in male subjects with symptoms associated with acute and recurrent diabetic gastroparesis to assess the safety and efficacy of Gimoti in men. The male companion trial was initiated in May 2014 and the design was the same as the Phase 3 trial in women. This trial was requested by FDA to confirm the Phase 2b trial results and to capture additional safety data in men. This trial was not required for submission of the Gimoti NDA for women; however, we expect to include safety data from this trial in the NDA submission. During November 2016, we determined the trial showed futility so that, even if the trial had fully been enrolled, the results would not have differed. As we anticipated at the beginning of the trial, based on the prior Phase 2b data, the results showed no benefit for Gimoti versus placebo in men. The safety results were consistent with findings from previous Gimoti studies that showed the nasal formulation of metoclopramide has a favorable safety profile and is well-tolerated by patients with diabetic gastroparesis.

We have no products approved for sale, and we have not generated any revenue from product sales or other arrangements. We have primarily funded our operations through the sale of our convertible preferred stock prior to our initial public offering, or IPO, in September 2013, borrowings under our bank loans and the sale of shares of our common stock on the NASDAQ Capital Market. We have incurred losses in each year since our inception. Substantially all of our operating losses resulted from expenses incurred in connection with advancing Gimoti through development activities and general and administrative costs associated with our operations. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. We may never become profitable, or if we do, we may not be able to sustain profitability on a recurring basis.

# **Business Strategy**

Our objective is to develop and bring to market products to treat acute and chronic GI motility disorders that are not satisfactorily treated with current therapies and that represent significant market opportunities. Our business strategy is to:

- *Pursue regulatory approval for Gimoti*. We have completed our Phase 3 trial of Gimoti in female subjects suffering from diabetic gastroparesis and are focused on preparing to conduct a comparative exposure PK trial to serve as a basis for submission of an NDA for Gimoti. We expect to begin and complete the comparative exposure PK trial in 2017, followed by a potential NDA submission in late 2017 or early 2018.
- Seek partnerships to accelerate and maximize the potential for Gimoti. As we continue to generate data on Gimoti, we are seeking partnering opportunities with pharmaceutical companies that have established development and sales and marketing capabilities to potentially enhance and accelerate the development and commercialization of Gimoti.
- Explore building in-house capabilities to potentially commercialize Gimoti in the United States. As Gimoti progresses through its Phase 3 clinical program, in addition to partnering opportunities, we are evaluating the development of a specialty sales force and marketing capabilities, either internally or externally, to allow us to directly market Gimoti in the United States, if approved by FDA.
- Explore regulatory approval of Gimoti outside the United States. We will initially seek approval of Gimoti in the United States and then will evaluate the market opportunity in other countries.
- Evaluate the development and/or commercialization of other therapies for GI motility disorders. Similar to our initial focus on gastroparesis, we will evaluate opportunities to in-license or acquire other product candidates, as well as commercial products, to treat patients suffering from predominantly GI disorders, seeking to identify areas of high unmet medical needs with limited treatment options.

# The Gastrointestinal Market

The health of the GI system has a major effect on an individual's daily activities and quality of life. A retrospective review published by the National Institute of Diabetes and Digestive and Kidney Diseases estimated that in 2004 there were more than 72 million ambulatory care visits with a diagnosis of a GI disorder in the United States alone. The annual cost of these GI disorders in 2004, not including digestive cancers and viral diseases, was estimated to be greater than \$114 billion in direct and indirect expenditures, including hospital, physician and nursing services as well as over-the-counter and prescription drugs.

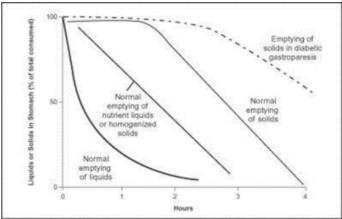
In 2004, the total cost of GI prescription drugs in the United States was \$12.3 billion, and over half of this cost (\$7.7 billion) was associated with drugs prescribed for gastroesophageal reflux disease, or GERD. Peptic ulcer disease, hepatitis C, irritable bowel syndrome, or IBS, and inflammatory bowel disease, or IBD, were major contributors to the remaining drug cost. Historically GI product development efforts have focused on indications with the largest patient populations such as GERD, constipation, peptic ulcers and IBS. As a result, limited innovation has occurred in other segments of the GI market, such as upper GI motility disorders, even though these disorders affect several million patients worldwide. Consequently, due to the limited treatment options available for upper GI motility disorders, we believe there is a substantial market opportunity for us to address significant unmet medical needs, initially for diabetic gastroparesis.

# **GI Motility Disorders**

Motility disorders are one of the most common GI disorders. Motility disorders affect the orderly contractions or relaxation of the GI tract which move contents forward and prevent backwards egress. This is important in the normal movement of food through the GI tract. Motility disorders are sometimes referred to as functional GI disorders to highlight that many abnormalities in stomach function can occur even when anatomic structures appear normal. Functional GI disorders affect the upper and lower GI tract and include gastroparesis, GERD, functional dyspepsia, constipation and IBS. It has been estimated by the International Foundation for Functional Gastrointestinal Disorders that one in four people in the United States suffer from functional GI disorders, having signs and symptoms such as abdominal pain, nausea, constipation, diarrhea, bloating, decreased appetite, early satiety, swallowing difficulties, heartburn, vomiting and/or incontinence.

#### Gastroparesis

Gastroparesis is a debilitating, chronic condition that has a significant impact on patients' lives. It is characterized by slow or delayed gastric emptying and evidence of gastric retention in the absence of mechanical obstruction. Muscular contractions in the stomach, which move food into the intestine, may be too slow, out of rhythm or erratic. The following graph depicts the timing associated with the emptying of solids in patients with diabetic gastroparesis compared to normal individuals:



Camilleri M. New England Journal of Medicine 2007

The stomach is a muscular sac between the esophagus and the small intestine where the digestion of food begins. The stomach makes acids and enzymes referred to as gastric juices which are mixed with food by the churning action of the stomach muscles. Peristalsis is the contraction and relaxation of the stomach muscles to physically breakdown food and propel it forward. The crushed and mixed food is liquefied to form chyme and is pushed through the pyloric canal into the small intestine in a controlled and regulated manner.

In gastroparesis, the stomach does not perform these functions normally, causing characteristic flares of signs and symptoms that include nausea, early satiety, prolonged fullness, bloating, upper abdominal pain, vomiting and retching. As a result of these signs and symptoms, patients may limit their food and liquid intake leading to poor nutrition, experience dehydration and electrolyte

disturbances due to vomiting, and have poor blood glucose control, ultimately requiring hospitalization. If left untreated or not adequately treated, gastroparesis causes significant acute and chronic medical problems, including additional diabetic complications resulting from poor glucose control.

# Gastroparesis in the Hospital Setting

When patients experience a flare of their gastroparesis symptoms that cannot be adequately managed by oral medications, they may be hospitalized for hydration, parenteral nutrition, and correction of abnormal blood glucose or electrolyte levels. In this setting, intravenous metoclopramide is the first line of treatment. Typically, these diabetic patients with severe gastroparesis symptoms remain in the hospital until they are stabilized and able to be effectively treated with oral metoclopramide. These hospitalizations are costly and expose patients to increased risks, including hospital-acquired infections. The number of patients with gastroparesis that require hospitalization due to their disease is growing, according to a study published in the *American Journal of Gastroenterology* in 2008. Additionally, the study reported, from 1995 to 2004, total hospitalizations with a primary diagnosis of gastroparesis increased 158%. Hospital admissions for patients with gastroparesis as the secondary diagnosis increased 136%. The average length of stay for a patient is approximately six days at an estimated cost of approximately \$22,000. Compared to the other four most common upper GI admission diagnoses (GERD, gastric ulcer, gastritis or nonspecific nausea/vomiting), gastroparesis had the longest length of stay and one of the highest total charges per stay. Additionally, the study estimates that costs associated with gastroparesis as the primary or secondary diagnosis for admission exceeded \$3.5 billion in 2004.

A study of patients in clinics at the University of Pittsburgh Medical Center between January 2004 and December 2008, published in the *Journal of Gastroenterology* and *Hepatology*, showed that patients with diabetic or post-surgical gastroparesis had significantly more emergency room visits than other gastroparesis groups. The study reinforced the view that gastroparesis constitutes a significant burden for patients and the healthcare system, with more than one-third of patients requiring hospitalization. The number of emergency room visits and annual days of inpatient treatment were comparable to patients with Crohn's disease. The study indicated that patients received an average of 6.7 prescriptions on admission. Eighty percent of the patients identified in the University of Pittsburgh study were women.

# Etiology

Gastroparesis can be a manifestation of many systemic illnesses, arise as a complication of select surgical procedures, or develop due to unknown causes. Any disease inducing neuromuscular dysfunction of the GI tract can result in gastroparesis, with diabetes being one of the leading known causes. In a 2007 study published in *Current Gastroenterology Reports*, 29% of gastroparesis cases were found in association with diabetes, 13% developed as a complication of surgery and 36% were due to unknown causes. According to the American Motility Society Task Force on Gastroparesis, up to 4% of the U.S. population experiences symptomatic manifestations of gastroparesis. As the incidence of diabetes rises worldwide, the prevalence of gastroparesis is expected to rise correspondingly.

The most common identified cause of gastroparesis is diabetes mellitus. The underlying mechanism of diabetic gastroparesis is unknown, though it is thought to be related in part to neuropathic changes in the vagus nerve and/or the myenteric plexus. Prolonged elevated serum glucose levels are also associated with vagus nerve damage. The vagus nerve controls the movement of food through the digestive tract and when it is damaged, movement of food through the GI tract may be abnormal. The prevalence of diabetes in the United States is rapidly rising, with the Centers for Disease Control estimating that one in ten adults currently suffer from the disease. Sedentary lifestyles, poor dietary habits and a consequent rising prevalence of obesity are expected to cause this number to grow substantially. According to a study published in the *Journal of Gastrointestinal and Liver Diseases* in July 2010, between 25% and 55% of type 1 and 15% and 30% of type 2 diabetics suffer from symptoms associated with the condition and diabetics are 29% of the total gastroparesis population.

A 2007 study published in *Current Gastroenterology Reports* states that approximately 36% of gastroparesis patients suffer from idiopathic gastroparesis. The development of idiopathic gastroparesis is thought to be related to loss of myenteric ganglion cells in the distal large bowel (myenteric hypoganglionosis) and reduction in the interstitial cells of Cajal, which help control contraction of the smooth muscle in the GI tract.

Post-surgical gastroparesis is a smaller subset of the total patient pool and accounts for approximately 13% of all cases of the disease, according to a 2007 study published in Current Gastroenterology Reports. Post-surgical gastroparesis is often associated with peptic ulcer surgery, bariatric procedures or esophageal procedures and is thought to result from damage/desensitization of the vagus nerve.

# Prevalence

In 2012, the American Diabetes Association estimated that diabetes affects approximately 29.1 million people of all ages in the United States, equating to about 9.3% of the population. Based on prevalence data, the potential gastroparesis patient pool in the United States is approximately 12 to 16 million adults with women making up 82% of this population, according to a 2007 study published in *Current Gastroenterology Reports*.

There are 2.3 million diabetic patients with moderate or severe gastroparesis symptoms who are seeking treatment in the United States by a health care professional, according to a study presented at the Digestive Disease Week 2013 conference in Orlando, Florida. When patients do receive treatment for gastroparesis, multiple medications are frequently used to address the individual signs and symptoms of gastroparesis. For example, patients may receive anti-emetics for nausea and vomiting and opioids for abdominal pain, which can exacerbate delayed gastric emptying in patients with gastroparesis.

# **Unmet Needs in Gastroparesis Treatment**

Market research and physician interviews demonstrate that existing treatment options for diabetic gastroparesis are inadequate and there is a high level of interest in effective outpatient options for managing patients with gastroparesis symptoms. The market is currently served by oral metoclopramide, intravenous metoclopramide, and the oral disintegrating tablet, or ODT, formulation of metoclopramide (Metozolv® ODT), with approximately 4.5 million prescriptions in the United States per year, according to IMS Health.

Due to the limited availability of FDA-approved treatments for gastroparesis, physicians may resort to using medications "off-label" in an attempt to address individual symptoms experienced by patients. Off-label therapies are pharmaceuticals prescribed by physicians for an unapproved indication or in an unapproved age group, unapproved dose or unapproved form of administration. Examples of drugs used without FDA approval in gastroparesis include erythromycin and Botox® injected via endoscopic procedure directly into the lower gastric sphincter. Previously-approved drugs, such as cisapride and tegaserod, are no longer commercially available in the United States because of safety concerns. Domperidone has never been approved by FDA but is obtained through certain compounding pharmacies for individual patients under special FDA usage rules.

Gimoti is a non-oral, promotility and anti-emetic treatment that we believe has the potential to significantly improve the standard of care for female gastroparesis patients. If metoclopramide nasal spray is approved for the treatment of diabetic gastroparesis in women, patients and physicians will have access to an outpatient therapy that could be administered and absorbed even when patients are experiencing delayed gastric emptying or nausea and vomiting.

# Our Solution: Gimoti (Metoclopramide Nasal Spray)

We are developing Gimoti, a dopamine antagonist / mixed 5-HT3 antagonist / 5-HT4 agonist with promotility and anti-emetic effects, for the relief of symptoms associated with acute and recurrent diabetic gastroparesis in women. Since oral metoclopramide was approved by FDA in 1980, oral and intravenous metoclopramide have been the only products approved in the United States to treat gastroparesis. Gimoti is a novel formulation of metoclopramide offering systemic delivery by nasal spray administration.

We are developing the nasal formulation of metoclopramide to provide our targeted patient population with acute or recurrent symptoms of diabetic gastroparesis with a product that can be systemically delivered as an alternative to the oral or intravenous routes of administration. Nasal delivery is possible because the mucosa of the nasal cavity is a single epithelial cell layer which is well-vascularized and allows metoclopramide molecules to be transferred directly to the systemic circulation. There is no first pass liver metabolism required prior to onset of action. Since gastroparesis is a disease that halts or slows the movement of the contents of the stomach to the small intestine, oral drug administration is often compromised. Unlike the oral tablet formulation of metoclopramide, we believe that Gimoti may be tolerated even when patients are experiencing nausea and vomiting. The nasal formulation may also provide a predictable and consistent means of delivering metoclopramide in patients with delayed gastric emptying and/or frequent vomiting.

A nasal spray formulation of metoclopramide could offer an alternative route of administration for female patients with severe symptoms of diabetic gastroparesis receiving the parenteral formulation of metoclopramide. Following hospitalization for intravenous metoclopramide, a nasal spray formulation would also provide a non-oral option for the transition to an outpatient treatment.

# Phase 3 Clinical Trial

In July 2016, we announced results from a Phase 3 clinical trial of Gimoti in female patients with symptoms associated with acute and recurrent diabetic gastroparesis. This U.S.-based, multicenter, randomized, double-blind, placebo-controlled, parallel group clinical trial evaluated the efficacy, safety and population PK of Gimoti in adult female patients with diabetic gastroparesis. Subjects received either Gimoti or placebo four times daily for 28 days. The primary endpoint was the change in symptoms from the baseline period to Week 4 as measured using a proprietary PRO instrument. On a daily basis, subjects reported the frequency and severity of their gastroparesis signs and symptoms using a telephone diary. The subjects' daily symptom scores were the basis for calculating their weekly scores using the PRO instrument.

A total of 205 women (mean age 52.7 years, 88% with type 2 diabetes; 79% postmenopausal, 51% using insulin, mean duration of diabetes 12.9 years, mean baseline glycosylated hemoglobin (HbA1c) 7.5%) were randomized and 93% completed the study. The primary endpoint for the ITT population was not statistically significant (*p*=0.881); however, in exploratory analyses, a treatment

effect was seen at Weeks 1 to 3 for patients with higher baseline symptom scores (moderate to severe) in the ITT population (n=105) and for all four weeks for the per protocol population (see Table 1 below). There were also clinically and statistically significant improvements in nausea and abdominal pain, which are two of the more severe and debilitating symptoms of gastroparesis (see Table 2 below).

In July 2015, the FDA issued a draft guidance document regarding the clinical evaluation of drugs for the treatment of gastroparesis, in which FDA states that in order to optimize the ability to demonstrate a treatment effect, clinical trials in this indication should enroll patients with higher symptom severity (moderate to severe). The improvements observed in our exploratory analyses of our Phase 3 study focused on this subset of patients enrolled in the study. At the time this draft guidance was issued, our Phase 3 study, designed to include patients with a range of symptom severity, had been actively enrolling for more than a year. The overall efficacy results were not significant, due in large part to the patients with less severe symptoms who responded to placebo. Importantly, patients with more severe symptoms experienced a statistically-significant treatment effect with Gimoti, consistent with the recommendation in the draft guidance on clinical studies of gastroparesis. Reports of treatment-emergent adverse events were similar in both groups (36% Gimoti and 35% placebo) and most were mild or moderate in severity. There were slightly more reports of nasal irritation in subjects receiving placebo than in subjects receiving Gimoti. In particular, there were no adverse events of special interest, such as the central nervous system, or CNS, effects observed (see Table 3 below).

These safety results were consistent with findings from previous Gimoti studies that showed the nasal formulation of metoclopramide has a favorable safety profile and is well-tolerated by healthy volunteers and patients with diabetic gastroparesis. There have been no reports of tardive dyskinesia among the 1,311 exposed healthy volunteers and patients over the metoclopramide nasal spray clinical development program.

Table 1: Phase 3 Change from Baseline in Daily Total Symptom Scores by Week in Analysis Populations with Moderate to Severe Symptoms at Baseline

	Time	Placebo1		
Population	Period		Gimoti <sup>1</sup>	<i>p</i> -value <sup>2</sup>
		(N = 53)	(N = 52)	
	Week 1	-0.387	-0.588	0.036
	Week 2	-0.614	-0.950	0.025
Intent-to-Treat	Week 3	-0.749	-1.096	0.039
	Week 4	-0.856	-1.220	0.085*
		(N = 40)	(N = 38)	
	Week 1	-0.362	-0.623	0.019
	Week 2	-0.625	-1.040	0.015
Per Protocol	Week 3	-0.714	-1.286	0.003
	Week 4	-0.841	-1.373	0.014

Table 2: Phase 3 Change from Baseline in Daily Nausea and Upper Abdominal Pain Scores by Week in Intent-to-Treat Population with Moderate to Severe Symptoms at Baseline

	Time	Placebo1	Gimoti <sup>1</sup>	
Symptom	Period	(N=53)	(N = 52)	<i>p</i> -value <sup>2</sup>
	Week 1	-0.370	-0.859	0.001
Nausea	Week 2	-0.696	-1.149	0.032*
Indused	Week 3	-0.818	-1.242	0.043
	Week 4	-0.905	-1.404	0.027
Upper Abdominal Pain	Week 1	-0.394	-0.641	0.025
	Week 2	-0.554	-0.990	0.016
	Week 3	-0.690	-1.194	0.008
	Week 4	-0.791	-1.218	0.047

<sup>&</sup>lt;sup>1</sup> LSMean from ANCOVA

Table 3: Selected Treatment-Emergent Adverse Events Reported by More than 2 Subjects in Any Treatment Group

	Placebo	Gimoti
Adverse Event	(N=103)	(N=102)
Headache	7 (7%)	5 (5%)
Nasal discomfort	4 (4%)	1 (1%)
Epistaxis	2 (2%)	1 (1%)
Fatigue	1 (1%)	2 (2%)

In December 2016, we announced the completion of a second pre-NDA meeting with FDA. The purpose of the meeting was to discuss efficacy and safety results from the Phase 3 clinical trial and submission strategies for an NDA. At the pre-NDA meeting, the FDA agreed that a comparative exposure PK trial was acceptable as a basis for submission of a Gimoti NDA. The comparative exposure PK trial will serve as a portion of the full 505(b)(2) data package to include prior efficacy and safety data developed by us and the FDA's prior findings of safety and efficacy for the Listed Drug, Reglan Tablets. We expect to begin and complete the comparative exposure PK trial in the second half of 2017, followed by a potential NDA submission in of 2017 or early 2018.

In the first pre-NDA meeting with FDA held in August 2016, we confirmed various regulatory, CMC, and non-clinical requirements for our potential NDA submission. In February 2017, we announced that we received a letter from the FDA exempting Gimoti from a HF Validation study requirement prior to submission of the NDA.

# **Male Companion Trial**

We also conducted a companion clinical trial with Gimoti in male patients with symptoms associated with acute and recurrent diabetic gastroparesis to assess the safety and efficacy of Gimoti in men. This trial was requested by FDA to confirm the Phase 2b trial results and to capture additional safety data in men. The design of the male study was the same as the study in women and was initiated in April 2014 at sites also enrolling the Phase 3 study in women. Given that diabetic gastroparesis is predominately a female disorder, enrollment was challenging and the trial spontaneously stopped enrolling with 53 randomized male subjects (26 on Gimoti).

In November 2016, the data from the study were analyzed and futility was demonstrated. Results confirmed that even if the trial had fully enrolled, the results would not have differed. As we anticipated at the beginning of the trial, based on the prior Phase 2b data, the results showed no statistically significant efficacy in men. The safety profile for Gimoti was well-tolerated and the safety profile was comparable to placebo. The male trial is not required for submission of the Gimoti NDA for women; however, we expect to include safety data from this study in the NDA submission.

 $<sup>^2</sup>$  p-value is obtained from an ANCOVA model with fixed effect for treatment group and the baseline value as a covariate. If the normality assumption was not met, the p-value was obtained from a rank ANCOVA test and denoted with an \*.

# Phase 2b Clinical Trial

We have evaluated Gimoti in a multicenter, randomized, double-blind, placebo-controlled parallel group, dose-ranging Phase 2b clinical trial in 287 subjects (71% female) with diabetic gastroparesis. Subjects in the trial were between the ages of 18 and 75, with a history of diabetes (type 1 and type 2) and diabetic gastroparesis, who had a baseline modified Gastroparesis Cardinal Symptom Index Daily Diary, or mGCSI-DD, of >2 and <4 for the seven days prior to randomization to blinded study drug (Gimoti or placebo).

In the pre-specified analysis of the primary endpoint, mean mGCSI-DD total score change from Baseline to Week 4, by gender, there was a benefit demonstrated in female subjects that was clinically and statistically significant (p<0.025) while male subjects demonstrated a high placebo response rate. This improvement in mGCSI-DD was supported by secondary and exploratory measures of efficacy in females across the majority of parameters evaluated. Due to the results in men, the primary objective of statistical significance in the overall population was not achieved (p=0.15).

We believe this Phase 2b trial is the largest ever conducted in a diabetic gastroparesis population for any approved metoclopramide dosage forms (oral tablet, orally disintegrating tablet and injection). Previous metoclopramide studies enrolled small numbers of subjects and did not evaluate treatment effects by gender. For example, fewer than 130 gastroparesis subjects were enrolled across all studies included in the NDA for Reglan Tablets, a branded form of metoclopramide currently marketed in the United States by Ani Pharmaceuticals.

The results of our Phase 2b trial are consistent with what is known about the gender effects in other GI motility disorders. GI motility and functional GI disorders, including gastroparesis, are more common in females than in males. Also, healthy females generally have slower gastric emptying rates. In a study conducted at Temple University (Parkman, et al), gastric emptying of solid food in normal young women was shown to be slower than in age-matched men, even in the first 10 days of the menstrual cycle when estrogen and progesterone levels are low, and the delay in gastric emptying of solids in women appears to be primarily due to altered distal gastric motor function. One explanation may be that less vigorous antral contractions may contribute to slower breakdown of food particles and thus delay the rate of emptying.

Gastrointestinal disorders present differently in males and females and responses to therapy vary by gender. There is general consensus among thought leaders in GI motility that women have a higher prevalence of symptoms, their neural and sensory pathways differ, and hormones, such as estrogen and progesterone, play a role. While the Gimoti Phase 2b trial is the first report of a gender- based difference in response to metoclopramide among subjects with diabetic gastroparesis, gender effects have been reported in drug studies for other GI disorders, such as IBS. For example, products such as Lotronex® (alosetron), Zelnorm® (tegaserod) and Amitiza® (lubiprostone) were approved by FDA based on effectiveness in women, but not in men.

#### Phase 2b Trial Design

The Phase 2b clinical trial consisted of up to a 23-day screening period and a seven-day washout period, followed by 28 days of treatment with study drug. We evaluated two dosage strengths of Gimoti: 10 mg and 14 mg; as well as placebo. The study drug was administered for the 28-day treatment period as a single nasal spray four times daily, 30 minutes before meals and at bedtime. Subjects recorded the severity of their gastroparesis symptoms in a telephonic diary using an interactive voice response system once each day. The symptoms were analyzed using a patient reported outcomes instrument, the Gastroparesis Cardinal Symptom Index Daily Diary, or GCSI-DD, developed for collecting and analyzing data to evaluate the effectiveness of treatments for gastroparesis.

The GCSI-DD contains nine signs and symptoms (nausea, retching, vomiting, stomach fullness, not able to finish a normal sized meal, feeling excessively full after meal, loss of appetite, bloating, and stomach or belly visibly larger) grouped in three subscales. The daily score is calculated as a mean of three subscale means. Additional signs and symptoms collected in the daily diary included abdominal pain, abdominal discomfort, number of hours of nausea, number of episodes of vomiting, and overall severity of gastroparesis symptoms. In close collaboration with the staff of FDA's Division of Gastroenterology and Inborn Errors Products and the Clinical Outcome Assessments, or COA, these additional symptom data were used to further refine the patient reported outcome instrument.

The result is the mGCSI-DD comprised of four symptoms (nausea, early satiety, bloating, and upper abdominal pain) rated from zero (none) to five (very severe). The instrument has been optimized to detect symptom variability on a severity continuum from nausea to vomiting.

# Phase 2b Efficacy Results

Two patient reported outcome endpoints (mGCSI-DD and GCSI-DD) were examined in ITT population based on the protocol design and FDA communications:

- The primary efficacy endpoint was the change from seven-day baseline to Week 4 of the treatment period in the mGCSI-DD total score (mean of four symptoms).
- The second efficacy endpoint analyzed was the change from seven-day baseline to Week 4 of the treatment period in the GCSI-DD total score (mean of three subset means with a total of nine symptoms).

Although an overall improvement in symptoms was observed in Gimoti-treated subjects with diabetic gastroparesis compared to placebo, the difference was not statistically significant due to a high placebo response among male subjects. However, statistically significant improvement in gastroparesis symptoms was observed in female subjects with diabetic gastroparesis as measured by the mGCSI-DD and GCSI-DD total scores for both doses of Gimoti compared to the placebo. The beneficial effect of treatment in females appears to be uniform. The results are consistent across the overall endpoints, the individual components, and the two dose groups.

The observed differences in efficacy were based on gender and were not due to severity of baseline disease or other demographic characteristics. No statistically significant differences were observed in efficacy between the 10 mg and 14 mg Gimoti doses; thus the 10 mg dose was considered the lowest effective dose in this study. The table below summarizes the *p*-values observed for both doses of Gimoti compared to placebo in the Phase 2b clinical trial across all subjects and for male and female subjects separately.

# Gimoti Phase 2b Clinical Trial Gastroparesis Study Endpoint Points P-Value Summary (Gimoti vs. Placebo: Change from Baseline to Week 4)

	Gimoti 10 mg p-values	Gimoti 14 mg p-values
mGCSI-DD Total Score (per FDA guidance) (1)		
All Subjects	0.1504	0.3005
Females	0.0247	0.0215
Males	0.4497	0.2174
GCSI-DD Total Score (per trial protocol) (2)		
All Subjects	0.2277	0.5266
Females	0.0485	0.0437
Males	0.4054	0.0972

*P*-values for pairwise comparisons are obtained from an analysis of covariance, or ANCOVA, model with effects for treatment group and Baseline value as a covariate.

<sup>(1)</sup> The mGCSI-DD was comprised of four symptoms collected on a severity rating scale of 0 to 5. Baseline was seven days prior to treatment or qualifying days during washout and Week 4 was days 21 to 27 of treatment.

<sup>(2)</sup> The GCSI-DD was comprised of nine symptoms collected on a severity rating scale of 0 to 5. Baseline was seven days prior to treatment or qualifying days during washout and Week 4 was days 21 to 27 of treatment.

# Gimoti Phase 2b Clinical Trial Primary Endpoint: Mean mGCSI-DD Total Score Change from Baseline to Week 4 by All Subjects and Gender (intent-to-treat, last observation carried forward on treatment)

Time Point	Placebo (N=95)	Metoclopramide 10 mg IN (N=96)	Metoclopramide 14 mg IN (N=96)
ALL SUBJECTS	(11.33)	(11 50)	(11 50)
Baseline (1)			
N	95	96	96
Mean (SD)	2.8 (0.57)	2.9 (0.60)	2.8 (0.62)
Week 4			
N	95	96	96
Mean (SD)	1.8 (1.00)	1.6 (1.06)	1.7 (0.90)
Change from Baseline to Week 4			
N	95	96	96
Mean (SD)	- 1.0 (0.89)	-1.2 (1.18)	-1.2 (0.94)
Difference of Least Square Means (95% CI)		-0.20 (-0.47, 0.07)	-0.14 (-0.42, 0.13)
Pairwise <i>p</i> -value vs. Placebo (2)		0.1504	0.3005
Difference of Least Square Means (95% CI)			0.06(-0.22, 0.33)
Pairwise <i>p</i> -value vs. Metoclopramide 10 mg (2)			0.6830
FEMALES			
Baseline (1)			
N	68	65	70
Mean (SD)	2.7 (0.54)	2.9 (0.62)	2.9 (0.62)
Week 4			
N (CD)	68	65	70
Mean (SD)	1.9 (1.02)	1.6 (1.08)	1.7(0.94)
Change from Baseline to Week 4		-	
N M	68	65	70
Mean (SD)	- 0.8 (0.79)	-1.2 (1.18)	-1.3(0.98)
Difference of Least Square Means (95% CI)		-0.38 (-0.71, -0.05)	-0.38 (-0.71, -0.06)
Pairwise <i>p</i> -value vs. Placebo (2)		0.0247	0.0215
Difference of Least Square Means (95% CI)			-0.00 (-0.33, 0.32)
Pairwise <i>p</i> -value vs. Metoclopramide 10 mg (2)  MALES			0.9864
Baseline (1)			
N	27	31	26
Mean (SD)	2.9 (0.63)	2.8(0.54)	2.5 (0.56)
Week 4	2.9 (0.03)	2.0(0.34)	2.5 (0.50)
N	27	31	26
Mean (SD)	1.4 (0.84)	1.6(1.05)	1.7 (0.79)
Change from Baseline to Week 4	1.4 (0.04)	1.0(1.03)	1.7 (0.75)
N	27	31	26
Mean (SD)	- 1.4 (0.98)	-1.2 (1.21)	-0.9 (0.78)
Difference of Least Square Means (95% CI)	11. (0.00)	0.18 (-0.30, 0.66)	0.32 (-0.19, 0.83)
Pairwise <i>p</i> -value vs. Placebo (2)		0.4497	0.2174
Difference of Least Square Means (95% CI)			0.14 (-0.35, 0.63)
Pairwise <i>p</i> -value vs. Metoclopramide 10 mg (2)			0.5805
			2.2200

<sup>(1)</sup> Baseline is defined as the mean mGCSI-DD total score during the washout period

<sup>(2)</sup> *p*-values for pairwise comparisons are obtained from an ANCOVA model with effects for treatment group and baseline value as a covariate

# **Phase 2b Safety Observations**

In the Phase 2b clinical trial, Gimoti 10 mg and 14 mg doses were well-tolerated and no differences in the safety profiles were observed between the two doses administered. No serious adverse events occurred related to study treatment. In addition, there were no clinically-meaningful differences observed in clinical laboratory parameters, physical examination findings, or electrocardiogram recordings.

Adverse events that occurred more commonly in both Gimoti 10 mg and 14 mg doses compared to placebo (≥2% difference between treated compared to placebo groups) were dysgeusia, headache, nasal discomfort, rhinorrhea, throat irritation, fatigue, hypoglycemia and hyperglycemia. The majority of adverse events were mild to moderate and transient in nature.

# Treatment-Emergent Adverse Events Reported by More than Two Subjects in Any Treatment Group

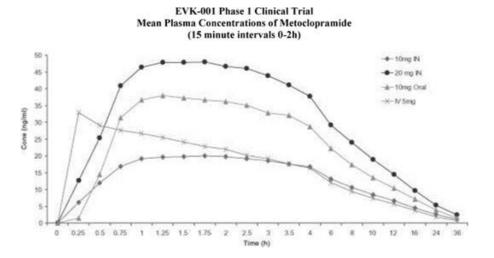
_	All Subjects			
System Organ Class Preferred Term	Placebo (N = 95)	Gimoti 10 mg (N = 95)	Gimoti 14 mg (N = 95)	
Nervous System Disorders	(14 – 55)	(14 = 55)	[14 – 33)	
Dysgeusia	4(4.2%)	12(12.6%)	13(13.7%)	
Headache	4(4.2%)	7(7.4%)	8(8.4%)	
Dizziness	2(2.1%)	3(3.2%)	3(3.2%)	
Gastrointestinal Disorders				
Diarrhea	9(9.5%)	3(3.2%)	2(2.1%)	
Nausea	4(4.2%)	1(1.1%)	4(4.2%)	
Gastroesophageal reflux disease	1(1.1%)	4(4.2%)	0(0.0%)	
Respiratory, Thoracic, and Mediastinal Disorders				
Epistaxis	2(2.1%)	2(2.1%)	3(3.2%)	
Cough	2(2.1%)	0(0.0%)	3(3.2%)	
Nasal discomfort	0(0.0%)	3(3.2%)	2(2.1%)	
Rhinorrhea	1(1.1%)	1(1.1%)	3(3.2%)	
Throat irritation	1(1.1%)	0(0.0%)	3(3.2%)	
Infections and Infestations				
Upper respiratory tract infection	4(4.2%)	0(0.0%)	2(2.1%)	
Nasopharyngitis	1(1.1%)	3(3.2%)	1(1.1%)	
General Disorders and Admin Site Conditions				
Fatigue	1(1.1%)	5(5.3%)	6(6.3%)	
Metabolism & Nutrition Disorders				
Hyperglycemia	1(1.1%)	1(1.1%)	3(3.2%)	
Hypoglycemia	1(1.1%)	1(1.1%)	3(3.2%)	
Psychiatric Disorders				
Depression	3(3.2%)	0(0.0%)	0(0.0%)	

# Phase 1 Comparative Bioavailability Bridging Study

Our Phase 1 clinical trial of Gimoti was an open-label, four-treatment, four-period, four-sequence crossover study conducted at a single study center. Forty healthy volunteers were enrolled and randomly assigned to one of four treatment sequences. After an overnight fast, subjects received a single dose of each of the metoclopramide treatments (10 mg Gimoti, 20 mg Gimoti, 10 mg Reglan tablet, and 5 mg/mL Reglan injection) in random sequence with a seven-day washout period between doses. Thirty nine subjects received at least one dose of metoclopramide. The pharmacokinetic analysis population consisted of 37 subjects who received all four treatments and two subjects who received three of the four treatments.

After nasal spray administration of the 10 mg and 20 mg doses of Gimoti, mean plasma metoclopramide concentrations increased in a dose-related manner, as did mean values for  $C_{max}$  and  $AUC_{inf}$ . The absolute bioavailability of Gimoti after nasal spray administration was comparable for the 10 mg (47.4%) and 20 mg (52.5%) doses as were the bioavailabilities relative to the oral tablet (60.1% and 66.5%, respectively).

The graphs below illustrate the mean plasma concentrations of the active ingredient in the two doses of Gimoti as well as the oral and injection forms.



# Thorough ECG (QT/QTc) Study

We conducted a randomized, double-blind, double-dummy, four-way crossover thorough ECG (QT/QTc) study of Gimoti in 2014. The study was designed in accordance with FDA's published guidance on clinical evaluation of QT/QTc interval, and compared the effects of Gimoti on the QT/QTc interval when administered at therapeutic and supratherapeutic doses in 48 healthy female and male volunteers. Moxifloxacin, an antibiotic known to prolong the QT/QTc interval, was used as the positive control.

In December 2014 we reported that data from the study met the pre-specified primary endpoint, demonstrating that Gimoti, at therapeutic and supratherapeutic doses, did not prolong the QT/QTc interval in healthy subjects. The study was conducted to satisfy a safety requirement by FDA in support of our submission of an NDA for Gimoti.

# Prior Development

From 1985 to present, we, or our predecessors, have conducted numerous clinical studies to evaluate the safety and pharmacokinetic profile of nasal spray formulations of metoclopramide in healthy volunteers and the safety, efficacy, pharmacokinetic and profile of metoclopramide nasal spray in patients. More than 1,311 subjects have been dosed in these studies with nasal formulations of metoclopramide at doses ranging from 10 mg to 80 mg.

In one study, a Phase 2A, multicenter, randomized, open-label, parallel design study, Questcor Pharmaceuticals, Inc., or Questcor (now part of Mallinckrodt plc), compared the efficacy and safety of two doses of metoclopramide nasal spray, 10 mg and 20 mg, with FDA-approved 10 mg metoclopramide tablet. For the primary efficacy endpoint in the per protocol population analysis, a statistically significant difference in the total symptom score between baseline and week 6 for both the nasal 10 mg (p=0.026) and nasal 20 mg (p=0.008) cohorts compared to the oral 10 mg group was observed. Metoclopramide nasal spray was initially developed by Nastech Pharmaceutical Company, Inc. in precursor formulations to Gimoti and subsequently acquired and developed by Questcor.

We acquired rights to this product candidate from Questcor in 2007. We then optimized the acquired formulation of metoclopramide nasal spray to improve stability and remove inactive ingredients to improve the palatability and tolerability of Gimoti for subjects. We also developed the current formulation with excipients that are at or below the levels listed in FDA's Inactive Ingredient Database for nasal products.

We evaluated the current formulation of Gimoti in five completed clinical trials enrolling a total of 636 patients and healthy volunteers (Phase 1 (39), Phase 2 (190), QT/QTc (54), Phase 3 (205) and Companion (53)) and the nasal spray pump used is the same.

The primary container closure system for Gimoti is comprised of an amber glass vial directly attached to a pre-assembled spray pump unit with a protection cap. Each multi dose sprayer system comes preassembled and capable of delivering a 30 day supply (120 doses at 4 doses per day.) The sprayer is a standardized metered sprayer technology utilized in other nasal spray products as well as the amber vial.

# **Intellectual Property and Proprietary Rights**

#### Overview

We are building an intellectual property portfolio for Gimoti in the United States and abroad. We seek patent protection in the United States and internationally for our product candidate, its methods of use and processes for its manufacture, and for other technologies, where appropriate. Our policy is to actively seek to protect our proprietary position by, among other things, filing patent applications in the United States and abroad relating to proprietary technologies that are important to the development of our business. We also rely on trade secrets, know-how, continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position. We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our technology.

Our success will depend significantly on our ability to obtain and maintain patent and other proprietary protection for the technologies we consider important to our business, defend our patents, preserve the confidentiality of our trade secrets and operate our business without infringing the patents and proprietary rights of third parties.

# Patent Portfolio

Our patent portfolio currently includes the following patents and applications:

- U.S. Patent 6,770,262—Nasal Administration of Agents for the Treatment of Gastroparesis. This patent expires in 2021.
- U.S. Patent 8,334,281—Nasal Formulations of Metoclopramide. This patent expires in 2030.
- Non-Provisional Patent Application No. PCT/US2012/052096—Treatment of Symptoms Associated with Female Gastroparesis. If granted, this patent would expire in 2032.

We have also been granted patents in the European Union for the method of use of metoclopramide via nasal delivery for gastroparesis. These patents provide protection through 2021.

The United States patent system permits the filing of provisional and non-provisional patent applications. A non-provisional patent application is examined by the U.S. Patent and Trademark Office, or USPTO, and can mature into a patent once the USPTO determines that the claimed invention meets the standards for patentability. A provisional patent application is not examined for patentability, and automatically expires 12 months after its filing date. As a result, a provisional patent application cannot mature into a patent. The requirements for filing a provisional patent application are not as strict as those for filing a non-provisional patent application. Provisional applications are often used, among other things, to establish an earlier filing date for a subsequent non-provisional patent application. The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the United States, a patent's term may be lengthened by patent term adjustment, or PTA, which compensates a patentee for administrative delays by the USPTO in granting a patent. In view of a recent court decision, the USPTO is under greater scrutiny regarding its calculations where the USPTO erred in calculating the patent term adjustment for the patents in question denying the patentee a portion of the patent term to which it was entitled. Alternatively, a patent's term may be shortened if a patent is terminally disclaimed over another patent.

The effective filing date of a non-provisional patent application is used by the USPTO to determine what information is prior art when it considers the patentability of a claimed invention. If certain requirements are satisfied, a non-provisional patent application can claim the benefit of the filing date of an earlier filed provisional patent application. As a result, the filing date accorded by the provisional patent application may supersede information that otherwise could preclude the patentability of an invention.

# Other Intellectual Property Rights

We currently have a registered trademarks for EVOKE PHARMA and Gimoti in the United States.

# Confidential Information and Inventions Assignment Agreements

We require our employees and consultants to execute confidentiality agreements upon the commencement of employment, consulting or collaborative relationships with us. These agreements provide that all confidential information developed or made known during the course of the relationship with us be kept confidential and not disclosed to third parties except in specific circumstances.

In the case of employees, the agreements provide that all inventions resulting from work performed for us, utilizing our property or relating to our business and conceived or completed by the individual during employment shall be our exclusive property to the extent permitted by applicable law. Our consulting agreements also provide for assignment to us of any intellectual property resulting from services performed for us.

#### Sales and Marketing

We plan to commercialize Gimoti in the United States alone, or in partnership with pharmaceutical companies that have established development and sales and marketing capabilities. Our strategy for Gimoti, if approved, will be to establish Gimoti as the prescription product of choice for diabetic gastroparesis in women. If the product candidate is approved, our expectation is that Gimoti would initially be sold to gastrointestinal and internal medicine specialists, primary care physicians and select health care providers. We may also utilize contract sales forces to assist in the marketing of Gimoti to approved patient populations.

# Manufacturing

We do not own or operate manufacturing facilities for the production of Gimoti, nor do we have plans to develop our own manufacturing operations in the foreseeable future. We currently depend on third-party contract manufacturers for all of our required raw materials, drug substance and finished product for our clinical trials.

In April 2015, we announced the completion of production of a commercial scale lot of Gimoti as required by FDA. With the completion of this large scale production of Gimoti, we believe we have demonstrated our ability to manufacture Gimoti at commercial scale quantities in accordance with CMC. In addition to data from this recent program, we have a three-year registration stability data package from previous studies which have all met proposed specifications. These CMC datasets will be submitted as part of our NDA submission following completion of our ongoing Phase 3 clinical trial and male companion trial.

We do not have any current contractual relationships for the manufacture of commercial supplies of Gimoti. We intend to enter into agreements with third-party contract manufacturers for the commercial production of Gimoti prior to regulatory approval. We currently utilize a third-party consultant, which we engage on an asneeded, hourly basis, to manage our manufacturing contractors.

# Competition

The pharmaceutical industry is characterized by intense competition and rapid innovation. Our potential competitors include large pharmaceutical and biotechnology companies, specialty pharmaceutical and generic drug companies, academic institutions, government agencies and research institutions. We believe the key competitive factors that will affect the development and commercial success of our product candidates are efficacy, safety and tolerability profile, reliability, convenience of dosing, coverage pricing and reimbursement.

Many of our potential competitors have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of products and the commercialization of those products. Accordingly, our competitors may be more successful than we may be in obtaining FDA approval for drugs and achieving widespread market acceptance. Our competitors' drugs may be more effectively marketed and sold, than any drug we may commercialize and may render our product candidates obsolete or non-competitive before we can recover the expenses of developing and commercializing any of our product candidates. We anticipate that we will face intense and increasing competition as new drugs enter the market and advanced technologies become available. Finally, the development of new treatment methods for the diseases we are targeting could render our drugs non-competitive or obsolete.

We expect that, if approved, Gimoti will compete directly with metoclopramide oral, erythromycin and domperidone as a treatment for gastroparesis. Metoclopramide is the only product currently approved in the United States to treat gastroparesis. Metoclopramide is available from a number of generic pharmaceutical manufacturers as well in branded form in the United States under the tradename Reglan® Tablets from Ani Pharmaceuticals.

Previously, Propulsid® (cisapride) and Zelnorm® (tegaserod) were prescribed off-label by physicians to treat gastroparesis. Propulsid® (cisapride) was approved for use in the treatment of dyspepsia and GERD. Zelnorm® (tegaserod) was approved for use in IBS and idiopathic chronic constipation. Both of these products have been withdrawn from the market because of cardiac safety issues.

Salix Pharmaceuticals, Inc. launched an orally dissolving tablet formulation of metoclopramide in 2009. Other programs in the gastroparesis pipeline include new chemical entities in earlier-stage clinical trials. In addition to our Gimoti product candidate, we are aware of the following development candidates; all of which are in Phase 2 clinical development.

# **Gastroparesis Treatment Development Pipeline**

Product	Class	Route	Company	Status
Gimoti	dopamine antagonist /mixed	nasal	Evoke Pharma	Post-Phase 3
	5-HT3 antagonist 5-HT4 agonist			
RM-131	ghrelin agonist	sub-cutaneous	Rhythm/Allergan	Phase 2b
Velusetrag	5-HT4 receptor agonist	oral	Theravance	Phase 2
Tradipitant	NK-1 antagonist	oral	Vanda	Phase 2
Renzapride	5-HT4 agonist/ 5-HT3 antagonist	oral	Endologic	Phase 2
ATC-1906	D2/D3 antagonist	oral	Takeda	Phase 1

RM-131 is a small-peptide analog of ghrelin, a hormone produced in the stomach that stimulates gastrointestinal activity. The compound is being developed for GI motility disorders and has shown efficacy in surgical and opiate-induced ileus in animal models due to a direct prokinetic effect. In October 2016, a Phase 2b study failed to reach statistical significance. Following the trial results, Allergan plc. executed its option to acquire Rhythm Holding Company, LLC. RM-131 reverses body weight loss in cachexia models.

TD-5108, also called Velusetrag, is a 5-HT4 receptor agonist compound under development for the treatment of gastroparesis by Theravance Biopharma, Inc., in collaboration with Alfa Wassermann S.p.A. Previously, TD-5108 was under development for chronic constipation.

Tradipitant is a NK-1 antagonist that has been tested in various other indications by Vanda Pharmaceuticals Inc. No known data related to gastroparesis is available for this program.

Renzapride, a 5-HT4 agonist and 5HT-3 antagonist, has been studied in more than 5,000 patients including one Phase 3 trial for the treatment of constipation-dominant irritable bowel syndrome (IBS-C). Renzapride demonstrated a small but statistically significant benefit in the Phase 3 study in IBS-C, however, the prior owner of the product decided to not continue to pursue development of the drug for this indication. The drug was well tolerated and showed no evidence of cardiotoxicity. A pilot Phase 2 study in patients with diabetic gastroparesis showed that doses of 0.5 mg, 1.0 mg and 2.0 mg, once-daily, showed significant improvement in gastric emptying in a dose-dependent manner. This endpoint does not meet the July 2015 FDA guidance for gastroparesis recommending measurement of symptoms associated with gastroparesis.

Altos Therapeutics LLC, or Altos, is developing the ATC-1906 compound as an oral dopamine D2/D3 receptor antagonist that addresses the symptoms of nausea and vomiting in gastroparesis patients. As part of the agreement, Takeda Pharmaceutical Company Limited, or Takeda, will provide Altos an upfront payment for the option to acquire Altos. If Takeda elects to exercise the option, Takeda would make an additional payment to acquire Altos, and would then assume control over development and commercialization of ATC-1906.

Erythromycin is a motilin receptor agonist and is frequently used off-label in the treatment of gastroparesis. Erythromycin is well known to induce nausea and vomiting across all indications and is particularly associated with exacerbated nausea when used in gastroparesis. Repeated administration of macrolides is also linked to desensitization of the motilin receptor and tachyphylaxis. Extended dosing with antibiotics can lead to the development of resistant organisms as well as pathologic changes in intestinal flora.

One additional medication, Motilium (domperidone), a dopamine receptor modulator, is not FDA-approved, but is available in the United States through various compounding pharmacies under a specific FDA restricted-access program. The safety and efficacy of Motilium as a promotility agent is not fully established.

# **Technology Acquisition Agreement**

In June 2007, we acquired all worldwide rights, data, patents and other related assets associated with Gimoti from Questcor pursuant to an asset purchase agreement. We paid Questcor \$650,000 in the form of an upfront payment and \$500,000 in May 2014 as a milestone payment based upon the initiation of the first patient dosing in our Phase 3 clinical trial for Gimoti. In August 2014, Mallinckrodt plc, or Mallinckrodt, acquired Questcor. As a result of that acquisition, Questcor transferred its rights included in the asset purchase agreement with us to Mallinckrodt. In addition to the payments we made to Questcor, we may also be required to make additional milestone payments to Mallinckrodt totaling up to \$51.5 million. These milestones include up to \$4.5 million in payments if Gimoti achieves the following development targets:

- \$1.5 million upon FDA's acceptance for review of an NDA for Gimoti; and
- \$3 million upon FDA's approval of Gimoti.

The remaining \$47 million in milestone payments depend on Gimoti's commercial success and will only apply if Gimoti receives regulatory approval. In addition, we will be required to pay to Mallinckrodt a low single digit royalty on net sales of Gimoti. Our obligation to pay such royalties will terminate upon the expiration of the last patent right covering Gimoti, which is expected to occur in 2030.

# **Government Regulation**

#### FDA Approval Process

In the United States, pharmaceutical products are subject to extensive regulation by FDA. The Federal Food, Drug, and Cosmetic Act, or FFDCA, and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Failure to comply with applicable FDA or other requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA's refusal to approve pending applications, a clinical hold, warning letters, recall or seizure of products, partial or total suspension of production, withdrawal of the product from the market, injunctions, fines, civil penalties or criminal prosecution.

FDA approval is required before any new unapproved drug or dosage form, including a new use of a previously approved drug, can be marketed in the United States. The process required by FDA before a drug may be marketed in the United States generally involves:

- completion of pre-clinical laboratory and animal testing and formulation studies in compliance with FDA's good laboratory practice regulations;
- submission to FDA of an Investigational New Drug Application, or IND, for human clinical testing which must become effective before human clinical trials may begin in the United States;
- approval by an independent institutional review board, or IRB, at each clinical trial site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practice, or GCP, regulations to establish the safety and efficacy of the proposed drug product for each intended use;
- satisfactory completion of an FDA pre-approval inspection of the facility or facilities at which the product is manufactured to assess compliance with FDA current good manufacturing practices, or cGMP, regulations, including, for devices and device components, the Quality System Regulation, or QSR, and to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;
- submission to FDA of an NDA;
- satisfactory completion of an FDA advisory committee review, if applicable; and
- FDA review and approval of the NDA.

