Evoke Pharma Inc
Form 10-K
March 04, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

Form 10-K

(Mark One)

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2014

or

¨TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to

Commission file number: 001-36075

Evoke Pharma, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	20-8447886
(State or Other Jurisdiction of	(I.R.S. Employer
Incorporation or Organization)	Identification No.)
505 Lomas Santa Fe Drive, Suite 270	
Solana Beach, California	92075
(Address of Principal Executive Offices)	(Zip Code)

858-345-1494

(Registrant's Telephone Number, Including Area Code)

Securities registered 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

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

None

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). x Yes ¨ No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See definitions of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	¨	Accelerated filer	¨
Non-accelerated filer	¨	Smaller reporting company	x

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Securities Exchange Act of 1934). Yes ¨ No x

As of February 23, 2015, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was approximately $16,009,719, based on the closing price of the registrant's common stock on the NASDAQ Capital Market of $5.44 per share.

The number of outstanding shares of the registrant's common stock, par value $0.0001 per share, as of February 23, 2015 was 6,137,091.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A in connection with the registrant's 2015 Annual Meeting of Stockholders, which will be filed subsequent to the date hereof, are incorporated by reference into Part III of this Form 10-K. Such proxy statement will be filed with the Securities and Exchange Commission not later than 120 days following the end of the registrant's fiscal year ended December 31, 2014.

EVOKE PHARMA, INC.

FORM 10-K — ANNUAL REPORT

For the Fiscal Year Ended December 31, 2014

Table of Contents

i

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, 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 forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "cor "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 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 trademark, EVOKE PHARMA, 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 ™ 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 EVK-001, a metoclopramide nasal spray for the relief of symptoms associated with acute and recurrent diabetic gastroparesis in women with diabetes mellitus. Diabetic gastroparesis is a GI disorder afflicting millions of sufferers worldwide in which the stomach takes too long to empty its contents resulting in serious digestive system symptoms. Metoclopramide is the only product currently approved in the United States to treat gastroparesis, and is currently available only in oral and intravenous forms. EVK-001 is a novel formulation of this drug, designed to provide systemic delivery of metoclopramide through intranasal administration.

Gastroparesis is a condition of delayed gastric emptying in the absence of mechanical obstruction. Gastroparesis results in food remaining in the stomach for a longer time than normal, yielding a variety of symptoms. Gastroparesis is a common problem in individuals with diabetes, but also is observed in patients with prior gastric surgery, a preceding infectious illness, pseudo-obstruction, collagen vascular disorders and anorexia nervosa. 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. Symptoms of gastroparesis include nausea,

vomiting, abdominal pain, bloating, early satiety, lack of appetite, and weight loss. The disorder can lead to considerable pain and discomfort, poor nutrition, impaired glycemic control and diminished quality of life. According to a 2008 study published in the American Journal of Gastroenterology, it is estimated that hospitalization costs associated with gastroparesis exceed $3.5 billion annually.

We believe intranasal administration has the potential to offer our target gastroparesis patients a preferred treatment option because, unlike oral metoclopramide which might be delayed in absorption due to gastroparesis itself, EVK-001 is designed to effectively bypass the digestive system and allow for more predictable drug administration across the thin mucosa in the nasal cavity. For patients suffering from nausea and vomiting who might not be able to absorb therapeutics via oral delivery, EVK-001 is designed to allow for rapid and predictable drug administration through the nasal route.

We have evaluated EVK-001 in a multicenter, randomized, double-blind, placebo-controlled parallel group, dose-ranging Phase 2b clinical trial in 287 patients with diabetic gastroparesis where EVK-001 was observed to be effective in improving the most prevalent and clinically relevant symptoms associated with gastroparesis in women while exhibiting a favorable safety profile. In April 2014, we commenced a Phase 3 clinical trial of EVK-001 in female patients with symptoms associated with acute and recurrent diabetic gastroparesis. This Phase 3 clinical trial is a multicenter, randomized, double-blind, placebo-controlled, parallel-group study evaluating the efficacy, safety and population pharmacokinetics of EVK-001 in adult female subjects with diabetic gastroparesis when dosed four times a day for 28 days. The Phase 3 trial is expected to enroll 200 patients at sites across the United States. As of February 2, 2015, we had randomized 74 subjects, and we anticipate fully enrolling this trial in the second half of 2015. We will need to successfully complete this trial before we are able to submit a new drug application, or NDA, to the U.S. Food and Drug Administration, or FDA, for EVK-001.

We reported in December 2014 that data from an electrocardiogram, or ECG, study that assessed the potential of EVK-001 to increase the cardiac QT and corrected QT, or QTc, interval across a range of plasma concentrations met the pre-specified primary endpoint, demonstrating that EVK-001, at therapeutic and supratherapeutic doses, did not prolong the QT/QTc interval in healthy subjects. The QT interval represents the amount of time the heart's electrical system takes to repolarize, or recharge, after each beat, and the QTc interval represents the QT interval corrected for differences in heart rate. Prolongation of the QT interval may increase the risk for cardiac arrhythmias. A thorough ECG (QT) study is a specialized clinical trial designed to assess whether an investigational medication has the potential to prolong the QT interval.

We are also conducting a companion clinical trial with EVK-001 in male patients with symptoms associated with acute and recurrent diabetic gastroparesis to assess the safety and efficacy of EVK-001 in men. The male companion trial was initiated in May 2014 and is designed similarly to the Phase 3 trial in women. This trial was requested by the FDA, but is not required for submission of the EVK-001 NDA for women; however, we expect to include safety data from this trial in our NDA submission.

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:

Continue development and pursue regulatory approval for EVK-001. We are currently conducting a Phase 3 trial of EVK-001 in female patients suffering from diabetic gastroparesis, which if successful, will allow us to file an NDA with the FDA.
Seek partnerships to accelerate and maximize the potential for EVK-001. As we continue to generate data on EVK-001, 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

EVK-001.

Explore building in-house capabilities to potentially commercialize EVK-001 in the United States. As EVK-001 progresses through its Phase 3 clinical program, in addition to partnering opportunities, we are evaluating the development of our own specialty sales force and marketing capabilities to allow us to directly market EVK-001 in the United States, if approved by the FDA.

Explore regulatory approval of EVK-001 outside the United States. We will initially seek approval of EVK-001 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 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 symptoms such as abdominal pain, nausea, vomiting, constipation, diarrhea, bloating, decreased appetite, early satiety, swallowing difficulties, heartburn 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 cease altogether. The following graph depicts the timing associated the emptying of solids in patients with diabetic gastroparesis compared to normal individuals:

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 symptoms that include nausea, vomiting, early satiety, bloating and abdominal pain. As a result of these symptoms, patients may limit their food and liquid intake leading to poor nutrition and dehydration with the patient 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 is delayed. 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 U.S. 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 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 and intravenous metoclopramide, and the oral disintegrating tablet, or ODT, formulation of metoclopramide (Metozolv® ODT), with approximately 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 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 the FDA but is obtained through certain compounding pharmacies for individual patients under special FDA usage rules.

EVK-001 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 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: EVK-001 (Metoclopramide Nasal Spray)

We are developing EVK-001, 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 with diabetes mellitus. Since its approval in 1980, oral and intravenous metoclopramide have been the only products approved in the United States to treat gastroparesis. EVK-001 is a novel formulation of metoclopramide offering systemic delivery by intranasal administration.

We are developing the intranasal formulation of metoclopramide to provide our targeted patients 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. Intranasal 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 EVK-001 may be tolerated even when patients are experiencing nausea and vomiting. The intranasal 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 2b Clinical Trial

We have evaluated EVK-001 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 I and type II) 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 on the drug or placebo.