The pre-clinical and clinical testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all. Pre-clinical tests include laboratory evaluation of product chemistry, formulation, stability and toxicity, as well as animal studies to assess the characteristics and potential safety and efficacy of the product. The results of pre-clinical tests, together with manufacturing information, analytical data and a proposed clinical trial protocol and other information, are submitted as part of an IND to FDA. Some pre-clinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by FDA, unless FDA, within the 30-day time period, raises concerns or questions relating to one or more proposed clinical trials and places the clinical trial on a clinical hold, including concerns that human research subjects will be exposed to unreasonable health risks. In such a case, the IND sponsor and FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, our submission of an IND may not result in FDA authorization to commence a clinical trial. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development.

Further, an IRB covering each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and informed consent information for subjects before the trial commences at that site, and it must monitor the study until completed. FDA, the IRB or the sponsor may suspend 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 or for failure to comply with the IRB's or regulatory requirements, or for other reasons, or FDA or IRB may impose other conditions.

Clinical trials involve the administration of the investigational new drug to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Sponsors of clinical trials generally must register and report, at the National Institutes of Health-maintained website ClinicalTrials.gov, key parameters of certain clinical trials. For purposes of an NDA submission and approval, human clinical trials are typically conducted in the following sequential phases, which may overlap or be combined:

- *Phase 1:* The drug is initially introduced into healthy human subjects or patients and tested for safety, dose tolerance, absorption, metabolism, distribution and excretion and, if possible, to gain an early indication of its effectiveness.
- *Phase 2:* The drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted indications and to determine dose tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more extensive Phase 3 clinical trials.
- *Phase 3:* These are commonly referred to as pivotal studies. When Phase 2 evaluations demonstrate that a dose range of the product appears to be effective and has an acceptable safety profile, Phase 3 trials are undertaken in large patient populations to further evaluate dosage, to obtain additional evidence of clinical efficacy and safety in an expanded patient population at multiple, geographically-dispersed clinical trial sites, to establish the overall risk-benefit relationship of the drug and to provide adequate information for the labeling of the drug.
- *Phase 4*: In some cases, FDA may condition approval of an NDA for a product candidate on the sponsor's agreement to conduct additional clinical trials to further assess the drug's safety and effectiveness after NDA approval. Such post-approval trials are typically referred to as Phase 4 studies.

The results of product development, pre-clinical studies and clinical trials are submitted to FDA as part of an NDA. NDAs must also contain extensive information relating to the product's pharmacology, chemistry, manufacturing and controls, or CMC, and proposed labeling, among other things.

Under federal law, the submission of most NDAs is subject to a substantial application user fee, and the manufacturer and/or sponsor under an approved NDA are also subject to annual product and establishment user fees. FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information and is subject to payment of additional user fees. The resubmitted application is also subject to review before FDA accepts it for filing.

Once the submission has been accepted for filing, FDA begins an in-depth substantive review. Under the Prescription Drug User Fee Act, or PDUFA, FDA agrees to specific performance goals for NDA review time through a two-tiered classification system, Standard Review and Priority Review. Standard Review NDAs have a goal of being completed within ten months of the date of receipt by FDA (for drugs that do not contain new molecular entities) and ten months of the 60-day filing date (for drugs that contain new molecular entities). A Priority Review designation is given to drugs that treat a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The goal for completing a Priority Review is six months from the date of receipt by FDA (for drugs that do not contain new molecular entities) and six months of the 60-day filing date (for drugs that contain new molecular entities). However, FDA does not always complete its review within these timelines and the Agency's review can take substantially longer.

We believe that our product candidate will be granted a Standard Review for a product that does not contain a new chemical entity. The review process may be extended to allow FDA to request and review additional information or obtain clarification regarding information provided in the original submission. FDA may refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. FDA is not bound by the recommendation of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, FDA may inspect the facility or facilities where the product is manufactured. FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements, including QSR requirements for the device component of the product, and are adequate to assure consistent production of the product within required specifications. Additionally, FDA will typically inspect one or more clinical sites to assure compliance with GCP requirements before approving an NDA.

After FDA evaluates the NDA and, in some cases, the related manufacturing facilities, it may issue an approval letter or a Complete Response Letter, or CRL, to indicate that the review cycle for an application is complete or that the application is not ready for approval. CRLs generally outline the deficiencies in the submission and may require substantial additional testing or information in order for FDA to reconsider the application. Even with submission of this additional information, FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when the deficiencies have been addressed to FDA's satisfaction, FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

Once issued, FDA may withdraw product approval if ongoing regulatory requirements are not met or if safety problems are identified after the product reaches the market. In addition, FDA may require post-approval testing, including Phase 4 studies, and surveillance programs to monitor the effect of approved products which have been commercialized, and FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved label, and, even if FDA approves a product, it may limit the approved indications for use for the product or impose other conditions, including labeling or distribution restrictions or other risk-management mechanisms. Further, if there are any modifications to the drug, including changes in indications, labeling, or manufacturing processes or facilities, we may be required to submit and obtain FDA approval of a new or supplemental NDA, which may require us to develop additional data or conduct additional pre-clinical studies and clinical trials.

# **Post-Approval Requirements**

Once an NDA is approved, a product will be subject to pervasive and continuing regulation by FDA, including, among other things, requirements relating to drug/device listing, recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved products are required to register their establishments with FDA and state agencies, and are subject to periodic unannounced inspections by FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and generally require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, FDA may suspend, restrict or withdraw the approval, require a product recall, or impose additional restrictions or limitations if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- · restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

FDA may require post-approval studies and clinical trials if FDA finds that scientific data, including information regarding related drugs, deem it appropriate. The purpose of such studies would be to assess a known serious risk or signals of serious risk related to the drug or to identify an unexpected serious risk when available data indicate the potential for a serious risk. FDA may also require a labeling change if it becomes aware of new safety information that it believes should be included in the labeling of a drug.

The Food and Drug Administration Amendments Act of 2007 gave FDA the authority to require a Risk Evaluation and Mitigation Strategy, or REMS, from manufacturers to ensure that the benefits of a drug outweigh its risks. In determining whether a REMS is necessary, FDA must consider the size of the population likely to use the drug, the seriousness of the disease or condition to be treated, the expected benefit of the drug, the duration of treatment, the seriousness of known or potential adverse events, and whether the drug is a new molecular entity. If FDA determines a REMS is necessary, the drug sponsor must agree to the REMS plan at the time of approval. A REMS may be required to include various elements, such as a medication guide or patient package insert, a communication plan to educate health care providers of the drug's risks, limitations on who may prescribe or dispense the drug, or other measures that FDA deems necessary to assure the safe use of the drug. In addition, the REMS must include a timetable to assess

the strategy at 18 months, three years, and seven years after the strategy's approval. FDA may also impose a REMS requirement on a drug already on the market if FDA determines, based on new safety information, that a REMS is necessary to ensure that the drug's benefits continue to outweigh its risks.

In March 2009, FDA informed drug manufacturers that it will require a REMS for metoclopramide drug products. FDA's authority to take this action is based on risk management and post market safety provisions within the Food and Drug Administration Amendments Act. The REMS consists of a Medication Guide, elements to assure safe use (including an education program for prescribers and materials for prescribers to educate patients), and a timetable for submission of assessments of at least six months, 12 months, and annually after the REMS is approved. In 2011, FDA determined that maintaining the Medication Guide as a part of the approved labeling is adequate to address the public health concern and meets the regulatory standards. As a result, FDA determined that a REMS for metoclopramide is no longer required. We intend to follow current labeling procedures to include a medication guide at the time of the NDA submission for Gimoti.

FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market, and FDA imposes a number of complex regulations on entities that advertise and promote pharmaceuticals, which include, among others, standards for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities, and promotional activities involving the internet. While physicians may prescribe for off-label uses, manufacturers may only promote for the approved indications and in accordance with the provisions of the approved label. FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. Indeed, FDA has very broad enforcement authority under the FFDCA, and failure to abide by these regulations can result in penalties, including the issuance of a warning letter directing entities to correct deviations from FDA standards, a requirement that future advertising and promotional materials are pre-cleared by FDA, and state and federal civil and criminal investigations and prosecutions.

The distribution of prescription pharmaceutical products is also subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of drugs and drug samples at the federal level and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution, including a drug pedigree which tracks the distribution of prescription drugs.

### Section 505(b)(2) New Drug Applications

As an alternate path to FDA approval for modifications to formulations or uses of products previously approved by FDA, an applicant may submit an NDA under Section 505(b)(2) of the FFDCA. Section 505(b)(2) was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Amendments, and permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The applicant may rely upon published literature and FDA's findings of safety and effectiveness based on certain pre-clinical or clinical studies conducted for an approved product. FDA may also require companies to perform additional studies or measurements to support the change from the approved product. FDA may then approve the new product candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

To the extent that a Section 505(b)(2) NDA relies on studies conducted for a previously approved drug product, the applicant is required to certify to FDA concerning any patents listed for the approved product in FDA Orange Book. FDA Orange Book is where patents associated with a FDA-approved product are listed. Specifically, the applicant must certify for each listed patent that (1) the required patent information has not been filed; (2) the listed patent has expired; (3) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patent is invalid, unenforceable or will not be infringed by the new product. A certification that the new product will not infringe the already approved product's listed patent or that such patent is invalid is known as a Paragraph IV certification. If the applicant does not challenge the listed patents through a Paragraph IV certification, the Section 505(b)(2) NDA application will not be approved until all the listed patents claiming the referenced product have expired. The Section 505(b)(2) NDA application also will not be accepted or approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a New Chemical Entity, listed in the Orange Book for the referenced product has expired.

If the 505(b)(2) NDA applicant has provided a Paragraph IV certification to FDA, the applicant must also send notice of the Paragraph IV certification to the referenced NDA and patent holders once the 505(b)(2) NDA has been accepted for filing by FDA. The NDA and patent holders may then initiate a legal challenge to the Paragraph IV certification. Under the FFDCA, the filing of a patent infringement lawsuit within 45 days of the NDA and patent holders' receipt of a Paragraph IV certification in most cases automatically prevents FDA from approving the Section 505(b)(2) NDA for 30 months, or until a court decision or settlement finding that the patent is invalid, unenforceable or not infringed, whichever is earlier. The court also has the ability to shorten or lengthen the 30-month stay if either party is found not to be reasonably cooperating in expediting the litigation. Thus, the Section 505(b)(2)

applicant may invest a significant amount of time and expense in the development of its product only to be subject to significant delay and patent litigation before its product may be commercialized.

The 505(b)(2) NDA applicant also may be eligible for its own regulatory exclusivity period, such as three-year exclusivity. Specifically, a product may be granted three-year Hatch-Waxman exclusivity if one or more clinical studies, other than bioavailability or bioequivalence studies, was essential to the approval of the application and was conducted/sponsored by the applicant. Should this occur, FDA would be precluded from making effective any other application for the same condition of use or for a change to the drug product that was granted exclusivity until after that three-year exclusivity period has expired. Additional non-patent exclusivities may also apply.

Additionally, the 505(b)(2) NDA applicant may have relevant patents in the Orange Book, and if so, it can initiate patent infringement litigation against those applicants that challenge such patents, which could result in a 30-month stay delaying those applicants.

# **Manufacturing Requirements**

We and our third-party manufacturers must comply with applicable FDA regulations relating to FDA's cGMP regulations including applicable QSR requirements. The cGMP regulations include requirements relating to, among other things, 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, records and reports, and returned or salvaged products. The manufacturing facilities for our products must meet cGMP requirements to the satisfaction of FDA pursuant to a pre-approval inspection before we can use them to manufacture our products. We and our third-party manufacturers are also subject to periodic unannounced inspections of facilities by FDA and other authorities, including procedures and operations used in the testing and manufacture of our products to assess our compliance with applicable regulations. Failure to comply with statutory and regulatory requirements subjects a manufacturer to possible legal or regulatory action, including, among other things, warning letters, the seizure or recall of products, injunctions, consent decrees placing significant restrictions on or suspending manufacturing operations and civil and criminal penalties.

# Other Regulatory Requirements

We are also subject to various laws and regulations regarding laboratory practices, the experimental use of animals, and the use and disposal of hazardous or potentially hazardous substances in connection with our research. In each of these areas, as above, FDA has broad regulatory and enforcement powers, including, among other things, 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 on us.

# **Coverage and Reimbursement**

Sales of our products, if approved, will depend, in part, on the extent to which our products will be covered by third-party payors, such as government health care programs, commercial insurance and managed healthcare organizations. These third-party payors are increasingly limiting coverage and reducing reimbursements for medical products and services. In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. Decreases in third-party reimbursement for our drug candidates or a decision by a third-party payor to not cover our drug candidates could reduce physician utilization of our products and have a material adverse effect on our sales, results of operations and financial condition.

# **Other Healthcare Laws**

Although we currently do not have any products on the market, if our drug candidates are approved and we begin commercialization, we will be subject to healthcare regulation and enforcement by the federal government and the states and foreign governments in which we conduct our business. These laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, privacy and security, and physician sunshine laws and regulations.

The federal Anti-Kickback Statute prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs. The Anti-Kickback Statute is subject to evolving interpretations. In the past, the government has enforced the Anti-Kickback Statute to reach large settlements with healthcare companies based on sham consulting and other financial arrangements with physicians. Further, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. 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 False Claims Act. The majority of states also have anti-kickback laws which establish similar prohibitions and in some cases may apply to items or services reimbursed by any third-party payor, including commercial insurers.

Additionally, the False Claims Act prohibits knowingly presenting or causing the presentation of a false, fictitious or fraudulent claim for payment to the U.S. government. Actions under the False Claims Act may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. Violations of the False Claims Act can result in very significant monetary penalties and treble damages. The federal government is using the False Claims Act, and the accompanying threat of significant liability, in its investigation and prosecution of pharmaceutical and biotechnology companies throughout the country, for example, in connection with the promotion of products for unapproved uses and other sales and marketing practices. The government has obtained multi-million and multi-billion dollar settlements under the False Claims Act in addition to individual criminal convictions under applicable criminal statutes. Given the significant size of actual and potential settlements, it is expected that the government will continue to devote substantial resources to investigating healthcare providers' and manufacturers' compliance with applicable fraud and abuse laws.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, also created new federal criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

We may also be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their respective implementing regulations, including the Final HIPAA Omnibus Rule published on January 25, 2013, impose specified requirements relating to the privacy, security and transmission of individually identifiable health information held by covered entities and their business associates. Among other things, HITECH made HIPAA's security standards directly applicable to "business associates," defined as independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same requirements, thus complicating compliance efforts.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians and other healthcare providers. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the Affordable Care Act, among other things, imposes new reporting requirements on certain drug manufacturers for payments made by them to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Failure to submit required information may result in civil monetary penalties of up to an aggregate of \$150,000 per year (or up to an aggregate of \$1 million per year for "knowing failures"), for all payments, transfers of value or ownership or investment interests that are not timely, accurately and completely reported in an annual submission. Drug manufacturers are required to submit reports to the government by the 90th day of each calendar year. Certain states also mandate implementation of commercial compliance programs, impose restrictions on drug manufacturer marketing practices and/or require the tracking and reporting of marketing expenditures and pricing information, as well as gifts, compensation and other remuneration to physicians.

The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance and/or reporting requirements in multiple jurisdictions increase the possibility that a healthcare company may violate one or more of the requirements. If our operations are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to operate our business and our financial results.

# **Employees**

We currently have seven full-time employees and several consultants in the regulatory, clinical, manufacturing and finance areas. None of our employees are represented by a collective bargaining arrangement, and we believe our relationship with our employees is good.

# **Research and Development**

We incurred \$7.0 million, \$8.2 million and \$10.0 million in research and development expenses for the years ended December 31, 2016, 2015, and 2014, respectively.

#### About Evoke

We were formed as a Delaware corporation in January 2007. Our principal executive offices are located at 420 Stevens Avenue, Suite 370, Solana Beach, California 92075, and our telephone number is (858) 345-1494.

# **Financial Information about Segments**

We have one operating segment, which is the development of pharmaceutical products. See Note 2 to our financial statements included in this Annual Report on Form 10-K. For financial information regarding our business, see "Management's Discussion and Analysis of Financial Condition and Results of Operations" and those financial statements and related notes.

#### **Available Information**

We file electronically with the Securities and Exchange Commission, or SEC, our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended. We make available copies of these reports, free of charge, on our website at www.evokepharma.com, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. The public may read or copy any materials we file with the SEC at the SEC's Public Reference Room at 100 F Street NE, Washington, D.C. 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains a website that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. The address of that website is www.sec.gov. The information in or accessible through the SEC and our website are not incorporated into, and are not considered part of, this report. Further, our references to the URLs for these websites are intended to be inactive textual references only.

#### Item 1A. Risk Factors

We operate in a dynamic and rapidly changing environment that involves numerous risks and uncertainties. Certain factors may have a material adverse effect on our business prospects, financial condition and results of operations, and you should carefully consider them. Accordingly, in evaluating our business, we encourage you to consider the following discussion of risk factors, in its entirety, in addition to other information contained in this Annual Report on Form 10-K and our other public filings with the Securities and Exchange Commission, or SEC. Other events that we do not currently anticipate or that we currently deem immaterial may also affect our business, prospects, financial condition and results of operations.

Risks Related to our Business, including the Development, Regulatory Approval and Potential Commercialization of our Product Candidate, Gimoti

Our business is entirely dependent on the success of Gimoti, which failed to achieve the primary endpoint of symptom improvement in a Phase 3 clinical trial in female patients with symptoms associated with diabetic gastroparesis. While we are continuing to pursue regulatory approval based on a planned comparative exposure PK trial, we cannot be certain that this trial will be successful or that we will be able to obtain regulatory approval for, or successfully commercialize, Gimoti.

To date, we have devoted all of our research, development and clinical efforts and financial resources toward the development of Gimoti, our patented nasal delivery formulation of metoclopramide for the relief of symptoms associated with acute and recurrent diabetic gastroparesis in adult women. Gimoti is our only product candidate. In July 2016, we announced topline results from our Phase 3 clinical trial that evaluated the efficacy and safety of Gimoti in women with symptoms associated with diabetic gastroparesis. In this study, Gimoti did not achieve its primary endpoint of symptom improvement in the Intent-to-Treat (ITT) group at Week

In December 2016, we announced the completion of a second pre-NDA meeting with FDA, in which FDA agreed that a comparative exposure PK trial was acceptable as a basis for submission of a Gimoti NDA. The comparative exposure PK trial will serve as a portion of the full 505(b)(2) data package to include prior efficacy and safety data developed by us and the FDA's prior findings of safety and efficacy for the Listed Drug, Reglan Tablets. We expect to begin and complete the comparative exposure PK trial in the second half of 2017, followed by a potential NDA submission in late 2017 or early 2018. If we are unable to establish bioequivalence in the comparative exposure PK trial, or FDA later determines to require the conduct of additional efficacy or safety trials, we will be unable to submit an NDA on this timeframe, or potentially at all.

Because our business is entirely dependent on the success of Gimoti, if we are unable to successfully complete development of and receive regulatory approval of this product candidate, we will be required to curtail all of our activities and may be required to liquidate, dissolve or otherwise wind down our operations. Any of these events could result in the complete loss of an investment in our securities.

In addition to the above factors, the future regulatory and commercial success of Gimoti is subject to a number of additional risks, including the following:

- · we may not have sufficient financial and other resources to complete clinical development for Gimoti;
- we may not be able to provide acceptable evidence of safety and efficacy for Gimoti;
- FDA may disagree with the design of our comparative exposure PK trial or any other future clinical trials, if any are necessary;
- variability in subjects, adjustments to clinical trial procedures and inclusion of additional clinical trial sites;
- FDA may not agree with the analysis of our clinical trial results;
- the results of our clinical trials may not meet the level of statistical or clinical significance or other bioequivalence parameters required by FDA for marketing approval;
- we may be required to undertake additional clinical trials and other studies of Gimoti before we can submit an NDA, to FDA or receive approval of the NDA:
- subjects in our clinical trials may die or suffer other adverse effects for reasons that may or may not be related to Gimoti, such as dysgeusia, headache, diarrhea, nasal discomfort, tremor, myoclonus, somnolence, rhinorrhea, throat irritation, and fatigue;
- if approved, Gimoti will compete with well-established products already approved for marketing by FDA, including oral and intravenous forms of metoclopramide, the same active ingredient in the nasal spray for Gimoti;

- · we may not be able to obtain, maintain and enforce our patents and other intellectual property rights; and
- we may not be able to obtain and maintain commercial manufacturing arrangements with third-party manufacturers or establish commercial-scale manufacturing capabilities.

Of the large number of drugs in development in this industry, only a small percentage result in the submission of an NDA to FDA and even fewer are approved for commercialization. Furthermore, even if we do receive regulatory approval to market Gimoti, any such approval may be subject to limitations on the indicated uses for which we may market the product.

# We will require substantial additional funding and may be unable to raise capital when needed, which would force us to liquidate, dissolve or otherwise wind down our operations.

Our operations have consumed substantial amounts of cash since inception. We believe, based on our current operating plan, that our existing cash and cash equivalents will be sufficient to fund our operations through at least February 2018, although there can be no assurance in that regard. We will be required to raise additional funds in order to continue as a going concern beyond that time.

Our estimates of the amount of cash necessary to fund our activities may prove to be wrong and we could spend our available financial resources much faster than we currently expect. Our future funding requirements will depend on many factors, including, but not limited to:

- the progress, costs and results of our planned comparative exposure PK trial;
- the need for, and the progress, costs and results of, any additional clinical trials of Gimoti we may initiate based on the results of our upcoming comparative exposure PK trial or discussions with FDA, including any additional trials FDA or other regulatory agencies may require evaluating the efficacy or safety of Gimoti;
- · the outcome, costs and timing of seeking and obtaining regulatory approvals from FDA, and any similar regulatory agencies;
- the costs and timing of completion of outsourced commercial manufacturing supply arrangements for Gimoti;
- the costs of establishing or outsourcing sales, marketing and distribution capabilities, should we elect to do so;
- · the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights associated with Gimoti;
- · the terms and timing of any collaborative, licensing, co-promotion or other arrangements that we may establish; and
- costs associated with any other product candidates that we may develop, in-license or acquire.

Additional funding may not be available to us on acceptable terms or at all. In addition, the terms of any financing may adversely affect the holdings or the rights of our stockholders. Furthermore, the issuance of additional shares or other securities by us, or the possibility of such issuance, may cause the market price of our shares to decline and dilute the holdings of our existing stockholders. If we raise additional funds by incurring debt, the terms of the debt may involve significant cash payment obligations, as well as covenants and specific financial ratios that may restrict our ability to operate our business. We cannot provide any assurance that our existing capital resources will be sufficient to enable us to identify or execute a viable plan for continued clinical development of Gimoti or to otherwise survive as a going concern.

# If we are not able to obtain regulatory approval for Gimoti, we will not be able to commercialize this product candidate and our ability to generate revenue will be limited.

We have not submitted an NDA or received regulatory approval to market any product candidates in any jurisdiction. We are not permitted to market Gimoti in the United States until we receive approval of an NDA for the product candidate in a particular indication from FDA. To date, we have completed a Phase 3 clinical trial in female subjects, a Phase 2b clinical trial and we acquired the results from a separate Phase 2 clinical trial in diabetic subjects with gastroparesis. In the Phase 2b clinical trial that we performed ourselves, which concluded in 2011, Gimoti failed to meet the primary endpoint for the trial. Although an overall improvement in symptoms was observed in Gimoti-treated subjects with diabetic gastroparesis compared to placebo in this Phase 2b clinical trial, the difference was not statistically significant due to a high placebo response among male subjects. The earlier Phase 2 clinical trial performed by Questcor was a multicenter, randomized, open-label, parallel design study. This head-to-head study compared the efficacy and safety of two doses of metoclopramide nasal spray, 10 mg and 20 mg, with FDA-approved 10 mg metoclopramide tablet. Although data from the earlier Phase 2 clinical trial will be referenced in the Gimoti NDA, the open-label study design limits the importance of the efficacy results in the NDA.

We completed our Phase 3 clinical trial in female subjects with symptoms associated with acute and recurrent diabetic gastroparesis and announced in July 2016 that Gimoti did not achieve its primary endpoint of symptom improvement at Week 4. While we are planning to conduct the comparative exposure PK trial to serve as a basis for an NDA submission for Gimoti, there is no guarantee that this trial, or any other future trials, will be successful or that regulators will agree with our assessment of the clinical trials for Gimoti conducted to date. In addition, we have only limited experience in filing the applications necessary to gain regulatory approvals and expect to rely on consultants and third party contract research organizations to assist us in this process. FDA and other regulators have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional clinical trials, or preclinical or other studies.

Varying interpretation of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate. Furthermore, we have acquired our rights to Gimoti from Questcor, who acquired its rights from a predecessor. Thus, much of the preclinical and a portion of the clinical data relating to Gimoti that we would expect to submit in an NDA for Gimoti was obtained from studies conducted before we owned the rights to the product candidate and, accordingly, was prepared and managed by others. These predecessors may not have applied the same resources and given the same attention to this development program as we would have if we had been in control from inception.

Gimoti and the activities associated with its development and potential commercialization, including its testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Failure to obtain regulatory marketing approval for Gimoti will prevent us from commercializing the product candidate, and our ability to generate revenue will be materially impaired.

# FDA may impose requirements on our clinical trials that are difficult to comply with, which could harm our business.

In July 2015 FDA published draft guidance intended to assist sponsors in the clinical development of drugs for the treatment of diabetic and idiopathic gastroparesis clinical trials, *Gastroparesis: Clinical Evaluation of Drugs for Treatment – Guidance for Industry.* We believe that FDA Guidance is consistent with the advice FDA provided to us regarding trial design and study endpoints for our completed Phase 3 trials. In addition, FDA Guidance explicitly states that there is an urgent medical need for development of drugs with a favorable risk-benefit profile to treat patients with gastroparesis and acknowledges that "patients with diabetic gastroparesis may experience further derangement of glucose control because of unpredictable gastric emptying and altered absorption of orally administered hypoglycemic drugs." FDA Guidance, however, does not create or confer any rights for or on any person and do not operate to bind FDA or the public, and FDA may ultimately disagree with our interpretation regarding the meaning or applicability of any published Guidance documents.

We conducted a Phase 3 trial in adult female subjects with diabetic gastroparesis, which failed to reach its primary endpoint. However, following our second pre-NDA meeting with FDA in December 2016, FDA agreed that a comparative exposure PK trial, along with prior efficacy and safety data from other completed Gimoti studies, would be sufficient for NDA submission seeking an indication of treatment of symptoms associated with diabetic gastroparesis in women. Although we believe successful results from the comparative exposure PK trial along with the prior data will be sufficient to allow us to submit an NDA for Gimoti, it is possible FDA will require additional clinical testing before submission or approval of the NDA. In addition, based on discussions with FDA, we also conducted a similar study for safety and efficacy in adult male subjects with diabetic gastroparesis which is not required for an NDA submission; however, we expect to include safety data from this trial in the NDA submission. If we are unable to comply with FDA's requirements, we will not be able to obtain approval for Gimoti and our ability to generate revenue will be materially impaired.

Any termination or suspension of, or delays in the completion of, any future clinical trials could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.

Delays in the completion of any future clinical trials for Gimoti, including the planned comparative exposure PK trial, could significantly affect our product development costs. We do not know whether any trials will produce data on schedule, if at all. The commencement and completion of clinical trials can be delayed for a number of reasons, including delays related to:

- FDA placing the clinical trial on hold;
- subjects failing to remain in our trial at the rate we expect (for example, due to variable patient frequency and severity of disease and variability in gastric emptying testing);
- · subjects choosing an alternative treatment for the indication for which we are developing Gimoti, or participating in competing clinical trials;
- subjects experiencing severe or unexpected drug-related adverse effects;

- a facility manufacturing Gimoti, or any of its components, being ordered by FDA or other government or regulatory authorities to temporarily or permanently shut down due to violations of FDA's current good manufacturing practices or other applicable requirements, or infections or cross-contaminations of product candidate in the manufacturing process;
- any changes to our manufacturing process that may be necessary or desired;
- third-party clinical investigators losing their license or permits necessary to perform our clinical trials, not performing our clinical trials on our
  anticipated schedule or consistent with the clinical trial protocol, good clinical practice and regulatory requirements, or other third parties not
  performing data collection and analysis in a timely or accurate manner;
- inspections of clinical trial sites by FDA or the finding of regulatory violations by FDA or an independent institutional review board, or IRB, that require us to undertake corrective action, result in suspension or termination of one or more sites or the imposition of a clinical hold on the entire trial, or that prohibit us from using some or all of the data in support of our marketing applications;
- third-party contractors becoming debarred or suspended or otherwise penalized by FDA or other government or regulatory authorities for violations of
  regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or any of the data produced by
  such contractors in support of our marketing applications; or
- one or more IRBs refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing its approval of the trial.

Product development costs will increase if we have delays in testing or approval of Gimoti, or if we need to perform more or larger clinical trials than planned. Additionally, changes in regulatory requirements and policies may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial. If we experience delays in completion of or if we, FDA or other regulatory authorities, the IRB, or other reviewing entities, or any of our clinical trial sites suspend or terminate any of our clinical trials, the commercial prospects for our product candidate may be harmed and our ability to generate product revenues will be delayed. In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. Also, if one or more clinical trials are delayed, our competitors may be able to bring products to market before we do, and the commercial viability of Gimoti could be significantly reduced.

Delays in the completion of any clinical trials and studies we may conduct for Gimoti could be harmful to our business and cause us to require additional funding.

Final marketing approval for Gimoti by FDA or other regulatory authorities for commercial use may be delayed, limited, or denied, any of which would adversely affect our ability to generate operating revenues.

If our planned comparative exposure PK trial is successful, we plan to submit an NDA for Gimoti. However, we cannot provide any assurance as to whether or when we will submit an NDA, or whether or when we will obtain regulatory approval to commercialize Gimoti. We cannot, therefore, predict the timing of any future revenue. Because Gimoti is our only product candidate this risk is particularly significant for us. We cannot commercialize Gimoti until the appropriate regulatory authorities have reviewed and approved marketing applications for this product candidate. We cannot assure you that the regulatory agencies will complete their review processes in a timely manner or that we will obtain regulatory approval for Gimoti. In addition, we may experience delays or the application may be rejected based upon additional government regulation from future legislation or administrative action or changes in FDA policy during the period of product development, clinical trials and FDA regulatory review. For example, in 2009 following an FDA review of metoclopramide spontaneous safety reports, FDA required a boxed warning be added to the metoclopramide product label concerning the chance of tardive dyskinesia, or TD, for patients taking these products. FDA requires a boxed warning (sometimes referred to as a "Black Box" Warning) for products that have shown a significant risk of severe or life-threatening adverse events. Recently, the European Medicines Agency's Committee on Medicinal Products for Human Use, or CHMP, has reviewed and has proposed labeling changes for marketed metoclopramide products in the European Union based on age, dosing guidelines or indications. Based on their assessment of the limited efficacy and safety data currently available to the CHMP, the CHMP recommended to the European Medicines Agency that indications with limited or inconclusive efficacy data, including GERD, dyspepsia and gastroparesis, be removed from the approved product label in the European Union. There can be no assurance as to whet

If FDA does not conclude that Gimoti satisfies the requirements for the Section 505(b)(2) regulatory approval pathway, or if the requirements under Section 505(b)(2) are not as we expect, the approval pathway for our primary product candidate will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in either case may not be successful.

We intend to seek FDA approval through the Section 505(b)(2) regulatory pathway for our primary product candidate, Gimoti. Gimoti is a drug/device combination product that will be regulated under the drug provisions of the FFDCA, enabling us to submit an NDA for its approval. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Amendments, added Section 505(b)(2) to the FDCA. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference.

If FDA does not allow us to pursue the Section 505(b)(2) regulatory pathway as anticipated, we may need to conduct additional clinical trials, provide additional data and information and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for Gimoti, and the complications and risks associated with our lead product candidate, would likely substantially increase. We may need to obtain additional funding, which could result in significant dilution to the ownership interests of our then existing stockholders to the extent we issue equity securities or convertible debt. We cannot assure you that we would be able to obtain such additional financing on terms acceptable to us, if at all. Moreover, inability to pursue the Section 505(b)(2) regulatory pathway could result in competitive products reaching the market before Gimoti, which could impact our competitive position and prospects. Even if we are allowed to pursue the Section 505(b)(2) regulatory pathway, we cannot assure you that Gimoti or any future product candidates will receive the requisite approvals for commercialization.

Even if we obtain marketing approval for Gimoti, it could be subject to restrictions or withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our product candidate, when and if Gimoti is approved.

Even if U.S. regulatory approval is obtained, FDA may still impose significant restrictions on Gimoti's indicated uses or marketing or impose ongoing requirements for potentially costly and time consuming post-approval studies, post-market surveillance or clinical trials. Gimoti will also be subject to ongoing FDA requirements governing the labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, recordkeeping and reporting of safety and other post-market information. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by FDA and other regulatory authorities for compliance with cGMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents. If we or a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requesting recall or withdrawal of the product from the market or suspension of manufacturing.

If we or the manufacturing facilities for Gimoti fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or untitled letters;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- · suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements or applications filed by us;
- · suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- · seize or detain products, refuse to permit the import or export of product, or request us to initiate a product recall.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our products and generate revenue.

FDA has the authority to require a REMS as a condition of approval of an NDA or following approval, which may impose further requirements or restrictions on the distribution or use of an approved drug, such as limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria and requiring treated patients to enroll in a registry. In March 2009, FDA informed drug manufacturers that it will require a REMS for metoclopramide drug products, including a Medication Guide, elements to assure safe use (including an education program for prescribers and materials for prescribers to educate patients), and a timetable for submission of assessments of at least six months, 12 months, and annually after the REMS is approved. We intend to submit a proposed REMS at the time of the NDA submission for Gimoti.

In addition, if Gimoti is approved, our product labeling, advertising and promotion would be subject to regulatory requirements and continuing regulatory review. FDA strictly regulates the promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by FDA as reflected in the product's approved labeling. If we receive marketing approval for Gimoti, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability. FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

The FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. For example, in December 2016, the 21st Century Cures Act, or Cures Act, was signed into law. The Cures Act, among other things, is intended to modernize the regulation of drugs and spur innovation, but its ultimate implementation is unclear. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. Notably, on January 23, 2017, President Trump ordered a hiring freeze for all executive departments and agencies, including the FDA, which prohibits the FDA from filling employee vacancies or creating new positions. Under the terms of the order, the freeze will remain in effect until implementation of a plan to be recommended by the Director for the Office of Management and Budget, or OMB, in consultation with the Director of the Office of Personnel Management, to reduce the size of the federal workforce through attrition. Although certain positions at the FDA may be exempt from the freeze, an understaffed FDA could result in delays in FDA's responsiveness or in its ability to review submissions or applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion or at all.

Moreover, on January 30, 2017, President Trump issued an Executive Order, applicable to all executive agencies, including the FDA, which requires that for each notice of proposed rulemaking or final regulation to be issued in fiscal year 2017, the agency shall identify at least two existing regulations to be repealed, unless prohibited by law. These requirements are referred to as the "two-for-one" provisions. This Executive Order includes a budget neutrality provision that requires the total incremental cost of all new regulations in the 2017 fiscal year, including repealed regulations, to be no greater than zero, except in limited circumstances. For fiscal years 2018 and beyond, the Executive Order requires agencies to identify regulations to offset any incremental cost of a new regulation and approximate the total costs or savings associated with each new regulation or repealed regulation. In interim guidance issued by the Office of Information and Regulatory Affairs within OMB on February 2, 2017, the administration indicates that the "two-for-one" provisions may apply not only to agency regulations, but also to significant agency guidance documents. It is difficult to predict how these requirement will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

Even if we receive regulatory approval for Gimoti, we still may not be able to successfully commercialize it and the revenue that we generate from its sales, if any, will be limited.

Gimoti's commercial success will depend upon the acceptance of the product candidate by the medical community, including physicians, patients and health care payors. The degree of market acceptance of our product candidate will depend on a number of factors, including:

- demonstration of clinical efficacy and safety compared to other more-established products;
- the limitation of our targeted patient population to women-only;
- limitations or warnings contained in any FDA-approved labeling, including the potential boxed warning on all metoclopramide product labels concerning the chance of TD for patients taking these products, or any limitations with respect to metoclopramide product labels in the European Union;
- acceptance of a new formulation by health care providers and their patients;
- the prevalence and severity of any adverse effects;

- new procedures or methods of treatment that may be more effective in treating or may reduce the incidences of diabetic gastroparesis;
- · pricing and cost-effectiveness;
- the effectiveness of our or any future collaborators' sales and marketing strategies;
- our ability to obtain and maintain sufficient third-party coverage and reimbursement from government health care programs, including Medicare and Medicaid, private health insurers and other third-party payors; and
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage.

If Gimoti is approved, but does not achieve an adequate level of acceptance by physicians, health care payors and patients, we may not generate sufficient revenue, and we may not be able to achieve or sustain profitability. Our efforts to educate the medical community and third-party payors on the benefits of Gimoti may require significant resources and may never be successful. In addition, our ability to successfully commercialize our product candidate will depend on our ability to manufacture our products, differentiate our products from competing products and defend the intellectual property of our products.

# It will be difficult for us to profitably sell Gimoti if coverage and reimbursement are limited.

Market acceptance and sales of our product candidate will depend on coverage and reimbursement policies and may be affected by healthcare reform measures. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors have been challenging the prices charged for products. They may also refuse to provide any coverage of uses of approved products for medical indications other than those for which FDA has granted marketing approval. This trend may impact the reimbursement for treatments for GI disorders especially, including Gimoti, as physicians typically focus on symptoms rather than underlying conditions when treating patients with these disorders and drugs are often prescribed for uses outside of their approved indications. In instances where alternative products are available, it may be required that those alternative treatment options are tried before coverage and reimbursement are available for Gimoti. Although Gimoti is a novel nasal spray formulation of metoclopramide, this is the same active ingredient that is already available in other formulations approved for the treatment of gastroparesis that are already widely available at generic prices. We cannot be sure that coverage will be available for Gimoti and, if coverage is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, this product candidate. In addition, in certain foreign countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. If reimbursement is not available only to limited levels, we may not be able to success

# We rely and will continue to rely on outsourcing arrangements for many of our activities, including clinical development and supply of Gimoti.

We have only seven full-time employees and, as a result, we rely on outsourcing arrangements for a significant portion of our activities, including clinical research, data collection and analysis and manufacturing, as well as functioning as a public company. We may have limited control over these third parties and we cannot guarantee that they will perform their obligations in an effective and timely manner.

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. We do not own or operate manufacturing facilities for the production of any component of Gimoti, including metoclopramide, the nasal spray device or associated bottle, nor do we have plans to develop our own manufacturing operations in the foreseeable future. We currently depend on third-party contract manufacturers for all of our required raw materials, drug substance and drug product for our clinical trials. For Gimoti, we are currently using, and relying on, single suppliers and single manufacturers for starting materials, the final drug substance and nasal spray delivery device. Although potential alternative suppliers and manufacturers for some components have been identified, we have not qualified these vendors to date. If we were required to change vendors, it could result in a failure to meet regulatory requirements or projected timelines and necessary quality standards for successful manufacturing of the various required lots of material for our development and commercialization efforts.

We do not have any current contractual relationships for the manufacture of commercial supplies of Gimoti. If Gimoti is approved for sale by any regulatory agency, we intend to enter into agreements with third-party contract manufacturers for commercial production. The number of third-party manufacturers with the expertise, required regulatory approvals and facilities to manufacture bulk drug substance on a commercial scale is limited. We have identified one manufacturer for potentially providing commercial supplies of Gimoti; however, no alternative providers have been identified to date. If we are unable to come to terms on becoming our

commercial supplier with this manufacturer, we would have to find replacements, which could delay the commercialization of our product candidate.

In addition, our reliance on third party CROs and contract manufacturing organizations, or CMOs, entails further risks including:

- non-compliance by third parties with regulatory and quality control standards;
- breach by third parties of our agreements with them;
- termination or non-renewal of an agreement with third parties; and
- sanctions imposed by regulatory authorities if compounds supplied or manufactured by a third party supplier or manufacturer fail to comply with applicable regulatory standards.

We face substantial competition, which may result in others selling their products more effectively than we do, and in others discovering, developing or commercializing product candidates before, or more successfully, than we do.

Our future success depends on our ability to demonstrate and maintain a competitive advantage with respect to the design, development and commercialization of Gimoti. We anticipate that Gimoti, if approved, would compete directly with metoclopramide, erythromycin and domperidone, each of which is available under various trade names sold by several major pharmaceutical companies, including generic manufacturers. Metoclopramide is the only molecule currently approved in the United States to treat gastroparesis. Metoclopramide is generically-available and indicated for the relief of symptoms associated with acute and recurrent diabetic gastroparesis, without the limitation of use in women only.

Many of our potential competitors have substantially greater financial, technical and personnel resources than we have. In addition, many of these competitors have significantly greater commercial infrastructures than we have. We will not be able to compete successfully unless we successfully:

- assure health care providers, patients and health care payors that Gimoti is beneficial compared to other products in the market;
- obtain patent and/or other proprietary protection for Gimoti;
- obtain and maintain required regulatory approvals for Gimoti; and
- collaborate with others to effectively market, sell and distribute Gimoti.

Established competitors may invest heavily to quickly discover and develop novel compounds that could make our product candidate obsolete. In addition to our Gimoti product candidate, we are aware of other development candidates in clinical development. Any of these product candidates could advance through clinical development faster than Gimoti and, if approved, could attain faster and greater market acceptance than our product candidate. If we are not able to compete effectively against our current and future competitors, our business will not grow and our financial condition and operations will suffer.

# We have no sales, marketing or distribution capabilities currently and we will have to invest significant resources to develop these capabilities.

Currently, we have no internal sales, marketing or distribution capabilities. If Gimoti ultimately receives regulatory approval, we may not be able to effectively market and distribute the product candidate. We will have to invest significant amounts of financial and management resources to develop internal sales, distribution and marketing capabilities, some of which will be committed prior to any confirmation that Gimoti will be approved. We may not be able to hire consultants or external service providers to assist us in sales, marketing and distribution functions on acceptable financial terms or at all. Even if we determine to perform sales, marketing and distribution functions ourselves, we could face a number of additional related risks, including:

- inability to attract and build an effective marketing department or sales force;
- the cost of establishing a marketing department or sales force may exceed our available financial resources and the revenues generated by Gimoti or any other product candidates that we may develop, in-license or acquire; and
- our direct sales and marketing efforts may not be successful.

If we fail to attract and retain senior management and key commercial personnel, we may be unable to successfully complete the development of Gimoti and commercialize this product candidate.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and commercial personnel. We are highly dependent upon our senior management team composed of three individuals: David A. Gonyer, R.Ph., our President and Chief Executive Officer, Matthew J. D'Onofrio, our Executive Vice President and Chief Business Officer,

and Marilyn Carlson, D.M.D., M.D., our Chief Medical Officer. The loss of services of any of these individuals could delay or prevent the successful development of Gimoti or the commercialization of this product candidate, if approved.

We will need to hire and retain qualified personnel to pursue the potential commercialization of Gimoti. We could experience problems in the future attracting and retaining qualified employees. For example, competition for qualified personnel in the biotechnology and pharmaceuticals field is intense, particularly in the San Diego, California area where we are headquartered. We may not be able to attract and retain quality personnel on acceptable terms who have the expertise we need to sustain and grow our business.

# We may encounter difficulties in managing our growth and expanding our operations successfully.

Because we currently have only seven full-time employees, we will need to grow our organization substantially to pursue the potential commercialization of Gimoti and to potentially conduct additional unplanned development activities. As we seek to commercialize Gimoti, we will need to expand our regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various strategic partners, suppliers and other third parties. Future growth will impose significant added responsibilities on members of management and require us to retain additional internal capabilities. Our future financial performance and our ability to commercialize Gimoti and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train and integrate additional management, clinical and regulatory, financial, administrative and sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company.

# Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize Gimoti and affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval for Gimoti, restrict or regulate post-approval activities and affect our ability to profitably sell our product candidate, assuming we obtain marketing approval.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We are not sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of Gimoti, if any, may be. In addition, increased scrutiny by the U.S. Congress of FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

In early 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the Affordable Care Act, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The Affordable Care Act, among other things, increased the Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program for both branded and generic drugs and revised the definition of "average manufacturer price" for reporting purposes, which could further increase the amount of Medicaid drug rebates to states. Further, the new law imposes a significant annual fee on companies that manufacture or import branded prescription drug products, increased the number of entities eligible for discounts under the 340B program and included a 50% discount on brand name drugs for Medicare Part D beneficiaries in the coverage gap, or "donut hole." Substantial new provisions affecting compliance have also been enacted, which may require us to modify our business practices with healthcare practitioners.

We expect that the new presidential administration and U.S. Congress will seek to modify, repeal, or otherwise invalidate all, or certain provisions of, the Affordable Care Act. Since taking office, President Trump has continued to support the repeal of all or portions of the Affordable Care Act. In January 2017, the House and Senate passed a budget resolution that authorizes congressional committees to draft legislation to repeal all or portions of the Affordable Care Act and permits such legislation to pass with a majority vote in the Senate. President Trump has also recently issued an executive order in which he stated that it is his administration's policy to seek the prompt repeal of the Affordable Care Act and directed executive departments and federal agencies to waive, defer, grant exemptions from, or delay the implementation of the provisions of the Affordable Care Act to the maximum extent permitted by law. There is still uncertainty with respect to the impact President Trump's administration and the U.S. Congress may have, if any, and any changes will likely take time to unfold, and could have an impact on coverage and reimbursement for healthcare items and services covered by plans that were authorized by the Affordable Care Act. However, we cannot predict the ultimate content, timing or effect of any healthcare reform legislation or the impact of potential legislation on us.

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. These changes include aggregate reductions to Medicare payments to providers of two percent per fiscal year, which went into effect on April 1, 2013, and due to subsequent legislative amendments, will remain in effect through 2025, unless additional Congressional action is taken. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Recently there has also been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed bills designed to, among other things, reform government program reimbursement methodologies. These new laws and the regulations and policies implementing them, as well as other healthcare reform measures that may be adopted in the future, may have a material adverse effect on our industry generally and on our ability to successfully develop and commercialize our products, if approved.

# If we market products in a manner that violates healthcare laws, or if we violate government price reporting laws, we may be subject to civil or criminal penalties.

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal healthcare fraud and abuse laws have been applied in recent years to restrict business activities in the pharmaceutical industry, including certain marketing practices. These laws include false claims, anti-kickback, data privacy and security and physician payment transparency laws and regulations. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of these laws.

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are several statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution, the exceptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability. Further, the Affordable Care Act, among other things, amends the intent requirement of the federal Anti-Kickback Statute and the criminal healthcare fraud statutes that prohibit executing a scheme to defraud any federal healthcare benefit program or making false statements relating to healthcare matters. A person or entity no longer needs to have actual knowledge of these statutes or specific intent to violate them in order to have committed a violation, the Affordable Care Act provides that 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 False Claims Act.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, or causing to be made, a false statement to get a false claim paid. Violations of the False Claims Act can result in very significant monetary penalties and treble damages. Over the past few years, several pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as: allegedly providing free trips, free goods, sham consulting fees and grants and other monetary benefits to prescribers; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off-label promotion that caused claims to be submitted to Medicaid for non-covered, off-label uses; and submitting inflated best price information to the Medicaid Rebate Program to reduce liability for Medicaid rebates. Most states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created additional federal criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Like the federal Anti-Kickback Statute, the Affordable Care Act amended the intent standard for certain healthcare fraud under HIPAA such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

In addition, we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's security standards directly applicable to business associates, independent contractors or agents of covered entities that receive or obtain protected health information in connection with

providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions.

In addition, the Affordable Care Act included the federal Physician Payment Sunshine Act, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the government information related to payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and applicable manufacturers and group purchasing organizations to report annually to the government ownership and investment interests held by physicians (as defined above) and their immediate family members. Manufacturers are required to report such data to the government by the 90th calendar day of each year. There are also several states with similar laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information, and/or require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers.

The risk of our being found in violation of these laws and regulations is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from governmental health care programs, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results.

Federal legislation and actions by state and local governments may permit re-importation of drugs from foreign countries into the United States, including foreign countries where the drugs are sold at lower prices than in the United States, which could materially adversely affect our operating results and our overall financial condition.

We may face competition in the United States for Gimoti, if approved, from lower priced products from foreign countries that have placed price controls on pharmaceutical products. This risk may be particularly applicable to drugs such as Gimoti. The MMA contains provisions that may change U.S. importation laws and expand pharmacists' and wholesalers' ability to import lower priced versions of an approved drug and competing products from Canada, where there are government price controls. These changes to U.S. importation laws will not take effect unless and until the Secretary of Health and Human Services certifies that the changes will pose no additional risk to the public's health and safety and will result in a significant reduction in the cost of products to consumers. The Secretary of Health and Human Services has not yet announced any plans to make this required certification.

A number of federal legislative proposals have been made to implement the changes to the U.S. importation laws without any certification and to broaden permissible imports in other ways. Even if the changes do not take effect, and other changes are not enacted, imports from Canada and elsewhere may continue to increase due to market and political forces, and the limited enforcement resources of FDA, U.S. Customs and Border Protection and other government agencies. For example, Pub. L. No. 111-83, which was signed into law in October 2009 and provides appropriations for the Department of Homeland Security for the 2010 fiscal year, expressly prohibits U.S. Customs and Border Protection from using funds to prevent individuals from importing from Canada less than a 90-day supply of a prescription drug for personal use, when the drug otherwise complies with the Federal Food, Drug, and Cosmetic Act, or FDCA. Further, several states and local governments have implemented importation schemes for their citizens and, in the absence of federal action to curtail such activities, we expect other states and local governments to launch importation efforts.

The importation of foreign products that compete with Gimoti could negatively impact our revenue and profitability, possibly materially.

# If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of Gimoti.

We face an inherent risk of product liability as a result of the clinical testing of Gimoti and will face an even greater risk if we commercialize the product candidate. For example, we may be sued if Gimoti allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product candidate, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts.

In particular, products containing metoclopramide have been reported to cause side effects, including TD. It is possible that a patient taking Gimoti will be found to experience a variety of side effects. In 2009, FDA required a boxed warning on all metoclopramide product labels concerning the chance of TD for patients taking these products. We expect that the label for Gimoti, if approved, will

likely contain a similar warning regarding TD. Several manufactures of metoclopramide products have been sued by patients regarding TD.

If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidate. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for Gimoti;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- · product recalls, withdrawals or labeling, marketing or promotional restrictions;
- · loss of revenue;
- the inability to commercialize Gimoti; and
- a decline in our stock price.

## We may form strategic alliances in the future, and we may not realize the benefits of such alliances.

We may form strategic alliances, create joint ventures or collaborations or enter into licensing arrangements with third parties that we believe will complement or augment our existing business, including for the continued development or commercialization of Gimoti. These relationships or those like them may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for Gimoti because third parties may view the development risk of Gimoti as too significant or the commercial opportunity for our product candidate as too limited. We cannot be certain that, following a strategic transaction or license, we will achieve the revenues or specific net income that justifies such transaction.

## 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 current and any future CROs and other contractors and consultants and collaborators are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such material 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 development program for Gimoti and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties to manufacture Gimoti and conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were 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 and commercialization of our product candidate could be delayed.

## Business disruptions could seriously harm our future revenues and financial condition and increase our costs and expenses.

Our operations could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or manmade disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce our Gimoti. Our ability to obtain clinical supplies of Gimoti could be disrupted, if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption. Our operations are located in Solana Beach, California near major earthquake faults and fire zones. The ultimate impact on us, our significant suppliers and our general infrastructure of being located near major earthquake faults and fire zones and being consolidated in certain geographical areas is unknown, but our operations and financial condition could suffer in the event of a major earthquake, fire or other natural disaster.

## If we fail to develop and commercialize other product candidates, we may be unable to grow our business.

As part of our growth strategy, we plan to evaluate the development and/or commercialization of other therapies for GI motility disorders. Similar to our initial focus on gastroparesis, we will evaluate opportunities to in-license or acquire other product candidates as well as commercial products to treat patients suffering from predominantly GI disorders, seeking to identify areas of high unmet medical needs with limited treatment options. These other product candidates will require additional, time-consuming development efforts prior to commercial sale, including preclinical studies, extensive clinical trials and approval by FDA and applicable foreign regulatory authorities. All product candidates are prone to the risks of failure that are inherent in pharmaceutical product development, including the possibility that the drug candidate will not be shown to be sufficiently safe and/or effective for approval by regulatory authorities. In addition, we cannot assure you that any such products that are approved will be manufactured or produced economically, successfully commercialized or widely accepted in the marketplace or be more effective than other commercially available alternatives.

## If we engage in an acquisition, reorganization or business combination, we will incur a variety of risks that could adversely affect our business operations or our stockholders.

From time to time we have considered, and we will continue to consider in the future, strategic business initiatives intended to further the development of our business. These initiatives may include acquiring businesses, technologies or products or entering into a business combination with another company. If we do pursue such a strategy, we could, among other things:

- issue equity securities that would dilute our current stockholders' percentage ownership;
- incur substantial debt that may place strains on our operations;
- · spend substantial operational, financial and management resources in integrating new businesses, technologies and products; and
- assume substantial actual or contingent liabilities.

## We may be unable to maintain sufficient product liability insurance.

Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. We currently carry product liability insurance covering our clinical studies. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. If we determine that it is prudent to increase our product liability coverage due to the commercial launch of any product, we may be unable to obtain such increased coverage on acceptable terms or at all. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

## **Risks Relating to Our Intellectual Property**

It is difficult and costly to protect our intellectual property rights, and we cannot ensure the protection of these rights. Any impairment of our intellectual property rights would materially affect our business.

We place considerable importance on obtaining patent protection for new technologies, products and processes because our commercial success will depend, in large part, on obtaining patent protection for new technologies, products and processes, successfully defending these patents against third-party challenges and successfully enforcing our patents against third party competitors. To that end, we have acquired and will file applications for patents covering formulations containing or uses of Gimoti or our proprietary processes as well as other intellectual property important to our business. One of our patents related to Gimoti was acquired from Questcor. This method of use patent was not written by us or our attorneys, and we did not have control over the drafting and prosecution of these patents. Further, Questcor and other predecessors might not have given the same attention to the drafting and prosecution of these patents and applications as we would have if we had been the owners of the patent and application and had control over the drafting and prosecution.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain and involves complex legal and factual questions for which legal principles remain unresolved. In recent years patent rights have been the subject of significant litigation, in particular due to *inter partes* review, introduced by the America Invents Act of 2012, which allows for quicker patent challenges decided by the U.S. Patent and Trademark Office's Patent Trial and Appeal Board rather than a lay jury. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or products or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. The laws of

foreign countries may not protect our rights to the same extent as the laws of the United States. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or our predecessors were the first to make the inventions claimed in our owned and licensed patents or pending patent applications, or that we or our predecessors were the first to file for patent protection of such inventions One or more of these factors could possibly result in findings of invalidity or unenforceability of one or more of the patents we own.

The patent rights we own covering Gimoti are limited to specific methods of use and formulations of metoclopramide. As a result, our ability to market Gimoti may be limited by the lack of patent protection for the active ingredient itself and other metoclopramide formulations may be developed by competitors. The active ingredient in Gimoti is metoclopramide. No patent protection is available for metoclopramide itself. As a result, competitors who develop and receive required regulatory approval for competing products using the same active ingredient as Gimoti may market their competing products so long as they do not infringe any of the method or formulation patents owned by us.

Others have filed, and in the future are likely to file, patent applications covering products and technologies that are similar, identical or competitive to ours, or important to our business. We cannot be certain that any patent application owned by a third party will not have priority over patent applications filed or in-licensed by us, or that we will not be involved in interference, opposition or invalidity proceedings before U.S. or foreign patent offices.

We have focused our intellectual property efforts on the United States. To the extent that our patent portfolio differs from country to country outside the United States, this may make protecting Gimoti as a product outside the United States even more difficult and unpredictable. Various countries maintain their own standards and interpretation of intellectual property law, potentially creating additional patent risk beyond even that experienced within the United States.

We also rely on trade secrets to protect technology in cases when we believe patent protection is not appropriate or obtainable. However, trade secrets are difficult to protect. While we require employees, consultants and other contractors to enter into confidentiality agreements, we may not be able to adequately protect our trade secrets or other proprietary information. Our research collaborators and scientific advisors may have rights to publish data and information in which we have rights. If we cannot maintain the confidentiality of our technology and other confidential information in connection with our collaborators and advisors, our ability to receive patent protection or protect our proprietary information may be imperiled.

# Claims by third parties that we infringe their proprietary rights may result in liability for damages or prevent or delay our developmental and commercialization efforts.

The biotechnology industry has been characterized by frequent litigation regarding patent and other intellectual property rights. Because patent applications are maintained in secrecy until the application is published, we may be unaware of third party patents that may be infringed by commercialization of Gimoti. In addition, identification of third party patent rights that may be relevant to our technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. Any claims of patent infringement asserted by third parties would be time consuming and could likely:

- result in costly litigation;
- divert the time and attention of our technical personnel and management;
- cause development delays;
- prevent us from commercializing Gimoti until the asserted patent expires or is held finally invalid or not infringed in a court of law;
- require us to develop non-infringing technology; or
- require us to enter into royalty or licensing agreements.

Although no third party has asserted a claim of infringement against us, others may hold proprietary rights that could prevent Gimoti from being marketed. Any patent-related legal action against us claiming damages or seeking to enjoin commercial activities relating to our product candidate or processes could subject us to potential liability for damages and could require us to obtain a license to continue to manufacture or market Gimoti, or, if no such license were available on commercially viable terms, could require us to cease manufacturing and marketing of Gimoti. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. In addition, we cannot be sure that we could redesign our product candidate or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing Gimoti, which could harm our business, financial condition and operating results. Whatever the outcome, any

patent litigation would be costly and time consuming, could be distracting to our management, and could have a material adverse effect on our business.

# We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers.

As is commonplace in our industry, we employ and consult with individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject in the future to claims that our employees or consultants are subject to a continuing obligation to their former employers or clients (such as non-competition or non-solicitation obligations) or claims that our employees, our consultants or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers or clients. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

## Risks Related to Our Financial Position and Need for Capital

## Our recurring losses from operations have raised substantial doubt regarding our ability to continue as a going concern.

Our recurring losses from operations raise substantial doubt about our ability to continue as a going concern, and as a result, our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements as of and for the year ended December 31, 2016 with respect to this uncertainty. This going concern opinion could materially limit our ability to raise additional funds through the issuance of new debt or equity securities or otherwise. Future reports on our financial statements may also include an explanatory paragraph with respect to our ability to continue as a going concern. We have incurred significant losses since our inception and have never been profitable, and it is possible we will never achieve profitability. We have devoted our resources to developing Gimoti, but it cannot be marketed until regulatory approvals have been obtained. Based upon our currently expected level of operating expenditures, we expect to be able to fund our operations through at least February 2018. This period could be shortened if there are any significant increases in planned spending on our Gimoti development program than anticipated. There is no assurance that other financing will be available when needed to allow us to continue as a going concern. The perception that we may not be able to continue as a going concern may cause others to choose not to deal with us due to concerns about our ability to meet our contractual obligations.

# We have incurred significant operating losses since inception, and we expect to incur losses for the foreseeable future. We may never become profitable or, if achieved, be able to sustain profitability.

We have incurred significant operating losses since we were founded in 2007 and expect to incur significant losses for the next several years related to completing development for Gimoti, and seeking regulatory approval from FDA to manufacture and commercialize Gimoti. Our net loss for the year ended December 31, 2016, was approximately \$10.7 million. As of December 31, 2016, we had an accumulated deficit of approximately \$58.8 million. Losses have resulted principally from costs incurred in our clinical trials, research and development programs and from our general and administrative expenses, especially since we became a public company in September 2013. In the future, we intend to continue to conduct research and development, clinical testing, regulatory compliance activities and, if Gimoti is approved, sales and marketing activities that, together with anticipated general and administrative expenses, will likely result in our incurring further significant losses for the next several years.

We currently generate no revenue from sales, and we may never be able to commercialize Gimoti or other marketable drugs. As a result, there can be no assurance that we will ever generate revenues or achieve profitability, which could impair our ability to sustain operations or obtain any required additional funding. If we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods.

## If we fail to obtain the capital necessary to fund our operations, we will be unable to successfully develop and commercialize Gimoti.

We will require substantial additional future capital in order to finance any additional development activities for Gimoti, including any requirements requested by FDA, as well as for any NDA preparation and pre-commercial activities, including marketing and manufacturing of Gimoti. The amount and timing of any expenditure needed to implement our development and commercialization programs will depend on numerous factors, including:

- · our assessment of continued development opportunities for Gimoti, including any feedback received from FDA;
- the need for, and the progress, costs and results of, any additional clinical trials of Gimoti we may initiate based on our discussions with FDA, including any additional trials FDA or other regulatory agencies may require evaluating the safety of Gimoti;

- FDA may disagree with the design of our comparative exposure PK trial or any other future clinical trials, if any are necessary;
- · the outcome, costs and timing of seeking and obtaining regulatory approvals from FDA, and any similar regulatory agencies;
- · the timing and costs associated with manufacturing Gimoti for clinical trials and other studies and, if approved, for commercial sale;
- our need and ability to hire additional management, development and scientific personnel;
- the cost to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- the timing and costs associated with establishing sales and marketing capabilities;
- market acceptance of Gimoti;
- the extent to which we are required to pay milestone or other payments under our Mallinckrodt asset purchase agreement and the timing of such payments;
- · the costs of acquiring, licensing or investing in additional businesses, products, product candidates and technologies; and
- · our need to implement additional internal systems and infrastructure, including financial and reporting systems.

Some of these factors are outside of our control. We cannot provide any assurance that our existing capital will be sufficient to enable us to fund any additional clinical development of Gimoti, and, in any event, we will need to raise additional capital to complete such clinical development and submit marketing applications for and prepare to commercialize Gimoti should we receive product approval. We may need to raise additional funds in the near future for commercialization for Gimoti.

We may seek additional funding through collaboration agreements, public or private equity financings, debt financings or receivables financings. For example, in April 2016 we entered into an At Market Issuance Sales Agreement with FBR, or the FBR Sales Agreement, pursuant to which we may sell from time to time, at our option, shares of our common stock through FBR, as sales agent. In March 2017, we filed a prospectus supplement permitting us to sell up to an aggregate of \$20.0 million of shares of our common stock pursuant to the FBR Sales Agreement are made on The NASDAQ Capital Market under our shelf registration statement on Form S-3 filed on November 13, 2014, which was declared effective by the SEC on November 25, 2014, by means of ordinary brokers' transactions at market prices. Although sales of our common stock have taken place pursuant to the FBR Sales Agreement, there can be no assurance that FBR will be successful in consummating future sales based on prevailing market conditions or in the quantities or at the prices that we deem appropriate. Under current SEC regulations, at any time during which the aggregate market value of our common stock held by non-affiliates, or public float, is less than \$75 million, the amount we can raise through primary public offerings of securities in any twelve-month period using shelf registration statements, including sales under the FBR Sales Agreement, is limited to an aggregate of one-third of our public float. As of March 10, 2017, our public float was \$40.1 million which means we may only sell approximately \$8.6 million of securities using our shelf registration statements. If our public float decreases, the amount of securities we may sell under our Form S-3 shelf registration statement will also decrease. In addition, FBR is permitted to terminate the Sales Agreement in its sole discretion upon ten days' notice, or at any time in certain circumstances, including the occurrence of an event that would be reasonably likely to have a material adverse effect on our

Additional funding may not be available to us on acceptable terms or at all. In addition, the terms of any financing may adversely affect the holdings or the rights of our stockholders. In addition, the issuance of additional shares by us, or the possibility of such issuance, may cause the market price of our shares to decline and dilute the holdings of our existing stockholders. If we raise additional funds by incurring debt, the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to operate our business.

If we are unable to obtain funding on a timely basis, if required, we will be unable to complete additional clinical development of Gimoti and may be required to significantly curtail all of our activities. We also could be required to seek funds through arrangements with collaborative partners or otherwise that may require us to relinquish rights to our product candidate or some of our technologies or otherwise agree to terms unfavorable to us.

Our ability to use net operating loss and tax credit carryforwards and certain built-in losses to reduce future tax payments is limited by provisions of the Internal Revenue Code, and may be subject to further limitation as a result of the transactions completed in connection with our initial public offering.

Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change" (generally defined as a greater than 50% change (by value) in its equity ownership over a three year period), the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. As a result of our initial public offering, our most recent private placement and other transactions that have occurred over the past three years, we may have experienced an "ownership change." We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As of December 31, 2016, we had federal and state net operating loss carryforwards of approximately \$5.0 million and \$42.9 million, respectively, and federal research and development credits of approximately \$1.8 million which could be limited if we experience an "ownership change."

## Risks Related to Ownership of Our Common Stock

## An active trading market for our common stock may not develop or be sustained.

Prior to our initial public offering in September 2013, there was no public market for our common stock. An active trading market may never develop or be sustained. If an active trading market does not develop or is not sustained, it may be difficult to sell shares of our common stock at a price that is desirable or at all. In addition, an inactive market may impair our ability to raise capital by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration, which, in turn, could materially adversely affect our business. Since the commencement of trading in connection with our initial public offering in September 2013 through March 10, 2017, the sale price per share of our common stock on The NASDAQ Capital Market has ranged from a low of \$1.35 to a high of \$14.25.

## The price of the shares of our common stock could be highly volatile, and purchasers of our common stock could incur substantial losses.

Our stock price is likely to be volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. The stock market in general and the market for biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the price at which they purchased the shares. The market price for our common stock may be influenced by many factors, including:

- the timing, progress and results of our comparative exposure PK trial, and the results of trials of our competitors or those of other companies in our market sector:
- regulatory developments in the United States and foreign countries, including a potential NDA submission;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems, especially in light of current reforms to the U.S. healthcare system;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- market conditions in the pharmaceutical and biotechnology sectors and issuance of securities analysts' reports or recommendations;
- sales of our stock by insiders and 5% stockholders;
- trading volume of our common stock;
- general economic, industry and market conditions other events or factors, many of which are beyond our control;
- · additions or departures of key personnel; and
- intellectual property, product liability or other litigation against us.

In addition, in the past, stockholders have initiated class action lawsuits against biotechnology and pharmaceutical companies following periods of volatility in the market prices of these companies' stock. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources, which could have a material adverse effect on our business, financial condition and results of operations.

## Our quarterly operating results may fluctuate significantly.

We expect our operating results to be subject to quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including:

- variations in the level of expenses related to our Gimoti development program, including NDA preparation and pre-commercialization costs;
- addition or termination of clinical trials;
- any intellectual property infringement lawsuit in which we may become involved;
- regulatory developments affecting Gimoti; and
- our execution of any collaborative, licensing or similar arrangements, and the timing of payments we may make or receive under these arrangements.

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws may delay or prevent an acquisition of us or a change in our management. These provisions include:

- authorizing the issuance of "blank check" preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
- limiting the removal of directors by the stockholders;
- creating a staggered board of directors;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- eliminating the ability of stockholders to call a special meeting of stockholders;
- · permitting our board of directors to accelerate the vesting of outstanding option grants upon certain transactions that result in a change of control; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which limits the ability of stockholders owning in excess of 15% of our outstanding voting stock to merge or combine with us. Although we believe these provisions collectively provide for an opportunity to obtain greater value for stockholders by requiring potential acquirors to negotiate with our board of directors, they would apply even if an offer rejected by our board were considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management.

We do not intend to pay dividends on our common stock and, consequently, the ability of our stockholders to achieve a return on their investment will depend on appreciation in the price of our common stock.

We have never declared or paid any cash dividend on our common stock and do not currently intend to do so for the foreseeable future. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business. In addition, any future debt financing arrangement may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Any return to stockholders will therefore be limited to the appreciation of their stock. Therefore, the success of an investment in shares of our common stock will depend upon any future appreciation in their value. There

is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which our stockholders have purchased their shares.

## Sales of a substantial number of shares of our common stock by our existing stockholders in the public market could cause our stock price to fall.

Persons who were our stockholders prior to the sale of shares in our initial public offering in September 2013 continue to hold a substantial number of shares of our common stock that they are able to sell in the public market, subject in some cases to certain legal restrictions. Significant portions of these shares are held by a small number of stockholders. Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales might occur, could significantly reduce the market price of our common stock and impair our ability to raise adequate capital through the sale of additional equity securities.

As of March 10, 2017, we had 15,388,325 shares of common stock outstanding. All of these shares are freely tradable without restriction in the public market, except for 2,541,814 shares that are held by directors, executive officers and other affiliates that are subject to volume limitations under Rule 144 under the Securities Act. In addition, shares of common stock that are either subject to outstanding options or reserved for future issuance under our employee benefit plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules and Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

As of March 10, 2017, the holders of 1,509,789 shares of our common stock are entitled to reasonable best efforts registration rights with respect to the registration of their shares under the Securities Act. In addition, holders of 84,000 shares of common stock issuable upon the exercise of warrants are also entitled to reasonable best efforts registration rights with respect to the registration of their shares under the Securities Act. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

# We are an emerging growth company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years following 2013, the year in which we completed our initial public offering, although circumstances could cause us to lose that status earlier, including if the market value of our common stock held by non-affiliates exceeds \$700.0 million as of any June 30 before that time or if we have total annual gross revenue of \$1.0 billion or more during any fiscal year before that time, in which cases we would no longer be an emerging growth company as of the following December 31 or, if we issue more than \$1.0 billion in non-convertible debt during any three year period before that time, we would cease to be an emerging growth company immediately. Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company" which would allow us to take advantage of many of the same exemptions from disclosure requirements including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, changes in rules of U.S. generally accepted accounting principles or their interpretation, the adoption of new guidance or the application of existing guidance to changes in our business could significantly affect our financial position and results of operations.

# We will continue to incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, we have incurred and will continue to incur significant legal, accounting and other expenses under the Sarbanes-Oxley Act and the Dodd-Frank Wall Street Reform and Consumer Protection Act, as well as rules adopted by the SEC and The

NASDAQ Stock Market. These rules impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls, changes in corporate governance practices, proxy access and "say on pay" votes. As an "emerging growth company," we are permitted to implement many of these requirements over a longer period of time. While we are taking advantage of this option to delay implementation, we cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

The rules and regulations applicable to public companies have substantially increased our legal and financial compliance costs and made some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition and results of operations. The increased costs will decrease our net income or increase our net loss, and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

## If securities or industry analysts publish unfavorable research or reports about our business, our stock price and trading volume could decline.

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us, our business, our market or our competitors. We currently have limited research coverage by securities and industry analysts. If one or more of the analysts who covers us downgrades our stock, our stock price would likely decline. If one or more of these analysts ceases to cover us or fails to regularly publish reports on us, interest in our stock could decrease, which could cause our stock price or trading volume to decline.

## We could be subject to securities class action litigation.

In the past, securities 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 pharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

If we fail to continue to meet all applicable Nasdaq Capital Market requirements and Nasdaq determines to delist our common stock, the delisting could adversely affect the market liquidity of our common stock and the market price of our common stock could decrease.

Our common stock is listed on the Nasdaq Capital Market. In order to maintain our listing, we must meet minimum financial and other requirements, including requirements for a minimum amount of capital, a minimum price per share and continued business operations so that we are not characterized as a "public shell company." In the event that our common stock is delisted from the Nasdaq Capital Market and is not eligible for quotation or listing on another market or exchange, trading of our common stock could be conducted only in the over-the-counter market or on an electronic bulletin board established for unlisted securities such as the Pink Sheets or the OTC Bulletin Board. In such event, it could become more difficult to dispose of, or obtain accurate price quotations for, our common stock, and there would likely also be a reduction in our coverage by securities analysts and the news media, which could cause the price of our common stock to decline further. Also, it may be difficult for us to raise additional capital if we are not listed on a major exchange.

## **Item 1B. Unresolved Staff Comments**

Not applicable.

## Item 2. Properties

We occupy approximately 3,000 square feet of office space in Solana Beach, California under a lease that we entered into in December 2016. This facility lease expires in December 2018. We believe that our facility is adequate to meet our needs and that, if necessary, additional space can be leased to accommodate any future growth on commercially reasonable terms.

## **Item 3. Legal Proceedings**

We are not currently a party to any material legal proceedings.

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

Not Applicable.

#### **PART II**

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

## **Market Information**

Our common stock has been traded on the NASDAQ Capital Market since September 25, 2013 under the symbol "EVOK." Prior to such time, there was no public market for our common stock. The following table sets forth the high and low sales price of our common stock, as reported by the NASDAQ Capital Market for the period indicated:

	High		Low	
Year Ended December 31, 2016	 			
Fourth Quarter	\$ 2.52	\$	1.35	
Third Quarter	\$ 11.11	\$	1.52	
Second Quarter	\$ 7.15	\$	4.57	
First Quarter	\$ 5.48	\$	2.37	
Year Ended December 31, 2015				
Fourth Quarter	\$ 4.57	\$	2.88	
Third Quarter	\$ 7.17	\$	2.54	
Second Quarter	\$ 8.00	\$	4.43	
First Quarter	\$ 8.32	\$	5.05	

## **Holders of Common Stock**

As of March 10, 2017, there were 17 holders of record of our common stock.

## **Dividend Policy**

We have never declared or paid any cash dividends on our capital stock and do not anticipate paying any cash dividends in the foreseeable future. We expect to retain available cash to finance ongoing operations and the potential growth of our business. Any future determination to pay dividends on our common stock will be at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions, business prospects and other factors our board of directors may deem relevant.

## **Unregistered Sales of Equity Securities**

None.

## **Issuer Repurchases of Equity Securities**

None.

## Securities Authorized for Issuance Under Equity Compensation Plans

Information about our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report on Form 10-K.

## Item 6. Selected Financial Data.

The following selected financial data should be read in conjunction with our financial statements and the related notes thereto appearing elsewhere in this Annual Report on Form 10-K and in the section of this Annual Report on Form 10-K entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations." We have derived the statements of operations data for the years ended December 31, 2016 and 2015 and the balance sheet data as of December 31, 2016 and 2015, from our audited financial statements appearing elsewhere in this Annual Report on Form 10-K. Our historical results for any prior period are not necessarily indicative of the results to be expected in any future period.

		Year Ended December 31,			
	2016			2015	
Statement of Operations Data:					
Operating Expenses:					
Research and development	\$	6,951,600	\$	8,154,144	
General and administrative		3,592,825		3,664,159	
Total operating expenses		10,544,425		11,818,303	
Loss from operations		(10,544,425)		(11,818,303)	
Total other expenses, net		(204,106)		(303,160)	
Net loss	\$	(10,748,531)	\$	(12,121,463)	
Net loss per common share, basic and diluted(1)	\$	(1.15)	\$	(1.87)	
Weighted-average shares used to compute basic and diluted net loss per share		9,338,068		6,485,794	

<sup>(1)</sup> See Note 2 to our audited financial statements included elsewhere in this Annual Report on Form 10-K for an explanation of the method used to calculate the historical net loss per share, basic and diluted, and the number of shares used in the computation of the per share amounts.

	As of December 31,		
	 2016		2015
Balance Sheet Data:	 		
Cash and cash equivalents	\$ 9,007,071	\$	8,691,155
Working capital	\$ 7,871,106	\$	7,689,991
Total assets	\$ 9,294,330	\$	9,532,428
Current liabilities	\$ 1,411,673	\$	1,834,440
Long-term debt, net of current portion	_	\$	4,233,059
Warrant liability	\$ 4,095,019		_
Accumulated deficit	\$ (58,809,143)	\$	(48,060,612)
Total stockholders' equity	\$ 3,787,638	\$	3,464,929

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

The following discussion and analysis of our financial condition and results of operations should be read together with our financial statements and the related notes and other financial information included elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors, including, but not limited to, those set forth under "Risk Factors" under Item 1A of Part I of this Annual Report on Form 10-K and elsewhere in this Annual Report on Form 10-K.

## Overview

We are a specialty pharmaceutical company focused primarily on the development of drugs to treat gastrointestinal disorders and diseases. We are developing Gimoti (formerly known as EVK-001), an investigational metoclopramide nasal spray for the relief of symptoms associated with acute and recurrent diabetic gastroparesis in women. Diabetic gastroparesis is a gastrointestinal disorder afflicting millions of sufferers worldwide in which the stomach takes too long to empty its contents resulting in serious digestive system symptoms and other complications. Metoclopramide is the only product currently approved in the United States to treat the symptoms associated with acute and recurrent diabetic gastroparesis, and is currently available only in oral tablet and injection dose forms. Gimoti is a novel formulation of this drug, designed to provide systemic delivery of metoclopramide through nasal spray administration.

In July 2016, we announced results from a Phase 3 clinical trial of Gimoti in female subjects with symptoms associated with acute and recurrent diabetic gastroparesis. This Phase 3 clinical trial was a multicenter, randomized, double-blind, placebo-controlled, parallel group clinical trial to evaluate the efficacy, safety and population pharmacokinetics, or PK, of Gimoti in adult female subjects with diabetic gastroparesis. Subjects received either Gimoti or placebo four times daily for 28 days. The primary endpoint was the change in symptoms from the baseline period to Week 4 as measured using a proprietary Patient Reported Outcome, or PRO, instrument. On a daily basis, subjects reported the frequency and severity of their gastroparesis signs and symptoms using a telephone diary. The subjects' daily symptom scores were the basis for calculating their weekly scores using the PRO instrument. A total of 205 subjects were randomized in this trial. Preliminary results of the trial showed that Gimoti did not achieve its primary endpoint of symptom improvement at Week 4 in the ITT population.

Although the Phase 3 trial failed to reach its primary endpoint, efficacy was demonstrated in patients with moderate to severe symptoms at Baseline which included 105 of the 205 patients (51%) enrolled in the study. In these patients with higher symptom severity, statistically significant benefits were demonstrated for those treated with Gimoti versus those receiving placebo. These statistically significant benefits were observed at Weeks 1, 2 and 3 in the ITT population and at all four weeks in the Per Protocol population. There were also clinically and statistically significant improvements in nausea and upper abdominal pain, two of the more severe and debilitating symptoms of gastroparesis, at all four weeks.

In December 2016, we announced we had completed a second pre-NDA meeting with FDA, in which FDA agreed that a comparative exposure PK trial was acceptable as a basis for submission of a Gimoti NDA. The comparative exposure PK trial will serve as a portion of the full 505(b)(2) data package to include prior efficacy and safety data developed by us and the FDA's prior findings of safety and efficacy for the Listed Drug, Reglan Tablets. We expect to begin and complete the comparative exposure PK trial in the second half of 2017, followed by a potential NDA submission in late 2017 or early 2018.

We have also conducted a companion clinical trial with Gimoti in male subjects with symptoms associated with acute and recurrent diabetic gastroparesis to assess the safety and efficacy of Gimoti in men. The male companion trial was initiated in May 2014 and the design was the same as the Phase 3 trial in women. This trial was requested by FDA to confirm the Phase 2b trial results and to capture additional safety data in men. This trial was not required for submission of the Gimoti NDA for women; however, we expect to include safety data from this trial in the NDA submission. As we anticipated at the beginning of the trial, based on the prior Phase 2b data, the results of the trial showed no statistical significant efficacy in men and the safety profile for Gimoti was favorable compared to placebo with good tolerability.

In 2014, we also completed a thorough ECG (QT/QTc) study and reported positive results in December 2014.

We have no products approved for sale, and we have not generated any revenue from product sales or other arrangements. We have primarily funded our operations through the sale of our convertible preferred stock prior to our initial public offering, or IPO, in September 2013, borrowings under our bank loans and the sale of shares of our common stock on the NASDAQ Capital Market. We have incurred losses in each year since our inception. Our net losses were \$10.7 million and \$12.1 million for the years ended December 31, 2016 and 2015, respectively. As of December 31, 2016, we had an accumulated deficit of \$58.8 million. Substantially all of our operating losses resulted from expenses incurred in connection with advancing Gimoti through development activities and general and administrative costs associated with our operations. We expect to continue to incur significant expenses and increasing

operating losses for at least the next several years. We may never become profitable, or if we do, we may not be able to sustain profitability on a recurring basis.

As of December 31, 2016 we had cash and cash equivalents of approximately \$9.0 million, which excludes our receipt of approximately \$7.1 million in net proceeds from our follow-on equity offering in February and March 2017. We believe our existing cash and cash equivalents will be sufficient to fund our operations through at least February 2018. Current funds on hand are intended to fund clinical development, pre-approval and pre-commercialization activities for Gimoti, including the planned comparative exposure trial and planned NDA submission, and for working capital and general corporate purposes.

## **Technology Acquisition Agreement**

In June 2007, we acquired all worldwide rights, data, patents and other related assets associated with Gimoti from Questcor Pharmaceuticals, Inc., or Questcor, pursuant to an asset purchase agreement. We paid Questcor \$650,000 in the form of an upfront payment and \$500,000 in May 2014 as a milestone payment based upon the initiation of the first patient dosing in our Phase 3 clinical trial for Gimoti. In August 2014, Mallinckrodt, plc, acquired Questcor. As a result of that acquisition, Questcor transferred its rights included in the asset purchase agreement with us to Mallinckrodt. In addition to the payments we made to Questcor, we may also be required to make additional milestone payments to Mallinckrodt totaling up to \$51.5 million. These milestones include up to \$4.5 million in payments if Gimoti achieves the following development targets:

- \$1.5 million upon FDA's acceptance for review of an NDA for Gimoti; and
- \$3 million upon FDA's approval of Gimoti.

The remaining \$47 million in milestone payments depend on Gimoti's commercial success and will only apply if Gimoti receives regulatory approval. In addition, we will be required to pay to Mallinckrodt a low single digit royalty on net sales of Gimoti. Our obligation to pay such royalties will terminate upon the expiration of the last patent right covering Gimoti, which is expected to occur in 2030.

#### **Financial Operations Overview**

## Research and Development Expenses

We expense all research and development expenses as they are incurred. Research and development expenses primarily include:

- clinical trial and regulatory-related costs;
- expenses incurred under agreements with CROs, investigative sites and consultants that conduct our clinical trials;
- manufacturing and stability testing costs and related supplies and materials; and
- employee-related expenses, including salaries, benefits, travel and stock-based compensation expense.

All of our research and development expenses to date have been incurred in connection with Gimoti. Following completion of our Phase 3 clinical trial in 2016, we expect our research and development expenses to decrease, but the costs related to our NDA preparation activities and our pre-commercialization activities, including marketing and manufacturing of Gimoti, are expected to increase. The process of conducting clinical trials necessary to obtain regulatory approval is costly and time consuming. We are unable to estimate with any certainty the costs we will incur in the continued development of Gimoti. Clinical development timelines, the probability of success and development costs can differ materially from expectations. We may never succeed in achieving marketing approval for our product candidate.

The costs of clinical trials may vary significantly over the life of a project owing to, but not limited to, the following:

- per patient trial costs;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible subjects;
- the number of subjects that participate in the trials;
- the number of doses that subjects receive;
- the cost of comparative agents used in trials;
- the drop-out or discontinuation rates of subjects;

- potential additional safety monitoring or other studies requested by regulatory agencies;
- the duration of patient follow-up; and
- the efficacy and safety profile of the product candidate.

We do not yet know when Gimoti may be commercially available, if at all.

#### **General and Administrative Expenses**

General and administrative expenses consist primarily of salaries and related benefits, including stock-based compensation. Other general and administrative expenses include professional fees for accounting, tax, patent costs, legal services, insurance, facility costs and costs associated with being a publicly-traded company, including fees associated with investor relations and directors and officers liability insurance premiums. We expect that general and administrative expenses will increase in the future as we expand our operating activities, prepare for the growth needs associated with commercialization and continue to incur additional costs associated with being a publicly-traded company and maintaining compliance with exchange listing and Securities and Exchange Commission requirements. These increases will likely include higher consulting costs, legal fees, accounting fees, directors' and officers' liability insurance premiums and fees associated with investor relations.

## Other Expenses

Other expenses consist of changes in the fair value of the warrant liability, which represents the change in the fair value of common stock warrants from the date of issuance to the end of the reporting period. The warrant liability will be revalued each reporting period until the liability is settled. We use the Black Scholes valuation model to value the related warrant liability. In addition, costs associated with the issuance of common stock warrants were recorded as other expense upon issuance. Other expense also consists of interest expense incurred on our former outstanding debt.

## Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which we have prepared in accordance with generally accepted accounting principles in the United States, or GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. We evaluate these estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Our actual results may differ materially from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 2 to our financial statements appearing elsewhere in this Annual Report on Form 10-K, we believe that the following accounting policies are the most critical for fully understanding and evaluating our financial condition and results of operations.

## Accrued Research and Development Expenses

As part of the process of preparing financial statements, we are required to estimate and accrue expenses, the largest of which are research and development expenses. This process involves the following:

- communicating with our applicable personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual cost;
- estimating and accruing expenses in our financial statements as of each balance sheet date based on facts and circumstances known to us at the time; and
- · periodically confirming the accuracy of our estimates with selected service providers and making adjustments, if necessary.

Examples of estimated research and development expenses that we accrue include:

- fees paid to CROs in connection with clinical studies;
- fees paid to investigative sites in connection with clinical studies;
- fees paid to CMOs in connection with the production of clinical study materials; and
- professional service fees for consulting and related services.

We base our expense accruals related to clinical studies on our estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that conduct and manage clinical studies on our behalf. The financial terms of these agreements vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors such as the successful enrollment of subjects, site initiation and the completion of clinical study milestones. Our service providers invoice us monthly in arrears for services performed. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If we do not identify costs that we have begun to incur or if we underestimate or overestimate the level of services performed or the costs of these services, our actual expenses could differ materially from our estimates. To date, we have not experienced significant changes in our estimates of accrued research and development expenses after a reporting period. However, due to the nature of estimates, we cannot assure you that we will not make changes to our estimates in the future as we become aware of additional information about the status or conduct of our clinical studies and other research activities.

## Warrant Accounting

Certain of the warrants to purchase shares of our common stock, issued as a part of our registered direct offerings in July and August 2016, are classified as warrant liability and recorded at fair value. These warrants contain a feature that could require the transfer of cash in the event a change of control occurs without the authorization of our Board of Directors, and therefore, are classified as a liability in accordance with the Financial Accounting Standards Board Accounting Standards Codification 480.

The fair value of each warrant is estimated on the date of issuance, and each subsequent balance sheet date, using the Black-Scholes valuation model using the appropriate risk-free interest rate, expected term and volatility assumptions. The expected life of the warrants were calculated using the remaining life of the warrant. Due to our limited historical data as a public company, the estimated volatility is calculated based upon our historical volatility and comparable companies whose share prices are publicly available for a sufficient period of time. The risk-free rate is based upon U.S. Treasury securities with remaining terms similar to the expected term of the stock award being valued.

This warrant liability is subject to remeasurement at each balance sheet date and we recognize any change in the fair value of the warrant liability in the statement of operations. We will continue to adjust the carrying value of the warrants for changes in the estimated fair value until the earlier of the modification, exercise or expiration of the warrants. At that time, the liabilities will be reclassified to additional paid-in capital, a component of stockholders' equity. We anticipate that the value of the warrants could fluctuate from quarter to quarter and that such fluctuation could have a material impact on our financial statements.

#### Stock-Based Compensation

Stock-based compensation expense is recorded at the estimated fair value of the award as of the grant date and is recognized as expense on a straight-line basis over the employee's requisite service period, which is generally the vesting period of the award. Stock-based compensation expense is based on awards ultimately expected to vest, and therefore, the recorded expense includes an estimate of future forfeitures. Forfeitures are to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

Prior to our initial public offering, or IPO, in September 2013, we granted stock options to purchase common stock to employees with exercise prices equal to the value of the underlying stock, as determined by the board of directors on the date the equity award was granted. The board of directors determined the fair value of the underlying common stock by considering a number of factors, including historical and projected financial results, the risks we faced at the time, the preferences of our preferred stockholders and the lack of liquidity of our common stock. Subsequent to the IPO, the exercise price of the stock options granted to our employees and members of our board of directors was determined by the closing market price of our stock on the date the stock options were granted.

The fair value of each option award is estimated on the date of grant using the Black-Scholes valuation model using the appropriate risk-free interest rate, expected term and volatility assumptions. The expected life of options was calculated using the simplified method, which calculates the life as the average of the contractual term of the stock option and the vesting period of the option. Due to our limited historical data as a public company, the estimated volatility is calculated based upon our historical volatility and comparable companies whose share prices are publicly available for a sufficient period of time. The risk-free interest rate is based upon U.S. Treasury securities with remaining terms similar to the expected term of the stock award being valued. We granted options to purchase 414,000 and 354,000 shares of common stock in 2016 and 2015, respectively.

In February 2016, we effected a one-time option exchange, wherein employees were offered the opportunity to exchange certain outstanding stock options for the grant of a lesser number of replacement stock options. The participants received three new stock options for every four stock options tendered for exchange. As a result, 703,500 stock options were exchanged for 527,625 replacement stock options. The replacement stock options have a three-year vesting schedule and an exercise price of \$3.04 per share, which was the closing price of our common stock on the date of the option exchange. All other terms of the replacement stock options remain the same as the original stock options that were exchanged.

#### Other Information

#### **Net Operating Loss Carryforwards**

As of December 31, 2016, we had federal and California tax net operating loss carryforwards of approximately \$53.0 million and \$42.9 million, respectively. The federal and California net loss carryforwards will begin to expire in 2027 and 2017, respectively, unless previously utilized. As of December 31, 2016, we also had federal and California research and development tax credit carryforwards of \$1.8 million and \$1.1 million, respectively. The federal research and development tax credit carryforwards will begin to expire in 2027 unless previously utilized. The California research and development tax credit will carry forward indefinitely.

Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change" (generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period), the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. We have not completed our analysis to determine what, if any, impact any prior ownership change has had on our ability to utilize our net operating loss carryforwards.

#### JOBS Act

On April 5, 2012, the Jumpstart Our Business Startups Act of 2012, or the JOBS Act was enacted. Section 107 of the JOBS Act provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. In other words, an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

Subject to certain conditions set forth in the JOBS Act, as an "emerging growth company," we intend to rely on certain of these exemptions, including without limitation, (i) providing an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and (ii) complying with any requirement that may be adopted by the Public Company Accounting Oversight Board, regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. We will remain an "emerging growth company" until the earliest of (a) the last day of the fiscal year in which we have total annual gross revenues of \$1 billion or more, (b) the last day of our fiscal year following the fifth anniversary of the date of the completion of our initial public offering, or IPO, (c) the date on which we have issued more than \$1 billion in nonconvertible debt during the previous three years or (d) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

## **Results of Operations**

## Comparison of Years Ended December 31, 2016 and 2015

The following table summarizes the results of our operations for the fiscal years ended December 31, 2016 and 2015:

	fear Elided December 51,					mcrease/
		2016		2015	(	(Decrease)
Research and development	\$	6,951,600	\$	8,154,144	\$	(1,202,544)
General and administrative	\$	3,592,825	\$	3,664,159		(71,334)
Other expenses, net	\$	204,106	\$	303,160		(99,054)

Von Ended December 21

Research and Development Expenses. Research and development expenses for the year ended December 31, 2016 compared to the year ended December 31, 2015 decreased by approximately \$1.2 million due primarily to the completion of the Phase 3 clinical trial in 2016 and the transition to the analysis of the trial data. Costs incurred in 2016 included approximately \$3.7 million related to the clinical trials, approximately \$2.3 million for wages, taxes and employee insurance, including approximately \$698,000 of stock-based compensation expense, and approximately \$860,000 related to costs associated with the preparation of an NDA. Costs incurred in 2015 included approximately \$5.7 million related to our ongoing clinical trials, approximately \$2.0 million for wages, taxes and employee insurance, including approximately \$579,000 of stock-based compensation expense, and approximately \$256,000 related to stability testing and the completion of the production of a commercial-size batch of Gimoti.

Included in research and development expenses for the years ended December 31, 2016 and 2015 were costs of approximately \$13,000 and \$218,000, respectively, for clinical trial services incurred by a company in which one of our officers serves on the executive management team.

*General and Administrative Expenses.* General and administrative expenses for the year ended December 31, 2016 compared to the year ended December 31, 2015 decreased by approximately \$71,000. Costs incurred in 2016 primarily included approximately \$1.9

million for wages, taxes and employee insurance, including approximately \$1.0 million of stock-based compensation expense, and approximately \$1.4 million for legal, accounting, directors and officers liability insurance and other costs associated with being a public company. Costs incurred in 2015 primarily included approximately \$1.8 million for wages, taxes and employee insurance, including approximately \$925,000 of stock-based compensation expense, approximately \$1.4 million for legal, accounting, directors and officers liability insurance and other costs associated with being a public company and approximately \$187,000 for market research activities.

Other Expenses. Other expenses for the year ended December 31, 2016 compared to the year ended December 31, 2015 decreased by approximately \$99,000 due primarily to the increase of approximately \$598,000 in income from the change in the value of the warrant liability since the issuance of such warrants, offset by the expensing of approximately \$534,000 of costs related to our 2016 equity financings. The warrants were initially valued at \$4.9 million in connection with our sale of such securities. Additional other expense for the years ended December 31, 2016 and December 31, 2015, consists of interest expense incurred on our former outstanding debt with Square 1. Net interest expense decreased by approximately \$35,000 in 2016 as a result of the loan with Square 1 being paid off in August 2016.

#### **Liquidity and Capital Resources**

Since our inception in 2007, we have funded our operations primarily from the sale of equity securities and borrowings under loan and security agreements. Prior to our IPO, we received \$17.7 million in net proceeds from the sale of our Series A convertible preferred stock and advances of \$5.5 million under the loan and security agreements. During 2013, we completed our IPO and raised approximately \$25.1 million, net of offering costs and commissions.

In November 2014, we entered into a sales agreement with MLV & Co., LLC, or the MLV Sales Agreement, which was subsequently acquired by FBR & Co., or FBR, pursuant to which we were able to sell from time to time, at our option, up to an aggregate of \$6.6 million worth of shares of common stock through MLV, as sales agent. The sales of shares of our common stock made through this equity program were made in "at-the-market" offerings as defined in Rule 415 of the Securities Act. During the year ended December 31, 2015, we sold 1,048,507 shares of common stock at a weighted average price per share of \$4.78 pursuant to the MLV Sales Agreement and received proceeds of approximately \$4.9 million, net of commissions and fees. We did not sell any shares of common stock through the MLV Sales Agreement during 2016.

On April 15, 2016, we terminated the MLV Sales Agreement and entered into a new At Market Issuance Sales Agreement with FBR, or the FBR Sales Agreement, and filed a prospectus supplement, pursuant to which we may sell from time to time, at our option up to an aggregate of 649,074 shares of our common stock through FBR as the sales agent. Through December 31, 2016, we have sold 56,000 shares of common stock and received net proceeds of approximately \$296,000 under the FBR Sales Agreement. On March 10, 2017, we filed a prospectus supplement, which replaced the prospectus supplement filed on April 15, 2016, permitting us to sell up to an aggregate of \$20.0 million of shares of our common stock through FBR as the sales agent. Future sales will depend on a variety of factors including, but not limited to, market conditions, the trading price of our common stock and our capital needs. There can be no assurance that FBR will be successful in consummating future sales based on prevailing market conditions or in the quantities or at the prices that we deem appropriate.

We will not be able to make future sales of our common stock pursuant to the FBR Sales Agreement unless certain conditions are met, which include the accuracy of representations and warranties made to FBR under the FBR Sales Agreement. Furthermore, FBR is permitted to terminate the FBR Sales Agreement in its sole discretion upon ten days' notice, or at any time in certain circumstances, including the occurrence of an event that would be reasonably likely to have a material adverse effect on our assets, business, operations, earnings, properties, condition (financial or otherwise), prospects, stockholders' equity or results of operations. We have no obligation to sell the remaining shares available for sale pursuant to the FBR Sales Agreement. However, under current SEC regulations, at any time during which the aggregate market value of our common stock held by non-affiliates, or public float, is less than \$75 million, the amount we can raise through primary public offerings of securities in any twelve-month period using shelf registration statements, including sales under the FBR Sales Agreement, is limited to an aggregate of one-third of our public float. As of March 10, 2017, our public float was \$40.1 million which means we may only sell approximately \$8.6 million of securities using shelf registration statements. If our public float decreases, the amount of securities we may sell under our Form S-3 shelf registration statements will also decrease.

In July 2016, we completed an at-the-market offering of 1,804,512 shares of common stock at a purchase price of \$2.49375 per share, or the July 2016 Financing. Concurrently in a private placement, for each share of common stock purchased by an investor, such investor received an unregistered warrant to purchase three-quarters of a share of our common stock, for a total of 1,353,384 shares, or the July Warrants. The July Warrants have an exercise price of \$2.41 per share, are immediately exercisable and will expire on January 25, 2022. The aggregate gross proceeds from the sale of the common stock and warrants were \$4.5 million, and the net proceeds after deduction of commissions and fees were approximately \$4.0 million.

In connection with the July 2016 Financing, we issued to our placement agent, Rodman & Renshaw, a unit of H.C. Wainwright & Co. LLC, or Wainwright, and its designees unregistered warrants to purchase an aggregate of 90,226 share of our common stock, or the July Wainwright Warrants. The July Wainwright Warrants have substantially the same terms as the July Warrants, except that the July Wainwright Warrants will expire on July 21, 2021 and have an exercise price equal to \$3.1172 per share of common stock.

In August 2016, we completed an at-the-market offering of 3,244,120 shares of common stock at a purchase price of \$3.0825 per share, the August 2016 Financing. Concurrently in a private placement, for each share of common stock purchased by an investor, such investor received from an unregistered warrant to purchase one half of a share of our common stock, for a total of 1,622,060 shares, or August Warrants. The August Warrants have an exercise price of \$3.03 per share, are immediately exercisable and will expire on February 3, 2022. The aggregate gross proceeds from the sale of the common stock and warrants were \$10.0 million, and the net proceeds after deduction of commissions and fees were approximately \$9.2 million.

In connection with the August 2016 Financing, we issued to our placement agent, Wainwright, and its designees unregistered warrants to purchase an aggregate of 162,206 shares of our common stock, or the August Wainwright Warrants. The August Wainwright Warrants have substantially the same terms as the August Warrants, except that the August Wainwright Warrants will expire on July 29, 2021 and have an exercise price equal to \$3.853125 per share of common stock.

In February and March 2017, we completed the sale of 2,775,861 shares of our common stock in an underwritten public offering led by Laidlaw & Company (UK) Ltd. The price to the public in this offering was \$2.90 per share resulting in gross proceeds to us of approximately \$8.0 million. After deducting underwriting discounts and commissions and estimated offering expenses payable by us, the net proceeds to us from this offering is expected to be approximately \$7.1 million.

In May 2014, we entered into a \$4.5 million loan and security agreement, the credit facility with Square 1, pursuant to which Square 1 agreed to make term loans available to us for general corporate and working capital purposes and for capital expenditures. In December 2014, we drew down the entire \$4.5 million. The credit facility had a fixed annual interest rate of 5.50%. On August 4, 2016, we repaid in full the entire \$4.5 million of outstanding principal and interest under the Loan and Security Agreement, dated as of May 28, 2014, as amended, or the Loan Agreement, between us and Square 1. In connection with such repayment, the Loan Agreement was terminated, and all security, liens or other encumbrances on assets of ours were released.

We incurred \$82,685 of loan origination costs related to this credit facility. The remaining unamortized costs of approximately \$38,000 were charged to interest expense upon the payment of the loan in August 2016.

In connection with the funding of the term loan, we issued to Square 1 a warrant to purchase 22,881 shares of our common stock at an exercise price of \$5.90 per share, the closing price of our common stock on the day of funding of the credit facility. During July 2016, Square 1 converted its warrant by a "cashless" conversion and received 9,887 shares of our common stock. The value determined for the warrant at the time of the grant of \$108,122 was recorded as a debt discount, as well as to stockholders' equity. The remaining unamortized debt discount associated with the warrant of approximately \$59,000 was charged to interest expense upon the payment of the loan in August 2016.

Our independent registered public accounting firm included an explanatory paragraph in their report on our financial statements as of and for the year ended December 31, 2016 with respect to our ability to continue as a going concern. This going concern opinion could materially limit our ability to raise additional funds through the issuance of new debt or equity securities or otherwise. Future reports on our financial statements may also include an explanatory paragraph with respect to our ability to continue as a going concern. We have incurred significant losses since our inception and have never been profitable, and it is possible we will never achieve profitability. We have devoted our resources to developing Gimoti, but it cannot be marketed until regulatory approvals have been obtained. Based upon our currently expected level of operating expenditures, we expect to be able to fund our operations through at least February 2018. This period could be shortened if there are any significant increases in planned spending on our Gimoti development program, including the comparative exposure PK trial, pre-approval and pre-commercialization activities, including marketing and manufacturing of Gimoti, completion of a planned NDA submission, and our general and administrative costs to support operations. There is no assurance that other financing will be available when needed to allow us to continue as a going concern. The perception that we may not be able to continue as a going concern may cause others to choose not to deal with us due to concerns about our ability to meet our contractual obligations.

We expect to continue to incur expenses and increase operating losses for at least the next several years. In the near-term, we anticipate incurring costs as we:

- prepare for and complete further clinical development, including a comparative exposure PK trial in healthy volunteers, and complete the manufacturing of doses of Gimoti for such trial;
- continue the pre-approval and pre-commercialization activities for Gimoti, including the preparation of the NDA;
- continue the preparation of the commercial manufacturing process;

- · maintain, expand and protect our intellectual property portfolio; and
- · continue to fund the additional accounting, legal, insurance and other costs associated with being a public company.

Although our current cash and cash equivalents are expected to be sufficient to fund our operations through at least February 2018, it may not be sufficient to complete any additional development requirements requested by FDA. Accordingly, we will continue to require substantial additional capital beyond our current cash and cash equivalents to continue our clinical and regulatory development and potential commercialization activities. The amount and timing of our future funding requirements will depend on many factors further described below, including the results of our comparative exposure PK trial and the extent of any additional clinical development required by FDA. We anticipate that we will seek to fund our operations through public or private equity or debt financings or other sources, such as potential collaboration arrangements. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategies.