In this trial, EVK-001 demonstrated effectiveness in reducing the most common and clinically relevant symptoms associated with gastroparesis in women, while exhibiting a favorable safety profile. EVK-001 was shown to provide a statistically significant clinical benefit as defined by a reduction in the symptoms of gastroparesis as measured by the mGCSI-DD in women ($p < 0.025$). Male subjects treated with EVK-001 showed some improvement in gastroparesis symptoms, but did not show a statistically significant difference compared to placebo. Due to these 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 intravenous). Previous metoclopramide studies enrolled small numbers of subjects and did not evaluate gender. For example, fewer than 150 subjects were enrolled across all studies included in the NDA for Reglan, a branded form of metoclopramide marketed in the United States by Ani Pharmaceuticals. The results of the Phase 2b trial are consistent with what is known about 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 EVK-001 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 EVK-001: 10 mg and 14 mg; as well as placebo. The study drug was administered for the 28-day treatment period as a single intranasal 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 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 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 FDA and its Study Endpoint and Labeling Division, these additional symptom data were used to further refine the patient reported outcome instrument. The result is a 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 the intention-to-treat population based 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 EVK-001-treated patients 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 EVK-001 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 EVK-001 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 EVK-001 compared to placebo in the Phase 2b clinical trial across all subjects and for male and female patients separately.

EVK-001 Phase 2b Clinical Trial

Gastroparesis Study Endpoint Points P -Value Summary

(EVK-001 vs. Placebo: Change from Baseline to Week 4)

	EVK-001 10 mg p -values	EVK-001 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.

(1) 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.
(2) 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.

The table below summarizes the key data from the trial across all subjects and for female and male patients separately:

EVK-001 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			
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 p -value vs. Placebo (2)		0.1504	0.3005
Difference of Least Square Means (95% CI)			0.06(-0.22, 0.33)
Pairwise p -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	68	65	70
Mean (SD)	1.9 (1.02)	1.6 (1.08)	1.7(0.94)
Change from Baseline to Week 4			
N	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 p -value vs. Placebo (2)		0.0247	0.0215
Difference of Least Square Means (95% CI)			-0.00 (-0.33, 0.32)
Pairwise p -value vs. Metoclopramide 10 mg (2)			0.9864
MALES			
Baseline (1)			
N	27	31	26
Mean (SD)	2.9 (0.63)	2.8(0.54)	2.5 (0.56)
Week 4			
N	27	31	26
Mean (SD)	1.4 (0.84)	1.6(1.05)	1.7 (0.79)
Change from Baseline to Week 4			

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)		0.18 (-0.30, 0.66)	0.32 (-0.19, 0.83)
Pairwise p -value vs. Placebo (2)		0.4497	0.2174
Difference of Least Square Means (95% CI)			0.14 (-0.35, 0.63)
Pairwise p -value vs. Metoclopramide 10 mg (2)			0.5805

(1) Baseline is defined as the mean mGCSI-DD total score during the washout period
(2) p -values for pairwise comparisons are obtained from an ANCOVA model with effects for treatment group and baseline value as a covariate

8

Phase 2b Safety Observations

In the Phase 2b clinical trial, EVK-001 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 EVK-001 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)	EVK-001 10 mg (N = 95)	EVK-001 14 mg (N = 95)
Nervous System Disorders			
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 EVK-001 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 EVK-001, 20 mg EVK-001, 10 mg oral tablet, and 5 mg/mL 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.

9

After intranasal administration of the 10 mg and 20 mg doses of EVK-001, mean plasma metoclopramide concentrations increased in a dose-related manner, as did mean values for C max and AUC (inf). The absolute bioavailability of EVK-001 after intranasal 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 EVK-001 as well as the oral and injection forms.

EVK-001 Phase 1 Clinical Trial

Mean Plasma Concentrations of Metoclopramide

(15 minute intervals 0-2h)

Thorough ECG (QT) Study

We conducted a randomized, double-blind, double-dummy, four-way crossover thorough ECG (QT) study of EVK-001 in 2014. The study was designed in accordance with the FDA's published guidance on clinical evaluation of QT/QTc interval, and compared the effects of EVK-001 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 EVK-001, 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 the FDA in support of our submission of an NDA for EVK 001.

Prior Development

From 1985 to present, we, or our predecessors, have conducted 24 clinical studies to evaluate the safety and pharmacokinetic profile of nasal spray formulations of metoclopramide in healthy volunteers and the safety, efficacy, pharmacokinetic and pharmacodynamic profile of metoclopramide nasal spray in patients. A total of 1,093 patients have been dosed in these studies with intranasal formulations of metoclopramide at doses ranging from 10 mg to 80 mg. In one study, a Phase 2, 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 the 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 EVK-001 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 EVK-001 for patients. We also developed the current formulation with excipients that are at or below the levels listed in the FDA's Inactive Ingredient Database for intranasal products. We evaluated the current formulation of EVK-001 in 329 patients in our completed Phase 1 and Phase 2 clinical trials and are evaluating the same formulation in our ongoing Phase 3 clinical trial. Similarly, the nasal spray pump used in our completed Phase 1 and Phase 2 clinical trials was identical and is also being used in our ongoing Phase 3 clinical trial.

The primary container closure system for EVK-001 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.

Our Ongoing Four-Week Phase 3 Clinical Trial in Female Subjects with Diabetic Gastroparesis

Based on discussions with the FDA, we have initiated one Phase 3 trial in women, which we believe, if successful, will be sufficient for NDA submission. In April 2014, we began enrolling the four-week, multicenter, randomized, double-blind, placebo-controlled, parallel Phase 3 clinical trial to evaluate the efficacy, safety and population pharmacokinetics of EVK-001 in adult female subjects with diabetic gastroparesis. We plan to enroll approximately 200 patients at approximately 60 sites across the United States. The trial population will consist of female diabetic patients with gastroparesis, identified by the presence of relevant symptoms and delayed gastric emptying. Female subjects with diabetic gastroparesis meeting the protocol-specified entry criteria will be studied in a parallel-group design with randomization in a 1:1 ratio to EVK-001 10 mg or placebo administered as a single intranasal spray four times daily, 30 minutes before meals and at bedtime.

On February 2, 2015, we disclosed the current recruitment status of the Phase 3 trial. While the study is progressing according to plan at many of the clinical trial sites with previous gastroparesis study experience, overall enrollment has been slower than previously anticipated. As of February 2, 2015, we had randomized 74 subjects, and we anticipate fully enrolling this trial in the second half of 2015. Although the trial sites have been screening significant numbers of subjects, patients with diabetic gastroparesis typically have symptoms that vary in timing and severity, unpredictable gastric emptying delays, and complex medical histories. This combination of factors creates a challenge for enrollment into diabetic gastroparesis trials.

Based on our discussions with the FDA, we plan to use specific symptoms from a composite score, the Gastroparesis Symptom Assessment, or GSA, as a patient-reported outcomes instrument to assess efficacy in this patient population. The primary efficacy endpoint for this Phase 3 clinical trial will be based upon a change from baseline in total composite score of the specific symptoms included in the GSA. Also based on discussions with FDA, and to assess safety in men, we are conducting a similar and concurrent companion study for safety and efficacy in diabetic men with gastroparesis. The trial design includes an early stop for futility. The FDA has indicated that completion of the male companion study is not required for submission of the NDA seeking approval of EVK-001 for use in women. Whether the male study stops early for futility or continues to enroll, we plan to include safety data from the male companion study in the NDA seeking approval for the drug for use in women.

Intellectual Property and Proprietary Rights

Overview

We are building an intellectual property portfolio for EVK-001 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 5,760,086—Nasal Administration for the Treatment of Delayed Onset Emesis. This patent expires in 2016.
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. We have also received patents in the European Union covering the intranasal use of metoclopramide for delayed onset emesis. These patents offer protection through 2016.