The following table summarizes our cash flows for the year ended December 31, 2016 and 2015:

	Year Ended I	Decemb	oer 31,
	2016		2015
Net cash used in operating activities	\$ (8,707,742)	\$	(10,495,838)
Net cash provided by financing activities	\$ 9,023,658	\$	5,031,184
Net increase (decrease) in cash and cash equivalents	\$ 315,916	\$	(5,464,654)

*Operating Activities.* The primary use of our cash has been to fund our clinical research and other general operations.

Financing Activities. During the year ended December 31, 2016, we received net proceeds of approximately \$355,000 from the sale of 56,000 shares of common stock pursuant to the FBR Sales Agreement and the sale of 34,067 shares of common stock through our employee stock purchase plan, or ESPP. In addition, through the 2016 Financings, we received net proceeds of approximately \$13.2 million from the sale of 5,048,632 shares of common stock and 2,975,444 warrants to purchase our common stock. During the year ended December 31, 2015, we received net proceeds of approximately \$5.0 million from the sale of 41,176 shares of common stock through our ESPP and the sale of 1,048,507 shares of common stock pursuant to the MLV Sales Agreement.

We believe that our existing cash and cash equivalents as of December 31, 2016, together with interest thereon, will be sufficient to meet our anticipated cash requirements through at least February 2018. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially.

The amount and timing of our future funding requirements will depend on many factors, including but not limited to:

- · we may not have sufficient financial and other resources to complete clinical development for Gimoti;
- · we may not be able to provide acceptable evidence of safety and efficacy for Gimoti;
- · FDA may disagree with the design of our comparative exposure PK trial or any other future clinical trials, if any are necessary;
- variability in subjects, adjustments to clinical trial procedures and inclusion of additional clinical trial sites;
- FDA may not agree with the analysis of our clinical trial results;
- the results of our clinical trials may not meet the level of statistical or clinical significance or other bioequivalence parameters required by FDA for marketing approval;
- we may be required to undertake additional clinical trials and other studies of Gimoti before we can submit an NDA, to FDA or receive approval of the NDA;
- subjects in our clinical trials may die or suffer other adverse effects for reasons that may or may not be related to Gimoti, such as dysgeusia, headache, diarrhea, nasal discomfort, tremor, myoclonus, somnolence, rhinorrhea, throat irritation, and fatigue;
- if approved, Gimoti will compete with well-established products already approved for marketing by FDA, including oral and intravenous forms of metoclopramide, the same active ingredient in the nasal spray for Gimoti;
- · we may not be able to obtain, maintain and enforce our patents and other intellectual property rights; and
- we may not be able to obtain and maintain commercial manufacturing arrangements with third-party manufacturers or establish commercial-scale manufacturing capabilities.

## **Off-Balance Sheet Arrangements**

Through December 31, 2016, we have not entered into and did not have any relationships with unconsolidated entities or financial collaborations, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purpose.

## **Contractual Obligations and Commitments**

In December 2016, we entered into an operating lease for office space in Solana Beach, California. The lease commenced on January 1, 2017 with an expiration date of December 31, 2018. We also pay pass through costs and utility costs, which are expensed as incurred.

As of December 31, 2016, future minimum lease payments for our operating lease are approximately \$135,000 and \$139,000 for the year ending December 31, 2017 and 2018, respectively.

#### Item 7A. Quantitative and Qualitative Disclosure about Market Risk

#### Interest Rate Fluctuation Risk

Our cash and cash equivalents as of December 31, 2016 consisted of cash and money market funds. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. However, because of the short-term nature of our cash and cash equivalents, a sudden change in market interest rates would not be expected to have a material impact on our financial condition and/or results of operations.

Our long-term debt bears interest at a fixed rate and therefore has minimal exposure to changes in interest rates.

#### Foreign Currency Exchange Risk

We contract with organizations to manufacture drug product, active pharmaceutical ingredient, and container closure system materials, and in the future may contract with CROs and investigational sites in foreign countries. We may become subject to fluctuations in foreign currency rates in connection with these agreements, though we do not believe such fluctuations will have a material impact to our operations.

## Inflation Risk

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation has had a material effect on our business, financial condition or results of operations during the years ended December 31, 2016 and 2015.

## Item 8. Financial Statements and Supplementary Data

Our financial statements and the report of our independent registered public accounting firm are included in this report on the pages indicated in Item 15 of Part IV of this Annual Report on Form 10-K.

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

None.

## Item 9A. Controls and Procedures

## Conclusions Regarding the Effectiveness of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the timelines specified in the Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Business 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. In addition, the design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, control may become inadequate because of changes in conditions, or the degree of compliance with

policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

As required by Securities and Exchange Commission Rule 13a-15(b), as of December 31, 2016 we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Business Officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as of the end of the period covered by this report. Based on the foregoing, our Chief Executive Officer and Chief Business Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2016.

## Management's 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 Business 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 authorizations of our management and directors; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

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

Management is responsible for establishing and maintaining adequate internal control over our financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act. Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Business Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting. Management has used the framework set forth in the report entitled "Internal Control — Integrated Framework (2013 Framework)" published by the Committee of Sponsoring Organizations of the Treadway Commission to evaluate the effectiveness of our internal control over financial reporting. Based on its evaluation, management has concluded that our internal control over financial reporting was effective as of December 31, 2016, the end of our most recent fiscal year.

## **Changes in Internal Control Over Financial Reporting**

There were no changes in our internal control over financial reporting identified in management's evaluation pursuant to Rules 13a-15(d) or 15d-15(d) of the Exchange Act during the quarter ended December 31, 2016 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## Item 9B. Other Information

None.

#### **PART III**

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

Information required by this item will be contained in our definitive proxy statement to be filed with the Securities and Exchange Commission in connection with our 2017 Annual Meeting of Stockholders, or the Definitive Proxy Statement, and which is expected to be filed not later than 120 days after the end of our fiscal year ended December 31, 2016, under the headings "Election of Directors," "Corporate Governance and Other Matters," "Executive Officers," and "Section 16(a) Beneficial Ownership Reporting Compliance," and is incorporated herein by reference.

We have adopted a Code of Business Conduct and Ethics that applies to our officers, directors and employees which is available on our internet website at www.evokepharma.com. The Code of Business Conduct and Ethics contains general guidelines for conducting the business of our company consistent with the highest standards of business ethics, and is intended to qualify as a "code of ethics" within the meaning of Section 406 of the Sarbanes-Oxley Act of 2002 and Item 406 of Regulation S-K. In addition, we intend to promptly disclose (1) the nature of any amendment to our Code of Business Conduct and Ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions and (2) the nature of any waiver, including an implicit waiver, from a provision of our code of ethics that is granted to one of these specified officers, the name of such person who is granted the waiver and the date of the waiver on our website in the future.

## **Item 11. Executive Compensation**

Information required by this item will be contained in our Definitive Proxy Statement under the heading "Executive Compensation and Other Information" and is incorporated herein by reference.

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

Information required by this item will be contained in our Definitive Proxy Statement under the headings "Security Ownership of Certain Beneficial Owners and Management" and is incorporated herein by reference.

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

Information required by this item will be contained in our Definitive Proxy Statement under the headings "Certain Relationships and Related Party Transactions" and "Independence of the Board of Directors" and is incorporated herein by reference.

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

Information required by this item will be contained in our Definitive Proxy Statement under the heading "Independent Registered Public Accounting Firm's Fees" and is incorporated herein by reference.

## **PART IV**

## Item 15. Exhibits, Financial Statement Schedules

- (a) Documents filed as part of this report.
- 1. *Financial Statements*. The following financial statements of Evoke Pharma, Inc., together with the report thereon of BDO USA, LLP, an independent registered public accounting firm, are included in this Annual Report on Form 10-K:

	rage
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2. Financial Statement Schedules.

None.

3. Exhibits.

A list of exhibits to this Annual Report on Form 10-K is set forth on the Exhibit Index immediately preceding such exhibits and is incorporated herein by reference.

- (b) See Exhibit Index.
- (c) See Item 15(a)(2) above.

## Item 16. Form 10-K Summary

None.

## Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders Evoke Pharma, Inc. Solana Beach, CA

We have audited the accompanying balance sheets of Evoke Pharma, Inc. as of December 31, 2016 and 2015 and the related statements of operations, stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2016. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, 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. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

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

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As described in Note 1 to the financial statements, the Company has suffered recurring losses from operations that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty. Our opinion is not modified with respect to this matter.

/s/ BDO USA, LLP

San Diego, CA March 15, 2017

## **Balance Sheets**

December 31,

2015

Assets				
Current Assets:			_	
Cash and cash equivalents	\$	9,007,071	\$	8,691,155
Prepaid expenses		267,711		833,276
Other current assets		7,997		
Total current assets		9,282,779		9,524,431
Other assets		11,551		7,997
Total assets	<u>\$</u>	9,294,330	\$	9,532,428
Liabilities and stockholders' equity				
Current Liabilities:				
Accounts payable and accrued expenses	\$	478,223	\$	927,606
Accrued compensation		933,450		760,782
Current portion of long-term debt		<u> </u>		146,052
Total current liabilities		1,411,673		1,834,440
Warrant liability		4,095,019		_
Long-term debt, net of current portion		_		4,233,059
Total liabilities		5,506,692		6,067,499
Commitments and contingencies				
Stockholders' equity:				
Preferred stock, \$0.0001 par value; authorized shares — 5,000,000				
at December 31, 2016 and 2015; issued and outstanding shares —				
0 at December 31, 2016 and 2015		_		_
Common stock, \$0.0001 par value; authorized shares — 50,000,000				
at December 31, 2016 and 2015; issued and outstanding shares —				
12,350,360 and 7,201,774 at December 31, 2016 and 2015, respectively		1,235		720
Additional paid-in capital		62,595,546		51,524,821
Accumulated deficit		(58,809,143)		(48,060,612)
Total stockholders' equity		3,787,638		3,464,929
Total liabilities and stockholders' equity	\$	9,294,330	\$	9,532,428

## **Statements of Operations**

	Year Ended December 31,			
		2016		2015
Operating expenses:				
Research and development	\$	6,951,600	\$	8,154,144
General and administrative		3,592,825		3,664,159
Total operating expenses		10,544,425		11,818,303
Loss from operations		(10,544,425)		(11,818,303)
Other expenses:				
Interest expense, net		(268,029)		(303,160)
Financing costs related to warrant liability		(533,692)		_
Change in fair value of warrant liability		597,615		<u> </u>
Total other expenses		(204,106)		(303,160)
Net loss	\$	(10,748,531)	\$	(12,121,463)
Net loss per common share, basic and diluted	\$	(1.15)	\$	(1.87)
Weighted-average shares used to compute basic and diluted net loss per share		9,338,068		6,485,794

## Statements of Stockholders' Equity

				Additional Paid-In	Accumulated	Total Stockholders'
	Comm	on Sto	ck	Capital	Deficit	Equity
	Shares	Α	mount			
Balance at December 31, 2014	6,112,091	\$	611	\$ 45,127,202	\$ (35,939,149)	\$ 9,188,664
Stock-based compensation expense	_		_	1,504,356	_	1,504,356
Issuance of common stock from At-The-Market offering, net	1,048,507		105	4,723,467	_	4,723,572
Issuance of common stock from employee stock purchase plan	41,176		4	169,796	_	169,800
Net loss					(12,121,463)	(12,121,463)
Balance at December 31, 2015	7,201,774		720	51,524,821	(48,060,612)	3,464,929
Stock-based compensation expense	_		_	1,706,524	_	1,706,524
Issuance of common stock from At-The-Market offering, net	56,000		6	256,107	_	256,113
Issuance of common stock from employee stock purchase plan	34,067		3	98,739	_	98,742
Issuance of common stock from warrant exercise	9,887		1	(1)	_	_
Issuance of common stock and warrants, net	5,048,632		505	8,802,531	_	8,803,036
Reclassification of warrant liability due to warrant amendment	_		_	206,825	_	206,825
Net loss					(10,748,531)	(10,748,531)
Balance at December 31, 2016	12,350,360	\$	1,235	\$ 62,595,546	\$ (58,809,143)	\$ 3,787,638

## **Statements of Cash Flows**

	Year Ended December 31,			
		2016		2015
Operating activities				
Net loss	\$	(10,748,531)	\$	(12,121,463)
Adjustments to reconcile net loss to net cash used in operating activities:				
Stock-based compensation expense		1,706,524		1,504,356
Non-cash interest		120,889		55,883
Deferred rent expense		_		(12,313)
Financing costs allocated to warrant liability		533,692		_
Change in fair value of warrant liability		(597,615)		_
Change in operating assets and liabilities:				
Prepaid expenses and other assets		554,014		98,185
Accounts payable and accrued expenses		(276,715)		(20,486)
Net cash used in operating activities		(8,707,742)		(10,495,838)
Financing activities				
Payment on bank loan		(4,500,000)		_
Proceeds from issuance of common stock, net		354,855		5,031,184
Proceeds from issuance of common stock and warrants, net		13,168,803		
Net cash provided by financing activities		9,023,658		5,031,184
Net increase (decrease) in cash and cash equivalents		315,916		(5,464,654)
Cash and cash equivalents at beginning of period		8,691,155		14,155,809
Cash and cash equivalents at end of period	\$	9,007,071	\$	8,691,155
Supplemental disclosure of cash flow information				
Interest paid	\$	169,813	\$	230,313
microst pund	Ψ	103,013	Ψ	230,313
Non-cash financing activities				
Deferred financing costs paid in prior year			\$	137,812
Fair value of warrants issued to placement agent	\$	369,863		

## **Notes to Financial Statements**

## 1. Organization and Basis of Presentation

Evoke Pharma, Inc. (the "Company") was incorporated in the state of Delaware in January 2007. The Company is a publicly-held specialty pharmaceutical company focused primarily on the development of drugs to treat gastroenterological disorders and disease.

Since its inception, the Company has devoted substantially all of its efforts to product development, raising capital and building infrastructure, and has not realized revenues from its planned principal operations. The Company does not anticipate realizing revenues for the foreseeable future. The Company's activities are subject to the significant risks and uncertainties associated with any specialty pharmaceutical company that has substantial expenditures for research and development, including funding its operations.

## **Clinical Trial Results**

On July 18, 2016, the Company announced topline results from its Phase 3 clinical trial that evaluated the efficacy and safety of Gimoti™ (formerly known as EVK-001) in women with symptoms associated with diabetic gastroparesis. In this study, Gimoti did not achieve its primary endpoint of symptom improvement at Week 4.

In December 2016, the Company announced the completion of a second pre-NDA meeting with the U.S. Food and Drug Administration ("FDA"), in which FDA agreed that a comparative exposure pharmacokinetic ("PK") trial was acceptable as a basis for submission of a Gimoti new drug application ("NDA"). The comparative exposure PK trial will serve as a portion of the full 505(b)(2) data package to include prior efficacy and safety data developed by the Company and FDA's prior findings of safety and efficacy for the Listed Drug, Reglan Tablets. The Company expects to begin and complete the comparative exposure PK trial in the second half of 2017, followed by a potential NDA submission in late 2017 or early 2018.

To confirm the results of the Phase 2b trial in male subjects, the FDA agreed that the Company could conduct a separate companion trial in men. FDA recommended that the trials be conducted in parallel and when the Phase 3 study in women was complete, the Company could conduct an interim analysis on the male trial to determine whether or not it would be futile to continue to full enrollment. During November 2016, the Company determined the trial showed futility so that, even if the trial had fully been enrolled, the results would not have differed. As the Company anticipated at the beginning of the trial, based on the prior Phase 2b data, the results showed no statistical significant efficacy in men and the safety profile for Gimoti was favorable compared to placebo with good tolerability.

#### Sales of Common Stock and Warrants

On July 25, 2016 and August 3, 2016, the Company completed registered direct offerings of an aggregate of 5,048,632 shares of common stock for gross proceeds of \$14.5 million. Concurrently in private placements, for each share of common stock purchased by an investor, such investor received from the Company an unregistered warrant to purchase shares of common stock. In addition, on February 22, 2017, the Company completed the sale of 2,413,793 shares of the Company's common stock in an underwritten public offering and on March 3, 2017, the underwriter of the offering exercised its option to purchase an additional 362,068 shares of the Company's common stock. Gross proceeds from this offering were \$8.0 million. See Note 6 for further description.

## Repayment of Debt

On August 4, 2016, the Company repaid in full the entire \$4.5 million of outstanding principal and interest under the Loan and Security Agreement, dated as of May 28, 2014, as amended (the "Loan Agreement"), between the Company, as borrower, and Square 1 Bank, a division of Pacific Western Bank ("Square 1"), as lender. In connection with such repayment, the Loan Agreement was terminated, and all security, liens or other encumbrances on assets of the Company were released. See Note 3 for further description.

## **Going Concern**

Despite the Company ending 2016 with approximately \$9.0 million, and raising \$8.0 million from the sale of common stock in February and March 2017, the Company's plan to fund additional clinical development, including the comparative exposure PK trial, pre-approval and pre-commercialization activities, including marketing and manufacturing of Gimoti and completion of a planned NDA submission, and support its general and administrative costs to support operations, the Company anticipates continuing its trend of having losses from operations and believes that there is substantial doubt about its ability to continue as a going concern within one year after the financial statements are issued.

The determination of going concern contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. In its report on the Company's financial statements for the year ended December 31, 2016, the Company's independent registered public accounting firm included an explanatory paragraph expressing substantial doubt regarding the Company's ability to continue as a going concern.

The Company has experienced significant losses since its inception, including net losses of \$10.7 million and \$12.1 million for the years ended December 31, 2016 and 2015, respectively. As of December 31, 2016, the Company had an accumulated deficit of \$58.8 million. The Company's net losses may fluctuate significantly from quarter to quarter and year to year.

The Company expects to continue to incur net losses for the foreseeable future until such time, if ever, that it can generate significant revenues from the sale of Gimoti. The Company believes that its current cash and cash equivalents will be sufficient to meet estimated working capital requirements and fund operations through at least February 2018. The Company will need to raise additional debt or equity financing to fund future operations. The can be no assurance that additional financing will be available when needed to on acceptable terms. If the Company is not able to secure adequate additional funding, the Company may be forced to make reductions in spending, extend payment terms with suppliers, and/or suspend or curtail planned programs. Any of these actions could materially harm the Company's business, results of operations, financial condition and future prospects.

## 2. Summary of Significant Accounting Policies

#### Use of Estimates

The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP"). The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ materially from those estimates.

## **Segment Reporting**

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker in making decisions regarding resource allocation and assessing performance. The Company views its operations and manages its business in one operating segment operating in the United States.

#### **Cash and Cash Equivalents**

The Company considers all highly liquid investments with an original maturity of three months or less from the date of purchase to be cash equivalents. Cash and cash equivalents include cash in readily available checking and savings accounts.

## **Fair Value of Financial Instruments**

The carrying amounts of all financial instruments, including accounts payable and accrued expenses, and employee-related liabilities, are considered to be representative of their respective fair values because of the short-term nature of those instruments. Based on the borrowing rates currently available to the Company for loans with similar terms, the Company believes that the fair value of long-term debt approximates its carrying value.

## **Concentrations of Risk**

Financial instruments that potentially subject the Company to significant credit risk consist primarily of cash and cash equivalents. The Company maintains deposits in a federally insured financial institution in excess of federally insured limits. The Company has established guidelines designed to maintain safety and liquidity, has not experienced any losses in such accounts and believes the exposure to significant risk to the cash balance is minimal.

The Company also relies on clinical research organizations ("CROs") to manage and recruit subjects for its clinical trials. If these CROs are unable to continue managing the clinical trials, or are unable to recruit the sufficient number of subjects, the delays could adversely affect the completion of the trials and the timing of the filing of the Company's NDA with FDA.

In addition, the Company relies on third-party manufacturers for the production of its drug candidate. If the third-party manufacturers are unable to continue manufacturing the Company's drug candidate, or if the Company loses one of its sole source suppliers used in its manufacturing processes, the Company may not be able to meet clinical trial supply demand for its product candidate and the development of the product candidate could be materially and adversely affected.

## **Warrant Accounting**

Certain of the warrants to purchase shares of the Company's common stock, issued as a part of the at-the-market registered direct offerings in July and August 2016, are classified as warrant liability and recorded at fair value. These warrants contain a feature that could require the transfer of cash in the event a change of control occurs without the authorization of our Board of Directors, and therefore, are classified as a liability in accordance with the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 480.

The fair value of each warrant is estimated on the date of issuance, and each subsequent balance sheet date, using the Black-Scholes valuation model using the appropriate risk-free interest rate, expected term and volatility assumptions. The expected life of the warrant was calculated using the remaining life of the warrant. Due to our limited historical data as a public company, the estimated volatility is calculated based upon our historical volatility and comparable companies whose share prices are publicly available for a sufficient period of time. The risk-free rate is based upon U.S. Treasury securities with remaining terms similar to the expected term of the stock award being valued.

This warrant liability is subject to remeasurement at each balance sheet date and the Company recognizes any change in the fair value of the warrant liability in the statement of operations. The Company will continue to adjust the carrying value of the warrants for changes in the estimated fair value until the earlier of the modification, exercise or expiration of the warrants. At that time, the liabilities will be reclassified to additional paid-in capital, a component of stockholders' equity.

## **Stock-Based Compensation**

Stock-based compensation expense for stock option grants and employee stock purchases under the Company's Employee Stock Purchase Plan (the "ESPP") is recorded at the estimated fair value of the award as of the grant date and is recognized as expense on a straight-line basis over the employee's requisite service period. The estimation of stock option and ESPP fair value requires management to make estimates and judgments about, among other things, employee exercise behavior, forfeiture rates and volatility of the Company's common stock. The judgments directly affect the amount of compensation expense that will be recognized.

The Company grants stock options to purchase common stock to employees and members of the board of directors with exercise prices equal to the Company's closing market price on the date the stock options are granted. The risk-free interest rate assumption was based on the yield of an applicable rate for U.S. Treasury instruments with maturities similar to those of the expected term of the award being valued. The weighted average expected term of options and employee stock purchases was calculated using the simplified method as prescribed by accounting guidance for stock-based compensation. This decision was based on the lack of relevant historical data due to the Company's limited historical experience. In addition, due to the Company's limited historical data, the estimated volatility was calculated based upon the Company's historical volatility, supplemented with historical volatility of comparable companies in the biotechnology industry whose share prices are publicly available for a sufficient period of time. The assumed dividend yield was based on the Company never paying cash dividends and having no expectation of paying cash dividends in the foreseeable future.

## **Research and Development Expenses**

Research and development costs are expensed as incurred and primarily include compensation and related benefits, stock-based compensation expense and costs paid to third-party contractors to perform research, conduct clinical trials and develop drug materials and delivery devices. The Company expenses costs relating to the purchase and production of pre-approval inventories as research and development expense in the period incurred until FDA approval is received.

The Company bases its expense accruals related to clinical studies on estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and contract research organizations ("CROs") that conduct and manage clinical studies on its behalf. The financial terms of these agreements vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors, such as the successful enrollment of patients, site initiation and the completion of clinical study milestones. Service providers typically invoice the Company monthly in arrears for services performed. In accruing service fees, the Company estimates the time period over which services will be performed and the level of effort to be expended in each period. If the Company does not identify costs that have begun to be incurred, or if the Company underestimates or overestimates the level of services performed or the costs of these services, actual expenses could differ materially from estimates. To date, the Company has not experienced significant changes in estimates of accrued research and development expenses after a reporting period. However, due to the nature of estimates, no assurance can be made that changes to the estimates will not be made in the future as the Company becomes aware of additional information about the status or conduct of clinical studies and other research activities.

The Company does not own or operate manufacturing facilities for the production of Gimoti, nor does it plan to develop its own manufacturing operations in the foreseeable future. The Company currently depends on third-party contract manufacturers for all of its required raw materials, drug substance and finished product for its preclinical research and clinical trials. Other than an agreement with Cosma S.p.A. to supply metoclopramide for the manufacture of Gimoti, the Company does not have any other contractual

relationships for the manufacture of commercial supplies of Gimoti. If Gimoti is approved by any regulatory agency, the Company intends to enter into agreements with third-party contract manufacturers for the commercial production at that time. The Company currently utilizes a third-party consultant, which it engages on an as-needed, hourly basis, to manage its manufacturing contractors.

#### **Income Taxes**

The Company accounts for income taxes in accordance with ASC 740, *Income Taxes*. Under ASC 740, deferred tax assets and liabilities reflect the future tax consequences of the differences between the financial reporting and tax basis of assets and liabilities using current enacted tax rates. The Company provides a valuation allowance against net deferred tax assets unless, based upon the available evidence, it is more likely than not that the deferred tax assets will be realized.

The Company's policy related to accounting for uncertainty in income taxes prescribes a recognition threshold and measurement attributed criteria for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more likely than not to be sustained upon examination by taxing authorities.

## **Net Loss Per Share**

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of common shares outstanding for the period, without consideration for common stock equivalents and adjusted for the weighted-average number of common shares outstanding that are subject to repurchase. The Company has excluded 45,000 shares subject to repurchase from the weighted-average number of common shares outstanding for the years ended December 31, 2016 and 2015. Diluted net loss per share is calculated by dividing the net loss by the weighted-average number of common share equivalents outstanding for the period determined using the treasury-stock method. Dilutive common stock equivalents are comprised of shares subject to repurchase, warrants for the purchase of common stock, options outstanding under the Company's equity incentive plans and potential shares to be purchased under the ESPP. For the periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding due to the Company's net loss position.

The following table sets forth the outstanding potentially dilutive securities that have been excluded from the calculation of diluted net loss per share because to do so would be anti-dilutive:

	Year Ended December 31,		
	2016	2015	
Common stock subject to repurchase	45,000	45,000	
Warrants to purchase common stock	3,323,876	118,881	
Common stock options	1,275,624	1,037,500	
Employee stock purchase plan	43,752	22,818	
Total excluded securities	4,688,252	1,224,199	

## **Recent Accounting Pronouncements**

In February 2016, the FASB issued ASU No. 2016-02, *Leases*. The new standard establishes a right-of-use ("ROU") model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. The new standard is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. The Company is currently evaluating the impact of its pending adoption of the new standard on the Company's financial statements.

In March 2016, the FASB issued ASU No. 2016-09 *Compensation-Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting.* This guidance changes the accounting for certain aspects of share-based payments to employees. The guidance requires the recognition of the income tax effects of awards in the income statement when the awards vest or are settled, thus eliminating additional paid-in capital pools. The guidance also allows for the employer to repurchase more of an employee's shares for tax withholding purposes without triggering liability accounting. In addition, the guidance allows for a policy election to account for forfeitures as they occur rather than on an estimated basis. This guidance is effective for annual and interim reporting periods of public entities beginning after December 15, 2016. The adoption of this statement is not expected to have a material impact on the Company's financial statements.

#### 3. Debt

In May 2014, the Company entered into a \$4.5 million loan and security agreement (the "credit facility") with Square 1, pursuant to which Square 1 agreed to make term loans available to the Company for general corporate and working capital purposes and for capital expenditures.

In December 2014, the Company drew down the entire \$4.5 million. The credit facility had a fixed annual interest rate of 5.50%. On August 4, 2016, the Company repaid in full the entire \$4.5 million of outstanding principal and interest under the Loan Agreement between the Company and Square 1 Bank. In connection with such repayment, the Loan Agreement was terminated, and all security, liens or other encumbrances on assets of the Company were released.

The Company incurred \$82,685 of loan origination costs related to this credit facility. The remaining unamortized costs of approximately \$38,000 were charged to interest expense upon the payment of the loan in August 2016.

In connection with the funding of the term loan, the Company issued to Square 1 a warrant to purchase 22,881 shares of the Company's common stock at an exercise price of \$5.90 per share, the closing price of the Company's common stock on the day of funding of the credit facility. During July 2016, Square 1 converted its warrant by a "cashless" conversion and received 9,887 shares of the Company's common stock. The value determined for the warrant at the time of the grant of \$108,122 was recorded as a debt discount, as well as to stockholders' equity. The remaining unamortized debt discount associated with the warrant of approximately \$59,000 was charged to interest expense upon the payment of the loan in August 2016.

Total interest incurred under the loan and security agreements for the years ended December 31, 2016 and 2015 was \$148,500 and \$250,938, respectively.

#### 4. Commitments

In December 2016, the Company entered into an operating lease for office space in Solana Beach, California. The lease commenced on January 1, 2017 with an expiration date of December 31, 2018. The Company has an option to extend the lease for an additional two years subject to specified prior written notice. The lease contains annual rent increases.

Rent expense for 2016 and 2015 was approximately \$116,000 and \$81,000, respectively. The Company also pays pass through costs and utility costs, which are expensed as incurred.

As of December 31, 2016, the Company has future minimum lease payments under its operating lease in 2017 and 2018 of approximately \$135,000 and \$139,000, respectively.

#### 5. Technology Acquisition Agreement

In June 2007, the Company acquired all worldwide rights, data, patents and other related assets associated with Gimoti from Questcor Pharmaceuticals, Inc. ("Questcor") pursuant to an Asset Purchase Agreement. The Company paid Questcor \$650,000 in the form of an upfront payment and \$500,000 in May 2014 as a milestone payment based upon the initiation of the first patient dosing in the Company's Phase 3 clinical trial for Gimoti. In August 2014, Mallinckrodt, plc, ("Mallinckrodt") acquired Questcor. As a result of that acquisition, Questcor transferred its rights included in the Asset Purchase Agreement with the Company to Mallinckrodt. In addition to the payments made to Questcor, the Company may also be required to make additional milestone payments to Mallinckrodt totaling up to \$51.5 million. These milestones include up to \$4.5 million in payments if Gimoti achieves the following development targets:

- \$1.5 million upon FDA acceptance for review of an NDA for Gimoti; and
- \$3 million upon FDA approval of Gimoti.

The remaining \$47 million in milestone payments depend on Gimoti's commercial success and will only apply if Gimoti receives regulatory approval. In addition, the Company will be required to pay to Mallinckrodt a low single digit royalty on net sales of Gimoti. The Company's obligation to pay such royalties will terminate upon the expiration of the last patent right covering Gimoti, which is expected to occur in 2030.

## 6. Preferred Stock, Common Stock and Stockholders' Equity

## **Preferred Stock**

Under the Company's amended and restated certificate of incorporation, the Company is authorized to issue 5,000,000 shares of preferred stock with a \$0.0001 par value. No shares of preferred stock were outstanding as of December 31, 2016 or 2015.

#### Common Stock

As of December 31, 2016, there were 12,350,360 shares of common stock outstanding. Each share of common stock is entitled to one vote. The holders of the common stock are also entitled to receive dividends whenever funds are legally available and when declared by the board of directors of the Company. To date, no dividends have been declared.

#### Sale of Common Stock and Warrants

On July 25, 2016, the Company completed a registered direct offering of 1,804,512 shares of common stock at a purchase price of \$2.49375 per share (the "July 2016 Financing"). Concurrently in a private placement, for each share of common stock purchased by an investor, such investor received from the Company an unregistered warrant to purchase three-quarters of a share of common stock, for a total of 1,353,384 shares (the "July Warrants"). The July Warrants have an exercise price of \$2.41 per share, are immediately exercisable and will expire on January 25, 2022. The aggregate gross proceeds from the sale of the common stock and warrants were \$4.5 million, and the net proceeds after deduction of commissions and fees were \$4.0 million.

In connection with the July 2016 Financing, the Company issued to its placement agent, Rodman & Renshaw, a unit of H.C. Wainwright & Co. LLC ("Wainwright"), and its designees unregistered warrants to purchase an aggregate of 90,226 shares of the Company's common stock (the "July Wainwright Warrants"). The July Wainwright Warrants have substantially the same terms as the July Warrants, except that the July Wainwright Warrants will expire on July 21, 2021 and have an exercise price equal to \$3.1172 per share of common stock.

On August 3, 2016, the Company completed a registered direct offering of 3,244,120 shares of common stock at a purchase price of \$3.0825 per share (the "August 2016 Financing") and together with the July 2016 Financing (the "2016 Financings"). Concurrently in a private placement, for each share of common stock purchased by an investor, such investor received from the Company an unregistered warrant to purchase one half of a share of common stock, for a total of 1,622,060 shares (the "August Warrants"). The August Warrants have an exercise price of \$3.03 per share, are immediately exercisable and will expire on February 3, 2022. The aggregate gross proceeds from the sale of the common stock and warrants were \$10 million, and the net proceeds after deduction of commissions and fees was approximately \$9.2 million.

In connection with the August 2016 financing, the Company issued to its placement agent, Wainwright, and its designees unregistered warrants to purchase an aggregate of 162,206 shares of the Company's common stock (the "August Wainwright Warrants"). The August Wainwright Warrants have substantially the same terms as the August Warrants, except that the August Wainwright Warrants will expire on July 29, 2021 and have an exercise price equal to \$3.853125 per share of common stock.

The warrants issued in connection with the 2016 Financings had a total initial fair value of \$4,899,459 on their respective closing dates as determined using the Black Scholes valuation model and such value was recorded as the initial carrying value of the warrant liability. The fair value of the warrants is remeasured at each financial reporting period with any change in fair value recognized as a change in fair value of the warrant liability in the Statement of Operations.

On December 15, 2016, the Company entered into amendments (the "Warrant Amendments") with certain of the holders (the "Holders") of the Company's outstanding warrants to purchase common stock issued on July 25, 2016 and August 3, 2016. Pursuant to the Warrant Amendments, the Holders' right to require the Company to purchase the outstanding warrants upon the occurrence of certain fundamental transactions will not apply if the fundamental transaction is a result of a transaction that has not been approved by the Company's board of directors. As a result of this amendment, warrants to purchase 252,432 shares of the Company's common stock were no longer required to be classified as liabilities. The value of amended warrants were adjusted to their fair value immediately prior to the amendment and approximately \$207,000 was reclassified from warrant liability to Additional Paid-in Capital.

In February 2017, an institutional investor from the Company's financing which closed in July 2016 converted its warrant to purchase shares of our common stock by a "cashless" exercise and received 211,860 shares of the Company's common stock. The warrant had an exercise price of \$2.41 per share. The shares were issued, and the warrants were sold, in reliance upon the registration exemption set forth in Section 4(a)(2) of the Securities Act of 1933, as amended. Subsequent to this transaction, warrants to purchase 2,449,129 shares of the Company's common stock remain classified as a liability.

In February and March 2017, the Company completed the sale of 2,775,861 shares of its common stock in an underwritten public offering led by Laidlaw & Company (UK) Ltd. The price to the public in this offering was \$2.90 per share resulting in gross proceeds to the Company of approximately \$8.0 million. After deducting underwriting discounts and commissions and estimated offering expenses payable by the Company, the net proceeds to the Company from this offering is expected to be approximately \$7.1 million.

## At the Market Equity Offering Program

On April 15, 2016, the Company terminated the MLV Sales Agreement and entered into a new At Market Issuance Sales Agreement with FBR ("FBR Sales Agreement"), and filed a prospectus supplement, pursuant to which the Company may sell from time to time, at its option, up to an aggregate of 649,074 shares of the Company's common stock through FBR as the sales agent. The sales of shares made through this equity program are made in "at-the-market" offerings as defined in Rule 415 of the Securities Act. Through December 31, 2016, the Company has sold 56,000 shares of common stock at a weighted average price per share of \$5.45 and received proceeds of approximately \$296,000, net of commissions and fees.

On March 10, 2017, the Company filed a prospectus supplement, which replaced the prospectus supplement filed on April 15, 2016, permitting the Company to sell up to an aggregate of \$20.0 million of shares of its common stock through FBR as a sales agent. Under current SEC regulations, if at the time the Company files its Annual Report on Form 10-K, or Form 10-K, for the year ended December 31, 2016, the Company's public float is less than \$75 million, and for so long as its public float remains less than \$75 million, the amount the Company can raise through primary public offerings of securities in any twelve-month period using shelf registration statements is limited to an aggregate of one-third of our public float, which is referred to as the baby shelf rules. The Company's public float exceeded \$75 million in July 2016, thereby allowing the Company to conduct primary offerings without being constrained by the baby shelf rules after that date until the filing of this Form 10-K, at which point the Company has determined it would be subject to the baby shelf rules. As of March 10, 2017, the Company's public float was approximately \$40.1 million, based on 12,846,511 shares of outstanding common stock held by non-affiliates and at a price of \$3.12 per share, which was the last reported sale price of the Company's common stock on The Nasdaq Capital Market on March 10, 2017. The Company expects to be limited by the baby shelf rules as of this filing of its Form 10-K for the year ended December 31, 2016, until such time as the Company's public float once again exceeds \$75 million, which means, since the Company has sold approximately \$4.8 million in the prior twelve month period under baby shelf rules, the Company only has the capacity to sell approximately \$8.6 million of shares, assuming the Company's public float remains unchanged until the filing of the Form 10-K. If the Company's public float decreases, the amount of securities we may sell under our Form S-3 shelf registration statement, including this prospect

Future sales will depend on a variety of factors including, but not limited to, market conditions, the trading price of the Company's common stock and the Company's capital needs. There can be no assurance that FBR will be successful in consummating future sales based on prevailing market conditions or in the quantities or at the prices that the Company deems appropriate.

In addition, the Company will not be able to make future sales of common stock pursuant to the FBR Sales Agreement unless certain conditions are met, which include the accuracy of representations and warranties made to FBR under the FBR Sales Agreement. Furthermore, FBR is permitted to terminate the FBR Sales Agreement in its sole discretion upon ten days' notice, or at any time in certain circumstances, including the occurrence of an event that would be reasonably likely to have a material adverse effect on the Company's assets, business, operations, earnings, properties, condition (financial or otherwise), prospects, stockholders' equity or results of operations. The Company has no obligation to sell the remaining shares available for sale pursuant to the FBR Sales Agreement.

## Warrants

The Company has issued warrants to purchase common stock to banks that have loaned funds to the Company, as well as to representatives of the underwriters of the Company's initial public offering and certain of its affiliates. A summary of the Company's warrant activity is as follows:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)
Outstanding at December 31, 2015	118,881	\$ 16.73	4.35
Issued	3,227,876	\$ 2.81	5.04
Exercised	(22,881)	\$ 5.90	8.00
Expired/Forfeited	<del></del>	_	_
Outstanding at December 31, 2016	3,323,876	\$ 3.29	4.96

## **Equity Incentive Award Plans**

The Company adopted the 2007 Equity Incentive Plan (the "2007 Plan") in May 2007 under which 450,000 shares of common stock were reserved for issuance to employees, nonemployee directors and consultants of the Company. As of December 31, 2016, no options were available for future grant under this plan.

In August 2013, the Company adopted the 2013 Equity Incentive Award Plan (the "2013 Plan") as a successor to the 2007 Plan. Under the 2013 Plan, the Company may grant stock options, stock appreciation rights, restricted stock, restricted stock units and other awards to individuals who are then employees, officers, non-employee directors or consultants of the Company. A total of 510,000 shares of common stock were initially reserved for issuance under the 2013 Plan. In addition, the number of shares of common stock available for issuance under the 2013 Plan will be annually increased on the first day of each fiscal year during the term of the 2013 Plan, beginning with the 2014 fiscal year, by an amount equal to the least of: (i) 300,000 shares; (ii) four percent of the outstanding shares of common stock as of the last day of the immediately preceding fiscal year; or (iii) such other amount as the Company's board of directors may determine.

In February 2016, the Company effected a one-time option exchange, wherein employees were offered the opportunity to exchange certain outstanding stock options for the grant of a lesser number of replacement stock options. The participants received three new stock options for every four stock options tendered for exchange. As a result, 703,500 stock options were exchanged for 527,624 replacement stock options. The replacement stock options have a three-year vesting schedule and an exercise price of \$3.04 per share, which was the closing price of the Company's common stock on the date of the option exchange. All other terms of the replacement stock options remain the same as the original stock options that were exchanged. As a result of this transaction, the Company recognized an incremental stock-based compensation expense of approximately \$4,700 at the time of the transaction and will recognize an additional approximately \$141,000 of stock-based compensation expense over the three-year vesting term of the exchanged options.

On April 27, 2016, the Company's stockholders approved an amendment and restatement of the Company's 2013 Equity Incentive Award Plan (the "Restated Plan") to increase the number of shares of common stock reserved under the Restated Plan by 500,000 shares, to an aggregate of 4,786,425 shares, and to extend the term of the Restated Plan into 2026.

As a result of the annual increases since the 2013 Plan originated, and the increase of stock options reserved under the Restated Plan approved by the Company's stockholders in April 2016, the Company has increased the number shares reserved for issuance under the 2013 Plan by 1,276,425 shares. As of December 31, 2016, 628,801 options remain available for future grant under the 2013 Plan. On January 1, 2017, the Company further increased the number of shares reserved for issuance under the 2013 Plan by 300,000 shares, making 928,801 options available for future grant under the 2013 Plan.

Options granted under the 2007 Plan and 2013 Plan have ten year terms from the date of grant and generally vest over a one to four year period. The Company granted options to purchase 414,000 and 354,000 shares of common stock in 2016 and 2015, respectively. The exercise price of all options granted during the years ended December 31, 2016 and 2015 was equal to the market value per share of the Company's common stock on the date of grant.

A summary of the Company's stock option activity under the 2007 Plan and 2013 Plan is as follows:

		Weighted				
			Weighted	Average		
			Average	Remaining		
			Exercise	Contractual		Aggregate
	Shares		Price	Term (Years)	Ir	trinsic Value
Outstanding at December 31, 2015	1,037,500	\$	7.19	8.04	\$	342,200
Granted	941,624	\$	3.26	9.12		_
Exercised	_			_		_
Expired/Forfeited/Exchanged	(703,500)		7.65	7.46		_
Outstanding at December 31, 2016	1,275,624	\$	4.04	8.34	\$	191,160
Vested and expected to vest at December 31, 2016	1,275,624	\$	4.04	8.34	\$	191,160
Exercisable at December 31, 2016	584,663	\$	4.86	7.42	\$	191,160

The intrinsic values above represent the aggregate value of the total pre-tax intrinsic value based upon a common stock price of \$2.02 and \$3.30 at December 31, 2016 and 2015, respectively, and the contractual exercise price.

The weighted average grant date fair value per share of employee stock options granted during the years ended December 31, 2016 and 2015, was \$2.04 and \$4.03, respectively.

The 2007 Plan permits the early exercise of options, but the Company has the option to repurchase any unvested shares at the original purchase price (the exercise price paid by the purchaser) upon any voluntary or involuntary termination. The shares of common stock issued from the exercise of stock options are restricted and vest over time or on the achievement of certain milestones. Any unvested shares immediately vest in the event of termination for reasons other than cause, and vesting accelerates in the event of a merger, sale,

or other change in control of the Company. Of the total 332,000 stock options exercised, 287,000 were vested as of December 31, 2016 and 2015. The remaining 45,000 exercised stock options vest upon the submission of the NDA for Gimoti.

There were no options exercised in 2016 and 2015.

The Company had the following nonvested options under the 2007 Plan and 2013 Plan:

	Shares	Average Grant Date Fair Value Per Share
Nonvested at December 31, 2015	507,421	\$ 7.60
Granted	941,624	\$ 2.04
Vested	(340,663)	\$ 4.53
Expired/Forfeited/Exchanged	(417,421)	_
Nonvested at December 31, 2016	690,961	\$ 3.34

Weighted

Vear Ended December 31

### **Employee Stock Purchase Plan**

On June 13, 2013, the Company's board of directors adopted the ESPP, and the Company's stockholders approved the ESPP on August 29, 2013. The ESPP became effective on the day prior to the effectiveness of the IPO. The ESPP permits participants to purchase the Company's common stock at 85% of the fair market value through payroll deductions of up to 20% of their eligible compensation. A total of 30,000 shares of common stock were initially reserved for issuance under the ESPP. In addition, the number of shares of common stock available for issuance under the ESPP is annually increased on the first day of each fiscal year during the term of the ESPP by an amount equal to the lesser of: (i) 30,000 shares; (ii) one percent of the outstanding shares of common stock as of the last day of the immediately preceding fiscal year; or (iii) such other amount as the Company's board of directors may determine. As a result, the Company increased the number shares reserved for issuance under the ESPP by 30,000 shares on each annual increase date since the inception of the ESPP. During 2016 and 2015, 34,067 and 41,176 shares of common stock, respectively, were issued under the ESPP. As of December 31, 2016, 37,463 shares remain available for future issuance under the ESPP. On January 1, 2017, the Company further increased the number of shares reserved for future issuance under the ESPP after that increase.

The estimated fair value of the shares to be acquired under the ESPP was determined on the initiation date of each six month purchase period using the Black-Scholes option-pricing valuation model with the following weighted-average assumptions for ESPP shares to be purchased during the year ended December 31, 2016 and 2015:

	Tear Ended I	Jecennoer 31,
	2016	2015
Risk free interest rate	0.47% - 0.50%	0.08% - 0.26%
Expected term	6 months	6 months
Expected volatility of common stock	83.83% - 212.80%	62.91% - 69.64%
Expected dividend yield	0.0%	0.0%

As a result of payroll withholdings from the Company's employees of approximately \$99,000 and \$170,000, the Company sold 34,067 and 41,176 shares of common stock through its ESPP during the years ended December 31, 2016 and 2015, respectively.

### **Stock-Based Compensation**

Stock-based compensation expense includes charges related to stock option grants and employee stock purchases under the Company's ESPP. The Company measures stock-based compensation expense based on the grant-date fair value of any awards granted to its employees. Such expense is recognized over the period of time that employees provide service and earn rights to the awards.

The estimated fair value of each option award granted was determined on the date of grant using the Black-Scholes option-pricing valuation model with the following weighted-average assumptions for options grants during the two years ended December 31, 2016:

	Year Ended	December 31,
	2016	2015
Risk free interest rate	1.25% - 1.58%	1.50% - 1.87%
Expected option term	5.3 - 6.0 years	5.5 - 6.0 years
Expected volatility of common stock	74.44 - 75.91%	71.99% - 76.74%
Expected dividend yield	0.0%	0.0%

The Company recognized non-cash stock-based compensation expense to employees and directors in its research and development and its general and administrative functions as follows:

Vear Ended December 31

		icai Endea December 31,			
	<u> </u>	2016		2015	
Research and development	\$	698,032	\$	579,078	
General and administrative		1,008,492		925,278	
Total stock-based compensation expense	\$	1,706,524	\$	1,504,356	

As of December 31, 2016, there was approximately \$1.8 million of unrecognized compensation costs related to outstanding employee and board of director options, which is expected to be recognized over a weighted average period of 0.95 years.

### **Common Stock Reserved for Future Issuance**

Common stock reserved for future issuance consists of the following at December 31, 2016 and 2015:

	December 31,			
	2016	2015		
Stock options issued and outstanding	1,275,624	1,037,500		
Authorized for future option grants	628,801	78,854		
Warrants to purchase common stock	3,323,876	118,881		
Authorized for employee stock purchase plan	37,463	41,530		
Total common stock reserved for future issuance	5,265,764	1,276,765		

### 7. Fair Value Measurements

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date.

During the year ended December 31, 2015, the Company had no assets or liabilities requiring fair value measurements. As noted in Note 6, during the third quarter of 2016 the Company entered into the 2016 Financings with an institutional investor providing for the issuance and sale by the Company of 5,048,632 shares of the Company's common stock and warrants to purchase up to 2,975,444 shares of the Company's common stock for aggregate gross proceeds of \$14.5 million. In addition, as partial payment for services, the Company issued to the underwriters warrants to purchase up to 252,432 shares of the Company's common stock.

The Company utilizes a valuation hierarchy for disclosure of the inputs to the valuations used to measure fair value. This hierarchy prioritizes the inputs into three broad levels as follows: Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities. Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument. Level 3 inputs are unobservable inputs based on the Company's own assumptions used to measure assets and liabilities at fair value. A financial asset or liability's classification within the hierarchy is determined based on the lowest level input that is significant to the fair value measurement.

The Company had no assets or liabilities classified as Level 1 or Level 2. The warrant liability is classified as Level 3.

The Company has classified the warrants as a liability and has remeasured the liability to estimated fair value at December 31, 2016, using the Black Scholes option valuation model with the following assumptions:

	December 31,
	2016
Risk-free interest rate	1.93%
Expected volatility	94.19
Expected term	5.08 years
Expected dividend yield	0%

The following fair value hierarchy table presents information about the Company's financial assets and liabilities measured at fair value on a recurring basis as of December 31, 2016:

	Fair Value Measurement as of December 31, 2016						
	Level 1		Level 2		Level 3		Balance
Warrant liability	\$	-	\$	- \$	4,095,019	\$	4,095,019
Total	\$	_	\$	- \$	4,095,019	\$	4,095,019

The following table presents a reconciliation of the Company's liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) for the year ended December 31, 2016:

	Warrant Liability
Balance at December 31, 2015	\$ =
Issuance of warrants	4,899,459
Change in fair value upon re-measurement	(597,615)
Reclassification to Additional Paid-in Capital	
due to warrant amendment	 (206,825)
Balance at December 31, 2016	\$ 4,095,019

There were no transfers between Level 1 and Level 2 in any of the periods reported.

### 8. Employee Benefit Plan

The Company has established a defined contribution 401(k) plan (the "Plan") for all employees who are at least 21 years of age. Employees are eligible to participate in the Plan beginning on the date of employment. Under the terms of the Plan, employees may make voluntary contributions as a percentage of compensation. The Company's contributions to the Plan are discretionary, and no contributions have been made by the Company to date. For the years ended December 31, 2016 and 2015, the Company adopted Safe Harbor 401(k) provisions. In order to maintain the Plan's compliance with Internal Revenue Service regulations, approximately \$7,700 was contributed to the accounts of certain employees for the year ended December 31, 2015 and approximately \$3,100 will be contributed to the accounts of certain employees for the year ended December 31, 2016.

# 9. Income Taxes

The Company accounts for uncertain tax positions in accordance with Accounting Standards Codification Topic 740, *Income Taxes* ("ASC 740"). The application of income tax law and regulations is inherently complex. Interpretations and guidance surrounding income tax laws and regulations change over time. As such, changes in the Company's subjective assumptions and judgments can materially affect amounts recognized in its financial statements.

The Company's policy is to recognize interest and/or penalties related to income tax matters in income tax expense. The Company had no accrual for interest and penalties on the balance sheet at December 31, 2016. The Company has an uncertain tax position of \$1.9 million related to California net operating losses at December 31, 2016. The Company is subject to taxation in the United States and state jurisdictions, and the Company's tax years beginning 2007 to date are subject to examination by taxing authorities. The Company does not foresee material changes to its gross uncertain income tax position liability within the next twelve months.

A reconciliation of the federal statutory income tax rate and the effective income tax rate is as follows for the years ended December 31, 2016 and 2015:

	Decembe	r 31,
	2016	2015
	(%)	(%)
Federal statutory rate	34	34
Change in valuation allowance	<del>-</del>	(2)
State income taxes, net of federal effect	_	6
Warrant liability FMV adjustment	6	
Stock issuance costs	(5)	_
Research and development credits	3	4
Removal of net operating loss and other credits	(33)	(39)
Stock compensation and other permanent items	(5)	(3)
Effective income tax rate	<u></u>	

Pursuant to Internal Revenue Code ("IRC") Sections 382 and 383, annual use of the Company's net operating loss and research and development credit carryforwards may be limited in the event a cumulative change in ownership of more than 50% occurs within a three-year period. The Company has not completed an IRC Section 382/383 analysis regarding the limitation of net operating loss and research and development credit carryforwards. Until this analysis has been completed, the Company has removed the deferred tax assets for net operating losses of approximately \$2.5 million and a research and development credit of approximately \$2.5 million generated through December 31, 2016 from its deferred tax asset schedule, and has recorded a corresponding decrease to its valuation allowance. When this analysis is finalized, the Company plans to update its unrecognized tax benefits accordingly. The Company does not expect this analysis to be completed within the next twelve months and, as a result, the Company does not expect that the unrecognized tax benefits will change within twelve months of this reporting date. Due to the existence of the valuation allowance, future changes in the Company's unrecognized tax benefits will not impact the Company's effective tax rate.

Significant components of the Company's deferred tax assets at December 31, 2016 and 2015 are as follows:

	December 31,			
	 2016		2015	
Acquired technology	\$ 201,000	\$	276,000	
Stock compensation expense	539,000		430,000	
Accruals and other	130,000		124,000	
Total deferred tax assets	870,000		830,000	
Less valuation allowance	(870,000)		(830,000)	
Net deferred tax assets	\$ 	\$	_	

At December 31, 2016, the Company has federal and California net operating loss carryforwards of approximately \$53.0 million and \$42.9 million, respectively. The federal and California loss carryforwards begin to expire in 2027 and 2017, respectively, unless previously utilized. The Company also has federal and California research tax credit carryforwards of approximately \$1.8 million and \$1.1 million, respectively. The federal research credit carryforwards will begin expiring in 2027 unless previously utilized. The California research credit will carry forward indefinitely.

A summary of the changes in the amount of unrecognized tax benefits (excluding interest and penalties) for 2016 and 2015 are as follows:

	2016			15
Beginning balance of unrecognized tax benefits	\$	_	\$	-
Additions based on tax positions of prior years		1,961,595		-
Ending balance of unrecognized tax benefits	\$	1,961,595	\$	_

Due to the full valuation allowance that the Company has on the deferred tax assets, there are no unrecognized tax benefits that would impact the effective tax rate, if recognized.

The Company recognizes interest and penalties related to unrecognized tax benefits in income tax expense. To date, as no benefit has been taken related to the uncertain tax position, there have been no interest and penalties recognized.

## 10. Related Party Transactions

An officer of the Company serves on the executive management team of a CRO that provided clinical trial services to the Company. For the years ended December 31, 2016 and 2015, the Company incurred an aggregate of approximately \$13,000 and \$218,000, respectively, in fees for these services. As of December 31, 2016 and 2015, accounts payable included \$13,000 and \$0, respectively, for related party transactions.

### 11. Subsequent Events

For the purposes of the financial statements as of December 31, 2016 and the year then ended, the Company has evaluated subsequent events through the date the audited annual financial statements were issued. The Company has concluded that no subsequent event has occurred other than what has been disclosed.

# 12. Summarized Quarterly Data (Unaudited)

The following financial information reflects all adjustments, which include only normal recurring adjustments, which are, in the opinion of management, necessary for a fair statement of the financial results of the interim periods. Summarized quarterly data for the years ended December 31, 2016 and 2015 are as follows:

		For the Quarters Ended						
	March 31,		June 30,		September 30,		December 31,	
2016				<u> </u>			<u> </u>	_
Research and development expense	\$	2,015,076	\$	2,095,149	\$	1,339,343	\$	1,502,032
General and administrative expense	\$	1,137,753	\$	802,655	\$	830,092	\$	822,325
Change in fair value of warrant liability		_		_	\$	198,945	\$	(796,560)
Net loss	\$	(3,225,409)	\$	(2,970,498)	\$	(3,025,281)	\$	(1,527,343)
Net loss per common share, basic and diluted (1)	\$	(0.45)	\$	(0.41)	\$	(0.29)	\$	(0.12)
Weighted average shares outstanding,								
basic and diluted		7,168,005		7,217,577		10,614,692		12,305,360
2015								
Research and development expense	\$	2,419,961	\$	2,188,138	\$	1,837,743	\$	1,708,302
General and administrative expense	\$	1,025,261	\$	976,418	\$	819,703	\$	842,777
Net loss	\$	(3,520,748)	\$	(3,241,163)	\$	(2,735,400)	\$	(2,624,152)
Net loss per common share, basic and diluted (1)	\$	(0.58)	\$	(0.52)	\$	(0.42)	\$	(0.37)
Weighted average shares outstanding,								
basic and diluted		6,103,783		6,212,803		6,494,845		7,123,163

<sup>(1)</sup> Net loss per share is computed independently for each of the quarters presented. Therefore, the sum of the quarterly per-share calculations will not necessarily equal the annual per share calculation.

# **SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

EVOKE PHARMA, INC.

Date: March 15, 2017 By: <u>/s/ David A. Gonyer</u>

David A. Gonyer

President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ David A. Gonyer David A. Gonyer, R.Ph.	President, Chief Executive Officer and Director (principal executive officer)	March 15, 2017
/s/ Matthew J. D'Onofrio Matthew J. D'Onofrio	Executive Vice President, Chief Business Officer, Treasurer and Secretary (principal financial and accounting officer)	March 15, 2017
/s/ Cam L. Garner Cam L. Garner	_ Chairman of the Board of Directors	March 15, 2017
/s/ Todd C. Brady, M.D., Ph.D. Todd C. Brady, M.D., Ph.D.	_ Director	March 15, 2017
/s/ Scott L. Glenn Scott L. Glenn	_ Director	March 15, 2017
/s/ Malcolm R. Hill, Pharm. D. Malcolm R. Hill, Pharm. D.	_ Director	March 15, 2017
/s/ Ann D. Rhoads Ann D. Rhoads	_ Director	March 15, 2017
/s/ Kenneth J. Widder, M.D. Kenneth J. Widder, M.D.	Director	March 15, 2017

# **Exhibit Index**

Exhibit Number	Description of Exhibit
3.1(2)	Amended and Restated Certificate of Incorporation of the Company
3.2(2)	Amended and Restated Bylaws of the Company
4.1(3)	Form of the Company's Common Stock Certificate
4.2(4)	Investor Rights Agreement dated as of June 1, 2007
4.3(4)	Warrant dated June 1, 2012 issued by the Company to Silicon Valley Bank
4.4(3)	Form of Warrant Agreement dated September 30, 2013 issued by the Company to the representative of the underwriters and certain of its affiliates in connection with the closing of the Company's initial public offering.
4.5(16)	Form of Warrant issued by the Company to certain investors under the Securities Purchase Agreement between the Company and such investors dated July 25, 2016
4.6(17)	Form of Warrant issued by the Company to certain investors under the Securities Purchase Agreement between the Company and such investors dated August 3, 2016
4.7 (18)	Form of Amendment to Common Stock Purchase Warrant, amending certain of the warrants dated July 25, 2016 and August 3, 2016
10.1(4)	Form of Indemnity Agreement for Directors and Officers
10.2(5)#	Amended and Restated Employment Agreement, effective as of June 7, 2013, between the Company and David A. Gonyer
10.3(5)#	Amended and Restated Employment Agreement, effective as of June 7, 2013, between the Company and Matthew D'Onofrio
10.4(4)	2007 Equity Incentive Plan, as amended, and form of option agreement thereunder
10.5(1)	2013 Equity Incentive Award Plan and form of option agreement thereunder
10.6(5)	2013 Employee Stock Purchase Plan
10.7(5)#	Amended and Restated Retention Letter, dated May 22, 2013, between the Company and David A. Gonyer
10.8(5)#	Amended and Restated Retention Letter, dated May 22, 2013, between the Company and Matthew D'Onofrio
10.9†(6)	Asset Purchase Agreement, dated as of June 1, 2007, between the Company and Questcor Pharmaceuticals, Inc.
10.10(8)	Second Amendment to Master Services Agreement, dated as of November 25, 2013, between the Company and SynteractHCR, Inc.
10.11(7)#	Employment Agreement, effective as of December 1, 2013, between the Company and Marilyn R. Carlson
10.12(8)	Third Amendment to Master Services Agreement, dated as of January 29, 2014, between the Company and SynteractHCR, Inc.
10.13(9)	Loan and Security Agreement, dated as of May 28, 2014, by and between the Company and Square 1 Bank
10.14(10)	At Market Issuance Sales Agreement, dated as of November 13, 2014, between the Company and MLV & Co. LLC.
10.15(11)	First Amendment to Loan and Security Agreement dated as of May 11, 2015 by and between the Company and Square 1 Bank
10.16(12)	Second Amendment to Loan and Security Agreement dated as of October 5, 2015 by and between the Company and Square 1 Bank
10.17(14)#	Non-Employee Director Compensation Policy, as Amended and Restated Effective January 28, 2016

Exhibit Number	Description of Exhibit
10.18(13)	Third Amendment to Loan and Security Agreement dated as of February 29, 2016 by and between the Company and Pacific Western Bank (as successor to Square 1 Bank)
10.19(15)	2013 Equity Incentive Award Plan, as amended and restated, effective April 27, 2016
10.20(16)	Form of Securities Purchase Agreement dated as of July 20, 2016 by and between the Company and certain investors party thereto
10.21(16)	Engagement Letter dated as of July 19, 2016 by and between the Company and Rodman & Renshaw, a unit of H.C. Wainwright & Co., LLC
10.22(17)	Form of Securities Purchase Agreement dated as of July 29, 2016 by and between the Company and certain investors party thereto
10.23(17)	Engagement Letter dated as of July 29, 2016 by and between the Company and Rodman & Renshaw, a unit of H.C. Wainwright & Co., LLC
10.24	Standard Office Lease, dated as of December 19, 2016, between the Company and SB Corporate Centre III-IV, LLC
10.25#	Amendment to Amended and Restated Employment Agreement, effective as of January 25, 2017 between the Company and Matthew D'Onofrio
10.26#	Amendment to Employment Agreement, effective as of January 25, 2017, between the Company and Marilyn R. Carlson
23.1	Consent of BDO USA, LLP, Independent Registered Public Accounting Firm
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934
31.2	Certification of Chief Financial Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934
32.1*	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2*	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
(1) Incorp	orated by reference to the Company's Amendment No. 4 to Registration Statement on Form S-1 filed with the SEC on August 30, 2013.

- Incorporated by reference to the Company's Amendment No. 4 to Registration Statement on Form S-1 filed with the SEC on August 30, 2013.
- (2) Incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on September 30, 2013.
- (3) Incorporated by reference to the Company's Amendment No. 3 to Registration Statement on Form S-1 filed with the SEC on August 16, 2013.
- (4) Incorporated by reference to the Company's Registration Statement on Form S-1 filed with the SEC on May 24, 2013.
- Incorporated by reference to the Company's Amendment No. 1 to Registration Statement on Form S-1 filed with the SEC on June 14, 2013. (5)
- Incorporated by reference to the Company's Amendment No. 2 to Registration Statement on Form S-1 filed with the SEC on July 3, 2013. (6)
- (7) Incorporated by reference to the Company's Current Report on Form 8-K filed on December 2, 2013.
- Incorporated by reference to the Company's Annual Report on Form 10-K filed on March 25, 2014. (8)
- (9) Incorporated by reference to the Company's Current Report on Form 8-K filed on May 28, 2014.
- (10) Incorporated by reference to the Company's Registration Statement on Form S-3 filed with the SEC on November 13, 2014.
- (11)Incorporated by reference to the Company's Quarterly Report on Form 10-Q filed with the SEC on May 14, 2015.
- (12)Incorporated by reference to the Company's Current Report on Form 8-K filed on October 7, 2014.
- Incorporated by reference to the Company's Current Report on Form 8-K filed on March 1, 2016. (13)
- Incorporated by reference to the Company's Annual Report on Form 10-K filed on March 10, 2016. (14)
- Incorporated by reference to Appendix A to the Company's Definitive Proxy Statement on Schedule 14A filed with the SEC on March 15, 2016. (15)

- (16) Incorporated by reference to the Company's Current Report on Form 8-K filed on July 20, 2016.
- (17) Incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on August 1, 2016.
- (18) Incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on December 16, 2016.
- † Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment pursuant to Rule 406 under the Securities Act of 1933.
- # Management contract or compensatory plan or arrangement.
- These certifications are being furnished solely to accompany this annual report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and are not to be incorporated by reference into any filing of Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

## **OFFICE LEASE AGREEMENT**

**BETWEEN** 

SB CORPORATE CENTRE III-IV, LLC
AS LANDLORD

AND

**EVOKE PHARMA, INC.** 

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# STANDARD FORM MODIFIED GROSS OFFICE LEASE

This Standard Form Modified Gross Office Lease ("Lease") is entered into effective as of December 19, 2016, between SB CORPORATE CENTRE III-IV, LLC, a Delaware limited liability company ("Landlord"), and EVOKE PHARMA, INC., a Delaware corporation ("Tenant"), who agree as follows:

- 1. Agreement to Let. Landlord hereby leases to Tenant, and Tenant hereby leases from Landlord, upon all of the terms, provisions, and conditions contained in this Lease, (i) those certain premises described in the Principal Lease Provisions below (the "Premises"), consisting of a portion of that certain building described in the Principal Lease Provisions below (the "Building"), which is in turn a part of the Project (as described in the Principal Lease Provisions below), along with (ii) the non-exclusive right to use, in common with Landlord, Landlord's invitees and licensees, and the other tenants and users of space within the Project, those portions of the Project intended for use by, or benefiting, tenants of the Project in common including, without limitation, the landscaped areas, passageways, walkways, hallways, elevators, parking areas, and driveways of the Building and the Project, but excluding all interior areas of the other buildings in the Project other than the Building (collectively, the "Common Areas"). This Lease confers no rights, however, to the roof, exterior walls, or utility raceways of the Building, nor rights to any other building in the Project, nor with regard to either the subsurface of the land below the ground level of the Project or with regard to the air space above the ceiling of the Premises; provided, however, that Tenant shall have the limited right to access systems and equipment exclusively serving the Premises (for which Tenant has maintenance and repair responsibilities pursuant to Paragraph 10.1, below) that may be located on the roof, in exterior or demising walls, in utility raceways, in the airspaces above the ceiling of the Premises, or in any other portion of the Building or the Common Areas for the sole purpose of maintaining, repairing, and replacing such systems and equipment.
- 2. <u>Principal Lease Provisions</u>. The following are the Principal Lease Provisions of this Lease. Other portions of this Lease explain and describe these Principal Lease Provisions in more detail and should be read in conjunction with this Paragraph. In the event of any conflict between the Principal Lease Provisions and the other portions of this Lease, the Principal Lease Provisions will control. (Terms shown in quotations are defined terms used elsewhere in this Lease)
- 2.1. "Project": That certain office project, commonly referred to as Solana Beach Corporate Centre, in Solana Beach, California, as more particularly depicted on the attached <a href="Exhibit">Exhibit "A."</a>
- 2.2. "Building": That certain building within the Project as designated on the attached <u>Exhibit "A"</u>, sometimes referred to as Solana Beach Corporate Centre III, whose mailing address is 420 Steven Avenue, Solana Beach, California 92075.
- 2.3. "Premises": Suite 370; consisting of a portion of the third (3rd) floor of the Building, as more particularly described on the attached <a href="Exhibit">Exhibit "B."</a>
- 2.4. Area of the Premises: Approximately 3,031 Rentable Square Feet of space. The term "Rentable Square Feet", "Usable Square Footage," and similar terms dealing with Rentable or Usable means of describing measurements of square footages, will have the meanings of such term adopted by the Building Owners and Managers Association International (relative to *multitenant* floors).
- 2.5. "Initial Lease Term": Two (2) years plus any additional days required for the Initial Expiration Date to occur on the last day of a month as set forth in Paragraph 2.5.2, below, beginning as of the Lease Commencement Date and ending as of the Initial Expiration Date.
  - 2.5.1. "Lease Commencement Date:" January 1, 2017.
- 2.5.2. "Initial Expiration Date": That date which is two (2) years (plus, if such date is not the final day of a calendar month, however many days are left in the final calendar month of the Term) after the Lease Commencement Date.
  - 2.5.3. Extension Rights: Yes: One (1) Option to Extend for a period of two (2) years (Section 3.2).

- 2.6. "Basic Monthly Rent": \$3.70 per Rentable Square Foot, net of electricity and other utilities, subject to adjustment pursuant to attached Addendum No. 1. Basic Monthly Rent will always be due and payable on or before the first day of the applicable month, except that the first month's Basic Monthly Rent will be due and payable upon the date of Landlord's execution of this Lease.
  - 2.7. "Rent Commencement Date": January 1, 2017.
- 2.8. "Security Deposit": \$11,551.14; Tenant's Security Deposit—which is due and payable on the date of Tenant's execution of this Lease—does not constitute last month's rent. Last month's rent must be separately paid by Tenant on or before the first day of the last month of the Lease Term. If Tenant exercises any Option to Extend (as defined below) contained herein, then as a condition precedent to the effectiveness of Tenant's exercise of such Option to Extend, Tenant shall pay to Landlord an amount equal to the difference between the Basic Monthly Rent for the last year of such Extension Term (as defined below) and the amount of the Security Deposit then held by Landlord; which additional amount will be added to, and constitute a part of, the Security Deposit from that point forward.
  - 2.9. "Base Year": Calendar year 2017.
  - 2.10. Guarantor: None.
  - 2.11. Address for Landlord:

SB Corporate Centre III-IV, LLC c/o American Assets Trust Management, LLC 11455 El Camino Real, Suite 200 San Diego, CA 92130 Attn: Property Management (Office)

2.12. Addresses for Tenant:

Legal Notices Addresses

(Following Occupancy)

At the Premises

- 2.13. "Permitted Use": The Premises shall be used for general office purposes, in accordance with all applicable laws, statutes, ordinances, and regulations and the provisions of this Lease, and for no other use.
  - 2.14. Building Standard Operating Hours:

Monday through Friday:

7:00 a.m.-6:00 p.m.

Saturday:

9:00 a.m.-1:00 p.m.

(excluding Sundays and any local, state, and federal holidays)

2.15. Participating Brokers:

Landlord's: CBRE, Inc. – Richard Balestri & Ryan Egli

Tenant's: RE:Align, Inc. – T.D. Rolf

- 2.16. Initial Payment Amounts: \$22,765.84 (which represents the Security Deposit of \$11,551.14, plus the first month's Basic Monthly Rent of \$11,214.70) is payable on the date Tenant executes this Lease (to be adjusted on the Lease Commencement Date to reflect the actual first month's Basic Monthly Rent based upon the actual Rentable Square Footage of the Premises if determined to be different than stated above pursuant to Paragraph 7.4, below.
  - 3. Term.
- 3.1. <u>Description of Term.</u> The term of this Lease ("Term") shall commence on the "Lease Commencement Date", and shall expire on the "Initial Expiration Date", subject to (i) any extension rights described in Paragraph 3.2, below, and (ii) earlier termination by Landlord, as provided in this Lease. The term "Expiration Date", as used in this Lease, shall mean the Initial Expiration Date, any earlier date upon which this Lease is terminated by Landlord, as provided

	Term is extended purs			

- 3.2. Extension Rights. Tenant shall, subject to all of the provisions of this Paragraph 3.2 (including all subparagraphs hereof), have the option to extend the Term (the "Option to Extend") for one (1) additional term(s) of two (2) years (the "Extension Term"), provided Tenant is in occupancy of not less than 90% of the Premises at the time of exercise of the Option to Extend and Tenant gives Landlord written notice via overnight nationally-recognized courier (such as FedEx or UPS), with signature acknowledgement by recipient required, of its election to exercise the Option to Extend no less than nine (9) months and no more than twelve (12) months prior to the then applicable Expiration Date of the Term. Such notice will constitute Tenant's irrevocable election to extend the Term and may not subsequently be revoked by Tenant except as provided below. Time is of the essence with respect to the timing of such requirement to give notice to Landlord.
- 3.2.1. <u>Restrictions on Transferability of Option</u>. The Option to Extend is personal to the Tenant originally named in this Lease or any Permitted Transferee (as defined below) and may not be exercised by anyone other than such originally named Tenant or a Permitted Transferee.
- 3.2.2. Conditions Terminating Tenant's Rights to Exercise Option. Tenant shall not have the right to exercise the Option to Extend, notwithstanding anything set forth above to the contrary: (a) during any period of time commencing from the date Landlord gives to Tenant a written notice that Tenant is in default under any provision of this Lease and continuing until the default alleged in said notice is cured; (b) during the period of time commencing on the day after a monetary obligation to Landlord is due from Tenant and unpaid (without any necessity for notice thereof to Tenant) and continuing until the obligation is paid; or (c) in the event that Landlord has given to Tenant two or more notices of default or two or more late charges have become payable under this Lease during the 12-month period prior to the time that Tenant attempts to exercise the Option to Extend. The period of time within which the Option to Extend may be exercised shall not be extended or enlarged by reason of Tenant's inability to exercise the Option to Extend because of the foregoing provisions of this Paragraph 3.2.2, even if the effect thereof is to eliminate Tenant's right to exercise the Option to Extend.
- 3.2.3. <u>Conditions Terminating Tenant's Option Rights</u>. All rights with respect to the Option to Extend (including rights as to subsequent Extension Terms, if any) shall terminate and be of no further force or effect even after Tenant's due and timely exercise of the Option to Extend, if, after such exercise, but prior to the commencement of the Extension Term, (a) Tenant fails to pay to Landlord a monetary obligation of Tenant for a period of ten days after such obligation became due (without imposing any obligation on the part of Landlord to give notice thereof to Tenant); (b) Tenant fails to cure a non-monetary default within 30 days after the date the Landlord gives notice to Tenant of such default or (c) Landlord gives to Tenant two or more notices of default or two or more late charges become payable for any monetary defaults, whether or not such defaults are cured.
- 3.2.4. Terms and Conditions of Extension of Term. If Tenant duly and timely exercises the Option to Extend, then this Lease shall remain in full force and effect for such additional two (2) year period, except that the Basic Monthly Rent will adjust as of the first day of the Extension Term such that for the first year of the Extension Term the Basic Monthly Rent shall be equal to the then prevailing base rental rate (ignoring tenant improvement and similar refurbishment or construction allowances, free rent, and other similar concessions—it being acknowledged that the Option to Extend reflects Tenant's negotiated right to defer its decision whether to initially lease the Premises for such longer period of time, as opposed to Tenant's right to enter into a new lease) for renewal leases of comparable Class A office space in the Solana Beach submarket, as projected for the first day of the applicable Extension Term and determined pursuant to Paragraph 3.2.5, below (the "Then-Prevailing Rate"). The Basic Monthly Rent will thereafter increase in accordance with the provisions of attached Addendum No. 1.
- 3.2.5. <u>Determination of Then-Prevailing Rate</u>. If Tenant exercises the Option to Extend, then Landlord shall, within 15 business days of receipt of Tenant's written notice of exercise, provide Tenant with written notice of the Then-Prevailing Rate and the calculation of the new Basic Monthly Rent to be effective during the first year of the Extension Term. Tenant shall have ten business days from the date of Landlord's notice in which to (a) accept the Landlord's determination of the Then-Prevailing Rate, (b) revoke Tenant's election to exercise the Option to Extend, in which case Tenant's Option to Extend shall be null and void, or (c) dispute Landlord's determination of the Then-Prevailing Rate. If Tenant fails to notify Landlord, in writing, of its disagreement with Landlord's determination of the Then-Prevailing Rate within such ten-business day period, then Tenant will be deemed to have accepted Landlord's determination and

Landlord's determination shall be binding on both parties. If Tenant disputes such determination, then its notice to Landlord disputing such determination must set forth Tenant's determination of the Then-Prevailing Rate. Upon receipt of Tenant's notice, Landlord and Tenant shall promptly meet and, in good faith, attempt to agree upon the Then-Prevailing Rate. If Landlord and Tenant are unable to reach agreement upon the Then-Prevailing Rate within 30 days of the date of Landlord's receipt of Tenant's dispute notice, then the parties shall promptly submit such dispute to the San Diego office of the American Arbitration Association (the "AAA"), or its successor, for resolution before a single arbitrator (who must have at least ten years' experience in the San Diego County commercial real estate market as a real estate broker or MAI appraiser) in accordance with Real Estate Industry Arbitration Rules of the AAA. Within ten days of the commencement of the arbitration, Landlord and Tenant shall each provide the arbitrator with their respective written determination of the Then-Prevailing Rate—which determination will not be disclosed by the arbitrator until both parties have submitted their respective written determinations. The arbitrator's sole authority will be to select between the Landlord's and the Tenant's respective written determination of the Then-Prevailing Rate, as set forth in the notices described above, as provided to the arbitrator in accordance with the preceding sentence; provided, however, if either party fails to timely submit such a written determination to the arbitrator, then the arbitrator shall use the written determination of such party as set forth in the notices described above as part of the initiation of the subject process. In no event may such arbitrator select any other amount as the Then-Prevailing Rate. The decision of the arbitrator shall be binding upon all parties and the cost of the arbitration shall be split equally between Landlord and Tenant.

### 4. <u>Delivery of Possession</u>.

- 4.1. <u>Delivery Requirements</u>. On or before the Lease Commencement Date, Landlord, at its cost, shall have Substantially Completed the work, if any, required to be completed by Landlord prior to the tender of possession of the Premises to Tenant, as described in <u>Exhibit "C"</u> to this Lease ("Landlord's Work") and shall tender possession of the Premises to Tenant (subject to Landlord's reserved rights hereunder and Landlord's right to continue the completion of Landlord's Work without material interference by Tenant). Landlord's tender of possession of the Premises shall consist of Landlord's notification (which notification may be telephonic, by written notice, or by electronic transmission—such as by facsimile or e-mail) that possession of the Premises is then available to Tenant, and instructing Tenant that Tenant may obtain the keys to the Premises from Landlord's offices. Tenant's refusal to accept such tender (or avoidance thereof) shall not affect the Lease Commencement Date or delay the Rent Commencement Date and such dates will be calculated as if no such refusal or avoidance had occurred.
- 4.2. <u>Definition of Substantial Completion</u>. For purposes of this Lease, the term "Substantially Complete" (and its grammatical variations, such as Substantial Completion) when used with reference to Landlord's Work, will mean that Landlord's Work has been completed to such an extent that Tenant can commence its work, if any, to be undertaken by Tenant, as described in <u>Exhibit "C"</u> to this Lease (the "Tenant's Work"), without material delay or interference due to the completion of Landlord's Work, or if no such Tenant's Work is to be undertaken, then such term will mean completed to such an extent that the Landlord's Work can be finally completed within 60 days and without material interference to Tenant's occupancy and use of the Premises.
- 4.3. <u>Final Completion</u>. Except for any items set forth on a written, detailed "punch-list" of excepted items delivered to Landlord upon the Lease Commencement Date, Tenant shall, as of the Lease Commencement Date, be deemed to have (i) thoroughly inspected the Premises, and determined that, to the best of Tenant's knowledge, the Premises comply with all applicable laws and ordinances, and that the Premises are in first-class condition and repair, (ii) acknowledged that Landlord's Work has been Substantially Completed, (iii) accepted the Premises in its then as-is condition with no right to require Landlord to perform any additional work therein, except as set forth on the punch list, and (iv) waived any express or implied warranties regarding the condition of the Premises, including any implied warranties of fitness for a particular purpose or merchantability.

### 5. <u>Use of Premises and Common Areas</u>.

- 5.1. <u>Permitted Use of Premises</u>. Tenant may use the Premises for the Permitted Use specified in the Principal Lease Provisions and for no other use without Landlord's consent. Any change in the Permitted Use will require Landlord's prior written consent, which consent may be granted or withheld in Landlord's sole and exclusive discretion.
- 5.2. <u>Compliance with Laws</u>. Landlord covenants that the Premises will comply with all applicable laws as of the Lease Commencement Date. Thereafter, Tenant shall comply

with all laws concerning the Premises and/or Tenant's use of the Premises, including without limitation the obligation at Tenant's sole cost to alter, maintain, or restore the Premises in compliance with all applicable laws, even if such laws are enacted after the date of this Lease, and even if compliance entails costs to Tenant of a substantial nature. Such obligation to comply with laws shall include without limitation compliance with Title III of the Americans With Disabilities Act of 1990 (42 U.S.C. 12181 et seq.) (the "ADA"). In addition to the foregoing obligations of Tenant relative to the Premises, if Tenant's particular use of the Premises (including the commencement of any Alterations, as defined below) results in the need for modifications or alterations to any other portion of the Project in order to comply with the ADA or other applicable laws, then Tenant shall additionally be responsible, upon demand, for the cost of such modifications and alterations plus a supervisory fee of ten percent of such cost payable to Landlord. Furthermore, pursuant to Section 1938 of the California Civil Code, Landlord confirms to the best of its knowledge that the entire Project has not undergone inspection by a Certified Access Specialist (CASp). Tenant shall indemnify, defend (with counsel satisfactory to Landlord), and hold Landlord (and its partners, members, shareholders, directors, officers, employees, agents, assigns, and any successors to Landlord's interest in the Project) harmless from and against any and all losses, costs, demands, damages, expenses (including reasonable attorneys' fees), claims, causes of action, judgments, penalties, fines, or liabilities, arising from Tenant's failure to satisfy its obligations under this Paragraph including, without limitation, (i) any costs, expenses, and liabilities incurred by Landlord in connection with responding to any demand by any governmental authority that Landlord undertake any modifications or alterations which are Tenant's responsibility pursuant to this Paragraph 5.2 or for which Tenant is obligated to reimburse Landlord hereunder, as well as (ii) any attorneys' fees, costs, expenses, and liabilities incurred by Landlord in responding to, defending, pursuing, or otherwise being involved with any action, suit, or proceeding arising out of any claim relating to the non-compliance of the Premises or the Project with the ADA or any similar law where such action, suit, or proceeding relates to, or arises from, Tenant's use of the Premises or any Alterations.

- 5.3. Condition During Periods of Non-Use; Recapture. During any period of time in which Tenant is not continuously using and occupying the Premises for the operation of its business, Tenant shall take such measures as may be necessary or desirable, in Landlord's reasonable opinion, to secure the Premises from break-ins and use by unauthorized persons, to minimize the appearance of non-use, and to otherwise maintain the interior and exterior portions of Tenant's Premises, including all windows and doors, in first class condition. Additionally, during any period of time in excess of 90 days in which Tenant is not continuously using and occupying the Premises (or at least 50% thereof) during normal business hours. Landlord may, at its election, by giving written notice (the "Non-Use Recapture Notice") to Tenant, recapture the Premises and terminate this Lease. If Landlord elects to exercise such right and delivers a Non-Use Recapture Notice to Tenant, and Tenant fails to cure such condition to Landlord's reasonable satisfaction within five days of such Non-Use Recapture Notice, this Lease will automatically be deemed terminated as of the effective date stated in the Non-Use Recapture Notice, and Tenant shall surrender possession of the Premises and all improvements therein to Landlord as of such date (and any failure to do so shall constitute an immediate Event of Default hereunder).
- 5.4. <u>Use of Common Areas</u>. Tenant's use of the Common Areas shall at all times comply with the provisions of all Rules (as defined below) regarding such use as Landlord may from time to time adopt. In no event shall the rights granted to Tenant to use the Common Areas include the right to store any property in the Common Areas, whether temporarily or permanently. Any property stored in the Common Areas may be removed by Landlord and disposed of, and the cost of such removal and disposal shall be payable by Tenant to Landlord upon demand. Additionally, in no event may Tenant use any portion of the Common Areas for loading, unloading, or parking, except in those areas specifically designated by Landlord for such purposes, nor for any group social event, sidewalk sale, employment fair or similar commercial or unauthorized purpose.
- 5.5. <u>General Covenants and Limitations on Use</u>. In addition to the Rules, Tenant's and Tenant's agents', employees', contractors', licensees', and invitees' (collectively, "Tenant's Invitees") use of the Premises and the Project, will be subject to the following additional general covenants and limitations on use.
- 5.5.1. Tenant shall not do, bring, or keep anything in or about the Premises that will cause a cancellation of any insurance covering the Premises. If the rate of any insurance carried by Landlord is increased as a result of Tenant's use or Tenant's failure to continuously use and occupy the Premises, Tenant shall pay the amount of such increase to Landlord, within ten days after Landlord delivers to Tenant a notice of such increase.
- 5.5.2. No noxious or unreasonably offensive activity shall be carried on, in or upon the Premises by Tenant or Tenant's Invitees, nor shall anything be done or kept in the

Premises which may be or become a public nuisance or which may cause unreasonable embarrassment, disturbance, or annoyance to others in the Project, or on adjacent or nearby property. To that end, Tenant additionally covenants and agrees that no light shall be emitted from the Premises which is unreasonably bright or causes unreasonable glare; no sounds shall be emitted from the Premises which are unreasonably loud or annoying; and no odor shall be emitted from the Premises which is or might be noxious or offensive to others in the Building, on the Project, or on adjacent or near-by property.

- 5.5.3. No unsightliness shall be permitted in the Premises which is visible from the Common Areas. Without limiting the generality of the foregoing, all equipment, objects, and materials shall be kept enclosed within the Premises and screened from view or in Common Areas trash enclosures; no refuse, scraps, debris, garbage, trash, bulk materials, or waste shall be kept, stored, or allowed to accumulate except as may be properly enclosed within appropriate containers in the Premises and promptly and properly disposed of.
- 5.5.4. The Premises shall not be used for sleeping or washing clothes, nor shall the Premises be used for cooking or the preparation, manufacture, or mixing of anything that might emit any offensive odor or objectionable noises or lights onto the Project or nearby properties. Additionally, Tenant shall be responsible for damage to the Project caused by any deliverymen who are at the Project to deliver goods to Tenant.
- 5.5.5. All pipes, wires, conduit, cabling, poles, antennas, and other equipment/facilities for or relating to utilities, telecommunications, computer equipment, or the transmission or reception of audio or visual signals must be kept and maintained enclosed within the Premises (except to the extent included as part of Landlord's Work, Tenant's Work, or otherwise approved by Landlord).
- 5.5.6. Tenant shall not keep or permit to be kept any motorcycle, or other vehicle, nor any animal (excluding seeing-eye dogs), bird, reptile, or other exotic creature in the Premises.
- 5.5.7. Neither Tenant nor Tenant's Invitees shall do anything that will cause damage or waste to the Project. Neither the floor nor any other portion of the Premises shall be overloaded. Tenant shall be responsible for all structural engineering required to determine structural load for items placed in the Premises by Tenant. Tenant shall fasten all files, bookcases, and like furnishings to walls in a manner to prevent tipping over in the event of earth movements. Landlord shall not be responsible for any damage or liability for such events. No machinery, equipment, apparatus, or other appliance shall be used or operated in or on the Premises that will in any manner injure, vibrate, or shake all or any part of the Project or be allowed to interfere with the equipment of any other tenant within the Project (or other property owned by Landlord or its affiliates), including, without limitation, interference with transmission and reception of telephone, telecommunications, television, radio, or similar signals.
- 5.6. Access Rights. Tenant will have 24 hour-a-day, seven day-a-week access to the Building and the Premises. Notwithstanding the foregoing, no failure of such access rights will constitute an eviction (constructive or otherwise) or a disturbance of Tenant's use and possession of the Premises or relieve Tenant from paying Rent or performing any of its obligations under this Lease; except that Tenant shall be entitled to equitable abatement of its Rent (as defined below) obligations hereunder to the extent such lack of access is due to Landlord's negligence or intentional misconduct and continues for a period in excess of three business days. Landlord will not be liable, under any circumstances, for a loss of or injury to property or for injury to or interference with Tenant's business, including loss of profits through, in connection with, or incidental to a failure to furnish access under this Paragraph. Notwithstanding the foregoing, Landlord agrees to use reasonable efforts to promptly correct any such interruption of access.
- 5.7. <u>Remedies for Breach</u>. In the event of any breach of this Paragraph 5 by Tenant or Tenant's Invitees, Landlord, at its election and in addition to its other rights and remedies under this Lease, may pay the cost of correcting such breach and Tenant shall immediately, upon demand, pay Landlord the cost thereof, plus a supervisory fee in the amount of ten percent of such cost.

### 6. Security Deposit.

6.1. <u>Security Deposit</u>. Upon Tenant's execution of this Lease, Tenant shall deposit with Landlord good funds in the amount of the Security Deposit (if any) set forth in the Principal Lease Provisions, to secure the performance by Tenant of its obligations under this Lease, including without limitation Tenant's obligations (i) to pay Basic Monthly Rent and Additional Rent (as defined below), (ii) to repair damages to the Premises and/or the Project

caused by Tenant or Tenant's Invitees, (iii) to surrender the Premises in the condition required by Paragraph 24, below, and (iv) to remedy any other defaults by Tenant in the performance of any of its obligations under this Lease. If Tenant commits any default under this Lease, Landlord may, at its election, use the Security Deposit to cure such default, and to compensate Landlord for all damages actually suffered by Landlord which are directly attributable to such default, including, without limitation, reasonable attorneys' fees and costs incurred by Landlord. Upon demand by Landlord, Tenant shall promptly pay to Landlord a sum equal to any portion of the Security Deposit so used by Landlord, in order to maintain the Security Deposit in the amount set forth in the Principal Lease Provisions above (subject to increase as set forth below). If the Basic Monthly Rent shall, from time to time, increase during the Term, then, upon demand by Landlord, Tenant shall deposit with Landlord cash in an amount necessary to increase the Security Deposit such that it shall at all times bear the same proportion to the then-current Basic Monthly Rent as the initial Security Deposit bears to the initial Basic Monthly Rent. Within 45 days following the Expiration Date or earlier termination of this Lease, Landlord shall deliver to Tenant, at Tenant's last known address, any portion of the Security Deposit not used by Landlord, as provided in this Paragraph. Landlord may commingle the Security Deposit (and any advance Rent received by Landlord) with Landlord's other funds and Landlord shall not pay interest on such Security Deposit to Tenant. Tenant waives the provisions of California Civil Code Section 1950.7 (or any successor statute), and any similar principals of law with respect to Landlord's ability to apply the Security Deposit against future rent damages. Furthermore, upon lawful termination of the Lease as a result of Tenant's default, Landlord shall be entitled to immediately apply the Security Deposit against damages computed under California Civil Code Section 1951.2, without the requirement that Tenant first be given notice and an opportunity to cure, and notwithstanding that the damages have not been finally adjudicated by a court.

### 7. Rent and Rent Adjustments.

- 7.1. Initial Monthly Rent. Tenant shall pay to Landlord as minimum monthly rent, without deduction, setoff, prior notice, or demand, the Basic Monthly Rent described in the Principal Lease Provisions (subject to adjustment as provided in the attached Addendum), in advance, on or before the first day of each calendar month, beginning on the Rent Commencement Date and thereafter throughout the Term. If the Rent Commencement Date is other than the first day of a calendar month, then the Basic Monthly Rent payable by Tenant for the second month of the Term following the Rent Commencement Date (acknowledging that the first month's rent is payable upon Lease execution) shall be prorated on the basis of the actual number of days during the Term occurring during the first partial calendar month thereof. Notwithstanding the foregoing, if Landlord is delayed in completion of Landlord's Work due to any Tenant Delays, then in addition to the Basic Monthly Rent payable for the first month of the Term following the Rent Commencement Date, Tenant shall additionally pay to Landlord, upon the Rent Commencement Date, additional rent, at the rate of one-thirtieth of the Basic Monthly Rent per day, for the number of days of such delay.
- 7.2. <u>Rental Adjustments.</u> The Basic Monthly Rent shall be increased periodically in accordance with the provisions of attached Addendum No. 1 to this Lease.
- 7.3. Additional Rent. In addition to paying the Basic Monthly Rent pursuant to this Paragraph 7, Tenant shall pay to Landlord (in accordance with Paragraph 8 below), commencing on January 1, 2018, Tenant's Share (as defined below) of the annual Operating Expenses (as defined below) that are in excess of the amount of Operating Expenses applicable to the Base Year. The amounts payable pursuant to this Paragraph, together with all other amounts of any kind (other than Basic Monthly Rent) payable by Tenant to Landlord under the terms of this Lease, constitute additional rent for the Premises and are collectively and individually referred to in this Lease as "Additional Rent."
- 7.4. <u>General Rental Provisions.</u> All "Rent" (which includes Basic Monthly Rent and all "Additional Rent" hereunder) shall be paid to Landlord at the same address as notices are to be delivered to Landlord pursuant to the Principal Lease Provisions, as Landlord may change such address from time to time pursuant to the terms of this Lease. The parties agree that they have had the opportunity to verify the Rentable Square Footage of the Premises and agree that the Rentable Square Footage of the Premises set forth in the Principle Lease Provisions shall be conclusive for all purposes of this Lease.

# 8. <u>Additional Rent</u>.

8.1. <u>Definitions</u>. The following definitions apply in this Paragraph 8 (and elsewhere in this Lease):

Operating Expenses. Subject to the Excluded Costs (as defined below) relating to the 8.1.1. Project, the term "Operating Expenses" means all expenses, costs, and amounts of every kind or nature that Landlord pays or incurs because of or in connection with the ownership, operation, management, maintenance, or repair of the Building, Common Areas-and Project. Operating Expenses include, without limitation, the following amounts paid or incurred by Landlord relative to the Building, Common Areas and Project: (a) the cost of supplying utilities to all portions of the Project (other than tenant suites), including without limitation water, waste deposit, power, electricity, heating, ventilation, and air conditioning, (b) Tax Expenses and Insurance Expenses (as such terms are defined below), (c) the cost of providing janitorial services, window washing services and of operating, managing, maintaining, and repairing all building systems, including without limitation utility, mechanical, sanitary, storm drainage, and elevator systems, and the cost of supplies, tools, and equipment, as well as maintenance and service contracts in connection with those systems, (d) the cost of licenses, certificates, permits, and inspections relating to the operation of the Project, (e) the cost of consumable materials, (f) the cost of contesting the validity or applicability of any government enactments that may affect the Operating Expenses, (g) the cost of maintenance, repair, and restoration of any parking areas or structures, including, without limitation, resurfacing, repainting, restriping, and cleaning costs, (h) fees, charges, and other costs, including administrative, management fees and accounting costs (or amounts in lieu of such fees), whether paid to Landlord, an affiliate of Landlord's, or a third party, consulting fees, legal fees, and accounting fees of all persons engaged by Landlord or otherwise reasonably incurred by Landlord in connection with the operation, management, maintenance, and repair of the Project, (i) wages, salaries, and other compensation and benefits of all persons engaged in the operation, maintenance, repair, or security of the Project plus employer's Social Security taxes, unemployment taxes, insurance, and any other taxes imposed on Landlord that may be levied on those wages, salaries, and other compensation and benefits. If any of Landlord's employees provide services for more than one project of Landlord's, only the prorated portion of those employees' wages, salaries, other compensation and benefits, and taxes reflecting the percentage of their working time devoted to the Project will be included in the Operating Expenses, (j) payments under any easement, CC&R's, license, operating agreement, declaration, restrictive covenant, or other instrument relating to the sharing of costs affecting the Project, (k) amortization (including interest on the unamortized cost at a rate equal to the floating commercial loan rate announced from time to time by Bank of America as its "reference rate" (or a comparable rate selected by Landlord if such reference rate ceases to be published) plus three percentage points per annum) of the cost of acquiring or renting personal property used in the maintenance, repair, and operation of the Project, (I) reasonable reserves (it being acknowledged, that, among other amounts, any amount of reserves required by any holder of a deed of trust or mortgage encumbering the Project ("Lender") will be deemed reasonable), (m) fees and expenses for consultants retained, from time to time, by Landlord for the purposes of energy conservation, waste treatment, and water recycling and for the costs of any capital improvements, equipment or devices installed or paid for by Landlord or, at Landlord option, an annual amount sufficient, on the basis of Landlord's experience or reasonable estimate, to establish in advance of the time for such installation a reserve to fund said costs, in order (i) to conform with any change in laws, rules, regulations or requirements of any governmental or quasi-governmental authority having jurisdiction or of the board of fire underwriters or similar insurance body or, (ii) to effect a labor saving, energy saving, or other economy (including, without limitation, as related to water recycling, waste treatment, and energy generation), amortized over the useful life of such capital improvement, equipment, or device (as reasonably determined by Landlord), and (n) the cost of maintenance of all heating, ventilating and air condition systems, including, without limitation, heating and condenser water to facilitate the production of air conditioning (collectively, "HVAC") relating to individual premises and/or the Common Areas, other than HVAC systems exclusively serving other tenants' premises that are directly paid for, or reimbursed, by such other tenants. All capital expenditures shall be amortized (including interest on the unamortized cost at the rate stated in subparagraph (k) of this Paragraph) over their useful life, as reasonably determined by Landlord's certified public accountant.

8.1.2. Excluded Costs. "Excluded Costs" means the following expenses, as they relate to the Operating Expenses: (i) depreciation, principal, interest, and fees on mortgages or ground lease payments, except as otherwise provided herein, (ii) legal fees incurred in negotiating and enforcing tenant leases, disputes with other tenants, (iii) real estate brokers' leasing commissions and advertising costs in connection with leasing space in the Project, (iv) initial improvements or alterations to tenant spaces in the Project, (v) the cost of providing any service directly to and paid directly by a single individual tenant, or costs incurred for the benefit of a single tenant, (vi) costs of any items to the extent Landlord actually receives reimbursement therefor from insurance proceeds, under warranties, or from a tenant or other third party (such costs shall be excluded or deducted – as appropriate – from Operating Expenses in the year in which the reimbursement is received), or which are paid out of reserves previously included in Operating Expenses, (vii) costs incurred due to Landlord's breach of a law or ordinance, (viii) repairs necessitated by the gross negligence or willful misconduct of Landlord or Landlord's

employees, agents, or contractors, (ix) capital expenses other than those specifically included in the definition of Operating Expenses, (x) charitable or political contributions and membership fees or other payments to trade organizations, (xi) costs of Landlord's Work which are to be borne by Landlord pursuant to attached <u>Exhibit "C"</u>, if any (xii) rent and similar charges for Landlord's on-site management office and/or leasing office or any other offices of Landlord or its affiliates (xiii) Landlord's general overhead expenses not related to the Project.

- 8.1.3. <u>Expense Year</u>. "Expense Year" means the Base Year, and each calendar year after the Base Year, in which any portion of the Lease Term falls, through and including the calendar year in which the Lease Term expires.
- 8.1.4. Tenant's Share. "Tenant's Share" means a fraction, the numerator of which is the total aggregate Rentable Square Feet in the Premises, and the denominator of 64,230 which is the total aggregate Rentable Square Feet in the Building. As of the Lease Commencement Date, the Tenant's Share will be 4.72%. If either the Premises or the Building are expanded or reduced, Tenant's Share shall be appropriately adjusted. Tenant's Share for the Expense Year in which that change occurs shall be determined on the basis of the number of days during the Expense Year in which each such Tenant's Share was in effect.
  - 8.2. <u>Adjustment of Operating Expenses</u>. Operating Expenses shall be adjusted as follows:
- 8.2.1. Gross Up Adjustment When a Project is Less Than Fully Occupied. If the occupancy of the total Rentable Square Footage of completed, partially occupied buildings within the Project (whose square footage is included in the calculation of the Project's Rentable Square Footage pursuant to Paragraph 8.1.2. above) during any part of any Expense Year (including the Base Year) is less than 95%. Landlord shall make an appropriate adjustment to the variable components of the Operating Expenses for that Expense Year, as estimated by Landlord in its sole discretion using sound accounting and management principles, to determine the amount of Operating Expenses that would have been incurred had such buildings been 95% occupied. This amount shall be considered to have been the amount of Operating Expenses for that Expense Year. For purposes of this Paragraph 8.2. "variable components" include only those component expenses that are affected by variations in occupancy levels, such as nightly janitorial service to Tenants' Premises or water usage.
- 8.2.2. <u>Adjustment When Landlord Adds Additional Buildings to the Project.</u> If Landlord adds additional buildings within the Project following the Base Year, Landlord shall make an appropriate adjustment to the Operating Expenses for the Base Year, as reasonably determined by Landlord using sound accounting and management principles, to determine the amount of Operating Expenses that would have been incurred for the Base Year if such additional building had been complete and 95% occupied during the Base Year.
- 8.2.3. Adjustment When Landlord Does Not Furnish a Service to All Tenants. If, during any part of any Expense Year (including the Base Year), Landlord is not furnishing a particular service or work (the cost of which, if furnished by Landlord, would be included in Operating Expenses) to a tenant (other than Tenant) that has undertaken to perform such service or work in lieu of receiving it from Landlord, Operating Expenses for that Expense Year shall be considered to be increased by an amount equal to the additional Operating Expenses that Landlord would reasonably have incurred during such period if Landlord had furnished such service or work to that tenant.
- 8.2.4. Additional Costs. If due to a change in the types of costs being incurred by Landlord as Operating Expenses (such as, for example, the commencement or cessation of security services—but not a mere change in how a particular cost is handled—such as going from an in-house to an outside landscaping service), the Base Year Operating Expenses need to be adjusted to eliminate the effect of such change, Landlord shall reasonably adjust the Base Year Operating Expenses and notify Tenant of such change in writing. Furthermore, Landlord shall have the right to reasonably decrease the amount of the Base Year Operating Expenses for purposes of calculating Increased Operating Expenses to eliminate the effect of abnormally high costs, or unusual costs, of a particular type or types (such as, by way of example, abnormally high energy costs associated with the "energy crisis" of 2001) occurring during the Base Year. There shall be no cap on Operating Expenses.
- 8.2.5. <u>Common Areas</u>. Landlord may elect to partition/separate portions of the Common Areas of the Project such that the Operating Expenses associated with such partitioned Common Areas are allocated to particular buildings or parcels within the Project.