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 trademark for EVOKE PHARMA 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 are initially seeking to commercialize EVK-001 in the United States alone, or in partnership with pharmaceutical companies that have established development and sales and marketing capabilities. Our strategy for EVK-001, if approved, will be to establish EVK-001 as the prescription product of choice for diabetic gastroparesis in women. If the product candidate is approved, our expectation is that EVK-001 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 EVK-001 to approved patient populations.

Manufacturing

We do not own or operate manufacturing facilities for the production of EVK-001, 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. We do not have any current contractual relationships for the manufacture of commercial supplies of EVK-001. We intend to enter into agreements with third-party contract manufacturers for the commercial production of EVK-001 prior to regulatory approval. We currently utilize a third-party consultant, which we engage on an as-needed, 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 effective, or 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, EVK-001 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® 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 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 EVK-001 product candidate, we are aware of four other development candidates. All are in Phase 2 clinical development.

Gastroparesis Treatment Development Pipeline

Product	Class	Route	Company	Status
EVK-001	dopamine antagonist /mixed	intranasal	Evoke Pharma	Phase 3
RM-131	5-HT3 antagonist 5-HT4 agonist ghrelin agonist	sub-cutaneous	Rhythm/Actavis Pharmaceuticals	Phase 2b
GSK962040	motilin agonist	oral	GlaxoSmithKline	Phase 2
TD-5108	5-HT4 receptor agonist	oral	Theravance	Phase 2
IW-9179	GC-C agonist	oral	Ironwood	Phase 2a

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. RM-131 reverses body weight loss in cachexia models.

Two other ghrelin analogs were previously being developed by Tranzyme Pharma: an intravenous ghrelin agonist, ulimorelin, in post-operative ileus and a different oral ghrelin agent, TZP-102, in diabetic gastroparesis. Development of both product candidates has been discontinued after ulimorelin was unsuccessful in two Phase 3 studies and TZP-102 was unsuccessful in two Phase 2b trials.

GSK962040 is a selective non-peptide motilin receptor agonist under development for the treatment of conditions associated with slow rates of gastric emptying. Motilin is an endogenous peptide, produced mainly in the duodenum, whose physiological action is mediated by motilin receptors located on enteric neurons, peripheral terminals of the vagus, and on the smooth muscle of the stomach. Motilin and non-peptide agonists of motilin receptors increase gastric emptying and may offer a new approach to the treatment of delayed gastric emptying conditions.

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

IW-9179 is an investigational guanylate cyclase-C, or GC-C, agonist and is under development for the treatment of functional dyspepsia and diabetic gastroparesis by Ironwood Pharmaceuticals.

TC-6499, is a neuronal nicotinic receptor modulator under development by Targacept. The program has recently entered exploratory phase 1/2 trials for gastroparesis and previously was tested for constipation-predominant IBS.

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.

Tegaserod, another 5-HT4 agonist, was approved in the United States and other countries for treatment of chronic idiopathic constipation and IBS-C. In 2007, Tegaserod was removed from the market in the United States by the FDA for cardiac safety concerns.

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 EVK-001 from Questcor pursuant to an asset purchase agreement. We have 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 EVK-001. 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 totaling up to $51.5 million. These milestones include up to $4.5 million in payments if EVK-001 achieves the following development targets:

$1.5 million upon the FDA's acceptance for review of an NDA for EVK-001; and
$3 million upon the FDA's approval of EVK-001.

The remaining $47 million in milestone payments depend on EVK-001's commercial success and will only apply if EVK-001 receives regulatory approval. In addition, we will be required to pay to Mallinckrodt a low single digit royalty on net sales of EVK-001. Our obligation to pay such royalties will terminate upon the expiration of the last patent right covering EVK-001, which is expected to occur in 2030.

Government Regulation

FDA Approval Process

In the United States, pharmaceutical products are subject to extensive regulation by the 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 the 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 the 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 the FDA's good laboratory practice regulations;

submission to the 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 the FDA's 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 the 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 the FDA. Some pre-clinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the 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 the 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. The 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 the 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, the 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 the 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. The 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. The 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 the FDA accepts it for filing.

Once the submission has been accepted for filing, the FDA begins an in-depth substantive review. Under the Prescription Drug User Fee Act, or PDUFA, the 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, the FDA does not always complete its review within these timelines and the Agency's review can take substantially longer.

It is likely that our product candidates will be granted a Standard Review. The review process may be extended to allow the FDA to request and review additional information or obtain clarification regarding information provided in the original submission. The 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. The FDA is not bound by the recommendation of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA may inspect the facility or facilities where the product is manufactured. The 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, the FDA will typically inspect one or more clinical sites to assure compliance with GCP requirements before approving an NDA.

After the 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 the FDA to reconsider the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when the deficiencies have been addressed to the FDA's satisfaction, the 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, the 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, the 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 the 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 the 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 the 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 the FDA and state agencies, and are subject to periodic unannounced inspections by the 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, the 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 the 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.

The FDA may require post-approval studies and clinical trials if the 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. The 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 the 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, the 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 the 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 the 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. The FDA may also impose a REMS requirement on a drug already on the market if the 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, the FDA informed drug manufacturers that it will require a REMS for metoclopramide drug products. The 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. We intend to submit a proposed REMS at the time of the NDA submission for EVK-001.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market, and the 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. The 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, the 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 the 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 the 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 the FDA's findings of safety and effectiveness based on certain pre-clinical or clinical studies conducted for an approved product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The 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 the FDA concerning any patents listed for the approved product in the FDA Orange Book. The 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 the 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 the 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 the 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, the 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 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 the 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 the 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 the 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, the 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 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.

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 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 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 employees and several consultants in the regulatory, clinical, manufacturing and finance areas. We expect that a number of consultants previously engaged in the development of EVK-001 will participate in the ongoing clinical and manufacturing development for the product candidate. None of our employees are represented by a collective bargaining arrangement, and we believe our relationship with our employees is good.

About Evoke

We were formed as a Delaware corporation on January 29, 2007. Our principal executive offices are located at 505 Lomas Santa Fe Drive, Suite 270, 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, EVK-001

Our business is entirely dependent on the success of a single product candidate, EVK-001, for which we initiated a Phase 3 clinical trial in April 2014. We cannot be certain that we will be able to obtain regulatory approval for, or successfully commercialize, EVK-001.

We have only one product candidate: EVK-001, a metoclopramide nasal spray to treat female patients with symptoms associated with acute and recurrent diabetic gastroparesis. We are entirely dependent on successful continued development and regulatory approval of this product candidate for our future business success. We have invested, and will continue to invest, a significant portion of our time and financial resources in the development of EVK-001. We will need to successfully enroll and complete our ongoing Phase 3 clinical trial of EVK-001, which we commenced in April 2014, and, if required, raise sufficient funds for the completion of this trial. The future regulatory and commercial success of this product candidate is subject to a number of risks, including the following:

- we may not have sufficient financial and other resources to complete the Phase 3 clinical trial;
- we may not be able to provide acceptable evidence of safety and efficacy for EVK-001;
- the results of our planned and ongoing clinical trials may not confirm the positive results of earlier clinical trials, particularly because we are utilizing a modified patient report outcomes, or PRO, instrument for our current Phase 3 clinical trial compared to our Phase 2b clinical trial;
- variability in patients, adjustments to clinical trial procedures and inclusion of additional clinical trial sites;
- the results of our clinical trial may not meet the level of statistical or clinical significance required by the FDA for marketing approval;
- we may be required to undertake additional clinical trials and other studies of EVK-001 before we can submit an NDA, to the FDA or receive approval of the NDA;
- patients in our clinical trials may die or suffer other adverse effects for reasons that may or may not be related to EVK-001, such as dysgeusia, headache, diarrhea, nasal discomfort, tremor, myoclonus, somnolence, rhinorrhea, throat irritation, and fatigue;
- if approved, EVK-001 will compete with well-established products already approved for marketing by the FDA, including oral and intravenous forms of metoclopramide, the same active ingredient in the nasal spray for EVK-001;
- 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 the FDA and even fewer are approved for commercialization. Furthermore, even if we do receive regulatory approval to market EVK-001, 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 suspend our Phase 3 clinical trial and otherwise delay, reduce or eliminate our development program for EVK-001.

Our operations have consumed substantial amounts of cash since inception. To date, our operations have been primarily financed through the proceeds from the sale of our common and preferred stock, and borrowings under our loan and financing agreements. We believe, based on our current operating plan, that our existing cash and cash equivalents, together with interest thereon, will be sufficient to fund our operations through December 31, 2015, although there can be no assurance in that regard. Since our ongoing Phase 3 clinical trial of EVK-001, which commenced in April 2014, has an approximately 18-month enrollment period, we may need to obtain additional funds to complete this trial, as well as finance any additional development requirements requested by the FDA. As of February 2, 2015, we had randomized 74 subjects, and we anticipate fully enrolling this trial in the second half of 2015.

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 rate of progress and cost of our Phase 3 clinical trial and any other clinical requirements for EVK-001;
- the timing of regulatory approval, if granted, of EVK-001 or any other product candidates;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights associated with EVK-001;
- the costs and timing of completion of outsourced commercial manufacturing supply arrangements for EVK-001;
- costs associated with any other product candidates that we may develop, in-license or acquire;
- the effect of competing technological and market developments; and
- the terms and timing of any collaborative, licensing, co-promotion or other arrangements that we may establish.

The results observed in female patients with symptoms associated with acute and recurrent diabetic gastroparesis in our Phase 2b clinical trial of EVK-001 may not be predictive of the safety and efficacy results in our ongoing Phase 3 clinical trial.

A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in earlier-stage development. We commenced our Phase 3 clinical trial in female patients with symptoms associated with acute and recurrent diabetic gastroparesis in April 2014. Our Phase 2b clinical trial of EVK-001 for the treatment of diabetic gastroparesis showed statistically significant improvement in clinically meaningful endpoints in female patients. This was a pre-specified analyses of the primary efficacy endpoint performed on a gender subgroup of the intent to treat, or ITT population. Due to a large placebo response in male patients, EVK-001 did not achieve the primary endpoint in the ITT population for all subjects in this Phase 2b clinical trial.

This risk may be particularly significant for us because the primary endpoint in our ongoing Phase 3 clinical trial is not identical to the primary endpoint used in our Phase 2b trial. In our Phase 2b clinical trial, the primary endpoint was the GCSI-DD, a PRO instrument. The GCSI-DD is a composite of clinically relevant diabetic gastroparesis symptoms which patients rate according to severity. Based on our discussions with the FDA, the primary endpoint for our Phase 3 trial will be the GSA, which is a PRO instrument derived from the GCSI-DD. We have analyzed our Phase 2b data utilizing the GSA's methodology. Although we observed statistically significant and nearly identical statistical improvement in the GSA compared to the GCSI-DD in females in our Phase 2b trial, we cannot assure you that our Phase 3 trials will achieve positive results.

A number of factors could contribute to a lack of favorable safety and efficacy results in our ongoing Phase 3 trial. For example:

- a multicenter trial could result in increased variability due to varying site characteristics, such as local standards of care;
- a multicenter trial could result in increased variability due to varying patient characteristics including demographic factors, health status, underlying reason for disease state and concomitant medications; and
- diagnosis of diabetic gastroparesis by physicians, including use of gastric emptying tests, could select for a patient population that differs from those patients included within previous clinical trials.

If we are not able to obtain regulatory approval for EVK-001, 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 EVK-001 in the United States until we receive approval of an NDA for the product candidate in a particular indication from the FDA. To date, we have completed one Phase 2b clinical trial for EVK-001 in diabetic subjects with gastroparesis and acquired the results from a separate Phase 2 clinical trial in diabetic patients with gastroparesis. In the Phase 2b clinical trial that we performed ourselves, which concluded in

2011, EVK-001 failed to meet the primary endpoint for the trial. Although an overall improvement in symptoms was observed in EVK-001-treated patients 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 the FDA-approved 10 mg metoclopramide tablet. Although data from the earlier Phase 2 clinical trial will be referenced in the EVK-001 NDA, the open-label study design limits the importance of the efficacy results in the NDA.

We commenced our Phase 3 clinical trial in female patients with symptoms associated with acute and recurrent diabetic gastroparesis in April 2014. There is no guarantee that this Phase 3 clinical trial or any other future trials will be successful or that regulators will agree with our assessment of the clinical trials for EVK-001 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. The 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 EVK-001 from Questcor, who acquired its rights from a predecessor. Thus, much of the preclinical and a portion of the clinical data relating to EVK-001 that we would expect to submit in an NDA for EVK-001 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.

EVK-001 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 the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Failure to obtain regulatory marketing approval for EVK-001 will prevent us from commercializing the product candidate, and our ability to generate revenue will be materially impaired.

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

The requirements that the FDA may impose on clinical trials for EVK-001 are uncertain. We are conducting one Phase 3 trial in adult female subjects with diabetic gastroparesis, which, along with a thorough ECG (QT) trial, we believe will be sufficient for NDA submission seeking an indication of treatment of symptoms associated with diabetic gastroparesis in women. In April 2014, we commenced a multicenter, randomized, double-blind, placebo-controlled, parallel-group Phase 3 clinical trial to evaluate the efficacy, safety and population pharmacokinetics of EVK-001 in adult female subjects with diabetic gastroparesis when dosed four times a day for 28 days. Although we believe successful results from this single Phase 3 clinical trial, along with the thorough ECG (QT) trial, will be sufficient to allow us to submit an NDA for EVK-001, it is possible the FDA will require additional clinical testing before submission or approval of the NDA. In addition, based on discussions with the FDA, we also are conducting a similar study for safety and efficacy in adult male subjects with diabetic gastroparesis which is not required for an NDA submission. If we are unable to comply with the FDA's requirements, we will not be able to obtain approval for EVK-001 and our ability to generate revenue will be materially impaired.

Any termination or suspension of, or delays in the enrollment or completion of, our ongoing Phase 3 clinical trial could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.

Delays in the enrollment or completion of our ongoing Phase 3 clinical trial for EVK-001 could significantly affect our product development costs. We do not know whether this trial will complete enrollment or 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:

- the FDA placing the clinical trial on hold;
- subjects failing to enroll or 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 EVK-001, or participating in competing clinical trials;
- subjects experiencing severe or unexpected drug-related adverse effects;

a facility manufacturing EVK-001 or any of its components being ordered by the FDA or other government or regulatory authorities to temporarily or permanently shut down due to violations of cGMP 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, GCP 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 the FDA or the finding of regulatory violations by the FDA or an 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 the 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 EVK-001, 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, the 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 EVK-001 could be significantly reduced.

On February 2, 2015, we announced that overall enrollment in our Phase 3 clinical trial of EVK-001 has been slower than anticipated and that enrollment is projected to be completed in the second half of 2015. As of February 2, 2015, we had randomized 74 subjects, and we anticipate fully enrolling this trial in the second half of 2015. Continued delays in the enrollment and completion of the Phase 3 trial, as well as potential delays in any other clinical trials and studies, could be harmful to our business and cause us to require additional funding sooner than anticipated.

Final marketing approval for EVK-001 by the 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.

After the completion of our Phase 3 clinical trial and, assuming the results of the trial are successful, the submission of an NDA, we cannot predict whether or when we will obtain regulatory approval to commercialize EVK-001 and we cannot, therefore, predict the timing of any future revenue. Because EVK-001 is our only product candidate this risk is particularly significant for us. We cannot commercialize EVK-001 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 EVK-001. 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, the 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. The 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 whether the FDA will re-review approved metoclopramide product labels as a result of any such regulatory actions in the European Union or otherwise. If marketing approval for EVK-001 is delayed, limited or denied, our ability to market the product candidate, and our ability to generate product sales, would be adversely affected.