- 8.3. Tax Expenses. "Taxes" means and refers to all federal, state, county, or local government or municipal taxes, school taxes sewer rates, fees, charges, or other impositions of every kind or nature, whether general, special, ordinary, or extraordinary. Taxes include taxes, fees, and charges such as real property taxes, general and special assessments, transit taxes, leasehold taxes, and taxes based on the receipt of rent (including gross receipts or sales taxes applicable to the receipt of rent, unless required to be paid by Tenant), and personal property taxes imposed on Landlord's fixtures, machinery, equipment, apparatus, systems, appurtenances, and other personal property used in connection with the Project or the Building, as the case may be, along with reasonable legal and other professional fees, costs and disbursements incurred in connection with proceedings to contest, determine or reduce real property taxes. Notwithstanding the foregoing, the following shall be excluded from Taxes: (a) all excess profits taxes, franchise taxes, gift taxes, capital stock taxes, inheritance and succession taxes, estate taxes, federal, state, and local income taxes, and other taxes applied or measured by Landlord's general or net income (as opposed to rents, receipts, or income attributable to operations at the Building), and (b) personal property taxes attributable to property owned or installed by or for other tenants of the Project; "Tax Expenses" means the sum of all Taxes that are paid or incurred by Landlord because of or in connection with the ownership, leasing, and/or operation of the Project from time to time.
- 8.4. <u>Calculation and Payment of Operating Expenses</u>. Tenant's Share of the increased Operating Expenses for any Expense Year shall be calculated and paid as follows:
- 8.4.1. <u>Calculation of Excess.</u> If Operating Expenses for any Expense Year (other than the Base Year) ending or beginning within the Lease Term exceeds the amount of Operating Expenses applicable to the Base Year, Tenant shall pay as Additional Rent to Landlord an amount equal to Tenant's Share of that excess, in the manner stated below.
- Statement/Payment of Operating Expenses. Tenant shall pay to Landlord, on the first day of each calendar month during the Lease Term, commencing January 1, 2018, as Additional Rent, without notice, demand, offset, or deduction (except as provided below), an amount ("Tenant's Monthly Payment") equal to one-twelfth of Tenant's Share of the amount by which the Operating Expenses for each Expense Year following the Base Year exceed the Base Year Operating Expenses (such excess being referred to herein as the "Increased Operating Expenses"), as estimated (and subsequently reconciled) by Landlord in the most recently delivered Estimated Statement (as defined below). Landlord intends to deliver to Tenant, prior to the commencement of each Expense Year following the Base Year during the Lease Term, a written statement ("Estimated Statement") setting forth Landlord's estimate of the Operating Expenses and Increased Operating Expenses allocable to the ensuing Expense Year, and Tenant's Share of such Increased Operating Expenses. Landlord may, at its option, during any Expense Year, deliver to Tenant a revised Estimated Statement, revising Landlord's estimate of the Operating Expenses and Increased Operating Expenses, in accordance with Landlord's most current estimate. Within approximately 90 days after the end of each Expense Year during the Lease Term, Landlord intends to deliver to Tenant a written statement ("Actual Statement") setting forth the actual Operating Expenses allocable to the preceding Expense Year. Tenant's failure to object to Landlord regarding the contents of an Actual Statement, in writing, within 90 days after delivery to Tenant of such Actual Statement, shall constitute Tenant's absolute and final acceptance and approval of the Actual Statement. If the sum of Tenant's Monthly Payments actually paid by Tenant during any Expense Year exceeds Tenant's Share of the actual Increased Operating Expenses allocable to such Expense Year, then such excess will be credited against future Tenant's Monthly Payments, unless such Expense Year was the Expense Year during which the Lease Expiration Date occurs (the "Last Calendar Year"), in which event either (i) such excess shall be credited against any monetary default of Tenant under this Lease, or (ii) if Tenant is not in default under this Lease, then Landlord shall (within the time frame for returning Tenant's Security Deposit) pay to Tenant such excess. If the sum of Tenant's Monthly Payments actually paid by Tenant during any Expense Year is less than Tenant's Share of the actual Increased Operating Expenses allocable to such Expense Year, then Tenant shall, within ten days of delivery of the Actual Statement, pay to Landlord the amount of such deficiency. Landlord's delay in delivering any Estimated Statement or Actual Statement will not release Tenant from its obligation to pay any Tenant's Monthly Payment or any such excess upon receipt of the Estimated Statement or the Actual Statement, as the case may be. The references in this Paragraph to the actual Increased Operating Expenses allocable to an Expense Year, shall include, if such Expense Year is the Last Calendar Year, the actual Increased Operating Expenses allocable to the portion of such year prior to the Lease Expiration Date, calculated on a pro rata basis, without regard to the date of a particular expenditure. The provisions of this Paragraph 8.4 shall survive the termination of this Lease, and even though the Term has expired and Tenant has vacated the Premises, when the final determination is made of Tenant's Share of Operating Expenses for the year in which this Lease terminates, Tenant shall immediately pay any increase due over the

estimated expenses paid by Tenant pursuant hereto and conversely any overpayment made in Tenant's estimated payments shall be immediately rebated by Landlord to Tenant.

Landlord's Books and Records. If Tenant disputes the amount of Additional Rent stated in an Actual Statement within 90 days of Tenant's receipt thereof, Tenant may, upon at least five business days' notice to Landlord, request an opportunity to inspect and audit Landlord's records and supporting documentation regarding such Actual Statement. Such inspection and audit must be conducted by an independent certified public accountant within 180 days of the date Tenant received the Actual Statement, shall be at Tenant's sole cost and expense (except as provided below), and Landlord shall, at its election, either provide copies of such records and supporting documentation to Tenant or make such records and supporting documentation available to Tenant for its inspection at Landlord's business office during normal business hours. If Tenant fails to dispute the amount of Additional Rent stated in an Actual Statement within 90 days of Tenant's receipt thereof, or Tenant's audit fails to disclose a discrepancy in such Actual Statement within 180 days after Tenant's receipt of the Actual Statement in question, then the Actual Statement will be deemed binding on Tenant. If it is determined as a result of Tenant's timely audit of Landlord's records (and Landlord's certified public accountant's concurrence therein) that Tenant was overcharged relative to the Operating Expenses, such overcharge shall entitle Tenant to a credit against its next payment of Operating Expenses in the amount of the overcharge plus, in the case of an overcharge exceeding three percent of the Operating Expenses, the reasonable third party costs of such audit (and if such credit occurs following the expiration of the Term, Landlord shall promptly pay the amount of such credit to Tenant). If it is determined as a result of Tenant's timely audit of Landlord's records (and Landlord's certified public accountant's concurrence therein), or otherwise, that Tenant was undercharged relative to the Operating Expenses, Tenant shall, within ten days of written demand, pay such undercharge to Landlord.

### 9. <u>Utilities and Services</u>.

- 9.1. <u>Tenant's Utility Costs</u>. Except as provided below, Tenant shall pay when due all bills for gas, electricity, and other utilities used at the Premises on and after the Rent Commencement Date and through and including the date of expiration of this Lease, including all separately metered and assessed charges for utility services servicing the Premises.
- 9.2. <u>Standard Tenant Services</u>. Subject to the terms and conditions contained herein, Landlord shall provide the following services during the Lease Term.
- 9.2.1. Subject to limitations imposed by all governmental rules, regulations and guidelines applicable thereto, Landlord shall provide HVAC when necessary for normal comfort for normal office use in the Premises during Building Standard Operating Hours.
- 9.2.2. Landlord shall provide adequate electrical wiring and facilities sufficient to provide electrical current to the Premises for Project-standard ordinary and customary office uses and excluding electrical power required for electric data processing equipment, computer rooms, special lighting in excess of Building standard lighting, or any other item of electrical equipment which (individually) consumes more than 1.8 kilowatts at rated capacity in which requires a voltage other than 120 volts single phase. In addition to the foregoing, Landlord shall replace lamps, starters, and ballasts for Project-standard lighting fixtures within the Premises upon Tenant's request; the expense of which will be an Operating Expense. Tenant shall replace lamps, starters, and ballasts for non-Project-standard lighting fixtures within the Premises at Tenant's sole expense. Landlord shall also provide electrical service in connection with Common Area needs, such as lighting.
- 9.2.3. Landlord shall provide city water from the regular Building outlets for drinking, lavatory and toilet purposes in the Building Common Areas.
- 9.2.4. Landlord shall provide five day per week ordinary and customary, basic janitorial services in and about the Premises in a manner consistent with other comparable buildings in the vicinity of the Building. Landlord shall not be required to provide janitorial services to above-Project-standard improvements installed in the Premises including but not limited to metallic trim, wood floor covering, glass panels, interior windows, kitchen/dining areas, executive washrooms, or shower facilities. Any janitorial services required by Tenant and provided by Landlord in excess of such ordinary and customary, basic janitorial services shall be separately paid for by Tenant, as Additional Rent, within ten days of written demand.
- 9.2.5. Landlord shall provide nonexclusive, non-attended automatic passenger elevator service during the Building Standard Operating Hours, shall have one elevator

available at all other times, including on the Holidays, and shall provide nonexclusive, non-attended automatic passenger escalator service during Building Standard Operating Hours only.

9.2.6. Landlord shall provide nonexclusive freight elevator service subject to scheduling by

Landlord.

Tenant shall cooperate fully with Landlord at all times and abide by all regulations and requirements that Landlord may reasonably prescribe for the proper functioning and protection of the HVAC, electrical, mechanical, and plumbing systems. Notwithstanding the foregoing, Tenant shall be responsible for all installation and recurring costs associated with utilities services at the Premises.

- 9.3. Over-Standard Tenant Use. Tenant shall not exceed the rated capacity of the Building's electrical and other utility systems, which systems will be consistent in capacity with other first class office buildings built at or about the same time as the Building. In the event of any damage to any of the Project's systems caused by Tenant's use thereof in excess of ordinary and customary usage for a professional office. Tenant shall be responsible for all costs and expenses incurred by Landlord as a result of such over-use. In addition, if Tenant requires any utilities or services described in this Paragraph 9, which are to be provided by Landlord, in excess of the standard levels being provided by Landlord, or during hours other than Building Standard Operating Hours, Landlord shall have the right to impose reasonable restrictions on such usage and/or commercially reasonable charges therefor. The initial charge to Tenant for heating and air conditioning during hours other than Building Standard Operating Hours will be \$45.00 per hour (or portion thereof), subject to increase over the Lease Term, including the Extension Term, if any. Such charges are Additional Rent relative to the provision of such services and are not an offset to any Operating Expenses.
- 9.4. Conduit and Wiring. Installation of all types of conduit and wiring exclusively serving the Premises (other than as part of Landlord's Work), including but not limited to Tenant's Work, is subject to the requirements of Paragraph 22, below, Exhibit "C", and the Landlord's reasonable approval of the location, manner of installation, and qualifications of the installing contractor. All such conduit and wiring will, at Landlord's option, become Landlord's property upon the expiration of the Term. Upon expiration of the Term, Landlord may elect to require Tenant to remove such conduit and wiring at Tenant's expense and return the Premises and the Common Areas to their pre-existing condition. If Landlord constructs new or additional utility facilities, including without limitation wiring, plumbing, conduits, and/or mains, resulting from Tenant's changed or increased utility requirements, Tenant shall on demand promptly pay (or advance) to Landlord the cost of such items as Additional Rent.
- 9.5. <u>Utilities Generally.</u> Tenant agrees that, except as provided below, Landlord will not be liable for damages, by abatement of Rent or otherwise, for failure to furnish or delay in furnishing any service (including telephone and telecommunication services) or for diminution in the quality or quantity of any service. Such failure, delay, or diminution will not constitute an eviction or a disturbance of Tenant's use and possession of the Premises or relieve Tenant from paying Rent or performing any of its obligations under this Lease, except that Tenant will be entitled to an equitable abatement of Rent for the period of such failure, delay, or diminution to the extent such failure, delay, or diminution is (i) is directly attributable to Landlord's gross negligence or intentional misconduct, (ii) prevents Tenant from using, and Tenant does not use, the Premises or the affected portion thereof for the conduct of Tenant's business operations therein, (iii) Tenant was using the Premises or such affected portion for the conduct of Tenant's business operations immediately prior to the failure, and (iv) such failure, delay, or diminution continues for more than two consecutive business days (or ten business days in any twelve month period) after delivery of written notice of such failure, delay, or diminution from Tenant to Landlord. Landlord will not be liable, under any circumstances, for a loss of or injury to property or for injury to or interference with Tenant's business, including loss of profits through, in connection with, or incidental to a failure to furnish any of the utilities or services under this Paragraph. Notwithstanding the foregoing, Landlord agrees to use reasonable efforts to promptly correct any such interruption of utilities or services. Tenant hereby waives the provisions of California Civil Code Section 1932(1) or any other applicable existing or future law, ordinance or governmental regulation permitting the termination of this Lease due to the interruption or failure of or inability to provide any services required to be provided by Landlord hereunder. If any governmental authority having jurisdiction over the Project imposes mandatory controls, or suggests voluntary guidelines applicable to the Project, relating to the use or conservation of water, gas, electricity, power, or the reduction of automobile emissions, Landlord, at its sole discretion, may comply with such mandatory controls or voluntary guidelines and, accordingly, require Tenant to so comply. Landlord shall not be liable for damages to persons or property for any such reduction, nor shall such reduction in any way be construed as a partial eviction of Tenant, cause an abatement of Rent, or operate to release Tenant from any of Tenant's obligations under this Lease, except as

specifically provided in this Paragraph 9.5. By executing this Lease, Tenant hereby authorizes Landlord to obtain information regarding Tenant's utility and energy usage at the Premises directly from the applicable utility providers or any governmental agency and Tenant shall execute, within five (5) days of Landlord's request, any additional documentation required by any applicable utility provider evidencing such authorization. Further, within five (5) days of Landlord's request, Tenant shall provide to Landlord all requested information regarding Tenant's utility and energy usage at the Premises, which information may include copies of Tenant's utilities bills.

### 10. <u>Maintenance</u>.

- Tenant's Duties. Tenant shall at its sole cost maintain, repair, replace, and repaint, all in first class 10.1. condition, the interior of the Premises, all building systems exclusively serving the Premises and located within the Premises or the walls of the Premises, and any damage to the Premises or the Project resulting from the acts or omissions of Tenant or Tenant's Invitees Tenant shall maintain all communications conduit, equipment, and wiring serving the Premises, whether in the Premises or not (and specifically including all of Tenant's Work and all wiring, equipment, and conduit located on the roof of the Building), regardless of the ownership of said conduit or wiring, subject to Landlord's reasonable approval of Tenant's maintenance/repair contractor and manner of maintenance/repair. Notwithstanding anything to the contrary contained herein, Tenant shall pay any and all maintenance and recurring costs for supplemental HVAC units exclusively serving the Premises, or any portion thereof, upon presentation of invoice from Landlord. If Tenant fails to maintain, repair, replace, or repaint any portion of the Premises or the Project as provided above then following ten days' written notice thereof to Tenant, Landlord may, at its election, maintain, repair, replace, or repaint any such portion of the Premises or the Project and Tenant shall promptly reimburse Landlord, as Additional Rent, for Landlord's actual cost thereof, plus a supervisory fee in the amount of ten percent of Landlord's actual cost. Notwithstanding the foregoing, if following Tenant's payment (or performance) of its obligations under this Paragraph, Landlord receives payment from an insurer for such work, Tenant will be entitled to receive such proceeds (after Landlord has first been fully reimbursed for its costs and expenses relative thereto including Landlord's costs and expenses in obtaining such proceeds) to the extent Tenant previously paid or incurred third party costs relative thereto...
- Landlord's Duties. Landlord shall, as part of the Operating Expenses, maintain, repair, replace, and repaint, all in good order and condition, consistent with other first-class office buildings in the vicinity of the Building, the Common Areas and all portions of the interior and exterior of the Building and any other buildings in the Project (including, without limitation, all electrical, mechanical, plumbing, fire/life safety, and other building systems), except to the extent of Tenant's obligations as set forth in Paragraph 10.1, above. Landlord's failure to perform its obligations set forth above will not release Tenant of its obligations under this Lease, including without limitation Tenant's obligation to pay Rent. Tenant waives the provisions of California Civil Code Section 1942 (or any successor statute), and any similar principles of law with respect to Landlord's obligations for tenantability of the Premises and Tenant's right to make repairs and deduct the expense of such repairs from rent. If Landlord fails to perform any of its repair and maintenance obligations under this Paragraph 10.2 and such failure materially and adversely impairs Tenant's ability to use and occupy the Premises for the Permitted Use, Tenant will have the right, to perform such repairs and/or maintenance to the extent necessary to enable Tenant to resume its use and occupancy of the Premises. Notwithstanding the foregoing, prior to exercising such right, Tenant must, except as provided below in connection with an emergency, have given Landlord at least 30 days' prior written notice of the nature of the problem and Tenant's intention to exercise its rights under this Paragraph if such matter is not resolved within such 30-day period; provided, however, if the nature of the matter giving rise to such repair or maintenance obligation will reasonably require more than 30 days to remedy and Landlord is proceeding with due diligence to remedy such matter, then such 30 day period will be extended for such additional time as may be necessary for Landlord to complete such repairs or maintenance. Notwithstanding the preceding sentence, in the case of an emergency which poses an imminent threat of death, injury, or severe damage to persons or property, the required notice from Tenant may be provided orally rather than in writing and for such shorter period of time (i.e., less than 30 days) as Tenant, in the exercise of its reasonable judgment deems appropriate under the exigent circumstances (however, at a minimum, Tenant shall at least contact Landlord telephonically prior to commencing such work so that Landlord may, at its election, make arrangements to handle such emergency itself). If Landlord fails to fulfill its repair and maintenance obligations under this Paragraph, and as a result thereof Tenant exercises the foregoing right to correct such matter, then Landlord shall reimburse Tenant for the reasonable third-party costs incurred by Tenant to complete such repairs and/or maintenance within 30 days after receipt of Tenant's written demand therefor, together with copies of the paid invoices evidencing the costs so incurred. Any such repairs or maintenance performed by Tenant, as permitted herein, must be performed in a good and workmanlike manner by licensed contractors. Under no circumstances may Tenant offset

any amount it is owed by Landlord pursuant to this Paragraph (or otherwise) against any Rent obligation under this Lease.

### 11. Parking.

- General Parking Rights. Subject to the remaining provisions of this Paragraph 11, Landlord grants to 11.1. Tenant (for the benefit of Tenant and Tenant's Invitees) the right to the non-exclusive use of the unreserved parking area within the boundaries of and serving the Project (the "Parking Area"). Tenant's use of the Parking Area shall be subject to such rules as Landlord may, in its sole discretion, adopt from time to time with respect to the Parking Area, including without limitation (i) rules providing for the payment of charges or fees by users of the Parking Area, and in such event the charges or fees shall be deemed Additional Rent, (ii) rules limiting tenants of the Project (including, without limitation, Tenant) to the use of, or excluding the use of, certain parking spaces or certain portions of the Parking Area, in order to maintain the availability of accessible parking spaces for clients, guests, and invitees of tenants of the Project, and (iii) rules limiting tenants of the Project (including without limitation Tenant), and their employees, to the use of a restricted number of parking spaces or a restricted area. If Tenant, or any of Tenant's employees, fails to comply with any such rules or requirement (such as, by way of example, parking in areas designated as visitor parking only), then Landlord will have the right to either have such vehicles towed from the Project at Tenant's expense, or to charge Tenant \$100.00 per day per car for any cars which are parked in violation of such requirements. Furthermore, Landlord shall have the right to immobilize such improperly parked vehicles by use of a "boot" or other device. Notwithstanding anything to the contrary in this Paragraph, Landlord may, at its election, construct improvements upon or otherwise alter in any manner the Parking Area, provided that Landlord makes parking available to Tenant elsewhere within the Project (or within a reasonable distance from the Premises that is equal to or greater than the applicable ratio described in Paragraph 11.2. below. Landlord reserves the right to grant certain tenants in the Project the exclusive right to park in specified areas of the Parking Area, to the exclusion of all other tenants. Tenant acknowledges that the exercise of the rights reserved to Landlord under this Paragraph may result in a decrease in the number of parking spaces available to Tenant and Tenant's Invitees, and no such decrease shall affect Tenant's obligations under this Paragraph or entitle Tenant to any abatement of Rent, provided the applicable parking ratio described in Paragraph 11.2. below, is maintained or exceeded.
- 11.2. <u>Parking Ratios</u>. As of the Rent Commencement Date (and subject to temporary interruptions in connection with Landlord's continued development of the Project, as provided below), the parking ratio within the Project applicable to Tenant will be four spaces per 1,000 Usable Square Feet ("USF") of space within the Premises. The foregoing (4:1,000 USF) parking ratio includes all spaces within the Project, including covered, uncovered, handicap, and visitor parking spaces. Such parking shall be provided on a free and unassigned basis (i.e., first come, first served).

# 12. <u>Signs</u>.

12.1. General Signage Conditions. Landlord may at any time change the name of either or both of the Building and/or the Project and install, affix, and maintain all signs on the exterior and interior of the Building and other buildings within the Project as Landlord may, in Landlord's sole discretion, desire. Tenant shall not have or acquire any property right or interest in the name of the Building or the Project. Subject to Tenant's signage rights under Paragraph 12.2. below. Tenant may not place, construct, or maintain any sign, advertisement, awning, banner, or other exterior decoration (collectively, "sign") inside or outside the Premises which is visible from the exterior of the Premises, or on the Building or any other portion of the Project, without Landlord's prior written consent. Any sign that Tenant is permitted by Landlord to place, construct, or maintain in the Premises or on the Building or the Project (including pursuant to Paragraph 12.2. below) must comply with Landlord's sign criteria applicable to the Project, including, without limitation, criteria relating to size, color, shape, graphics, and location (collectively, the "Sign Criteria"), and shall comply with all applicable laws, ordinances, CC&R's (or similar recorded instruments), rules, or regulations, and Tenant shall obtain any approvals required by such laws, ordinances, CC&R's (or similar recorded instruments), rules, and regulations. Landlord makes no representation or warranty with respect to Tenant's ability to obtain any such approval. Tenant shall, at Tenant's sole cost, make any changes to any sign, whether in the Premises or on the Building, as required by any new or revised applicable laws, ordinances, rules, or regulations or any changes in the Project Sign Criteria. Tenant shall, additionally, maintain, repair, and replace all of Tenant's signs (including, specifically, those installed pursuant to Paragraph 12.2. below) in first class condition. Nothing contained in this Paragraph 12 will limit the Landlord's right to grant signage rights to other tenants of the Building, or to affect the signage rights of any tenant of the Building.

- 12.2. <u>Tenant's Individual Signage Rights</u>. Subject to compliance with the requirements of Paragraph 12.1, above, Tenant is hereby granted the following signage rights in/on the Building and at the Project.
- 12.2.1. <u>Directory/Suite Signage</u>. The Tenant will be provided, at Landlord's expense, with both a Project-standard lobby directory sign and suite signage. Tenant shall be entitled to be listed on such signs, subject to prior approval of the Tenant's graphics by Landlord, if applicable.
- Rules, Regulations, and Covenants. Tenant shall observe (and shall cause Tenant's Invitees to observe) faithfully and comply strictly with any rules and regulations which Landlord may from time to time adopt for the Project (and provide Tenant with a copy of), as well as any recorded easement agreements, maintenance agreements, CC&R's or like instruments affecting the Building and/or the Project, whether now existing or hereafter adopted or amended from time to time (all of the foregoing, collectively, "Rules"). Landlord has no duty or obligation to enforce any Rule against any other tenant, and Landlord will not be liable to Tenant for violation of any Rule by any other tenant, or any other tenant's agents, employees, officers, independent contractors, customers, invitees, visitors, or licensees. Tenant acknowledges that Landlord reserves the right, from time to time, to enter into leases or other agreements by which Landlord agrees to restrict the use of all or any portion of the Project (including the Premises) from certain uses. All such leases and other agreements, whether now existing or entered into in the future, shall be binding upon Tenant and in no event shall Tenant utilize the Premises for any use so prohibited; provided, however, no such restriction may prevent Tenant from using the Premises for the Permitted Use.
- 14. <u>Early Access/Insurance</u>. If prior to the Rent Commencement Date Tenant is planning to (and permitted by Landlord to-see attached <u>Exhibit "C"</u>) make any Alterations (as defined below) to the Premises , perform any of the Tenant's Work, or install any of Tenant's personal property, then in addition to complying with the provisions of attached <u>Exhibit "C"</u>, (i) Tenant shall, at Tenant's sole cost, prior to first entering onto the Project, obtain and thereafter at all times maintain (a) "Builder's Risk" or "Course of Construction" insurance with respect to any actual construction work, and (b) all of the insurance to be maintained by Tenant during the Term, and (ii) the Term, and all obligations of Tenant under the provisions of this Lease other than those relating to the obligation to pay Rent, shall be operative. Any work pursuant to this Paragraph shall be subject to all of the provisions of Paragraph 22, below. Nothing in this Paragraph shall be construed as granting permission to Tenant to enter the Premises, or to make any Alterations, prior to the Lease Commencement Date and no such right shall exist unless specified in <u>Exhibit "C"</u> or agreed to by Landlord in its sole discretion.
- 15. <u>Tenant's Liability Insurance</u>. Tenant shall maintain, at Tenant's sole cost and expense, Commercial General Liability Insurance covering the insured against (i) any and all Claims (as defined below) of bodily injury, personal injury and property damage (including loss of use thereof) arising out of or connection with Tenant's use, occupancy and operations within the Premises and Building, and (ii) all contractual liabilities under this Lease, including, without limitation, indemnity provisions contained herein, for limits of liability of \$1,000,000 per occurrence and \$2,000,000 annual aggregate with such aggregate limit shall apply combined to each location and may be met with primary and excess liability policy along with an umbrella policy of \$2,000,000 per occurrence and \$2,000,000 aggregate for all premises combined.
- 16. Tenant's Property Damage Insurance. Tenant shall maintain, at Tenant's sole cost and expense, Physical Damage Insurance covering (i) all office furniture, business and trade fixtures, office equipment, free-standing cabinet work, movable partitions, merchandise and all other items of Tenant's property on the Premises installed by, for, or at the expense of Tenant, (ii) all Tenant improvements (installed and/or constructed per <a href="Exhibit" ("C")">Exhibit "C"</a> attached hereto), and any other improvements which exist in the Premises as of the Commencement Date (excluding the base building structure and building systems), and (iii) all other improvements, Alterations, Personal Property and additions to the Premises. Such insurance shall be written on specified perils of physical loss or damage basis, for the full replacement cost value, new without deduction for depreciation of the covered items and shall include coverage for damage or other loss caused by fire or other peril including, but not limited to, vandalism and malicious mischief, theft, coverage with respect to increased costs due to building ordinances. Such "full replacement cost value" shall be determined by the insurance company issuing such policy at the time the policy is initially obtained. Not more frequently than once every two years, either Landlord or Tenant may, at its election, notify the other that it elects to have the replacement cost value re-determined by an insurance company. Such redetermination shall be made promptly and in accordance with the rules and practices of the Board of Fire Underwriters, or a like board recognized and generally accepted by the insurance company, and Landlord and Tenant shall be promptly notified of the results by the company. Such policy shall be promptly adjusted according to such redetermination

- 17. <u>Tenant's Additional Insurance</u>. In addition to the foregoing coverages, Tenant shall maintain, at Tenant's sole cost and expense:
- 17.1 Workers' compensation insurance in an amount not less than the statutory limits in the state in which the Project is located;
- 17.2 Employer's Liability with limits of at least \$1,000,000 bodily injury by disease policy limit, \$1,000,000 bodily injury by disease each employee and \$1,000,000 bodily injury by accident each accident for the protection of its employees or other similar insurance pursuant to all applicable laws;
- 17.3. Business Interruption Insurance in amounts sufficient to reimburse Tenant (over a 12 month period) for direct or indirect loss of earnings attributable to all perils commonly insured against by prudent tenants or attributable to prevention of access to the Premises or to the Project as a result of such perils, including, without limitation, reimbursement for payment of rental and all other monetary obligations required herein;
- 17.4. Automobile Liability with a combined single limit of \$1,000,000 per occurrence covering the operation, ownership, maintenance, and use of owned (if any), non-owned, and hired automobiles, bodily injury and property damage, as aforesaid; and
- 17.5. In the event Tenant distributes, sells and/or manufactures liquor on the Premises, Tenant shall maintain liquor liability with limits of \$2,000,000 each claim and \$2,000,000 annual aggregate, such requirement may be met with primary and excess liability policy. Notwithstanding anything in the Lease, should Tenant maintain liquor on Premises for consumption, Tenant, at a minimum, shall maintain dram shop coverage with limits of \$2,000,000. Coverage shall be on a per occurrence form. Notwithstanding the foregoing, in no event shall Tenant be permitted to distribute, sell or manufacture liquor on the Premises without Landlord's prior written consent, which may be withheld by Landlord in its sole and absolute discretion.
- Form of Tenant's Insurance Policies. The minimum limits of policies of insurance required of Tenant under this Lease shall in no event limit the liability of Tenant under this Lease. Such insurance (i) shall name Landlord, American Assets Trust, Inc. and American Assets Trust, LP. and any other party with an insurable interest in the Project which the Landlord so specifies by written notice to Tenant, as an additional insured, including Landlord's managing agent, American Assets Trust Management, LLC, as such agent may be changed from time to time; (ii) shall cover the liability assumed by Tenant under the indemnification provisions of this Lease; (iii) shall consist of "occurrence" based coverage, without provision for subsequent conversion to "claims" based coverage; (iv) shall be issued by an insurance company having a rating of not less than A XV in Best's Insurance Guide or which is otherwise acceptable to Landlord and authorized to do business in the state in which the Project is located; (v) shall be primary insurance and non-contributing with respect to all Claims thereunder and any policies carried by Landlord and that any coverage carried by Landlord shall be excess insurance; (vi) be in form and content reasonably acceptable to Landlord; and (vii) shall provide that said insurance shall not be canceled or modified in coverage unless 30 days' prior notice shall have been given to Landlord, and (viii) shall not provide for a deductible or coinsurance provision in excess of \$10,000. Tenant shall deliver said policy or policies or certificates and applicable endorsements thereof or reasonable evidence that such insurance is in place to Landlord on or before the Commencement Date. In the event Tenant shall fail to procure such insurance, or to deliver such policies or certificate and applicable endorsements, Landlord may, at its option upon 5 business days' notice to Tenant, procure such policies for the account of Tenant unless Tenant provides same within such 5 day period, and the cost thereof shall be paid to Landlord within 5 days after delivery to Tenant of bills therefore. Tenant shall, at least 30 days prior to the expiration of each such policy, furnish Landlord with a renewal certificate and applicable endorsement of or "binder" extending such policy. Not more frequently than once every year, if in the opinion of Landlord the amount or scope of such insurance at that time is not adequate, Tenant shall increase such insurance as reasonably required by Landlord.
- 19. <u>Waiver of Subrogation</u>. Landlord and Tenant release each other, Tenant's Invitees, Landlord's guests, invitees, customers and licensees (collectively, "Landlord's Invitees") and Landlord's agents, affiliates, officers, directors and employees from all claims for damage, loss, or injury to the Project, to Tenant's Personal Property, and to the fixtures and Alterations of either Landlord or Tenant in or on the Project to the extent such damage, loss or injury is covered by any insurance policies carried by Landlord and Tenant and in force at the time of such damage, or which would have been covered by insurance policies required by this Lease to be carried by Tenant, but which Tenant failed to carry. Subject to the remaining provisions of this Paragraph, Landlord and Tenant shall each cause all insurance policies obtained by it pursuant to this Lease

to provide that the insurance company waives all right of recovery by way of subrogation against Landlord, American Assets Trust, Inc., American Assets Trust, L.P., American Assets Trust Management, LLC, and Landlord's agents, employees and representatives and Tenant in connection with any damage, loss, or injury covered by such policy. If any such policy cannot be obtained with a waiver of subrogation, or is obtainable only by the payment of an additional premium charge above that charged by insurance companies issuing policies without waiver of subrogation endorsements, the party undertaking to obtain such policy (the "Undertaking Party") shall so notify the other party (the "Notified Party"). The Notified Party shall, within ten days after the giving of such notice, either obtain such policy from a company that is reasonably satisfactory to the Undertaking Party and that will issue such policy with a waiver of subrogation endorsement, or agree to pay the additional premium if such policy is obtainable at additional cost. If such policy cannot be obtained with a waiver of subrogation endorsement or the Notified Party refuses to pay such additional premium, then the Undertaking Party shall not be required to obtain a waiver of subrogation endorsement with respect to such policy. Notwithstanding the foregoing, if any claim to which the foregoing release by Landlord and waiver of subrogation provision would apply is for an amount which is less than Landlord's applicable deductible, and Landlord elects not to submit such claim to its insurer, then the provisions of the foregoing release by Landlord shall not be applicable.

- 20. <u>Landlord's Insurance</u>. Landlord may, at its election, maintain any of the following insurance, and any other insurance deemed appropriate or necessary, in Landlord's sole discretion, in such amounts and with such limits as Landlord shall determine in its reasonable discretion: (i) Public liability and property damage insurance, and products liability insurance; (ii) Fire and extended coverage and special form insurance, coverage with respect to increased costs due to building ordinances, demolition coverage, and sprinkler leakage coverage; (iii) boiler and machinery insurance; (iv) fidelity insurance; (v) Plate-glass insurance; (vi) earthquake insurance; (vii) terrorism insurance, (viii) flood insurance; (ix) rental interruption and/or business interruption insurance; and (x) pollution legal liability insurance. The premiums, costs, expenses, and deductibles (or similar costs or charges) of and/or with respect to any such insurance (all of the preceding, collectively, "Insurance Expenses") shall be included in Operating Expenses. Any such coverage may be part of an umbrella or blanket policy, whereupon the premiums, costs, and expenses hereof will be reasonably apportioned between the Building and the other properties so included under such policy(ies).
- 21. Personal Property Taxes. Tenant shall pay before delinquency all taxes, assessments, license fees, and other charges that are levied or assessed against, or based upon the value of, Tenant's personal property installed or located in or on the Premises including without limitation trade fixtures, furnishings, equipment, Alterations, and inventory (collectively, "Tenant's Personal Property"). On written demand by Landlord, Tenant shall furnish Landlord with satisfactory evidence of such payments. If any such taxes, assessments, license fees, and/or other charges are levied against Landlord or Landlord's property, or if the assessed value of the Premises is increased by the inclusion of a value placed on Tenant's Personal Property, and if Landlord pays such taxes, assessments, license fees, and/or other charges or any taxes based on the increased assessments caused by Tenant's Personal Property, then Tenant, on demand, shall immediately reimburse Landlord, as Additional Rent, for the sum of such taxes, assessments, license fees, and/or other charges so levied against Landlord, or the proportion of taxes resulting from such increase in Landlord's assessment. Landlord may, at its election, pay such taxes, assessments, license fees, and/or other charges or such proportion, and receive such reimbursement, regardless of the validity of the levy.
- 22. <u>Alterations</u>. Tenant shall not make any alterations, improvements, additions, installations, or changes of any nature in or to the Premises (any of the preceding, "Alterations") unless Tenant first obtains Landlord's written consent to such Alteration and otherwise complies with the provisions of this Paragraph 22; provided, however, no such consent will be required in connection with any Minor Alterations (as defined below).
- 22.1. Request for Consent. At least 15 days prior to making any Alterations, Tenant shall submit to Landlord, in written form, proposed detailed plans of such Alterations, which plans must (i) in the case of a Minor Alterations, be in sufficient detail to, among other things, provide Landlord with reasonable evidence that such Alterations are of a nature that Landlord's consent is not required, and (ii) in the case of any other Alterations, in sufficient detail to allow Landlord and its consultants to fully evaluate the proposed Alterations and their affect upon the Premises and the Project. Landlord will not unreasonably withhold, condition, or delay its consent to any Alterations for which consent is required; except that, in the case of exterior Alterations or Alterations which will be visible from outside the Premises or which will affect any structural components of the Project, Landlord shall have the right to grant or withhold its consent in the exercise of its sole discretion. In addition to the foregoing requirements, if the proposed Alteration requires approval by or notice to the lessor of a ground or underlying lease or the holder

of a deed of trust encumbering the Project, no Alteration shall be commenced until such approval has been received, or such notice has been given, as the case may be, and all applicable conditions and provisions of said superior lease or deed of trust with respect to the proposed Alteration or Alterations have been met or complied with at Tenant's expense; and Landlord, if it approves the Alteration, will request such approval or give such notice expeditiously, as the case may be, and thereafter diligently pursue obtaining such approval.

- 22.2. <u>Minor Alterations</u>. Notwithstanding anything to the contrary contained herein, minor, interior cosmetic Alterations such as painting, wall papering, carpeting or hanging pictures or moving furniture and temporary partitions or cubicles (the aggregate cost of which will not exceed \$10,000.00, and which Alterations will not be visible from outside the Premises or affect any structural components of the Project) will not require Landlord's prior consent so long as (i) Tenant notifies Landlord in accordance with Paragraph 22.1(i) and (ii) Tenant complies with all reasonable conditions which may be imposed by Landlord including, but not limited to, the requirements of Paragraph 22.3 below, Landlord's selection of specific contractors or construction techniques and the requirements of the attached <u>Exhibit "C."</u> Any Alterations meeting the foregoing requirements to avoid the necessity of obtaining Landlord's consent are referred to herein as a "Minor Alterations").
- 22.3. Additional Requirements. Tenant shall, prior to the commencement of any Alterations, and at Tenant's sole cost, (i) acquire (and deliver to Landlord a copy of) any required permit from the appropriate governmental agencies to make such Alterations (any conditions of which permit Tenant shall comply with, at Tenant's sole cost, in a prompt and expeditious manner), (ii) provide Landlord with ten business days' prior written notice of the date the installation of the such Alterations is to commence, so that Landlord can post and record an appropriate notice of non-responsibility, (iii) pay Landlord the reasonable costs and expenses of Landlord for architectural, engineering, or other consultants which reasonably may be incurred by Landlord in determining whether to approve any such Alterations (excluding Minor Alterations), and (iv) if applicable, obtain (and deliver to Landlord proof of) reasonably adequate workers compensation insurance with respect to any of Tenant's employees installing or involved with such Alterations (which insurance Tenant shall maintain on an occurrence basis in force until completion of the Alterations). In addition, Tenant shall comply with all reasonable conditions which may be imposed by Landlord relative to such Alterations including, but not limited to, (v) Landlord's Selection of specific contractors or construction techniques and (2) the requirements of the attached Exhibit "C" applicable to Tenant's Work. Notwithstanding anything to the contrary contained in this Paragraph 22.3, in no event may Tenant remove any ceiling tiles or ceiling gridwork or lighting without Landlord's prior consent, and any such consent may be conditioned upon requiring Tenant to post a deposit to cover the cost of restoring the Premises to their prior condition upon termination of the Term and to secure Tenant's obligation to so restore the Premises.
- 22.4. Ownership of Alterations. All Alterations shall, upon the Expiration Date of this Lease, become the property of Landlord and shall remain on and be surrendered with the Premises on the Expiration Date; except that, Landlord may, at its election, require Tenant to remove any or all of the Alterations, provided that Landlord notifies Tenant in writing prior to commencement of the Alterations. If Landlord so elects to have the Alterations removed, Tenant shall, at its sole cost, on or before the Expiration Date, repair and restore the Premises to the condition of the Premises prior to the installation of the Alterations which are to be removed. Tenant shall pay all costs for Alterations and other construction done or caused to be done by Tenant and Tenant shall keep the Premises free and clear of all mechanics' and materialmen's liens resulting from or relating to any Alterations or other construction. Tenant may, at its election, contest the correctness or validity of any such lien provided that (a) within 20 days after written demand by Landlord, Tenant procures and records a lien release bond, issued by a corporation satisfactory to Landlord and authorized to issue surety bonds in California, in an amount equal to 125% of the amount of the claim of lien, which bond meets the requirements of California Civil Code Section 8424 or any successor statute, and (b) Landlord may, at its election, require Tenant to pay Landlord's attorneys' fees and costs incurred in participating in such an action.

# 22.5. <u>Control over Tenant's Wi-Fi Use.</u>

- (a) Wi-Fi. Tenant shall have the right to install, at its sole cost and expense, a wireless intranet, Internet, and communications network (also known as "Wi-Fi") utilizing IEEE 802.XX protocols within the Premises for the use of Tenant and its employees (the "Network") subject to the provisions of this Paragraph 22.5 and the other provisions of Paragraph 22. All telecommunications service providers shall be subject to Landlord's prior written approval.
- (b) No solicitation. Tenant shall not solicit, suffer, or permit other tenants or occupants of the Building to use the Network or any other communications service, including,

without limitation, any wired or wireless Internet service that passes through, is transmitted through, or emanates from the Premises.

- (c) Interference. Tenant agrees that the Network, Tenant's communications equipment and the communications equipment of Tenant's service providers located in or about the Premises or installed in the Building to service the Premises including, without limitation, any antennas, switches, or other equipment (collectively, "Tenant's Communications Equipment") shall be of a type and, if applicable, a frequency that will not cause radio frequency, electromagnetic, or other interference to any other party or any equipment of any other party including, without limitation, Landlord, other tenants, or occupants of the Building, Landlord reserves the right to cause Tenant to operate on a channel or frequency band that Landlord selects, in its sole discretion. In the event that Tenant's Communications Equipment causes or is believed by Landlord to cause any such interference, upon receipt of notice from Landlord of such interference, Tenant will promptly take all steps necessary to correct and eliminate the interference. If the interference is not eliminated within 24 hours (or a shorter period if Landlord believes a shorter period to be appropriate) then, upon notice from Landlord, Tenant shall use other channels or frequencies as determined solely by Landlord, or, at Landlord's election, shut down the Tenant's Communications Equipment pending resolution of the interference (with the exception of intermittent testing upon prior notice to, and with the prior approval of, Landlord). Landlord shall have no obligation or liability with respect to any interruption, curtailment or discontinuance of telecommunications services.
- (d) Maintenance. Tenant shall maintain Tenant's Telecommunications Equipment in good order and repair at its sole cost and expense.
- (e) Acknowledgment. Tenant acknowledges that Landlord has granted and/or may grant lease rights, licenses, and other rights to other tenants and/or occupants of the Building and to telecommunications service providers.

### 23. <u>Surrender of Premises and Holding Over.</u>

- Surrender. On the Expiration Date, Tenant shall surrender to Landlord the Premises and all Alterations (except for Alterations that Tenant is obligated to remove as expressly set forth above) in a first class and clean condition, less any normal wear and tear, free of trash and debris including cleaning of all flooring; all walls shall be patched and painted; all signage installed by Tenant on any portion of the Buildings or Project shall be removed and the surfaces repaired, including restoration of the signage mounting surfaces to their pre-existing condition; all sign circuits, electrical circuits, and lighting fixtures shall be in good operating condition; all roof penetrations arising from Tenant's occupancy of the Premises shall be in a watertight condition; and all doors, windows, locks, and hardware shall be in operable condition upon the termination of this Lease. Tenant shall additionally, as of the Expiration Date, remove all of Tenant's Personal Property and perform all repairs and restoration required by the removal of any Alterations or Tenant's Personal Property, and Tenant shall surrender to Landlord all keys to the Premises (including without limitation any keys to any exterior or interior doors). Landlord may elect to retain or dispose of in any manner any Alterations or Tenant's Personal Property that Tenant does not remove from the Premises on the Expiration Date as required by this Lease by giving written notice to Tenant. Any such Alterations or Tenant's Personal Property that Landlord elects to retain or dispose of shall immediately upon notice to Tenant vest in Landlord. Tenant waives all claims against Landlord for any damage to Tenant resulting from Landlord's retention or disposition of any such Alterations or Tenant's Personal Property. Tenant will be liable to Landlord for Landlord's costs for storing, removing (including related restoration work), or disposing of any such Alterations or Tenant's Personal Property. If Tenant fails to surrender the Premises to Landlord on the Expiration Date in the condition required by this Paragraph, Tenant shall indemnify, defend, and hold Landlord harmless from and against all liabilities, damages, losses, costs, expenses, attorneys' fees and claims resulting from such failure, including without limitation any claim for damages made by a succeeding tenant.
- 23.2. Holding Over. If Tenant, with Landlord's consent, remains in possession of the Premises after the Expiration Date, such possession by Tenant shall be deemed to be a month-to-month tenancy terminable on 30-days' written notice given at any time by Landlord or Tenant. During any such month-to-month tenancy, or any other holdover tenancy which is without Landlord's consent, Tenant shall pay, as Basic Monthly Rent, 150% of the Basic Monthly Rent in effect immediately prior to the Expiration Date; which rental amount Tenant acknowledges is fair and reasonable under all of the facts and circumstances existing as of the date of this Lease. All provisions of this Lease except for those pertaining to Term shall apply to any such tenancy. If Tenant holds over after the Expiration Date without the express written consent of Landlord, Tenant shall become a tenant at sufferance only, at a rental rate equal to 175% of the Basic Monthly Rent and Additional Rent in effect immediately prior to expiration of the Term (prorated

on a daily basis), and otherwise subject to the terms, provisions, and conditions herein specified, so far as applicable. Acceptance by Landlord of rent after such expiration or earlier termination shall not constitute consent to a holdover tenancy hereunder or result in a renewal. The foregoing provisions this Paragraph 23.2 are in addition to, and do not affect, Landlord's right of re-entry or any rights of Landlord hereunder or as otherwise provided by law. Landlord expressly reserves the right to require Tenant to surrender possession of the Premises to Landlord as provided in this Lease upon expiration or other termination of this Lease. The provisions of this Paragraph 23.2 shall not be considered to limit or constitute a waiver of any other rights or remedies of Landlord provided in this Lease or at law. In addition to the foregoing, if Tenant fails to surrender the Premises to Landlord on the Expiration Date in the condition required by Paragraph 23.1, above, Tenant shall indemnify, defend, and hold harmless Landlord from and against all actions, demands, liabilities, damages, losses, costs, expenses, attorneys' fees, and claims resulting from such failure, including, without limitation, any claim for damages made by a succeeding tenant.

- 24. <u>Default</u>. The occurrence of any of the following shall constitute a material default and breach of this Lease by Tenant (each an "Event of Default"):
  - 24.1. The abandonment (as defined in the California Civil Code 1951.3) of the Premises by Tenant.
- 24.2. Tenant's failure to make any payment of Rent (including late charges) as and when due. No grace period prior to the imposition of a late charge pursuant to Paragraph 26 below, shall extend the date when such Rent is due and payable, and Tenant shall be in default under this Lease if such payment is not timely made. In the case of Basic Monthly Rent, payments must be received on or before the first day of each calendar month, and Tenant shall be in default if such Rent is not paid by such date.
- 24.3. Tenant's failure to timely deliver an estoppel certificate to Landlord in accordance with the provisions of Paragraph 41, below, or to timely deliver a subordination, non-disturbance, and attornment agreement in accordance with the provisions of Paragraph 40, below.
- 24.4. Tenant's failure to restore the Security Deposit pursuant to Paragraph 6, above, within ten days after written notice from Landlord demanding such restoration; provided, however, that any such notice shall be in lieu of, and not in addition to, any notice required under applicable unlawful detainer statutes.
- 24.5. Tenant is in default beyond any notice and cure period under any other lease or agreement with Landlord at the Building or Project.
- 24.6. Tenant's failure to observe or perform any of the provisions of this Lease to be observed or performed by Tenant, other than described in the preceding six paragraphs, where such failure shall continue for a period of ten days after written notice of such failure from Landlord to Tenant; provided, however, that any such notice shall be in lieu of, and not in addition to, any notice required under applicable unlawful detainer statutes; and provided further, that if the nature of Tenant's default is such that more than ten days are reasonably required for its cure, then Tenant shall not be deemed to be in default if Tenant commenced such cure within such ten day period and thereafter diligently prosecutes such cure to completion within 60 days after Landlord's written notice. Such written notice will be deemed to satisfy the statutory notice requirements of applicable unlawful detainer statutes and will be in lieu thereof (and not in addition thereto). Tenant acknowledges that Landlord only agreed to the inclusion of such notice requirement on the condition that such notice would constitute the legally required notice following a default and Tenant waives any claim, counterclaim, or defense to any action relating to an unlawful detainer on the basis that such notice, was insufficient to meet such statutory notice requirement or was in any other manner defective, and Tenant agrees that it will be estopped from raising any such argument in any action by Landlord.
- 24.7. Tenant's failure to pay its debts (other than under this Lease) as they become due. For purposes of this Paragraph, a debt shall be deemed overdue when the earliest of the following occurs: (i) 30 days from the date a statement for such debt is rendered; (ii) the date on which any action or proceeding for such debt is commenced; or (iii) the date on which a formal notice of default or demand is sent.
- 24.8. Tenant's failure to deliver to Landlord, within ten days after Landlord's written request, any publically available financial statement of Tenant (including without limitation a current annual balance sheet of Tenant) reasonably requested by Landlord, or if any publically available financial statement given to Landlord by Tenant, or by any assignee, subtenant, or guarantor of Tenant, is materially false or evidences that Tenant's net worth is negative, and

Tenant fails to furnish to Landlord, within ten days after written notice from Landlord to Tenant, with cash as an additional security deposit in an amount equal to the aggregate Rental payable under this Lease for the six full calendar months immediately following such notice.

24.9. The making by Tenant of any general arrangement or assignment for the benefit of creditors; Tenant's becoming bankrupt, insolvent or a "debtor" as defined in 11 U.S.C. Section 101, or any successor statute (unless, in the case of a petition filed against Tenant, such petition is dismissed within 60 days after its original filing); the institution of proceedings under the bankruptcy or similar laws in which Tenant is the debtor or bankrupt; the appointing of a trustee or receiver to take possession of substantially all of Tenant's assets located at the Premises or of Tenant's interest in this Lease (unless possession is restored to Tenant within 60 days after such taking); the attachment, execution, or judicial seizure of substantially all of Tenant's assets located at the Premises or Tenant's interest in this Lease (unless such attachment, execution, or judicial seizure is discharged within 60 days after such attachment, execution, or judicial seizure); or, if Tenant is a partnership or consists of more than one person or entity, any partners of the partnership or any such other person or entity becoming bankrupt or insolvent or making a general arrangement or assignment for the benefit of creditors.

Notwithstanding the foregoing, if (i) Tenant commits two similar defaults during any 12-month period or less, (ii) Tenant receives notices of default on each separate occasion, and (iii) each such default could have been cured within a 24-hour period from the date Tenant received notice of such default, then, as to any further, similar default that thereafter occurs during the same 12-month period. Landlord may treat such default as an Event of Default and exercise its remedies under Paragraph 25, below, without giving Tenant any further notice of default or opportunity to cure.