If the FDA does not conclude that EVK-001 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, EVK-001. EVK-001 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 the 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 EVK-001, 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 EVK-001, 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 EVK-001 or any future product candidates will receive the requisite approvals for commercialization.

Even if we obtain marketing approval for EVK-001, 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 EVK-001 is approved.

Even if U.S. regulatory approval is obtained, the FDA may still impose significant restrictions on EVK-001's indicated uses or marketing or impose ongoing requirements for potentially costly and time consuming post-approval studies, post-market surveillance or clinical trials. EVK-001 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 the 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 EVK-001 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.

The 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, the 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 EVK-001.

In addition, if EVK-001 is approved, our product labeling, advertising and promotion would be subject to regulatory requirements and continuing regulatory review. The 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 the FDA as reflected in the product's approved labeling. If we receive marketing approval for EVK-001, 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. The 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. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

Even if we receive regulatory approval for EVK-001, we still may not be able to successfully commercialize it and the revenue that we generate from its sales, if any, will be limited.

EVK-001'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 EVK-001 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 EVK-001 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 EVK-001 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 these 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 the FDA has granted marketing approval. This trend may impact the reimbursement for treatments for GI disorders especially, including EVK-001, 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 EVK-001. Although EVK-001 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 EVK-001 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 or is available only to limited levels, we may not be able to successfully commercialize our product candidate.

We rely and will continue to rely on outsourcing arrangements for many of our activities, including clinical development and supply of EVK-001.

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.

We have retained SynteractHCR, a contract research organization, or CRO, to conduct our ongoing Phase 3 clinical trial of EVK-001. We rely on our CRO to recruit suitable patients to participate in the trial at each trial site. Enrollment in our Phase 3 clinical trial of EVK-001 has progressed more slowly than anticipated, and although we have undertaken additional initiatives to increase enrollment and to further assist clinical trial sites in the identification of eligible study subjects, our CRO is ultimately responsible for recruitment efforts.

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 EVK-001, 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 EVK-001, 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 EVK-001. If EVK-001 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 EVK-001; 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 EVK-001. We anticipate that EVK-001, 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 EVK-001 is beneficial compared to other products in the market;
obtain patent and/or other proprietary protection for EVK-001;
obtain and maintain required regulatory approvals for EVK-001; and
collaborate with others to effectively market, sell and distribute EVK-001.

Established competitors may invest heavily to quickly discover and develop novel compounds that could make our product candidate obsolete. In addition to our EVK-001 product candidate, we are aware of other development candidates in clinical development. Any of these product candidates could advance through clinical development faster than EVK-001 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 EVK-001 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 EVK-001 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 EVK-001 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 EVK-001 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 EVK-001 or the commercialization of this product candidate, if approved.

We will need to hire and retain qualified personnel. 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 continue the development and pursue the potential commercialization of EVK-001. As we seek to advance EVK-001, we will need to expand our development, 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 EVK-001 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 EVK-001 and affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval for EVK-001, 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 the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of EVK-001, if any, may be. In addition, increased scrutiny by the U.S. Congress of the 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 the United States, the Medicare Modernization Act, or MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for outpatient drug purchases by Medicare beneficiaries under a new Part D and introduced a new reimbursement methodology based on average sales prices for Medicare Part B physician-administered drugs. In addition, this legislation authorized Medicare Part D prescription drug plans to use formularies where they can limit the number of drugs that will be covered in any therapeutic class. As a result of this legislation and the expansion of federal coverage of drug products, we expect that there will be additional pressure to contain and reduce costs. These cost reduction initiatives and other

provisions of this legislation could decrease the coverage and price that we receive for any approved products and could seriously harm our business. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and any reduction in Medicare reimbursement may result in a similar reduction in payments from private payors.

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 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. Although it is too early to determine the full effect of the Affordable Care Act, the new law appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. In August 2011, the Budget Control Act of 2011 among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee did not achieve its targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This includes 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 2024 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 providers, including hospitals, imaging centers and cancer treatment centers. 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 fraud and abuse 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 certain marketing practices in the pharmaceutical industry. These laws include false claims, anti-kickback 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. In addition, 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.

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/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 EVK-001, 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 EVK-001. 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 the 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 EVK-001 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 EVK-001.

We face an inherent risk of product liability as a result of the clinical testing of EVK-001 and will face an even greater risk if we commercialize the product candidate. For example, we may be sued if EVK-001 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 EVK-001 will be found to experience a variety of side effects. In 2009, the 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 EVK-001,

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 EVK-001;
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 EVK-001; 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 EVK-001. 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 EVK-001 because third parties may view the risk of success in our ongoing Phase 3 clinical trial 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 EVK-001 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 EVK-001 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 EVK-001. Our ability to obtain clinical supplies of EVK-001 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 the 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 EVK-001 or our proprietary processes as well as other intellectual property important to our business. One of our patents related to EVK-001 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. 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 EVK-001 are limited to specific methods of use and formulations of metoclopramide. As a result, our ability to market EVK-001 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 EVK-001 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 EVK-001 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 EVK-001 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 EVK-001. 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 EVK-001 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 EVK-001 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 EVK-001, or, if no such license were available on commercially viable terms, could require us to cease manufacturing and marketing of EVK-001. 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 EVK-001, 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, 2014 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 our product candidate, 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 the end of 2015. This period could be shortened if there are any significant increases in planned spending on our EVK-001 development program or more rapid progress of our ongoing Phase 3 clinical trial 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 our Phase 3 clinical trial for EVK-001, and seeking regulatory approval from the FDA to manufacture and commercialize EVK-001. Our net loss for the year ended December 31, 2014, was approximately $13.2 million. As of December 31, 2014, we had an accumulated deficit of approximately $35.9 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 EVK-001 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 EVK-001 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 EVK-001.

We will require substantial future capital in order to complete the remaining clinical development for EVK-001 and to potentially commercialize this product candidate. The amount and timing of any expenditure needed to implement our development and commercialization programs will depend on numerous factors, including:

- the progress, costs, results of and timing of our clinical development program for EVK-001, including our ongoing Phase 3 clinical trial;
- the need for, and the progress, costs and results of, any additional clinical trials of EVK-001 we may initiate based on the results of our planned and ongoing clinical trials or discussions with the FDA, including any additional trials the FDA or other regulatory agencies may require evaluating the safety of EVK-001;
- the outcome, costs and timing of seeking and obtaining regulatory approvals from the FDA, and any similar regulatory agencies;
- the timing and costs associated with manufacturing EVK-001 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 EVK-001;
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 resources, which include the proceeds from our initial public offering, will be sufficient to enable us to fund the completion of our Phase 3 clinical trial and remaining development program, and, in any event, we will need to raise additional capital to submit marketing applications for and prepare for commercialization of EVK-001 should we receive product approval. We may need to raise additional funds in the near future to complete development activities for EVK-001.

We may seek additional funding through collaboration agreements and public or private financings. For example, in November 2014 we entered into an At Market Issuance Sales Agreement, or the Sales Agreement, with MLV & Co. LLC, or MLV, pursuant to which we may sell from time to time, at our option, up to an aggregate of $6.6 million of shares of our common stock through MLV, as sales agent. Sales of our common stock made pursuant to the 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 Sales Agreement, there can be no assurance that MLV 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 $75.0 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 Sales Agreement, is limited to an aggregate of one-third of our public float. As of November 11, 2014, our public float was 2.9 million shares, the value of which was $20.0 million based upon the closing price of our common stock of $6.86 on such date. The value of one-third of our public float calculated on the same basis was $6.6 million. In addition, we will not be able to make future sales of our common stock pursuant to the Sales Agreement unless certain conditions are met, which include the accuracy of representations and warranties made to MLV under the Sales Agreement. Furthermore, MLV 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 assets, business, operations, earnings, properties, condition (financial or otherwise), prospects, stockholders' equity or results of operations.