- 25. <u>Landlord's Remedies</u>. Landlord shall have the following remedies if Tenant commits an Event of Default under this Lease. These remedies are not exclusive, but are cumulative and in addition to any remedies provided elsewhere in this Lease or now or later allowed by law.
- 25.1. Continuation of Lease. No act by Landlord shall terminate Tenant's right to possession unless Landlord notifies Tenant in writing that Landlord elects to terminate Tenant's right to possession. As long as Landlord does not terminate Tenant's right to possession, Landlord may (i) continue this Lease in effect, (ii) continue to collect Rent when due and enforce all the other provisions of this Lease, and (iii) enter the Premises and relet them, or any part of them, to third parties for Tenant's account, for a period shorter or longer than the remaining Term of this Lease. Tenant shall immediately pay to Landlord all costs Landlord incurs in such reletting, including, without limitation, brokers' commissions, attorneys' fees, advertising costs, and expenses of remodeling the Premises for such reletting. The parties agree that Landlord is to have the remedy described in California Civil Code Section 1951.4 (which effectively provides that a lessor may continue a lease in effect after the lessee's breach and recover rent as it becomes due), and the Tenant hereby acknowledges that this Lease meets the requirements of such statutory provision and that Tenant's rights to sublet or assign hereunder are subject only to reasonable limitations.
- 25.2. Rent from Reletting. If Landlord elects to relet all or any portion of the Premises as permitted above, rent that Landlord receives from such reletting shall be applied to the payment of, in the following order and priority, (i) any indebtedness from Tenant to Landlord other than Rent due from Tenant, (ii) all costs incurred by Landlord in such reletting, and (iii) Rent due and unpaid under this Lease. After applying such payments as referred to above, any sum remaining from the rent Landlord receives from such reletting shall be held by Landlord and applied in payment of future Rent as it becomes due under this Lease. In no event shall Tenant be entitled to any excess rent received by Landlord unless and until all obligations of Tenant under this Lease, including all future obligations, are satisfied in full.
- 25.3. <u>Termination of Tenant's Right to Possession</u>. Landlord may terminate Tenant's right to possession of the Premises at any time, by notifying Tenant in writing that Landlord elects to terminate Tenant's right to possession. Such written notice will result in the immediate termination of this Lease upon the date such right of possession is terminated. Upon termination of this Lease, Landlord has the right to recover from Tenant (i) the worth at the time of the award of the unpaid Rent which had been earned at the time of such termination, (ii) the worth at the time of the award of the amount by which the unpaid Rent which would have been reasonably avoided, (iii) the worth at the time of the award of the amount by which the unpaid Rent for the balance of the Term after the time of award (had there been no such termination) exceeds the amount of such loss of Rent that Tenant proves could be reasonably avoided, and (iv) any other amount necessary to compensate Landlord for

all detriment proximately caused by Tenant's failure to perform Tenant's obligations under this Lease or in the ordinary course of things would be likely to result therefrom. The "worth at the time of the award" of the amounts referred to in clauses (i) and (ii) above is to be computed by allowing interest at the Default Rate. The "worth at the time of the award" of the amount referred to in clause (iii) above is to be computed by discounting such amount at the discount rate of the Federal Reserve Bank of San Francisco at the time of award plus one percent (1%). If Landlord takes possession of the Premises pursuant to the authority herein granted, then Landlord shall have the right to keep in place and use all of the furniture, fixtures and equipment at the Premises, including that which is owned by or leased to Tenant at all times prior to any foreclosure thereon by Landlord or repossession thereof by any lessor thereof or third party having a lien thereon. Landlord shall also have the right to remove from the Premises (without the necessity of obtaining a distress warrant, writ of sequestration or other legal process and without being liable for prosecution or any claim for damages therefor) all or any portion of such furniture, fixtures, equipment and other property located thereon and place the same in storage at any place within the county in which the Premises is located or dispose of the same; and in such event, Tenant shall be liable to Landlord for costs incurred by Landlord in connection with such removal, storage, and/or disposal and shall indemnify and hold Landlord harmless from all loss, damage, cost, expense, and liability in connection with such removal, storage and/or disposal. Landlord shall also have the right to relinquish possession of all or any portion of such furniture, fixtures, equipment, and other property to any person ("Claimant.") claiming to be entitled to possession thereof who presents to Landlord a copy of any instrument purporting to have been executed by Tenant (or any predecessor of Tenant) granting Claimant the right under various circumstances to take possession of such furniture, fixtures, equipment or other property, without the necessity on the part of Landlord to inquire into the authenticity of said instrument and without the necessity of Landlord's making any investigation or inquiry as to the validity of the factual or legal basis upon which Claimant purports to act; and Tenant agrees to indemnify, defend and hold Landlord Parties harmless from all cost, expense, loss, damage, and liability incident to Landlord's relinquishment of possession of all or any portion of such furniture, fixtures, equipment, or other property to Claimant. Should Tenant abandon the Premises and leave property therein, Landlord may elect whether or not to accept the property, liquidate said property and apply the proceeds against any sums due and owing by Tenant, or to dispose of said property, and Tenant waives any claim to such property after any such abandonment. For purposes of the foregoing, Tenant shall be deemed to have abandoned its interest in such property if the same is not removed from the Premises by Tenant within ten days after Landlord's proper demand that Tenant remove same, or within ten days after expiration or earlier termination of this Lease, whichever first occurs. Notwithstanding the foregoing, Landlord shall also be entitled to exercise its rights pursuant to California Civil Code Section 1980 et. seq. with respect to the disposition of Tenant's personal property. The provisions of this Paragraph 25.3 shall additionally apply at the time of Tenant's surrender of the Premises pursuant to Paragraph 20.1. The provisions hereof shall survive the termination of this Lease.

- 25.4. <u>Landlord's Right to Cure Default</u>. Landlord, at any time after Tenant commits an Event of Default, may cure such Event of Default at Tenant's sole cost. If Landlord at any time, by reason of Tenant's default or breach, pays any sum or does any act that requires the payment of any sum, such sum shall be due immediately from Tenant to Landlord at the time such sum is paid, along with a supervisory fee in the amount of ten percent of such amount so expended by Landlord, and shall be deemed Additional Rent under this Lease. If Tenant fails to timely pay any amount due under this Paragraph within ten business days of receipt of Landlord's invoice for such costs, then (without curing such default) interest at the Default Rate shall accrue (and be immediately payable) on such overdue amount until it is paid.
- 25.5. <u>Enforcement Costs.</u> All costs and expenses incurred by Landlord in connection with collecting any amounts and damages owing by Tenant pursuant to the provisions of this Lease, or to enforce any provision of this Lease, including reasonable attorneys' fees, whether or not any action is commenced by Landlord, shall be paid by Tenant to Landlord upon demand. If Tenant fails to timely pay any amount due under this Paragraph, then (without curing such default) interest at the Default Rate shall accrue (and be immediately payable) on such overdue amounts until it is paid.
- 25.6. <u>Independent Covenants</u>. If Landlord shall commence any proceeding for nonpayment of Rent, or any other payment of any other kind to which Landlord may be entitled, or which it may claim hereunder, Tenant will not interpose any counterclaim or setoff of whatever nature or description, (other than compulsory counterclaim) in such proceedings. The parties hereto specifically agree that Tenant's covenants to pay Rent or any other payments required of it hereunder are independent of all other covenants and agreements herein contained and, as such, among other things, Tenant shall have no offset rights against the Rent payable hereunder by Tenant to Landlord. The foregoing shall not be construed as a waiver of Tenant's right to

assert any such claim in a separate action brought by Tenant against Landlord nor a waiver of any compulsory counterclaim under applicable Law.

- 26. Interest and Late Charges. Late payment by Tenant to Landlord of Rent or other charges will cause Landlord to incur costs not contemplated by this Lease, the exact amount of which would be impracticable or extremely difficult to fix. Such costs include, without limitation, processing, collection and accounting charges, and late charges that may be imposed on Landlord by the terms of any deed of trust covering the Premises. Therefore, if any Rent or other charge (in the form of good funds) is not received by Landlord within ten days of its due date, then, without any requirement for notice to Tenant, Tenant shall owe and pay to Landlord an additional sum of ten percent of such overdue amount as a late charge. Such late charge represents a fair and reasonable estimate of the costs that Landlord will incur by reason of any late payment by Tenant, and therefore this Paragraph is reasonable under the circumstances existing at the time this Lease is made. Acceptance of such late charge by Landlord shall not constitute a waiver or cure of Tenant's default with respect to such overdue amount, nor prevent Landlord from exercising any of the other rights and remedies available to Landlord under this Lease any or all of which may be exercised before, concurrently, or after Landlord's exercise of its rights hereunder. In addition to the late charge payable by Tenant, as provided above, if any such Rent or other charge is not paid within 30 days of the date such Rent or other charge was due, then Tenant shall pay to Landlord interest on such overdue Rent or other charge (from such 30th day until all amounts, including interest, are paid in full) at the rate of seven percent (7%) per annum above the "reference rate" announced from time to time by Bank of America, NT&SA or the maximum amount permitted by law, whichever is less (the "Default Rate"). If such reference rate ceases to be announced, then a comparable "prime rate" shall be utilized, as selected by Landlord.
- 27. <u>Landlord Default Tenant's Remedies</u>. Landlord shall not be in default hereunder unless Landlord fails to perform the obligations required of Landlord within a reasonable time, but in no event later than thirty (30) days after notice by Tenant to Landlord, and to the holder of any first mortgage or deed of trust covering the Premises, whose name and address shall have theretofore been furnished to Tenant, specifying the nature of Landlord's failure to perform; provided, however, that if the nature of Landlord's obligation is such that more than thirty (30) days are required for performance, then Landlord shall not be in default if Landlord commences performance within such thirty (30)-day period and thereafter diligently prosecutes the same to completion. In no event shall Tenant have the right to terminate this Lease as a result of Landlord's default, and Tenant's remedies shall be limited to monetary damages; provided, however, that in no event shall Landlord be liable under any circumstances for any consequential damages incurred by Tenant, including, without limitation, any injury to, or interference with, Tenant's business (including any loss of profits), arising in connection with this Lease. Nothing herein contained shall be interpreted to mean that Tenant is excused from paying Rent due hereunder as a result of any default by Landlord.
- Quarterly Payments. If a late charge is payable under this Lease, whether or not collected, for two installments of Basic Monthly Rent or Additional Rent due under this Lease during any one calendar year during the Term, then Basic Monthly Rent and Additional Rent shall automatically become due and payable quarterly in advance, rather than monthly. All monies paid to Landlord under this Paragraph may be commingled with other monies of Landlord and shall not bear interest. If Tenant breaches any provision of this Lease, then any balance remaining from funds paid to Landlord under the provisions of this Paragraph may, at Landlord's election, be applied to the payment of any monetary default of Tenant in lieu of being applied to the payment of personal property taxes, real property taxes and insurance premiums. Further, if three or more installments of Basic Monthly Rent or Additional Rent due under this Lease, or if any three payments made by Tenant in the form of a personal or business check are returned by the bank it was drawn upon for whatever reason, including, but not limited to, insufficient funds, then Landlord, at Landlord's option, may require Tenant to submit all future payments to Landlord in the form of a certified cashier's check, money order, or by wire transfer with all wire transfer fees of both Landlord and Tenant being the responsibility of Tenant. Tenant's obligation to provide payment in the aforementioned manner shall continue in full force and effect until Landlords, in its reasonable discretion, determines otherwise. Tenant further agrees to reimburse Landlord, as Additional Rent, Landlord's actual costs imposed by Landlord's bank or financial institution arising from Tenant's returned check(s). These costs shall be in addition to any late charges payable by Tenant pursuant to this Lease.
- 29. <u>Destruction</u>. If the Building is totally or partially destroyed during the Term, rendering the Premises totally or partially inaccessible or unusable, then, subject to the remainder of this Paragraph, (i) Landlord shall promptly commence work necessary to restore the Building to substantially the same condition as it was in immediately before such destruction and shall diligently prosecute such restoration work until completed, (ii) Landlord shall not be required to

restore Tenant's Alterations or Tenant's Personal Property, unless they are an integral part of the Premises and they are specifically covered by insurance proceeds received by Landlord, such excluded items being the sole responsibility of Tenant to restore, (iii) such destruction shall not terminate this Lease (except as provided below), and (iv) all obligations of Tenant under this Lease shall remain in effect, except that the Basic Monthly Rent and Additional Rent shall be abated or reduced, between the date of such destruction and the date of Substantial Completion of restoration, by the ratio of (a) the Rentable Square Footage of the Premises rendered unusable or inaccessible by the destruction, to (b) the Rentable Square Footage of the Premises prior to such destruction. Notwithstanding anything to the contrary in this Paragraph, either party shall have ten business days from the date of Landlord's determination that this sentence applies to the subject destruction/reconstruction, in which to terminate this Lease if Landlord determines that (1) it will likely take more than either (A) 330 days following the date of such casualty, or (B) 270 days from obtaining all required permits for such reconstruction, in which to complete such work, (2) such destruction (which is not de minimus in nature) occurs during the last year of the Term, or (3) thenexisting laws do not permit such restoration. Additionally, Landlord may, at its election, terminate this Lease by so notifying Tenant in writing on or before the later of 60 days after such destruction or 30 days after Landlord's receipt of the proceeds (or written notice of the amount of proceeds) from insurance maintained by Landlord, if (I) such destruction exceeds 20% of the then-replacement value of the Premises, the Building, or the Project, or (II) Landlord reasonably determines that the cost of such restoration will exceed the amount of insurance proceeds relating to such destruction actually received by Landlord from insurance maintained by Landlord, excluding deductibles, by more than five percent of such cost of restoration. If Landlord or Tenant so terminates this Lease, then (x) Landlord shall have no obligation to restore the Project, (y) Landlord shall retain all insurance proceeds relating to such destruction, and (z) this Lease shall terminate as of 30 days after such notice of termination from Landlord to Tenant. Tenant hereby waives the provisions of California Civil Code Sections 1932(2) and 1933(4) or any successor statute with respect to any destruction of the Premises. If Landlord restores the Premises following any such destruction, Tenant shall immediately refixturize, re-equip, and (if applicable) restock the Premises and shall re-open the Premises for business as soon thereafter as is reasonably practicable, not to exceed 60 days. intend to so reopen the Premises for business, it must notify Landlord in writing within 20 business days of such damage or destruction, whereupon Landlord may cease its repair work and terminate this Lease. Additionally, if Landlord fails to Substantially Complete such restoration work within one year, Tenant may, by 30 days' written notice to Landlord delivered after such year (during which period of time such restoration is not Substantially Completed), terminate this Lease.

Condemnation. If during the Term, or during the period of time between the execution of this Lease and the Lease Commencement Date, there is any taking of all or any part of the Premises or any interest in this Lease by the exercise of any governmental power, whether by legal proceedings or otherwise, by any public or quasi-public authority, or private corporation or individual, having the power of condemnation (any of the preceding a "Condemnor"), or a voluntary sale or transfer by Landlord to any Condemnor, either under threat of condemnation or while legal proceedings for condemnation are pending (any of the preceding, a "Condemnation"), the rights and obligations of Landlord and Tenant shall be determined pursuant to this Paragraph. Condemnation is of the entire Premises, then this Lease shall terminate on the date the Condemnor takes possession of the Premises (the "Date of Condemnation"). If such Condemnation is of any portion, but not all, of the Premises, then this Lease shall remain in effect, except that, if the remaining portion of the Premises is rendered unsuitable for Tenant's continued use of the Premises, then Tenant may elect to terminate this Lease, by so notifying Landlord in writing (the "Termination Notice") within 30 days after the date that the nature and extent of the Condemnation have been determined. Such termination shall be effective on the earlier of (i) the date that is 30 days after the giving of the Termination Notice, or (ii) the Date of Condemnation. If Tenant does not give to Landlord the Termination Notice within such 30-day period, then all obligations of Tenant under this Lease shall remain in effect, except that (unless the Premises are restored as set forth below) Basic Monthly Rent shall be reduced by the ratio of (a) the Rentable Square Footage of the Premises taken to (b) the Rentable Square Footage of the Premises immediately prior to the Date of Condemnation. Notwithstanding anything to the contrary in this Paragraph, if, within 30 days after Landlord's receipt of the Termination Notice, Landlord notifies Tenant that Landlord at its cost will add to the remaining Premises (or substitute for the Premises other comparable space in the Project) so that the Rentable Square Footage of the Premises will be substantially the same after the Condemnation as they were before the Condemnation, and Landlord commences the restoration promptly and completes it within 150 days after Landlord so notifies Tenant, then all obligations of Tenant under this Lease shall remain in effect, except that Basic Monthly Rent and Additional Rent shall be abated or reduced during the period from the Date of Condemnation until the completion of such restoration by the ratio of (A) the Rentable Square Footage of the Premises taken to (B) the Rentable Square Footage of the Premises immediately prior to the Date of Condemnation. Unless Landlord restores the Premises pursuant to the preceding sentence, or unless Tenant gives to Landlord the Termination

Notice within the relevant 30-day period, Tenant at its sole cost shall accomplish any restoration required by Tenant to use the Premises. A temporary Condemnation of the Premises, or any part of the Premises, for less than 180 days, shall not constitute a Condemnation under this Paragraph; but the Basic Monthly Rent shall abate as to the portion of the Premises affected during such temporary Condemnation. All compensation, sums, or anything of value awarded, paid, or received on a total or partial Condemnation (the "Award") shall belong to and be paid to Landlord. Tenant shall have no right to any part of the Award, and Tenant hereby assigns to Landlord all of Tenant's right, title, and interest in and to any part of the Award, except that Tenant shall receive from the Award any sum paid expressly to Tenant from the Condemnor for Tenant's Personal Property or for severance damages. Landlord and Tenant waive the provisions of any statute (including without limitation California Code of Civil Procedure Section 1265.130 or any successor statute) that allows Landlord or Tenant to petition the superior court (or any other court) to terminate this Lease in the event of a partial Condemnation of the Premises.

# 31. <u>Assignment and Other Transfers</u>.

31.1. Restriction on Transfer. Without Landlord's prior written consent, which shall not be unreasonably withheld, and except as permitted by Paragraph 31.3, below, none of the following shall occur (nor be permitted by Tenant to occur), voluntarily, involuntarily, by operation of law, or otherwise (any of the following, a "Transfer"): (i) any assignment, sublease, disposition, sale, concession, license, license agreement for the use of any portion of the Premises, mortgage, encumbrance, hypothecation, pledge, collateral assignment, or other transfer, by Tenant of this Lease, any interest in this Lease, or all or any portion of the Premises; or (ii) any assignment, disposition, sale, transfer, acquisition, or issuance of equitable interests (whether stock, partnership or otherwise) in Tenant, to or by any person, entity, or group of related persons or affiliated entities, whether in a single transaction or in a series of related or unrelated transactions, which results in such person, entity, or group holding (or assigning, transferring, disposing of, or selling) 50% or more of the aggregate issued and outstanding equitable interests in Tenant.

# 31.2. <u>Transfer Provisions Generally.</u>

31.2.1. Landlord shall not be liable in damages to Tenant or to any proposed subtenant, assignee or other transferee (any of the preceding a "Proposed Transferee") if such consent is adjudicated to have been unreasonably withheld, and, in such event, Tenant's sole remedy shall be to have the proposed Transfer declared as valid as if Landlord's consent had been given, although Tenant shall be entitled to reasonable attorney's fees if Tenant is the prevailing party in such litigation. At least 30 days prior to entering into any proposed Transfer, Tenant shall submit to Landlord the sum of \$1,000.00 (as payment toward Landlord's and Landlord's attorneys' cost of reviewing, consenting to, rejecting and/or consummating any proposed Transfer), and a written notice ("Tenant's Notice") which includes (i) a fully executed copy of the instrument of transfer (i.e., the sublease or assignment) relating to the proposed Transfer, along with all related agreements, documents, instruments, exhibits, and escrow instructions, (ii) the name and address of the Proposed Transferee, (iii) an abstract of the terms and conditions of the proposed Transfer, including without limitation the economics of such Proposed Transfer and the commencement or effective date of the proposed Transfer, which shall be at least 30 days after Tenant's Notice is given, and (iv) the nature, character, and current banking, financial, and other credit information and references with respect to the Proposed Transferee and the business of the Proposed Transferee (including without limitation tax returns for the three most-recent years, a business plan with cash-flow projections and financial projections with assumptions and competitive market analysis), in reasonably sufficient detail to enable Landlord to determine the Proposed Transferee's financial responsibility.

31.2.2. Within 30 days after Landlord's receipt from Tenant of such sum and Tenant's Notice, and all documentation requested of Tenant by Landlord, Landlord shall notify Tenant whether Landlord has consented to the proposed Transfer. Any consent by Landlord to any proposed Transfer shall not constitute a consent with respect to any other Transfer. If Landlord consents to any proposed Transfer, and Tenant fails to consummate such Transfer within 30 days of the commencement or effective date of the proposed Transfer (as set forth in Tenant's Notice) or, if Tenant's Notice fails to identify such a date, then within 150 days of the Tenant's Notice, then such consent shall be deemed withdrawn and Tenant shall be required again to comply with this Paragraph before making a Transfer. Landlord shall not have unreasonably withheld its consent with respect to any Transfer if (among other things) Landlord shall not have received such sum or Tenant's Notice, if the nature or character of the Proposed Transferee is not in keeping with the dignity and character of the Building and the surrounding area, if the Proposed Transferee's proposed use is materially and adversely different than the Permitted Use or Tenant's prior use, if the proposed Transfer will result in the diminution of the value or marketability of the Building or the Project, if Landlord is not reasonably satisfied that the

Proposed Transferee is creditworthy, or if the proposed Transfer will conflict with or result in a breach of any of the provisions of, or constitute a default under, any agreement, instrument, or document to which Landlord is a party or by which the Project may be bound. No Transfer shall release or discharge Tenant from any liability, whether past, present, or future, under this Lease and Tenant shall continue to remain directly and primarily liable under this Lease (and not as a mere surety); provided, however, as a condition to granting consent to any assignment (or like Transfer) Landlord may require the assigning Tenant to execute a guaranty on Landlord's standard form—which guaranty shall serve to release such assigning Tenant from direct liability hereunder and such assigning Tenant will then only have liability for matters first accruing under this Lease thereafter pursuant to such guaranty (it being understood that if such assigning Tenant fails to execute such Guaranty, the such assignment shall constitute an Event of Default, such Transfer will be void, and such assigning Tenant shall remain primarily liable hereunder). Tenant irrevocably assigns to Landlord, as security for Tenant's obligations under this Lease, all rent and other amounts generated from any Transfer, and Landlord, as assignee and as special attorney-in-fact for Tenant, or a receiver for Tenant appointed on Landlord's application, may collect such rent and other amounts and apply them toward Tenant's obligations under this Lease; except that, unless a default occurs under this Lease, Tenant shall have the right to collect such rent and other amounts.

- 31.2.3 Unless otherwise agreed to by all parties, the Tenant's Security Deposit (if any) shall be retained by Landlord and returned to the lawful tenant in possession of the Premises at the time of the Lease termination, subject to the terms and conditions of Paragraph 6 of this Lease. Any Transfer documentation shall contain the following provisions, which provisions whether contained in such Transfer documentation or not, shall apply to such Transfer: (a) Such Transfer shall be subject and subordinate to, and bound by, all provisions of this Lease; (b) No Proposed Transferee shall be permitted to enter into any Transfer without Landlord's prior written consent; and (c) At Landlord's option, in the event of cancellation or termination of this Lease for any reason or the surrender of this Lease, whether voluntarily, involuntarily, by operation of law or otherwise, prior to the expiration of such Transfer, the Proposed Transferee shall make full and complete attornment to Landlord for the balance of the term of such Transfer. Such attornment shall be evidenced by an agreement in form and substance reasonably satisfactory to Landlord that the Proposed Transferee shall execute and deliver to Landlord within five days after request by Landlord.
- 31.2.4. Tenant shall promptly reimburse Landlord for Landlord's reasonable cost (less the \$1,000.00 previously paid) of reviewing, consenting to, rejecting and/or consummating any proposed Transfer, including without limitation reasonable attorneys' fees and costs/fees of Landlord's Lender (if any) in connection therewith. If Tenant fails to pay such amount within ten business days of written demand, Tenant shall be in default hereunder and Landlord shall have the right, in addition to its other rights and remedies under this Lease, to revoke its prior approval of the proposed Transfer if such Proposed Transferee has not yet taken over possession of the Premises.
- 31.3. Excess Rent and Recapture. Tenant shall promptly pay to Landlord, as and when received, 50% of all rents and other consideration after all of Tenant's reasonable third-party expenses incurred in connection with such Transfer are deducted, of whatever nature, payable by the Proposed Transferee (or receivable by Tenant) pursuant to or as a result of any Transfer, which exceed (i) in the case of a sublease of a portion of the Premises, the portion of the Basic Monthly Rent that is allocable to the portion of the Premises subleased (such allocation based on the Rentable Square Footage of the portion subleased), or (ii) in the case of any other Transfer, the Basic Monthly Rent. Landlord additionally has the right, in the event Tenant indicates in the Tenant's Notice that it desires to assign this Lease or sublet greater than 50% of the Premises, at its election, by giving written notice (the "Recapture Notice") to Tenant within 15 days after receipt of Tenant's Notice, to recapture the Premises and terminate this Lease. If Landlord elects to exercise such right and delivers a Recapture Notice to Tenant, this Lease shall automatically be deemed terminated as of the commencement or effective date stated in Tenant's Notice for the proposed Transfer, and Tenant shall surrender possession of the Premises as of such date (and any failure to do so shall constitute a default hereunder). Landlord's giving of a Recapture Notice shall not constitute Landlord's consent to Tenant's proposed Transfer.
- 31.4. <u>Permitted Transferee.</u> Notwithstanding anything to the contrary contained in Paragraphs 31.1 or 31.3, above, no consent of Landlord will be required for, and no amounts will be payable to Landlord in connection with, any assignment or subletting to any of the following (any of which will constitute a "Permitted Transferee"):
- 31.4.1. Any parent, wholly-owned subsidiary, or other company of which Tenant owns all or substantially all of the voting and beneficial interests, or which company owns all or substantially all of the voting and beneficial interests in Tenant, and which parent, subsidiary,

or other company has a net worth (determined in accordance with GAAP) equal to or greater than Tenant's net worth as of the day before such transaction or as of the Lease Commencement Date, whichever is less;

31.4.2. Any surviving or successor entity resulting from a merger, consolidation, or sale of substantially all of the assets of Tenant, where the net worth of the resulting or acquiring company exceeds (as determined in accordance with GAAP), the net worth of the Tenant as of the day prior to such transaction or as of the Lease Commencement Date, whichever is less; or

31.4.3. Any sale of stock as part of a "public offering" on one of the nationally recognized securities exchanges (such as, without limitation, NYSE or NASDAQ).

Notwithstanding the foregoing, and as a condition precedent to the effectiveness of any such Transfer to a Permitted Transferee, at least 20 days prior to any proposed Transfer to a Permitted Transferee, Tenant shall notify Landlord in writing of its intention to undertake such a Transfer and provide Landlord with sufficient information to confirm that such entity will in fact be a Permitted Transferee and the assigning Tenant shall execute Landlord's form guaranty—which guaranty shall serve to release such assigning Tenant from direct liability hereunder and such assigning Tenant will then only have liability for matters first accruing under this Lease thereafter pursuant to such guaranty (it being understood that if such assigning Tenant fails to execute such a Guaranty, then such assignment shall constitute an Event of Default, such Transfer will be void, and such assigning Tenant shall remain primarily liable hereunder). Landlord shall keep all such information confidential. Other than the right to engage in such a Transfer to a Permitted Transferee without Landlord's consent, all other provisions of Paragraph 31.2 shall apply to such a Transfer.

Landlord hereby approves the subleasing of one office space and one work station to Leading Biosciences, Inc. upon the Rent Commencement Date through April 30, 2017 (the "Leasing Biosciences Sublease"). With respect to the Leading Biosciences Sublease only, Tenant shall not (i) be required to obtain Landlord's written approval, or (ii) be required to pay any consent fees to Landlord.

# 32. <u>Landlord's Reserved Rights</u>.

- 32.1. General Rights Reserved. In addition to the specific reserved rights identified in Paragraph 32.2, below, Landlord, as owner of the Project, in addition to Landlord's other rights, reserves the right from time to time: (i) to temporarily utilize portions of the Common Areas for, among other things, entertainment, outdoor shows, displays, automobile and other product shows, the leasing of kiosks, or such other uses which, in Landlord's reasonable judgment, are appropriate; (ii) to utilize the lighting standards and other areas or improvements in the Common Areas for advertising, notice purposes, or other reasonable purposes; (iii) to close any of the Common Areas to the extent required in the opinion of Landlord's legal counsel to prevent a dedication of any of the Common Areas or the accrual of any rights to any person or to the public in and to any portion of the Common Areas; (iv) to close, temporarily, any of the Common Areas for maintenance purposes; (v) to designate other property outside the boundaries of the Project to become part of the Common Areas; (vi) to close off or otherwise utilize portions of the Common Areas while constructing improvements or making repairs or alterations to any portion of the Project; (vii) to utilize portions of the Common Areas, on a temporary basis, as a staging area for any construction work by Landlord or its affiliates, agents, tenants, or contractors; and (viii) to make any changes to the Common Areas, or any part of the Project, including without limitation changes to buildings or other improvements, the addition of new buildings or other improvements, and/or changes in (among other things) the location of driveways, entrances, exits, vehicular parking spaces, or the direction of the flow of traffic. In exercising such rights, Landlord agrees to use commercially reasonable efforts to minimize any interference with Tenant's use of the Premises.
- 32.2. <u>Future Construction</u>. Tenant acknowledges that, as more particularly provided below, the development of the Project is continuing and may, at Landlord's election, include the construction of additional buildings and improvements within the Project, including in areas which currently constitute Common Areas. Tenant is entering into this Lease with a full understanding of the possible ramifications/effects of such future development work on its tenancy and the rental charged hereunder takes such factors into account. Tenant further acknowledges and agrees that Landlord may, from time to time, at its sole election, construct (including, without limitation, additional buildings), reconstruct (including without limitation the replacement of certain improvements with other improvements), improve (including tenant improvements), modify, expand, or otherwise alter the Project or portions thereof, including a remodel, renovation, or refurbishment of the Premises (collectively, "Construction Work") (in no event however will

Landlord have any obligation to do so). Tenant acknowledges that any such Construction Work will necessarily involve, among other things, the generation of noise, dust, and vibrations, barricading portions of the Project and the placement of scaffolding within the Project, demolition, structural alterations, storage of materials and equipment within the Project, and the presence of workmen within the Project, all of which may require the rearrangement of the Common Areas, including, without limitation, landscaping, parking areas (which may include the provision of temporary parking areas during periods of construction), roadways, lighting facilities, and the re-direction of vehicular and pedestrian traffic. Tenant agrees that the performance of any Construction Work shall not constitute an eviction (constructive or otherwise). Further, Landlord hereby reserves such licenses and easements in, on, above or below the Premises as may be reasonably required (i) for the installation, inspection, surveying, maintenance, or construction of mains, conduits, shafts, columns, footings, piers, pipes or other facilities to serve any building within the Project, or (ii) for any Construction Work; provided, however, Landlord will use its commercially reasonable efforts to minimize any unreasonable interference with Tenant's use, occupancy, or enjoyment of the Premises as contemplated by this Lease. Except as provided below, Tenant waives any and all claims, defenses, rights of offset, or deductions based upon any inconvenience suffered by Tenant or any interruption of or interference with Tenant's business including, without limitation, any loss of business, decreased sales, damage to property, loss of electronic information, or inconvenience to Tenant or Tenant's Invitees as a result of or relating to such Construction Work. Landlord hereby reserves for itself and its agents, employees, licensees and contractors, the right to enter the Premises to the extent reasonably necessary to pursue such Construction Work upon twenty-four (24) hours' prior notice to Tenant. The exercise of any of Landlord's rights pursuant to this Paragraph will not entitle Tenant to any abatement of Rent or other claim, right of offset, or defense against Landlord, except that (subject to the provisions of Paragraphs 19, 36, 44, and other provisions of this Lease) (a) Tenant shall have the right to bring an action against Landlord (as Tenant's sole remedy) in the event Tenant suffers any damages as a result of Landlord's gross negligence or intentional misconduct in pursuing such Construction Work, and (b) if such Construction Work results in Tenant being unable to access the Premises, or portions thereof, for the Permitted Use for a period of greater than five business days, Tenant shall be entitled (as Tenant's sole remedy with respect to such lack of access) to equitable abatement of the Rent for such period of time during which it is unable to access the Premises. The foregoing rights will constitute Tenant's sole and absolute rights against Landlord or otherwise in connection with any such Construction Work and Tenant releases and waives any other claims, defenses, or rights in connection therewith. Tenant further acknowledges that expansion of the Project may affect the amount of the Operating Expenses and the portion thereof payable by Tenant.

- 32.3. Relocation. Landlord may, at its election, upon at least 30 days' written notice to Tenant, relocate Tenant and substitute for the Premises other space in the Project containing at least as much useable area as the Premises. If Tenant confirms in writing to Landlord, within in five days of receipt of such written notice from Landlord that it will vacate the Premises and occupy the new location within the time frame set forth in the notice from Landlord, then Landlord shall, at its cost, improve such substitute space with improvements at least equal in quantity and quality to those then existing in the Premises and Landlord shall reimburse Tenant for Tenant's reasonable expenses incurred in connection with such relocation, including moving expenses, door lettering, and telephone relocation. If Tenant fails to send such written confirmation notice to Landlord within such five day period, such failure shall be deemed to constitute Tenant's election to continue to occupy the Premises for an additional 15 day period beyond the time frame set forth in Landlord's notice, in which event Landlord shall have no obligations to improve such substitute space and pay Tenant's reasonable relocation costs as set forth in the preceding sentence. Failure by Tenant to relocate as provided in this Paragraph shall constitute a default under this Lease and Tenant acknowledges that it will, in addition, be liable for Landlord's additional damages incurred as a result of any failure by Tenant to timely vacate the Premises (including damages resulting from lost opportunities). Landlord shall not be held liable for any damages arising out of Tenant's relocation. Such substitute space shall become the Premises for purposes of this Lease following Tenant's taking possession of such substitute space.
- 33. <u>Easements</u>. Landlord may, at its election, from time to time, grant such easements, rights and dedications, and cause the recordation of parcel maps, easement and operating agreements, and restrictions affecting the Premises and the Project, provided that no such acts materially and adversely affect Tenant's rights of ingress or egress to the Building and the Premises or Tenant's right to use the Premises. Tenant shall promptly sign any documents or instruments to accomplish the foregoing upon request by Landlord. Tenant irrevocably appoints Landlord as Tenant's special attorney-in-fact to execute and deliver such documents or instruments on behalf of Tenant if Tenant refuses or fails to do so within ten days of written request.

- Access by Landlord. Landlord and any of Landlord's Invitees shall have the right to enter the Premises at all reasonable times, during normal business hours if feasible under the circumstances, and upon 24 hours' notice, if feasible under the circumstances, (i) to determine whether the Premises are in good condition and whether Tenant is complying with its obligations under this Lease, (ii) to do any necessary maintenance or make any restoration to the Premises that Landlord has the right or obligation to perform, (iii) to serve, post, or keep posted any notices required or allowed under this Lease, (v) to post "for sale" or "for rent" or "for lease" signs during the final nine months of the Term, (vi) to show the Premises to brokers, lenders, agents, prospective buyers, prospective tenants, or other persons interested in a listing of, financing, purchasing, or occupying the Project, the Premises or any portion of the Project or the Premises, and (vii) to shore the foundations, footings, and walls of the Project, and to erect scaffolding and protective barricades around and about the Premises, but not so as to prevent entry to the Premises, and to do any other act or thing necessary for the safety or preservation of the Premises if any excavation or other construction is undertaken or is about to be undertaken on any adjacent property or nearby street. In the event of an emergency Landlord shall have the right to enter the Premises at any time, without prior notice to Tenant. Landlord's rights under this Paragraph extend, with Landlord's consent, to the owner of adjacent property on which excavation or construction is to take place and the adjacent property owner's agents, employees, officers, and contractors. Landlord shall not be liable for any inconvenience, disturbance, loss of business, nuisance, or other damage arising out of any entry on the Premises as provided in this Paragraph except damage resulting directly from the grossly negligent acts or willful misconduct of Landlord or Landlord's Invitees. Tenant shall not be entitled to any abatement or reduction of Basic Monthly Rent or other Rent because of the exercise by Landlord of any rights under this Paragraph.
- 35. Indemnity. Tenant hereby agrees to indemnify, defend, protect, and hold harmless Landlord and its shareholders, officers, directors, agents, property managers, employees, contractors, and the partners comprising Landlord (if any) from and against all Claims (as defined below) and all costs, expenses, and attorneys' fees incurred in the defense or handling of any such Claims or any action or proceeding brought on any of such Claims. For purposes of this Lease, the term "Claims" shall mean all liabilities, damages, losses, costs, expenses, attorneys' fees, and claims (except to the extent they result from Landlord's negligent acts or willful misconduct) arising from or which seek to impose liability under or because of (i) Tenant's or Tenant's Invitees' use of the Premises, (ii) the conduct of Tenant's business, (iii) any activity, work, or things done, permitted, or suffered by Tenant or any of Tenant's Invitees in or about the Premises or elsewhere, (iv) any breach or default in the performance of any obligation to be performed by Tenant under this Lease, and/or (v) any negligence of Tenant or any of Tenant's Invitees. If any action or proceeding is brought against Landlord or its shareholders, officers, directors, agents, property managers, employees, contractors, or the partners comprising Landlord (if any) by reason of any such Claims, Tenant upon notice from Landlord shall defend such action or proceeding at Tenant's sole cost by legal counsel satisfactory to Landlord.
- Exemption of Landlord from Liability. Except to the extent caused by Landlord's negligent acts or willful misconduct, Tenant assumes all risk of, Tenant waives all claims against Landlord in respect of, and Landlord shall not be liable for, any of the matters set forth in the preceding Paragraph or any of the following: injury to Tenant's business, loss of income from such business, or damage or injury to the goods, wares, merchandise, or other property or the person of Tenant, Tenant's Invitees, or any other persons in, upon, or about the Premises, whether such damage, loss, or injury is caused by or results from criminal acts, fire, steam, electricity, gas, water, rain, the breakage, leakage, obstruction or other defects of pipes, sewer lines, sprinklers, wires, appliances, plumbing, air-conditioning or lighting fixtures, or any other cause, conditions arising upon the Premises, or other sources or places, and regardless of whether the cause of such damage, loss, or injury or the means of repairing such damage, loss, or injury is inaccessible to Tenant. In connection with the foregoing, Tenant hereby waives any defense would otherwise be provided by Section 1542 of the California Civil Code (which states "A general release does not extend to claims which the creditor does not know or suspect to exist in his or her favor at the time of executing the release, which if known by him or her must have materially affected his or her settlement with the debtor"), or laws of a similar nature, which would limit any such release to matters known or suspected to exist by Tenant. This Lease shall not be affected or impaired by any change to any part of the Project or any sidewalks, streets or improvements nearby the Project.

# 37. <u>Hazardous Substances</u>.

37.1. <u>Landlord's Covenants</u>. Landlord hereby notifies Tenant, and Tenant hereby acknowledges that, prior to the leasing of the Premises pursuant to this Lease, Tenant has been notified, pursuant to California Health and Safety Code Section 25359.7 (or any successor statute), that Landlord knows, or has reasonable cause to believe, that certain hazardous substances (as such term is used in such Section 25359.7), such as common cleaning

supplies, office supplies, spillage of petroleum products from motor vehicles, and other consumer products, may have come (and may in the future come) to be located on or beneath the Premises and/or the Project. Notwithstanding the foregoing, Landlord shall not cause any unlawful accumulations of Hazardous Material (as defined below) to be generated, brought onto, used, stored, or disposed of in or about the Premises, the Building, or the Project by Landlord or its agents, employees, or contractors, except for limited quantities of standard office and janitorial supplies and petroleum and petroleum-related products commonly used on or at similar office projects. Furthermore, Landlord shall: (a) use, store, and dispose of all such permitted Hazardous Material in strict compliance with all applicable statutes, ordinances, and regulations in effect during the Lease Term that govern and/or relate to Hazardous Material, public health and safety and protection of the environment, and (b) comply at all times during the Lease Term with all environmental laws (as defined in Paragraph 37.2, below). Except as to those matters which are Tenant's responsibility pursuant to Paragraph 37.2, below, Landlord shall be responsible, at its expense (or the expense of others; but not as an Operating Expense) to cause any unlawful accumulations of Hazardous Materials to be remediated in accordance with the requirements of all applicable environmental laws.

Tenant's Covenants. Tenant covenants, represents, and warrants to the Landlord that its use of the 37.2. Premises, the Building, and the Project will be in full compliance with all environmental laws. Tenant hereby agrees to indemnify Landlord against all actions, liabilities, damages, losses, costs, expenses, attorneys' fees, and claims (except to the extent they arise as a result of Landlord's grossly negligent acts or willful misconduct), arising from or relating to: (i) any discharges, releases, or threatened releases of any Hazardous Material into ambient air, water, or land by Tenant or Tenant's Invitee's from, on, under, or above the Premises, (ii) the manufacture, processing, distribution, use, treatment, storage, disposal, transport, or handling of pollutants, contaminants, or hazardous or toxic wastes, substances, or materials by Tenant or Tenant's Invitees, or otherwise from, on, or under, the Premises, or (iii) a violation of any environmental law on, under, or above the Premises (for purposes of this Lease, "environmental laws" shall mean any Federal, State, or local law, statute, regulation, ordinance, guideline, or common law principle relating to public health or safety or the use or control of the environment, including without limitation the Federal Comprehensive Environmental Response, Compensation and Liability Act of 1980, the Carpenter-Presley-Tanner Hazardous Substance Account Act, the California Hazardous Waste Control Law, the Federal Clean Air Act, the California Air Resources Act, the Federal Clean Water Act, the California Porter-Cologne Water Quality Control Act, the Federal Resource Conservation and Recovery Act, the California Nejedly-Z'berg-Dills Solid Waste Management and Recovery Act, and California Health and Safety Code Section 25359.7) and any other laws governing environmental or Hazardous Material matters in California. Tenant agrees to promptly reimburse Landlord for all of Landlord's costs arising from periodic monitoring of Tenant's use, handling, or storage of Hazardous Substances at or surrounding the Premises. Tenant shall not cause or permit any Hazardous Material to be generated, brought onto, used, stored, or disposed of in or about the Premises, the Building, or the Project by Tenant or its agents, employees, contractors, subtenants, or invitees, except for limited quantities of standard office and janitorial supplies. Tenant shall: (a) use, store, and dispose of all such permitted Hazardous Material in strict compliance with all applicable statutes, ordinances, and regulations in effect during the Lease Term that govern and/or relate to Hazardous Material, public health and safety and protection of the environment, and (b) comply at all times during the Lease Term with all environmental laws. If the Premises are contaminated (or, due to the acts or omissions of Tenant or Tenant's Invitees, the Project is contaminated) by any Hazardous Material during the Term, then (1) Tenant shall promptly notify Landlord in writing of such contamination, and (2) Landlord may elect to either (A) demand that Tenant perform all remediation required by Landlord (to Landlord's satisfaction and at Tenant's sole cost, necessary to return the Premises (and/or the Project) to at least as good a condition as the Premises (or the Project) are in as of the date of this Lease, which Tenant shall immediately do upon receipt of notice from Landlord, or (B) proceed to cause such investigation, clean-up, and remediation work which Landlord deems necessary or desirable to be undertaken, whereupon the entire cost thereof (plus a supervisory fee equal to ten percent of such cost) will be payable by Tenant to Landlord upon demand as Additional Rent. If, after demand by Landlord, as provided in this Paragraph, Tenant does not promptly commence and diligently pursue such remediation, then Landlord may, at Landlord's election, perform or cause to be performed such remediation and Tenant shall immediately, upon demand, pay the cost thereof to Landlord, plus a supervisory fee in the amount of ten percent of such cost. Tenant's obligations and liability under this Paragraph shall survive the termination of Tenant's tenancy and the Term of this Lease, except that nothing contained in this Paragraph shall be deemed to impose liability on Tenant for any problem arising after the Term of this Lease provided neither Tenant nor Tenant's Invitees contributed to such problem during the Term of the Lease.

37.3. <u>Definition of Hazardous Materials</u>. As used in this Lease the term "Hazardous Material" shall mean any hazardous or toxic substance, material, or waste that is or

becomes regulated by the United States, the State of California, or any local government authority having jurisdiction over the Building. Hazardous Material includes, without limitation: (a) any "hazardous substance", as that term is defined in the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA) (42 United States Code Sections 9601-9675); (b) "hazardous waste", as that term is defined in the Resource Conservation and Recovery Act of 1976 (RCRA) (42 United States Code Sections 6901-6992k); (c) any pollutant, contaminant, or hazardous, dangerous, or toxic chemical, material, or substance, within the meaning of any other applicable federal, state, or local law, regulation, ordinance, or requirement (including consent decrees and administrative orders imposing liability or standards of conduct concerning any hazardous, dangerous, or toxic waste, substance, or material, now or hereafter in effect); (d) petroleum products; (e) radioactive material, including any source, special nuclear, or byproduct material as defined in 42 United States Code Sections 2011-2297; (f) asbestos in any form or condition; and (g) polychlorinated biphenyls (PCBs) and substances or compounds containing PCBs.

- Prohibition Against Mold, Lead-Based Paint, and Asbestos-Containing Materials. Tenant shall not allow or permit any lead-based paint to be used in the Premises, nor shall Tenant allow or permit any condition to occur which could result in the growth of mold within the Premises. Additionally, Tenant shall not allow or permit any materials which contain asbestos in any form or concentration ("Asbestos-Containing Materials") to be used or stored in the Premises or used in the construction of any improvements or alterations to the Premises, including, without limitation, building or construction materials and supplies. Such prohibition against Asbestos-Containing Materials shall apply regardless of whether the Asbestos-Containing Materials may be considered safe or approved for use by a manufacturer, supplier, or governmental authority, or by common use or practice. Landlord shall have the right, upon 24hours' notice, to enter upon and conduct inspections of the Premises to determine Tenant's compliance with this Paragraph. If Tenant violates the foregoing covenants relating to lead-based paint, mold, and Asbestos-Containing Materials (collectively "Prohibited Substances"), then (a) Tenant shall, upon notice from Landlord, immediately remove and remediate any damage from such Prohibited Substances at Tenant's sole cost, (b) such removal and remediation shall comply with all applicable laws, regulations, and requirements, (c) Tenant shall reimburse Landlord for all expenses incurred in connection with any inspection and testing of the Premises conducted by Landlord, and (d) unless Tenant completes such removal within 30 days after notice from Landlord, Landlord may, at its election, do either or both of the following: (i) declare an Event of Default (without the requirement of any notice under Paragraph 24.4) and exercise Landlord's remedies hereunder, including, without limitation, terminate this Lease upon ten days prior written notice to Tenant, and/or (ii) remove and remediate such Prohibited Substances and obtain reimbursement from Tenant for the cost of such removal and remediation, including a supervisory fee payable to Landlord in the amount of ten percent of the removal and disposal cost. Tenant shall indemnify Landlord and Landlord's directors, officers, employees, and agents against all costs, liabilities, expenses, penalties, and claims for damages, including, without limitation, litigation costs and attorneys' fees, arising from (A) the presence of Prohibited Substances upon the Premises, to the extent that such Prohibited Substances are used, stored, or otherwise permitted in the Premises or used in the construction of any Alterations by Tenant or Tenant's agents, employees, representatives, or independent contractors, (B) any lawsuit, settlement, governmental order, or decree relating to the presence, handling, removal, or disposal of Prohibited Substances upon or from the Premises, to the extent that such Prohibited Substances are used, stored, or otherwise permitted in the Premises or used in the construction of any improvements or Alterations to the Premises by Tenant or Tenant's agents, employees, representatives or independent contractors, or (C) Tenant's failure to perform its obligations to remove such Prohibited Substances under this Paragraph. The provisions of this Paragraph shall not apply to any Prohibited Substances brought onto the Premises by Landlord or Landlord's Invitees or resulting from the acts of Landlord or Landlord's Invitees.
- 39. <u>Security Measures</u>. Tenant acknowledges that, although the Building may contain a restricted access entry system (if provided for as part of Landlord's Work), (i) the Basic Monthly Rent does not include the cost of any security measures for any portion of the Project (ii) Landlord shall have no obligation to provide any such security measures, (iii) Landlord has made no representation to Tenant regarding the safety or security of the Project, and (iv) Tenant will be solely responsible for providing any security it deems necessary to protect itself, its property, and Tenant's Invitees in, on, or about the Project. If Landlord provides any security measures at any time, then the cost thereof shall be included as part of the Operating Expenses, but Landlord will not be obligated to continue providing such security measures for any period of time, Landlord may discontinue such security measures without notice and without liability to Tenant, and Landlord will not be obligated to provide such security measures with any particular standard of care. Tenant assumes all responsibility for the security and safety of Tenant, Tenant's property, and Tenant's Invitees. Tenant releases Landlord from all claims (other than due to Landlord's gross negligence or intentional misconduct) for damage, loss, or injury to Tenant, Tenant's Invitees, and/or to the personal property of Tenant and/or of Tenant's Invitees, even if such

damage, loss, or injury is caused by or results from the criminal, reckless, or negligent acts of third parties. In connection with the foregoing, Tenant hereby waives any defense would otherwise be provided by Section 1542 of the California Civil Code (which states "A general release does not extend to claims which the creditor does not know or suspect to exist in his or her favor at the time of executing the release, which if known by him or her must have materially affected his or her settlement with the debtor"), or laws of a similar nature, which would limit any such release to matters known or suspected to exist by Tenant. Tenant is hereby instructed to conduct its own investigation through local police agencies regarding any criminal acts or dangerous conduct that has occurred in or near the Project. Landlord shall have no duty to warn Tenant of any criminal acts or dangerous conduct that has occurred in or near the Project, regardless of Landlord's knowledge of such crimes or conduct, and Tenant hereby undertakes to remain informed regarding such issues.

- Subordination and Attornment. This Lease and Tenant's rights under this Lease are subject and subordinate to any mortgage, deed of trust, ground lease, or underlying lease (and to all renewals, modifications, consolidations, replacements, or extensions thereof), now or hereafter affecting the Premises. The provisions of this Paragraph shall be self-operative, and no further instrument of subordination shall be required. In confirmation of such subordination, however, Tenant shall promptly execute and deliver any commercially reasonable instruments that Landlord, any Lender, or the lessor under any ground or underlying lease, may request to evidence such subordination, provided such instrument contains customary non-disturbance language in favor of Tenant and is consistent with the provisions of the next sentence including, without limitation, a Subordination, Attornment, and Non-Disturbance Agreement in the form to be commercially reasonable and acceptable to Lender. If any Lender, or the lessor of any ground or underlying lease affecting the Premises, shall hereafter succeed to the rights of Landlord under this Lease, whether by foreclosure, deed in lieu of foreclosure, or otherwise, then (i) such successor landlord shall not be subject to any offsets or defenses which Tenant might have against Landlord, (ii) such successor landlord shall not be bound by any prepayment by Tenant of more than one month's installment of Basic Monthly Rent or any other Rent, (iii) such successor landlord shall not be subject to any liability or obligation of Landlord except those arising after such succession, (iv) Tenant shall attorn to and recognize such successor landlord as Tenant's landlord under this Lease, (v) Tenant shall promptly execute and deliver any commercially reasonable instruments that may be necessary to evidence such attornment, (vi) upon such attornment, this Lease shall continue in effect as a direct lease (whether separately documented or not) between such successor landlord and Tenant upon and subject to all of the provisions of this Lease, and (vii) Tenant shall be entitled to quiet enjoyment of the Premises for so long as Tenant is not in default under the terms of this Lease or any substitute lease referenced above. Notwithstanding the preceding provisions of this Paragraph, if any ground lessor or Lender elects to have this Lease prior to the lien of its ground lease, deed of trust, or mortgage, and gives written notice thereof to Tenant that this Lease shall be deemed prior to such ground lease, deed of trust, or mortgage, whether this Lease is dated prior or subsequent to the date of such ground lease, deed of trust, or mortgage, then this Lease shall be deemed to be prior to the lien of such ground lease or mortgage and such ground lease, deed of trust, or mortgage shall be deemed to be subordinate to this Lease.
- Estoppel Certificate. Within ten days after written request from Landlord, Tenant shall execute and deliver to Landlord, in recordable form, a certificate ("Estoppel Certificate") stating (i) that this Lease is unmodified and in full force and effect, or in full force and effect as modified, and stating all modifications, (ii) the then-current Basic Monthly Rent, (iii) the dates to which Basic Monthly Rent has been paid in advance, (iv) the amount of any security deposit, prepaid rent or other payment constituting Rent which has been paid, (v) whether or not Tenant or Landlord is in default under this Lease and whether there currently exist any defenses or rights of offset under the Lease in favor of Tenant, (vi) that any work required to be performed by Landlord under this Lease is complete (or stating any exceptions), (vii) that any tenant improvement allowance has been paid (or stating any exceptions), and (viii) such other matters as Landlord may reasonably request. Tenant's failure to deliver such certificate within such ten day period shall be conclusive upon Tenant for the benefit of Landlord, and any successor in interest to Landlord, any lender or proposed lender, and any purchaser or proposed purchaser of the Project that, except as may be represented by Landlord, this Lease is unmodified and in full force and effect, no Rent has been paid more than 30 days in advance, neither Tenant nor Landlord is in default under this Lease, no defenses or rights of offset under the Lease exist in favor of Tenant, and that all Landlord's Work required by this Lease is complete. Landlord will similarly, in connection with any lending or Transfer transaction, upon ten days written request from Tenant, execute an estoppel certificate in favor of Tenant's proposed lender or Transferee confirming (i) that this Lease is unmodified and in full force and effect, or in full force and effect as modified, and stating all modifications, (ii) the then-current Basic Monthly Rent, (iii) the dates to which Basic Monthly Rent has been paid in advance, (iv) the amount of any security deposit, prepaid rent, or other payment constituting Rent which has been paid, and (v) whether or not to

the best of Landlord's knowledge Tenant is in default under this Lease. The requirement for Tenant to execute and deliver to Landlord, the Estoppel Certificate, as required above, shall not be delayed, conditioned, or withheld for any reason; this requirement shall be an independent covenant of Tenant under this Lease. If Tenant fails to execute and deliver to Landlord a requested estoppel certificate within ten days after its receipt of request therefor, then in addition to Landlord's other rights and remedies on account of such default, Tenant shall owe Landlord Additional Rent (which amount shall be payable upon demand) in an amount equal to \$100.00 for each day beyond such ten-day period that it delays in the execution and delivery thereof (as such daily sum may be increased from time-to-time pursuant to the Rules).