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 are unable to obtain funding on a timely basis, if required, we will be unable to complete the ongoing Phase 3 clinical trial for EVK-001 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.

The terms of our secured debt facility require us to meet certain operating and financial covenants and place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.

We have a $4.5 million loan and security agreement with Square 1 Bank, or Square 1, that is secured by a lien covering substantially all of our personal property, excluding intellectual property. On December 31, 2014, we drew the entire $4.5 million line. The credit facility contains affirmative and negative covenants applicable to us and any subsidiaries we create in the future. The affirmative covenants include, among others, covenants requiring us to maintain our legal existence and governmental approvals, deliver certain financial reports, maintain insurance coverage and meet certain covenants with respect to enrollment and results of our Phase 3 trial for EVK-001. The negative covenants include, among others, restrictions on transferring collateral, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions, making investments, creating liens and selling assets, in each case subject to certain exceptions. The credit facility also includes events of default, the occurrence and continuation of which provide Square 1 with the right to exercise remedies against us and the collateral securing the term loans under the credit

facility, including foreclosure against our properties securing the credit facilities, including our cash. These events of default include, among other things, our failure to pay any amounts due under the credit facility, a breach of covenants under the credit facility, our insolvency, a material adverse change, the occurrence of any default under certain other indebtedness in an amount greater than $400,000 and a final judgment against us in an amount greater than $400,000. Square 1 could declare a default upon the occurrence of any event that they interpret as a material adverse change as defined under the loan agreement, thereby requiring us to repay the loan immediately or to attempt to reverse the declaration of default through negotiation or litigation. Any declaration by the lender of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline. If we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

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, 2014, we had federal and state net operating loss carryforwards of approximately $33.2 million and $32.5 million, respectively, and federal research and development credits of approximately $1.1 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 February 23, 2015, the sale price per share of our common stock on The NASDAQ Capital Market has ranged from a low of $4.72 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:

our ability to enroll patients in our ongoing Phase 3 clinical trial;
results of the clinical 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;

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 EVK-001 development program;

addition or termination of clinical trials;

any intellectual property infringement lawsuit in which we may become involved;

regulatory developments affecting EVK-001; 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.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

As of February 23, 2015, our executive officers, directors and greater than 5% stockholders, in the aggregate, owned approximately 52.05% of our outstanding common stock. As a result, such persons, acting together, will have the ability to control our management and affairs and substantially all matters submitted to our stockholders for approval, including the election and removal of directors and approval of any significant transaction. These persons will also have the ability to control our management and business affairs. This concentration of ownership may have the effect of delaying, deferring or preventing a change in control, impeding a merger, consolidation, takeover or other business combination involving us, or discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of our business, even if such a transaction would benefit other stockholders.

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, our loan and security agreement with Square 1 currently prohibits us from paying dividends on our equity securities, and 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 February 23, 2015, we had 6,137,091 shares of common stock outstanding. All of these shares are freely tradable without restriction in the public market, except for 3,194,128 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 February 23, 2015, the holders of 2,673,622 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 exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

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, 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 and changes in corporate governance practices. Further, in 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as “say on pay” and proxy access. Recent legislation permits smaller “emerging growth companies” to implement many of these requirements over a longer period and up to five years following their initial public offering. We are taking advantage of this new legislation but 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.

We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make 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.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 2. Properties

We occupy approximately 2,741 square feet of office space in Solana Beach, California under a lease that we entered into in November 2013. This facility lease expires in December 2015. 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, 2014		
Fourth Quarter	$7.00	$4.72
Third Quarter	$8.18	$4.95
Second Quarter	$10.28	$6.48
First Quarter	$13.40	$7.36
Year Ended December 31, 2013		
Fourth Quarter	$14.25	$6.75
Third Quarter	$12.29	$10.55

Holders of Common Stock

As of February 23, 2015, there were 28 holders of record of our common stock.

Stock Performance Graph

The following stock performance graph illustrates a comparison of the total cumulative stockholder return on our common stock since September 25, 2013, which is the date our common stock first began trading on the NASDAQ Capital Market, to two indices: the NASDAQ Composite Index and the NASDAQ Biotechnology Index. The graph assumes an initial investment of $100 on September 25, 2013, and that all dividends were reinvested. The comparisons in the graph are required by the Securities and Exchange Commission and are not intended to forecast or be indicative of possible future performance 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. In addition, our loan and security agreement with Square 1 currently prohibits us from paying dividends on our equity securities, and 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 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.

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, 2014 and 2013 and the balance sheet data as of December 31, 2014 and 2013, 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,	
	2014	2013
Statement of Operations Data:		
Operating Expenses		
Research and development	$9,991,855	$956,980
General and administrative	3,158,179	1,644,848
Total operating expenses	13,150,034	2,601,828
Loss from operations	(13,150,034)	(2,601,828)
Total other expense	(97,647)	(234,637)
Net loss	$(13,247,681)	$(2,836,465)
Net loss per common share, basic and diluted(1)	$(2.20)	$(1.20)
Weighted-average shares used to compute basic and diluted net loss per share	6,032,560	2,368,006

(1) 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,	
	2014	2013
Balance Sheet Data:		
Cash and cash equivalents	$14,155,809	$24,196,691
Working capital	13,377,089	22,146,047
Total assets	15,301,729	24,986,458
Current liabilities	1,871,617	2,284,906
Long-term debt, net of current portion	4,241,448	1,511,461
Accumulated deficit	(35,939,149)	(22,691,468)
Total stockholders' equity	9,188,664	21,183,261

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 GI disorders and diseases. We are developing EVK-001, a 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 sufferers worldwide in which the stomach takes too long to empty its contents resulting in serious digestive system symptoms. Metoclopramide is the only product currently approved in the United States to treat gastroparesis, and is currently available only in oral and intravenous forms. EVK-001 is a novel formulation of this drug, designed to provide systemic delivery of metoclopramide through intranasal administration.

We have evaluated EVK-001 in a multicenter, randomized, double-blind, placebo-controlled parallel-group, dose-ranging Phase 2b clinical trial in 287 patients with diabetic gastroparesis where EVK-001 was observed to be effective in improving the most prevalent and clinically relevant symptoms associated with gastroparesis in women while exhibiting a favorable safety profile. In April 2014, we commenced a Phase 3 clinical trial of EVK-001 in female patients with symptoms associated with acute and recurrent diabetic gastroparesis. This Phase 3 clinical trial is a multicenter, randomized, double-blind, placebo-controlled, parallel-group study evaluating the efficacy, safety and population pharmacokinetics of EVK-001 in adult female subjects with diabetic gastroparesis when dosed four times a day for 28 days. The Phase 3 trial is expected to enroll 200 patients at sites across the United States, and as of February 2, 2015, we had randomized 74 subjects, and we anticipate fully enrolling this trial in the second half of 2015. We will need to successfully complete this trial before we are able to submit an NDA to the FDA for EVK-001.

On February 2, 2015, we disclosed the current recruitment status of the Phase 3 trial. While the study is progressing according to plan at many of the clinical trial sites with previous gastroparesis study experience, overall enrollment has been slower than previously anticipated. As of February 2, 2015, we had randomized 74 subjects, and we anticipate fully enrolling this trial in the second half of 2015. Although the trial sites have been screening significant numbers of subjects, patients with diabetic gastroparesis typically have symptoms that vary in timing and severity, unpredictable gastric emptying delays, and complex medical histories. This combination of factors creates a challenge for enrollment into diabetic gastroparesis trials.

We commenced a thorough ECG (QT) study in August 2014 and reported positive results in December 2014. Data from the thorough ECG (QT) study met the pre-specified primary endpoint, demonstrating that EVK-001, at therapeutic and supratherapeutic doses, did not prolong the QT/QTc interval in healthy subjects. FDA approval of the NDA is required in order for us to commercially market EVK-001 in the United States.

We are also conducting a companion clinical trial with EVK-001 in male patients with symptoms associated with acute and recurrent diabetic gastroparesis to assess the safety and efficacy of EVK-001 in men. The male companion trial was initiated in May 2014 and is designed similarly to the Phase 3 trial in women. This trial was requested by the FDA, but is not required for submission of the EVK-001 NDA for women, however, we expect to include safety data from this trial in the NDA submission.

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, borrowings under our loan and security agreements 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 $13.2 million and $2.8 million for the years ended December 31, 2014 and 2013, respectively. As of December 31, 2014 and 2013, we had an accumulated deficit of $35.9 million and $22.7 million, respectively. Substantially all of our operating losses resulted from expenses incurred in connection with advancing EVK-001 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 more fully described below, on December 31, 2014 we borrowed $4.5 million from Square 1 to increase our cash balance at December 31, 2014 to approximately $14.2 million. In addition, in January 2015 we sold 25,000 shares of our common stock pursuant to the Sales Agreement with MLV and received net proceeds of approximately $163,000, net of commissions and fees. Under the terms of the Sales Agreement, we may sell up to $6.6 million worth of common stock. Though we have such capability, we may not be able to raise additional capital on terms acceptable to us, or at all. Any failure to raise capital as and when needed could

have a material adverse effect on our results of operations, financial condition and our ability to execute on our business plan. In its report on our financial statements for the year ended December 31, 2014, our independent registered public accounting firm included an explanatory paragraph expressing substantial doubt regarding our ability to continue as a going concern.

Technology Acquisition Agreement

In June 2007, we acquired all worldwide rights, data, patents and other related assets associated with EVK-001 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 EVK-001. In August 2014, 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 totaling up to $51.5 million. These milestones include up to $4.5 million in payments if EVK-001 achieves the following development targets:

$1.5 million upon the FDA's acceptance for review of an NDA for EVK-001; and
$3 million upon the FDA's approval of EVK-001.

The remaining $47 million in milestone payments depend on EVK-001's commercial success and will only apply if EVK-001 receives regulatory approval. In addition, we will be required to pay to Mallinckrodt a low single digit royalty on net sales of EVK-001. Our obligation to pay such royalties will terminate upon the expiration of the last patent right covering EVK-001, which is expected to occur in 2030.

Initial Public Offering

In September 2013, we completed our initial public offering, or IPO, whereby we issued and sold 2,100,000 shares of common stock at a public offering price of $12.00 per share. Concurrently with the completion of the IPO, all outstanding shares of convertible preferred stock were converted into 2,439,002 shares of our common stock. In addition, warrants to purchase 84,000 shares of our common stock were issued to the representative of the underwriters of our IPO and certain of its affiliates. The warrants became exercisable at a price of $21.00 per share beginning on September 24, 2014 and will expire on September 24, 2018. Finally, warrants to purchase 110,000 shares of convertible preferred stock were converted into warrants to purchase 22,000 shares of our common stock. In October 2013, the underwriters for our IPO exercised an option to purchase 315,000 additional shares of common stock at $12.00 per share. Total net proceeds from the IPO, after deducting underwriter discounts, commissions and other offering expenses of $3.9 million, were $25.1 million.

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 EVK-001. We expect our research and development expenses to increase for the foreseeable future as we advance EVK-001 through clinical development, including the conduct of our ongoing Phase 3 clinical trial. 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 EVK-001. However, we currently estimate that the costs to

complete our Phase 3 clinical trial in women and our companion clinical trial in men will be approximately $16.5 million, of which, through December 31, 2014, $7.8 million have been incurred related to those clinical activities. 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 patients;
the number of patients that participate in the trials;
the number of doses that patients receive;
the cost of comparative agents used in trials;
the drop-out or discontinuation rates of patients;
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 expect EVK-001 to be commercially available, if at all, for the next few years.

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. We expect that general and administrative expenses will increase in the future as we expand our operating activities and 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.

Total Other Expense

Total other expense consists primarily of interest income we earn on interest-bearing accounts and money market funds for cash and cash equivalents, interest expense incurred on our outstanding debt and changes in the fair value of our warrant liability.

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 toxicology studies and 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 patients, 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.

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 the IPO, 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 64,000 and 501,500 shares of common stock in 2014 and 2013, respectively.

Other Information

Net Operating Loss Carryforwards

As of December 31, 2014, we had federal and California tax net operating loss carryforwards of approximately $33.2 million and $32.5 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, 2014, we also had federal and California

research and development tax credit carryforwards of $1.1 million and $737,000, 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 of 1933, as amended, or 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.

We are in the process of evaluating the benefits of relying on other exemptions and reduced reporting requirements provided by the JOBS Act. 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, or PCAOB, 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 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 Securities and Exchange Commission.

Results of Operations

Comparison of Years Ended December 31, 2014 and 2013

The following table summarizes the results of our operations for the fiscal years ended December 31, 2014 and 2013:

	Year Ended December 31,		Increase/
	2014	2013	(Decrease)
Research and development	$9,991,855	$956,980	$9,034,875
General and administrative	3,158,179	1,644,848	1,513,331
Other income (expense):			
Interest income	10,187	7,248	2,939
Interest expense	(107,834)	(159,885)	(52,051)
Change in fair value of warrant liability	—	(82,000)	(82,000)
Total other expense	(97,647)	(234,637)	(136,990)

Research and Development Expenses. Research and development expenses for the year ended December 31, 2014 compared to the year ended December 31, 2013 increased by approximately $9.0 million primarily due to research and development activities expanding subsequent to our IPO in September 2013. Costs incurred in 2014 include approximately $7.1 million related to the ongoing clinical trials for EVK-001, $522,000 related to stability testing and preparation for the production of additional EVK-001, the payment of $500,000 to Questcor for achieving a milestone associated with the acquisition of our technology, and approximately $1.9 million for wages, taxes and employee insurance, including $410,000 of stock-based compensation expense, as we added clinical personnel subsequent to our IPO. The allocation of time spent by our executive team related to research and development activities in 2014 also

increased compared to the time allocated in 2013 when they were primarily preparing for our IPO. For 2013, research and development costs primarily consisted of approximately $417,000 for wages, taxes and employee insurance, $342,000 related to the start-up of our Phase 3 clinical trial and $144,000 related to stability testing of prior manufactured batches of EVK-001. In addition, during the first quarter of 2013, the 2012 bonus accrual was reversed due to the election by our board of directors to not pay 2012 bonuses in order to conserve cash.

Included in research and development expenses were costs of approximately $255,000 and $1,200 for the years ended December 31, 2014 and 2013, respectively, for clinical trial services incurred by a related party of one of our officers.

General and Administrative Expenses. General and administrative expenses for the year ended December 31, 2014 compared to the year ended December 31, 2013 increased by approximately $1.5 million primarily due to general and administrative activities expanding subsequent to our IPO. Costs incurred in 2014 primarily included approximately $1.5 million for wages, taxes and employee insurance, including $692,000 of stock-based compensation expense as we added general and administrative personnel subsequent to our IPO, and approximately $1.4 million for legal, accounting, directors and officers liability insurance and other costs associated with being a public company. For 2013, general and administrative costs primarily consisted of approximately $997,000 for wages, taxes and benefits, including the payment of $355,000 for retention payments to the executive team, and approximately $445,000 for legal, accounting, directors and officers liability insurance and other costs associated with being a public company. In

addition, during the first quarter of 2013, the 2012 bonus accrual was reversed due to the election by our board of directors to not pay 2012 bonuses in order to conserve cash.