- Waiver. No delay or omission in the exercise of any right or remedy of Landlord in the event of any default or Event of Default by Tenant shall impair such right or remedy or be construed as a waiver. The receipt and acceptance by Landlord of delinquent Rent shall not constitute a waiver of any default other than the particular Rent payment accepted. Landlord's receipt and acceptance from Tenant, on any date (the "Receipt Date"), of an amount less than the Rent actually due on such Receipt Date, or to become due at a later date but applicable to a period prior to such Receipt Date, shall not release Tenant of its obligation (i) to pay the full amount of such Rent due on such Receipt Date or (ii) to pay when due the full amount of such Rent to become due at a later date but applicable to a period prior to such Receipt Date. No act or conduct of Landlord, including without limitation, the acceptance of the keys to the Premises, shall constitute an acceptance by Landlord of the surrender of the Premises by Tenant before the Expiration Date. Only a written notice from Landlord to Tenant stating Landlord's election to terminate Tenant's right to possession of the Premises shall constitute acceptance of the surrender of the Premises and accomplish a termination of this Lease. Landlord's consent to or approval of any act by Tenant requiring Landlord's consent or approval shall not be deemed to waive or render unnecessary Landlord's consent to or approval of any other or subsequent act by Tenant. Any waiver by Landlord of any default must be in writing and shall not be a waiver of any other default concerning the same or any other provision of this Lease. Tenant hereby waives any rights granted to Tenant under California Code of Civil Procedure Section 1179, California Civil Code Section 3275, and/or any successor statute(s). Tenant represents and warrants that if Tenant breaches this Lease and, as a result, this Lease is terminated. Tenant will not suffer any undue hardship as a result of such termination and, during the Term, will make such alternative or other contingency plans to provide for its vacation of the Premises and relocation in the event of such termination. Tenant acknowledges that Tenant's waivers set forth in this Paragraph are a material part of the consideration for Landlord's entering into this Lease and that Landlord would not have entered into this Lease in the absence of such waivers.
- 43. <u>Brokers</u>. Tenant represents that no real estate broker, agent, finder, or other person is responsible for bringing about or negotiating this Lease other than the Tenant's broker, if any, listed in the Principal Lease Provisions, and Tenant has not dealt with any other real estate broker, agent, finder, or other person, relative to this Lease in any manner. Tenant shall indemnify, defend, and hold Landlord harmless from and against all liabilities, damages, losses, costs, expenses, attorneys' fees and claims arising from any claims that may be made against Landlord by any real estate broker, agent, finder, or other person (other than as set forth above), alleging to have acted on behalf of or to have dealt with Tenant. Landlord shall be responsible, upon satisfaction of the requirements of a separate written listing agreement between Landlord and Landlord's broker, for the payment of the commission due and owing to Landlord's brokers identified in the Principal Lease Provisions (or any other brokers engaged by Landlord), pursuant to such separate written agreement between Landlord and Landlord's broker. Landlord's broker will in turn split such commission with Tenant's broker as such parties may agree.
- 44. <u>Limitations on Landlord's Liability.</u> If Landlord is in default of this Lease, and as a consequence Tenant recovers a money judgment against Landlord, such judgment shall be satisfied only out of the proceeds of sale received upon execution of such judgment and levy against the right, title, and interest of Landlord in the Project, and out of rent or other income from the Project receivable by Landlord or out of the consideration received by Landlord from the sale or other disposition of all or any part of Landlord's right, title, and interest in the Project. Notwithstanding anything contained in this Lease to the contrary, under no circumstances whatsoever shall Landlord nor any of Landlord's shareholders, members, officers, directors, agents, property managers, employees, contractors, or the partners comprising Landlord (if any) be liable for any incidental, indirect, special, consequential or punitive damages, including, without limitation, lost profits, nor be personally liable for any deficiency.
- 45. <u>Sale or Transfer of Premises</u>. If Landlord sells or transfers the Project (whether voluntarily or involuntarily), Landlord, on consummation of the sale or transfer, shall be released from any liability thereafter accruing under this Lease. If any Security Deposit or prepaid Rent has been paid by Tenant, Landlord may transfer the Security Deposit and/or prepaid Rent to

Landlord's successor-in-interest and on such transfer Landlord shall be discharged from any further liability arising from the Security Deposit or prepaid Rent.

- 46. <u>Quitclaim Deed</u>. Tenant shall execute and deliver to Landlord on the Expiration Date, promptly on Landlord's request, a quitclaim deed to the Premises, in recordable form, designating Landlord as transferee.
- 47. <u>No Merger</u>. The voluntary or other surrender of this Lease by Tenant, or a mutual cancellation of this Lease, or a termination by Landlord, shall not work a merger, and shall, at the option of Landlord, terminate any existing subleases or may, at the option of Landlord, operate as an assignment to Landlord of any such subleases.
- 48. <u>Confidentiality.</u> Except as essential to the consummation of the transaction contemplated by this Lease (together with all amendments and addenda hereto):
- 48.1. Tenant shall keep and maintain the terms of this Lease and the transactions contemplated by this Lease or any aspect of this Lease in strict confidence; and
- 48.2. Except as required by regulation, rule, or law, Tenant may not make or allow any notices, statements, disclosures, communication, or news releases concerning this Lease, the terms of this Lease and the transactions contemplated by this Lease or any aspect of this Lease.
- 48.3. Nothing provided herein, however, shall prevent Tenant from disclosing to its legal counsel and/or certified public accountants, prospective purchasers, or any lenders or prospective lenders the existence and terms of this Lease or any transaction under this Lease, or any aspect of this lease, or from complying with any governmental or court order or similar legal requirement which requires such party to disclose this Lease, the terms of this Lease, the transaction contemplated by this Lease and/or any aspect of this Lease; provided that such party uses reasonable and diligent good faith efforts to disclose no more than is absolutely required to be disclosed by such legal requirement. If Tenant violates this confidentiality provision, in addition to all other remedies to which Landlord may be entitled under law or in equity, Landlord shall be entitled to receive immediately the entire value of any rent relief, rent abatement, free rent, reimbursement, or other concession which Landlord has previously granted to Tenant.
- 48.4. <u>Disclosure.</u> Notwithstanding anything contained herein to the contrary, Landlord shall be entitled to disclose the terms of this Lease in connection with public filings and/or presentations of its parent and/or affiliates.

# 49. <u>Miscellaneous</u>.

- 49.1. This Lease may be executed in any number of counterparts, each of which shall be deemed an original for all purposes, and all counterparts shall constitute one and the same instrument. Notwithstanding anything contained in this Lease to the contrary, Landlord and Tenant agree that the electronic signature of each party to this Lease shall be as valid as an original signature of such party and shall be effective to bind such party to this Lease. The parties agree that any electronically signed document (including this Lease) shall be deemed (a) to be "written" or "in writing," (b) to have been signed and (c) to constitute a record established and maintained in the ordinary course of business and an original written record when printed from electronic files. Such paper copies or "printouts," if introduced as evidence in any judicial, arbitral, mediation or administrative proceeding, will be admissible as between the parties to the same extent and under the same conditions as other original business records created and maintained in documentary form. Neither Landlord nor Tenant shall contest the admissibility of true and accurate copies of electronically signed documents on the basis of the best evidence rule or as not satisfying the business records exception to the hearsay rule. For purposes hereof, "electronic signature" means a manually signed original signature that is then transmitted by electronic means; "transmitted by electronic means" means sent in the form of a facsimile or sent via the internet as a "pdf" (portable document format) or other replicating image attached to an e-mail message; and, "electronically signed document" means a document transmitted by electronic means and containing, or to which there is affixed, an electronic signature.
- 49.2. Within ten days of written request, Tenant shall promptly furnish to Landlord, from time to time, publically available financial statements certified by Tenant to be true and correct, reflecting Tenant's then current financial condition. Such publically available financial statements shall include a current balance sheet and a profit and loss statement covering the most recent 12-month period available. In addition, upon Landlord's written request, Tenant shall allow Landlord, or a certified public accountant of Landlord's choosing, to determine Tenant's current financial condition by reviewing Tenant's current publically available financial books,

records, and accounts. Landlord will hold said information confidential, except as may be required by any court or authority of competent jurisdiction or which information is already in the public domain, or except for the disclosure of such information to any Landlord Parties' prospective buyers and lenders or the advisers and professionals of any Landlord Affiliate or such prospective buyers and lenders. The individuals executing this Lease on Tenant's behalf represent and warrant that the publically available financial statements and other information submitted to Landlord by Tenant relating to Tenant or any guarantor of this Lease prior to the execution hereof are true, complete, and accurate, were prepared in accordance with generally accepted cash accounting principles applied on a consistent basis, and accurately reflect Tenant's (and, if applicable, each guarantor's) net worth as of the effective date of this Lease.

- 49.3. Notwithstanding any other provision in this Lease to the contrary, Tenant shall refrain from selling or otherwise distributing any alcoholic beverages and such sales are expressly forbidden under this Lease notwithstanding the fact that Tenant may hold the appropriate license as issued and/or approved by the California Alcoholic Beverage Control Agency.
- 49.4. This Lease shall be governed by and construed in accordance with the laws of the state in which the Premises are located. If the Premises are located outside of California, then the references in this Lease to California statutes shall be deemed to include any relevant statute of the jurisdiction in which the Premises are located that is comparable to such California statutes.
- 49.5. For purposes of venue and jurisdiction, this Lease shall be deemed made and to be performed in the City of San Diego, California (whether or not the Premises are located in San Diego, California) and Landlord and Tenant hereby consent to the jurisdiction of the Courts of the County of San Diego.
- 49.6. Tenant covenants and agrees not to protest or in any way oppose any application for a license to serve or sell liquor filed by tenants or other users of space within the Project.
- 49.7. Whenever the context so requires, all words used in the singular shall be construed to have been used in the plural (and vice versa), each gender shall be construed to include any other genders, and the word "person" shall be construed to include a natural person, a corporation, a firm, a partnership, a joint venture, a limited liability company, a trust, an estate or any other entity.
- 49.8. Each provision of this Lease shall be valid and enforceable to the fullest extent permitted by law. If any provision of this Lease or the application of such provision to any person or circumstance shall, to any extent, be invalid or unenforceable, the remainder of this Lease, or the application of such provision to persons or circumstances other than those as to which it is held invalid or unenforceable, shall not be affected by such invalidity or unenforceability, unless such provision or such application of such provision is essential to this Lease.
- 49.9. In the event any litigation, arbitration, mediation, or other proceeding ("Proceeding") is initiated by any party against any other party to enforce, interpret or otherwise obtain judicial or quasi-judicial relief in connection with this Lease the prevailing party in such Proceeding shall be entitled to recover from the unsuccessful party all costs, expenses, and reasonable attorney's fees and expert witness fees relating to or arising out of such Proceeding (whether or not such Proceeding proceeds to judgment), and any post-judgment or post-award proceeding including without limitation one to enforce any judgment or award resulting from any such Proceeding. Any such judgment or award shall contain a specific provision for the recovery of all such subsequently incurred costs, expenses, and actual attorney's fees and expert witness fees.
- 49.10. This Lease shall become effective and binding upon the parties when it has been executed by each of Landlord and Tenant; notwithstanding the fact that the Term of this Lease (i.e. Tenant's rights of full occupancy hereunder) will not commence until the Lease Commencement Date.
- 49.11. Subject to any restriction on transferability contained in this Lease, this Lease shall be binding upon and shall inure to the benefit of the successors-in-interest and assigns of each party to this Lease. Nothing in this Paragraph shall create any rights enforceable by any person not a party to this Lease, except for the rights of the successors-in-interest and assigns of each party to this Lease, unless such rights are expressly granted in this Lease to other specifically identified persons.

- 49.12. The headings of the Paragraphs of this Lease have been included only for convenience, and shall not be deemed in any manner to modify or limit any of the provisions of this Lease, or be used in any manner in the interpretation of this Lease.
- 49.13. Time and strict and punctual performance are of the essence with respect to each provision of this Lease. All references to "days" in this Lease will refer to calendar days, unless such reference specifically indicates that "business days" are intended. Business days will mean and refer to all calendar days other than Saturdays, Sundays, and national or California state holidays.
- 49.14. Each party to this Lease and its legal counsel has had an opportunity to review and revise this Lease. The rule of construction that any ambiguities are to be resolved against the drafting party shall not be employed in the interpretation of this Lease or any Addendum or Exhibit to this Lease, and such rule of construction is hereby waived by Tenant.
- All notices required or permitted to be given by Tenant to Landlord shall be in writing and shall be 49.15. personally delivered, sent by certified mail, postage prepaid, return receipt requested, or sent by a nationally or locally recognized overnight express courier service that provides written confirmation of delivery to Landlord at the address set forth in the Principal Lease Provisions of this Lease. Each such notice or other communication shall be deemed given, delivered and received upon its actual receipt, except that if it is sent by mail in accordance with this Paragraph, then it shall be deemed given, delivered and received three days after the date such notice or other communication is deposited with the United States Postal Service in accordance with this Paragraph, and if it is sent by nationally recognized overnight express courier service, it shall be deemed given one business day after deposit with the courier. Landlord or Tenant must give a notice of a change of its address to the other, if such address changes. All notices required or permitted to be given to Tenant by Landlord shall Landlord shall, except as otherwise provided in this Lease, be in writing, and such notice shall be personally delivered, sent by certified mail, postage prepaid, return receipt requested, or sent by a nationally recognized overnight express courier service that provides written confirmation of delivery, to Tenant at the address set forth in the Principal Lease Provisions of this Lease. Each such notice or other communication shall be deemed given, delivered and received upon its actual receipt, except that if it is sent by mail in accordance with this Paragraph, then it shall be deemed given, delivered and received three days after the date such notice or other communication is deposited with the United States Postal Service in accordance with this Paragraph. Notwithstanding the foregoing, routine correspondence between Landlord and Tenant shall be deliverable by regular U.S. mail, by fax, or by other such means of delivery as may become customary.
- 49.16. If more than one person is Tenant, then the obligations of Tenant under this Lease shall be the joint and several obligations of each of such persons; provided, however, that any act or signature of one or more of any of such persons and any notice or refund given to or served on any one of such persons shall be fully binding on each of such persons.
- 49.17. All provisions, whether covenants or conditions, to be performed or observed by Tenant shall be deemed to be both covenants and conditions. All indemnity, defense, and hold harmless obligations of Tenant hereunder shall survive the termination of this Lease.
- 49.18. Upon Landlord's request, Tenant shall provide Landlord with a statement reflecting the dollar amount of all sales and business transacted at or through the Premises, for an interval period to be determined by Landlord, but in no event more frequently than once every six months. Tenant shall provide such information within 30 days of Landlord's request. Landlord shall be entitled to use such information as it deems appropriate, including providing such information to prospective lenders and purchasers.
  - 49.19. All payments to be made by Tenant to Landlord under this Lease shall be in United States currency.
- 49.20. Any claim, demand, rights, or defense by Tenant that arises out of this Lease or the negotiations that preceded this Lease shall be barred unless Tenant commences an action thereon, or interposes a defense by reason thereof, within 12 months after the date of the inaction, omission, event, or action that gave rise to such claim, demand, right, or defense. Tenant acknowledges and understands, after having consulted with its legal counsel, that the purpose of this Paragraph is to shorten the period within which Tenant would otherwise have to raise such claims, demands, rights, or defenses under applicable laws.
- 49.21. This Lease, the Exhibits and Addenda, if any, attached hereto (which are incorporated herein by this reference), constitute all of the covenants, promises, assurances,

representations, warranties, statements, agreements, conditions and understandings between Landlord and Tenant concerning the Premises and the Project, and there are no other covenants, promises, assurances, representations, warranties, statements, conditions, or understandings, either oral or written, between them. Except as herein otherwise provided, no subsequent alteration, change, modification, or addition to this Lease shall be binding upon Landlord or Tenant unless reduced to writing and signed by each of them. Notwithstanding the foregoing, the Landlord may, from time to time, establish and amend such Rules, regulations, and signage criteria, in a written form, for the benefit of the Project and Building, as it deems appropriate. Violations of such Rules, regulations, and signage criteria by Tenant or Tenant's Invitees shall constitute a material default of this Lease.

- 49.22. This Lease, upon full execution, supersedes and revokes any and all previous leases governing the Premises, lease negotiations, arrangements, letters of intents, offers to lease, lease proposals or drafts, brochures, representations, and information conveyed, whether oral or written, between parties hereto or their respective representations or any other person purported to represent Landlord or Tenant. The Tenant acknowledges it has not been induced to enter into this Lease by any representations not set forth in the Leases, nor has it relied on any such representations. No such representations should be used in the interpretation or construction of this Lease and the Landlord shall have no liability for any consequences arising as a result of any such representations.
- 49.23. LANDLORD AND TENANT WAIVE THEIR RESPECTIVE RIGHTS TO TRIAL BY JURY OF ANY CONTRACT OR TORT CLAIM, COUNTERCLAIM, CROSS COMPLAINT, OR CAUSE OF ACTION IN ANY ACTION, PROCEEDING, OR HEARING BROUGHT BY EITHER PARTY AGAINST THE OTHER ON ANY MATTER ARISING OUT OF OR IN ANY WAY CONNECTED WITH THIS LEASE, THE RELATIONSHIP OF LANDLORD AND TENANT, OR TENANT'S USE OR OCCUPANCY OF THE PREMISES, INCLUDING ANY CLAIM OF INJURY OR DAMAGE OR THE ENFORCEMENT OF ANY REMEDY UNDER ANY CURRENT OR FUTURE LAW, STATUTE, REGULATION, CODE, OR ORDINANCE.

# LANDLORD'S INITIALS

# **TENANT'S INITIALS**

- 49.24. Landlord and Tenant share a commitment to operating the Project, Premises and the Building in a sustainable, environmentally-friendly manner, so as to reduce energy consumption, nonrecycled wastes, and their collective carbon footprints. Landlord and Tenant agree to the following terms and conditions in order to pursue these goals:
- 49.24.1. <u>Sustainability Practices</u>. For the purposes of this Lease, the term "Sustainability Practices" shall mean Landlord's sustainability practices, programs, rules, and goals for the Project and/or the Building, as such practices, programs, rules, and goals may be adopted, modified, or amended from time to time.
- 49.24.2. <u>Sustainable Building Operations</u>. Tenant shall, at its sole cost and expense, comply with the requirements of the Sustainability Practices. Upon reasonable request from Tenant, Landlord shall promptly provide Tenant with a copy of Landlord's then current Sustainability Practices, if any.
- 49.24.3. <u>Permitted Use</u>. Tenant shall not use or operate the Premises in any manner that will cause the Project, the Building or any part thereof to fail to comply with the Sustainability Practices or with the requirements of any third-party sustainability certification or rating for the Building.
- 49.24.4. <u>Recycling and Waste Management</u>. Tenant shall, at its sole cost and expense: (a) comply with Landlord's recycling policy or program; (b) sort and separate its trash and recycling into such categories as required by Landlord; and (c) place sorted trash and recycling into receptacles as directed by Landlord.
- 49.24.5. <u>Maintenance and Repairs</u>. All maintenance and repairs performed by Tenant must comply with the Sustainability Practices.

- 49.24.6. <u>Alterations</u>. All Alterations performed by Tenant must comply with the Sustainability Practices. Such Sustainability Practices include, without limitation, the use of low or no-VOC paints, solvents, and adhesives.
- 49.24.7. Removal at End of Lease Term. To the extent any equipment, furnishings, improvements, or other items required to be removed from the Premises by Tenant at the end of the term or any earlier termination of the Lease are to be recycled or disposed of, Tenant shall conduct such recycling or disposal in an environmentally sustainable manner and in accordance with applicable Laws and the Sustainability Practices. Tenant shall pay all costs, expenses, fines, penalties, and damages that may be imposed on Landlord, the Project, the Building or Tenant by reason of Tenant's failure to comply with the provisions of this Section. The obligation of Tenant in the preceding sentence shall survive the expiration or earlier termination of the Lease.
- 49.24.8. <u>Energy Providers</u>. Landlord reserves the right to change electricity providers at any time and to purchase green or renewable energy for the Building.
- 49.24.9. <u>Electricity Consumption</u>. If Tenant is permitted or required pursuant to this Lease to contract directly with an electricity provider, Tenant shall pay all costs for separate electricity metering and shall submit to Landlord electricity consumption data in a format reasonably required by Landlord.
- 49.24.10. <u>LEED Requirements</u>. Tenant shall comply with such practices as Landlord deems appropriate in order for the Building or the Project to obtain or continue to comply with LEED certification requirements.
- 49.24.11. <u>Reporting Requirements</u>. Tenant shall provide information and data as reasonably requested by Landlord regarding Tenant's use and occupancy of the Premises as necessary to allow Landlord to comply with reporting requirements imposed by applicable Laws, to apply for or maintain certifications or ratings for the Project, the Building, or to apply for fee waivers related to green or sustainable improvements.
- 49.24.12. <u>Tenant Improvements</u>. In addition to the costs described in the Work Letter, the costs of Tenant's improvements shall include all reasonable costs associated with the Sustainability Practices, including any related documentation, registration, and certification. Tenant shall cause all contractors engaged by Tenant to comply with Landlord's rules and regulations for the Project or the Building, including without limitation, the Sustainability Practices.
- 49.24.13. <u>Energy Management</u>. Tenant agrees to use reasonable efforts to operate the Building's mechanical, electrical, and plumbing systems efficiently so as to reduce water and energy usage and minimize waste and carbon emissions to the fullest extent possible. All electrical equipment or appliances installed by Tenant in the Premises must conform to the Building's standards for energy management and connect to Building controls and monitoring systems, if any.
- 49.24.14. <u>Sustainability Reporting Requirements</u>. If required by law, Tenant shall provide and deliver sustainability consumption information and data (collectively, "<u>Sustainability Information</u>") as reasonably requested by Landlord which shall include, without limitation, documentation relating to Tenant's specific use and occupancy of the Premises in regard to sustainability objectives. Additionally, Tenant authorizes Landlord to request Tenant's Sustainability Information from third parties including utility companies or vendors, as Landlord deems reasonably appropriate. Requested Sustainability Information may include, but shall not be limited to: (a) energy consumption (including electrical, gas and other) using EnergyStar energy performance rating or other agreed upon system, (b) estimate of carbon and other greenhouse gas emissions, (c) water consumption, (d) waste generated, and (e) environmental characteristics (shading, bikes, etc.). Landlord shall be entitled to utilize such Sustainability Information as it deems reasonably necessary, including, without limitation, for the following purposes: (a) monitoring and improving utility usage, (b) benchmarking the Project or the Building against any sustainable targets, (c) confirming the compliance of its sustainability practices, (d)

maintaining, submitting or obtaining certifications or rating for the Project or the Building, or (e) applying for fee waivers, credits and/or rebates related to green or sustainable improvements.

- 49.25. <u>Anti-Money Laundering/OFAC Requirements</u>. Tenant represents and warrants as follows, with the understanding that the Landlord will rely on the accuracy of these representations and warranties to establish the Landlord's compliance with the laws enforced by the United States Department of Treasury's Office of Foreign Assets Control ("OFAC"), and any other applicable laws, rules, regulations and other legal requirements relating to the combating of money laundering and/or terrorism (i.e., Patriot Act).
- 49.25.1. If Tenant is an entity (e.g., a corporation, partnership, limited liability company, trust), (i) Tenant has exercised due diligence to establish the identity of each person who possesses the power, directly or indirectly, to direct or cause the direction of Tenant's management and policies; (ii) if ownership interests in Tenant are not publicly traded on an exchange or an organized over-the-counter market that is regulated by any foreign government, or any governmental body or regulatory organization empowered by a foreign government to administer or enforce its laws as they relate to securities matters, Tenant has exercised due diligence to establish the identity of each person who holds, directly or indirectly, a beneficial interest in Tenant; and (iii) if Tenant is a financial intermediary (e.g., a bank, brokerage firm, depository), Tenant has exercised due diligence to establish the identity of each of its account holders (each of the foregoing persons listed in this Paragraph being an "Affiliated Person"). Tenant (x) maintains records of all documents it uses to verify the identities of its Affiliated Persons; (y) will maintain all such records for a period of at least five (5) years after the expiration of the Lease; and (z) will make such documentation available to the Landlord at any time upon request.
- 49.25.2. Tenant is not a "Prohibited Person" (as defined below), none of its Affiliated Persons is a Prohibited Person, and Tenant is not acquiring, and does not intend to enter into this Lease for the direct or indirect benefit of any Prohibited Person. Tenant acknowledges and agrees that if, at any time, the Landlord determines that Tenant is or may be a Prohibited Person, or that any Prohibited Person holds or may hold a direct or indirect interest in Tenant, the Landlord may, in its sole discretion, terminate the Lease.
- 49.25.3. For purposes of the foregoing representations and warranties, "Prohibited Person" means any person or entity that acts or has acted (i) in contravention of any statute, rule, regulation or other legal requirement to which that person is subject relating to the combating of terrorism and/or money laundering, or (ii) on behalf of any person or organization (A) residing or having a place of business in a country or territory subject to embargo under laws enforced by OFAC, or (B) identified as a terrorist, terrorist organization, specially designated national or blocked person by OFAC, any other department, agency, division, board, bureau or other instrumentality of the United States Government, or any recognized international organization, multilateral expert group or governmental or industry publication. OFAC's lists of specially designated nationals, blocked persons and embargoed countries and territories can be found at <a href="https://www.treas.gov/ofac">www.treas.gov/ofac</a>,
- 49.25.4. Tenant acknowledges and agrees that, any provision of this Lease to the contrary notwithstanding, the Landlord may release confidential information regarding Tenant to law enforcement authorities and/or regulators if the Landlord determines, in the Landlord's sole discretion, that it is in the best interests of the Landlord to do so in light of the Landlord's obligations and/or potential liability under any applicable statute, rule, regulation or other legal requirement relating to the combating of terrorism and/or money laundering.
- 49.25.5. Tenant acknowledges and agrees that the foregoing representations and warranties are subject to Tenant's indemnification obligations under this Lease.
- 49.25.6. If Tenant becomes aware of any fact or circumstance that may render any of the foregoing representations and warranties inaccurate in any respect, Tenant will immediately notify the Landlord.
- 50. <u>Electronic Signatures</u>. Landlord and Tenant consent to the use of electronic signatures on this Lease and all documents relating to this Lease (including, without limitation, this Lease, the Guaranty (if any), the Work Letter, and any amendments to any of the foregoing (collectively, together with the Lease, the "<u>Lease Documents</u>")). Landlord and Tenant agree that any electronic signatures appearing on the Lease Documents are the same as handwritten signatures for the purposes of validity, enforceability and admissibility, and that any electronically signed Lease Document shall, for all purposes of the Lease Documents and applicable law, be deemed to be "written" or "in writing," to have been executed, and to constitute an original written

record when printed, and shall be fully admissible in any legal proceeding. For purposes hereof, "electronic signature" shall have the meaning set forth in the Uniform Electronic Transactions Act, as the same may be amended from time to time.

# [Signature page to follow]

LANDLORD: TENANT:

SB CORPORATE CENTRE III-IV, LLC, a Delaware limited EVOKE PHARMA, INC., a Delaware liability company corporation

By:American Assets Trust Management, LLC, a Delaware limited liability

LLC, a Delaware limited liability By:/s/ David A. Gonyer company, as Agent

Name:David A. Gonyer

By: /s/ James R. Durfey James R. Durfey

urfey
V.P. of Office Properties
Dated: December 19, 2016

Title:President & CEO

By: /s/ Chris Sullivan Chris Sullivan

V.P. of Retail Properties

Dated: December 19, 2016

# ADDENDUM NO. 1 TO STANDARD OFFICE LEASE

This Addendum to Lease ("Addendum") constitutes part of the Office Lease Agreement ("Lease") dated as of December 19, 2016, between SB CORPORATE CENTRE III-IV, LLC, a Delaware limited liability company ("Landlord"), and EVOKE PHARMA, INC., a Delaware corporation ("Tenant"). The terms of this Addendum are incorporated in the Lease for all purposes. All capitalized terms not otherwise defined in this Addendum are defined by the terms of the Lease.

# 1. BASIC MONTHLY RENT

Basic Monthly Rent during the Lease Term shall be as follows:

Lease Period	Approximate Basic Monthly Rent Per Rentable Square Foot	Actual Basic Monthly Rent for the Premises
1/1/2017 – 12/31/2017	\$3.70	\$11,214.70
1/1/2018 – 12/31/2018	\$3.81	\$11,551.14

In addition, Tenant shall pay for all individually and separately metered utilities.

# 2. CONDITION OF THE PREMISES

Tenant acknowledge that Tenant shall accept and occupy the Premises in its currently existing "as-is" condition pursuant to the terms of this Lease. Tenant acknowledges and agrees that Landlord has no obligation to improve the Premises, other than as may be set forth specifically in the Lease. In particular, Tenant acknowledges that any improvements or alterations needed to accommodate Tenant's intended use shall be made solely at Tenant's sole cost and expense, and strictly in accordance with the requirements of this Lease (including the requirement to obtain Landlord's consent thereto), unless such improvements and alterations are specifically required of Landlord and expressly set forth in this Lease and in Exhibit "C". Should tenant improvements be made to the Premises in the future, the Premises shall be constructed in accordance with the procedures outlined in Exhibit "C" of this Lease. Landlord shall have no responsibility to do any work required under any building codes or other governmental requirements not in effect or applicable on the Lease Commencement Date, including without limitation any requirements related to sprinkler retrofitting, seismic structural requirements, accommodation of disabled persons, or hazardous materials.

# 3. <u>UTILITIES</u>

Notwithstanding the terms of Paragraph 9 of the Lease, the Premises are separately metered for electricity. Tenant shall make all arrangements for the establishment of an account or accounts with the appropriate utility provider(s), and Tenant shall make all payments with respect thereto for use of said utilities within the Premises during the term of the Lease, including any periods of early occupancy or holdover thereof. In the event the Premises are sub-metered and direct payment to the utility is impractical, Tenant shall reimburse Landlord or Landlord's designee directly for all such costs, fees, and consumption charges arising from said sub-meter.

# 4. <u>ELECTRONIC SIGNATURES</u>

The parties hereto agree that this Addendum may be electronically signed, and that any electronic signature appearing on this Addendum is the same as a handwritten signature for the purposes of validity, enforceability and admissibility. The provisions of Section 50 of the Lease shall apply to any electronic signature on this Addendum.

[Signature page to follow]

Unless modified by this Addendum, each term of the Lease remains unamended and in full force. The parties have executed this Addendum as of the date of the Lease.

LANDLORD: TENANT:

SB CORPORATE CENTRE III-IV, LLC, a Delaware limited EVOKE PHARMA, INC., a Delaware liability company corporation

By:American Assets Trust Management, LLC, a Delaware limited liability company, as Agent

Name:David A. Gonyer

By:/s/ David A. Gonyer

By: /s/ James R. Durfey James R. Durfey

Title:President & CEO

V.P. of Office Properties

Dated: December 19, 2016

By: /s/ Chris Sullivan Chris Sullivan

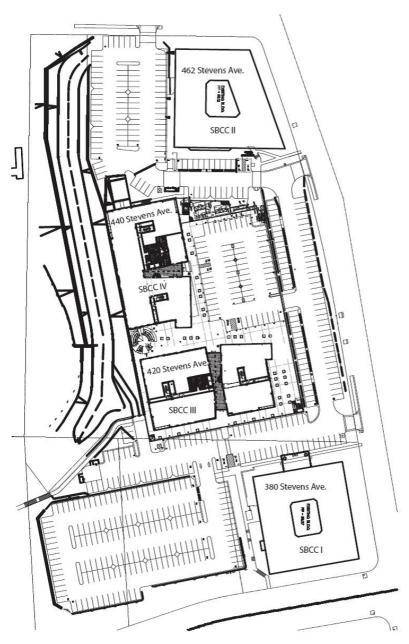
V.P. of Retail Properties

Dated: December 19, 2016

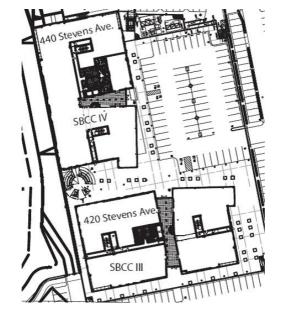
# **EXHIBIT "A"**

# **Project Site Plan**

This Exhibit "A" is intended to show the approximate configuration of the Project and the Building as of the Commencement Date and is not a representation or warranty by Landlord as to the size, nature or exact configuration of the Project or Building.



"Building"



# 275653555118000

☑ SBCC III – 420 Stevens Avenue

☐ SBCC IV – 440 Stevens Avenue

# EXHIBIT "B" FLOOR PLANS OF PREMISES



# EXHIBIT "C"

# **WORK LETTER**

Tenant shall accept the Premises in its existing "as-is" "where-is" condition, and Landlord shall not be obligated to provide or pay for any improvement work or services related to the improvement of the Premises. Tenant also acknowledges that neither Landlord nor any agent of Landlord has made any representation or warranty regarding the condition of the Premises or with respect to the suitability of the Premises for the conduct of Tenant's business.

### **EXHIBIT "D"**

# **BUILDING RULES AND REGULATIONS**

Tenant shall comply with the following Rules and Regulations. Landlord shall not be responsible to Tenant for the nonperformance of any of these rules and Regulations.

- 1. <u>Locks; Keys.</u> Tenant shall not alter any lock or install any new or additional locks or bolts on any doors or windows of the Premises without obtaining Landlord's prior written consent. Tenant shall bear the cost of any lock changes or repairs required by Tenant. Landlord for the Premises shall furnish two keys, and any additional keys required by Tenant must be obtained from Landlord at a reasonable cost to be established by Landlord.
- 2. <u>Doors Opening to Public Corridors.</u> All doors opening to public corridors must be kept closed at all times except for normal ingress to and egress from the Premises.
- 3. Securing Doors; Admission to Building. Landlord reserves the right to close and keep locked all entrance and exit doors of the Building during the hours when Comparable Building are customarily closed and locked. When departing after the Building's normal Business Hours, Tenant and Tenant's employees and agents must be sure that the doors to the Building are securely closed and locked. Any person, including Tenant and Tenant's employees and agents, who enters or leaves the Building at any time when it is locked or at any time considered to be after the Building's normal Business Hours, may be required to sign the Building register. Access to the Building may be refused unless the person seeking access has proper identification or has previously arranged a pass for access to the Building. Landlord and its agents shall not be liable for damages for any error concerning the admission to, or exclusion from, the Building of any person. Landlord reserves the right, in the event of invasion, mob, riot, public excitement, or any other commotion, to prevent access to the Building or Project during the continuance of that event by any means it considers appropriate for the safety and protection of life and property.
- 4. <u>Furniture, Freight, and Equipment; Service Deliveries</u>. No furniture, freight, or equipment of any kind may be brought into the Building without prior notice to Landlord. All moving activity into or out of the Building must be scheduled with Landlord and done only at a time and in the manner designated by Landlord. No service deliveries (other than Messenger services) shall be allowed between the hours of 4:00 PM and 6:00 PM, Monday through Friday. Landlord may at any time restrict the elevators and areas of the Building into which messengers may enter and may require that Tenant leave deliveries at the lobby security desk for pickup. Landlord may prescribe the weight, size, and position of all safes and other heavy property brought into the Building and the times and manner of moving those items within and out of the Building. Tenant shall not overload the floor of the Premises. If considered necessary by Landlord, safes and other heavy objects must stand on supports that are adequate to distribute the weight properly. Landlord shall not be responsible for loss of or damage to any safe or property. Any damage to any part of the Building or to its contents, occupants, or visitors caused by moving or maintaining any safe or other property referred to in this clause shall be the sole responsibility and expense of Tenant.
- 5. <u>Receipt of Deliveries; Use of Elevators.</u> No furniture, packages, supplies, equipment, or merchandise may be received in the Building or carried up or down the elevators, except between those hours and in that specific elevator that Landlord shall designate.
- 6. <u>No Disturbance of Other Occupants.</u> Tenant shall not disturb, solicit, or canvass any occupant of the Project and shall cooperate with Landlord and Landlord's agents to prevent these actions.
- 7. <u>Use of Restrooms; Responsibility for Damage.</u> The restrooms, urinals, wash bowls, and other apparatus shall not be used for any other purpose other than that for which they were constructed, and no foreign substance of any kind shall be thrown into them. The expense of any breakage, stoppage, or damage resulting from the violation of this rule shall be borne by the tenant who caused, or whose employees or agents caused, the breakage, stoppage, or damage.

- 8. <u>Heating and Air-Conditioning.</u> Tenant shall not use any method of heating or air-conditioning, other than that supplied by Landlord, without Landlord's prior written consent.
- 9. <u>Foul or Noxious Gases or Substances; Noninterference With Others</u>. Tenant shall not use or keep, or allow to be used or kept, any foul or noxious gas or substance in or on the Premises. Tenant shall not allow the Premises to be occupied or used in a manner causing noise, odors, or vibrations that are offensive or objectionable to Landlord or other occupants of Project.
- 10. <u>Animals, Birds, and Vehicles</u>. Tenant shall not bring into, or keep within, the Premise, Building or Project any animals, birds, or vehicles (e.g., bicycles).
- 11. <u>Cooking; No use of the Premises for Improper Purposes</u>. No cooking shall be done or permitted on the Premises, except that Underwriter's Laboratory (UL)-approved equipment and microwave ovens may be used in the Premises for heating food and brewing coffee, tea, hot chocolate, and similar beverages for employees and visitors. This must be in accordance with all applicable federal, state, and city laws, codes, ordinances, rules, and regulations.
- 12. <u>Telephone and Other Wires</u>. Tenant may not introduce telephone wires or other wires into the Premises without first obtaining Landlord's approval of the method and location of such introduction. No boring or cutting for telephone wires or other wires shall be allowed without Landlord's consent. The location of telephones, call boxes, and other office equipment affixed to the Premises shall be subject to Landlord's approval.
- 13. <u>Exclusion or Expulsion</u>. Landlord reserves the right to exclude or expel from the Project any person who, in Landlord's judgment, is under the influence of alcohol or drugs or commits and act in violation of theses Rules and Regulations.
- 14. <u>Loitering Prohibited</u>. Tenant and Tenant's employees and agents shall not loiter in or on the entrances, corridors, sidewalks, lobbies, halls, stairways, elevators, or common areas for the purpose of smoking tobacco products or for any other purpose. Tenant and Tenant's employees and agents shall not obstruct these areas but use them only as a means of ingress to and egress from the Premises.
- 15. Operation of Electricity, Water, and Air Conditioning. Tenant shall not waste electricity, water, or air-conditioning and shall cooperate fully with Landlord to ensure the most effective operation of the Building's heating and air-conditioning system. Tenant shall not adjust any controls of that heating and air-conditioning system.
- 16. <u>Disposal of Trash and Garbage</u>. Tenant shall store all trash and garbage within the interior of the Premises. Tenant shall not place or have placed in the trash boxes or receptacles any material that may not or cannot be disposed of in the ordinary and customary manner of removing and disposing of trash in the vicinity of the Building. In disposing of trash and garbage, Tenant shall comply fully with any law or ordinance governing that disposal. All trash, garbage, and refuse disposal shall be made only through entry-ways and elevators provided for that purpose and shall be made only at times designated by Landlord.
- 17. <u>Compliance With Safety Regulations</u>. Tenant shall comply with all safety, fire protection and evacuation procedures and regulations established by Landlord or by any government agency and participate in practice drills scheduled from time to time by Landlord.
- 18. <u>Protection of Premises</u>. Tenant shall assume all responsibility, including keeping doors locked and other means of entry to the Premises closed, for protecting the Premises from theft, robbery, and pilferage.
- 19. Awnings, Curtains, and Electrical Ceiling Fixtures. No awnings or other projection shall be attached to the outside walls of the Building without Landlord's prior written consent. No curtains, blinds, shades, or screens, shall be attached to, hung in, or used in connection with any window or door of the Premises without Landlord's prior written consent. All electrical ceiling fixtures hung in offices or spaces along the perimeter of the Building must be fluorescent or of a quality, type, design, and bulb color approved by Landlord. Tenant shall abide by Landlord's regulations concerning the opening and closing of window coverings attached to those windows, if any, in the Premises that have a view of any interior portion of the Building or Building Common Area.

- 20. <u>Non-obstruction of Light</u>. Tenant shall not cover or obstruct the sashes, sash doors, skylights, windows, and doors that reflect or admit light and air into halls, passageways, or other public places in the Building. Tenant shall not place any bottles, parcels, or other articles on the windowsills.
- 21. <u>Provision of Information to Tenant's Employees</u>. Tenant shall comply with requests by Landlord that Tenant informs Tenant's employees of items of importance to Landlord.
- 22. <u>Hand Trucks and Similar Equipment.</u> Without Landlord's prior consent, Tenant shall not use, in any space or in the public halls of the Building, any hand trucks unless they are equipped with rubber tires and side guards or similar equipment. Tenant shall not bring any other vehicles of any kind into the Building.
- 23. <u>Use of Building's Name or Likeness</u>. Without Landlord's prior written consent, Tenant shall not use the Building's name or any photograph or other likeness of the Building in connection with, or in promoting or advertising, Tenant's business, except that Tenant may include the Building's name in the Tenant's address.
- 24. <u>Parking Rules and Regulations.</u> Without Landlord's prior written consent, no automobile detailing or washing shall be permitted in the parking areas of the Building or Project.
- 25. <u>Rules Changes; Waivers</u>. Landlord reserves the right at any time to change or rescind any one or more of these Rules and Regulations or to make any additional reasonable Rules and Regulations that, in Landlord's judgment, may be necessary for: (a) The management, safety, care, and cleanliness of the Premises, Building, and Project; (b) The preservation of good order, and (c) The convenience of other occupants and tenants in the Premises, Building, and Project.
- 26. <u>Flammables</u>. Tenant shall not have any open flames in the Premises, Building or Project at any time whatsoever, including, but not limited to, lit candles, lighters, matches or as it relates to cooking. No inflammable, explosive or dangerous fluids or substances shall be used or kept by Tenant in the Premises, Building or about the Property, except for those substances as are typically found in similar premises used for general office purposes and are being used by Tenant in a safe manner and in accordance with all applicable Laws. Tenant shall install and maintain, at Tenant's sole cost and expense, an adequate, visibly marked (at all times properly operational) fire extinguisher next to any duplication or photocopying machine or similar heat producing equipment (which may or may not contain combustible material) in the Premises. Tenant shall install in the Premises as many other fire extinguishers in such locations as required by City code. Tenant shall not, without Landlord's prior written consent, use, store, install, spill, remove, release or dispose of, within or about the Premises or any other portion of the Property, any asbestos-containing materials or any solid, liquid or gaseous material now or subsequently considered toxic or hazardous under the provisions of 42 U.S.C. Section 9601 et seq. or any other applicable environmental Law which may now or later be in effect. Tenant shall comply with all Laws pertaining to and governing the use of these materials by Tenant and shall remain solely liable for the costs of abatement and removal.
- 27. Tenant and Tenant's Invitees shall not engage in any personal training or group fitness training in the Building's gym facilities or at any other location within the Project, without the prior written approval of Landlord in its sole discretion.

Landlord may waive any one or more of these Rules and Regulations for the benefit of any particular tenants. No waiver by Landlord shall be constructed as a waiver of those Rules and Regulations in favor of any other tenant, and no waiver shall prevent Landlord from enforcing those Rules and Regulations against any other tenant of the Project. Tenant shall be considered to have read these Rules and Regulations and to have agreed to abide by them as a condition of Tenant's occupancy of the Premises.

### AMENDMENT TO AMENDED AND RESTATED EMPLOYMENT AGREEMENT

THIS AMENDMENT TO AMENDED AND RESTATED EMPLOYMENT AGREEMENT ("<u>Amendment</u>") is made effective as of the 25th day of January, 2017, by and between Evoke Pharma, Inc. (the "<u>Company</u>"), and Matthew D'Onofrio ("<u>Executive</u>").

WHEREAS, the Company and Executive are parties to that certain Amended and Restated Employment Agreement, effective as of June 7, 2013 ("Original Agreement"); and

WHEREAS, the Company and Executive desire to amend the Original Agreement on the terms and conditions set forth below.

NOW, THEREFORE, in consideration of the mutual promises herein contained, the parties agree as follows:

1. <u>Section 3(b) of the Original Agreement</u>. The second sentence of Section 3(b) of the Original Agreement is hereby amended and restated to read as follows:

"For each year during the term of this Agreement, Executive's target Annual Bonus shall be 45% of his base salary actually paid for such year."

2. <u>Miscellaneous</u>. This Amendment shall be and is hereby incorporated in and forms a part of the Original Agreement. All other terms and provisions of the Original Agreement shall remain unchanged except as specifically modified herein. This Amendment may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same agreement. This Amendment shall be governed by and construed in accordance with the laws of the State of California applicable to contracts made and to be performed wholly within such State, and without regard to the conflicts of laws principles thereof. The headings of the sections in this Amendment are inserted solely for the convenience of the parties and are not a part of and are not intended to govern, limit or aid in the construction of any term of provision hereof. This Amendment may not be amended or modified otherwise than by a written agreement executed by the parties hereto or their respective successors and legal representatives.

(Signature Page Follows)

Exhibit 10.25

IN WITNESS WHEREOF, the parties have executed this Amendment as of the date(s) set forth below.

EVOKE PHARMA, INC.

By: /s/ David A. Gonyer Name: David A. Gonyer Title: Chief Executive Officer

EXECUTIVE

Dated: 3-13-17 /s/ Matthew D'Onofrio

Dated: 3-8-17

Matthew D'Onofrio

### AMENDMENT TO EMPLOYMENT AGREEMENT

THIS AMENDMENT TO EMPLOYMENT AGREEMENT ("<u>Amendment</u>") is made effective as of the 25th day of January, 2017, by and between Evoke Pharma, Inc. (the "<u>Company</u>"), and Marilyn R. Carlson, M.D. ("<u>Executive</u>").

WHEREAS, the Company and Executive are parties to that certain Employment Agreement, effective as of December 1, 2013 ("Original Agreement"); and

WHEREAS, the Company and Executive desire to amend the Original Agreement on the terms and conditions set forth below.

NOW, THEREFORE, in consideration of the mutual promises herein contained, the parties agree as follows:

1. <u>Section 3(b) of the Original Agreement</u>. The second sentence of Section 3(b) of the Original Agreement is hereby amended and restated to read as follows:

"For each year during the term of this Agreement, Executive's target Annual Bonus shall be 40% of her base salary actually paid for such year."

2. <u>Miscellaneous</u>. This Amendment shall be and is hereby incorporated in and forms a part of the Original Agreement. All other terms and provisions of the Original Agreement shall remain unchanged except as specifically modified herein. This Amendment may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same agreement. This Amendment shall be governed by and construed in accordance with the laws of the State of California applicable to contracts made and to be performed wholly within such State, and without regard to the conflicts of laws principles thereof. The headings of the sections in this Amendment are inserted solely for the convenience of the parties and are not a part of and are not intended to govern, limit or aid in the construction of any term of provision hereof. This Amendment may not be amended or modified otherwise than by a written agreement executed by the parties hereto or their respective successors and legal representatives.

(Signature Page Follows)

Exhibit 10.26

IN WITNESS WHEREOF, the parties have executed this Amendment as of the date(s) set forth below.

EVOKE PHARMA, INC.

By: /s/ David A. Gonyer Name: David A. Gonyer

Title: Chief Executive Officer

EXECUTIVE

/s/ Marilyn R. Carlson Marilyn R. Carlson Dated: 09MAR2017

Dated: 3-8-17

# CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Evoke Pharma, Inc. Solana Beach, California

We hereby consent to the incorporation by reference in Registration Statements on Form S-3 (No. 333-200176) and Form S-8 (No. 133-191518) of Evoke Pharma, Inc. of our report dated March 15, 2017, relating to the financial statements, which appears in this Annual Report on Form 10-K. Our report contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

/s/ BDO USA, LLP

San Diego, California March 15, 2017

# CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

#### I, David A. Gonyer, certify that:

- 1. I have reviewed this Annual Report on Form 10-K of Evoke Pharma, 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 15, 2017

/s/ David A. Gonyer
David A. Gonyer
President and Chief Executive Officer
(Principal Executive Officer)

# CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

#### I, Matthew J. D'Onofrio, certify that:

- 1. I have reviewed this Annual Report on Form 10-K of Evoke Pharma, 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 15, 2017

/s/ Matthew J. D'Onofrio
Matthew J. D'Onofrio
Executive Vice President, Chief Business Officer,
Treasurer and Secretary
(Principal Financial Officer)

# CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Evoke Pharma, Inc. (the "Company") for the period ended December 31, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, David A. Gonyer, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 15, 2017

/s/ David A. Gonyer

David A. Gonyer President and Chief Executive Officer

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing. A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

# CERTIFICATION PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002 (SUBSECTIONS (A) AND (B) OF SECTION 1350, CHAPTER 63 OF TITLE 18, UNITED STATES CODE)

In connection with the Annual Report on Form 10-K of Evoke Pharma, Inc. (the "Company") for the period ended December 31, 2016, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Matthew J. D'Onofrio, Executive Vice President, Chief Business Officer, Treasurer and Secretary of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 15, 2017

/s/ Matthew J. D'Onofrio

Matthew J. D'Onofrio Executive Vice President, Chief Business Officer, Treasurer and Secretary

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing. A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.