Other Income (Expense). Other income (expense) for the year ended December 31, 2014 primarily related to approximately ($52,000) of net interest expense incurred related to our bank loans and the write-off of approximately ($46,000) of unamortized debt discount costs upon the repayment of the loan extended to us by Silicon Valley Bank. Other income (expense) for the year ended December 31, 2013 primarily consisted of approximately $153,000 of net interest expense related to advances under our bank loan and $82,000 of expenses related to the increase in the fair value of our outstanding warrant liability in effect prior to our IPO.

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. We have incurred losses since inception and have negative cash flows from operating activities. As of December 31, 2014, we had approximately $14.2 million in cash and cash equivalents and working capital of approximately $13.4 million.

In June 2012, we entered into a $3 million loan and security agreement with Silicon Valley Bank, or SVB, collateralized by our personal property and containing only non-financial covenants. By January 2013, we had been advanced the entire $3 million to fund working capital. Interest on advances under the agreement was at a fixed interest rate equal to 4.50%. Advances under the loan and security agreement had an interest-only period through December 31, 2013, and had a 24-month payback period that commenced in January 2014. In connection with the loan and security agreement, we issued a warrant to SVB, which is immediately exercisable for an aggregate of 12,000 shares of our common stock, at an exercise price of $7.50 per share.

Through May 1, 2014, we repaid approximately $603,000 of principal on the SVB loan. On May 23, 2014, we repaid the outstanding principal and accrued interest of approximately $2.4 million to SVB. With such payoff, the loan and security agreement with SVB and the documents entered into in connection therewith were deemed to be terminated. SVB’s security interest in substantially all of our assets was also terminated.

On May 28, 2014, or the closing date, we entered into a loan and security agreement, or 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 a principal amount of up to $4.5 million.

In December 2014, we drew down the entire $4.5 million. The credit facility bears interest at a fixed annual rate of 5.50%. We are required to make interest-only payments through November 28, 2015 on the credit facility. The outstanding principal balance plus interest will begin amortizing at the end of the interest-only period, with monthly payments of principal and interest being made by us to Square 1 in consecutive monthly installments following November 28, 2015 until the credit facility matures on November 28, 2017. Payments of principal and interest for the years ended December 31, 2015, 2016 and 2017 are approximately $436,000, $2,434,000 and $2,120,000, respectively. At our option, we may prepay the outstanding principal balance of the credit facility before November 28, 2017 without penalty or premium.

The credit facility includes affirmative and negative covenants applicable to us and any subsidiaries we create in the future. The affirmative covenants include, among others, covenants requiring us to maintain our legal existence and governmental approvals, deliver certain financial reports, maintain insurance coverage and meet certain covenants with respect to enrollment and results of our EVK-001 Phase 3 trial. After we receive positive results from the Phase 3 trial, if at all (which we must achieve on or prior to September 30, 2015), we must either maintain a ratio of our cash

at Square 1 to our cash burn over the preceding month of at least 3.00 to 1.00, or we must deliver evidence of a forthcoming financing or strategic partnership arrangement to Square 1, in each case in an amount satisfactory to Square 1. The negative covenants include, among others, restrictions on our transferring collateral, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions, making investments, creating liens and selling assets, in each case subject to certain exceptions.

The credit facility also includes events of default, the occurrence and continuation of which provide Square 1 with the right to exercise remedies against us and the collateral securing the term loans under the credit facility, including foreclosure against our properties securing the credit facilities, including our cash. These events of default include, among other things, our failure to pay any amounts due under the credit facility, a breach of covenants under the credit facility, our insolvency, a material adverse change, the occurrence of any default under certain other indebtedness in an amount greater than $400,000 and a final judgment against us in an amount greater than $400,000.

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. The warrant will

expire ten years from its date of issuance. If the warrant has not been exercised prior to its expiration date, it will be deemed to automatically convert by "cashless" conversion. In the event that we are acquired, the warrant will be exercisable or deemed automatically converted, which shall be determined based upon whether our successor assumes the obligations of the warrant.

We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. In the near-term, we anticipate that our expenses will increase substantially as we:

- continue our clinical trials associated with EVK-001, including our ongoing Phase 3 clinical trial in women and the companion clinical trial in men that we commenced in April 2014;
- 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 for us to complete our ongoing Phase 3 clinical trial of EVK-001 in women and the companion trial in men, they will not be sufficient to complete any additional development requirements requested by the FDA, or, if applicable, to prepare for commercialization of EVK-001 should we receive product approval. At this time, due to the risks inherent in the drug development process, we are unable to estimate with any certainty the costs we will incur in the continued development of EVK-001 for potential commercialization. However, we currently estimate the costs to complete our Phase 3 clinical trial in women and our companion clinical trial in men of EVK-001 will be approximately $16.5 million, of which, through December 31, 2014, $7.8 million have been incurred related to those clinical activities. Accordingly, we will continue to require substantial additional capital beyond our current cash and cash equivalents to continue our clinical development and potential commercialization activities. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our clinical development efforts. 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.

On November 13, 2014, we entered into the Sales Agreement with MLV, pursuant to which we may sell from time to time, at our option, up to an aggregate of $6.6 million of shares of our common stock through MLV, as sales agent. The sales of shares of our common stock made through the ATM equity program are made in "at-the-market" offerings as defined in Rule 415 of the Securities Act. As of December 31, 2014, we had not issued any shares of our common stock pursuant to the Sales Agreement. In January 2015, we sold 25,000 shares of common stock at a weighted average price per share of $6.74 pursuant to the Sales Agreement and received net proceeds of approximately $163,000, net of commissions and fees. We intend to use the net proceeds to continue to fund our ongoing Phase 3 clinical trial and for general corporate purposes. We currently have the capacity to issue up to approximately $6.4 million of additional shares of common stock pursuant to the Sales Agreement.

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. Although sales of our common stock have taken place pursuant to the Sales Agreement, there can be no assurance that MLV 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 $75.0 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 Sales Agreement, is limited to an aggregate of one-third of our public float. As of November 11, 2014, our public float was 2.9 million shares, the value of which was $20.0 million based upon the closing price of our common stock of $6.86 on such date. The value of one-third of our public float calculated on the same basis was $6.6 million.

In addition, we will not be able to make future sales of our common stock pursuant to the Sales Agreement unless certain conditions are met, which include the accuracy of representations and warranties made to MLV under the Sales

Agreement. Furthermore, MLV 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 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 Sales Agreement.

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, 2014 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 our product candidate, 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 the end of 2015. This

period could be shortened if there are any significant increases in planned spending on our EVK-001 development program or more rapid progress of our ongoing Phase 3 clinical trial 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.

The following table summarizes our cash flows for the year ended December 31, 2014 and 2013:

	Year Ended December 31,	
	2014	2013
Net cash used in operating activities	$(11,501,072)	$(3,040,270)
Net cash provided by financing activities	$1,460,190	$27,120,948
Net increase (decrease) in cash and cash equivalents	$(10,040,882)	$24,080,678

Operating Activities. The primary use of our cash has been to fund our operations.

Financing Activities. During the year ended December 31, 2014, we repaid our outstanding loan balance of $3 million to SVB, drew down a $4.5 million loan from Square 1 and paid approximately $83,000 for origination costs related to our loan and security agreement with Square 1. During the year ended December 31, 2013, our financing activity consisted of the receipt of a $2 million advance on our loan and security agreement with SVB to fund working capital requirements and the net proceeds of approximately $25.1 million from our IPO.

We believe that our existing cash and cash equivalents as of December 31, 2014, together with interest thereon, will be sufficient to meet our anticipated cash requirements until December 31, 2015. 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:

- the progress, costs, results of and timing of our clinical development program for EVK-001, including our ongoing Phase 3 clinical trial;
- the need for, and the progress, costs and results of, any additional clinical trials of EVK-001 we may initiate based on the results of our ongoing clinical trials or discussions with the FDA, including any additional trials the FDA or other regulatory agencies may require evaluating the safety of EVK-001;
- the outcome, costs and timing of seeking and obtaining regulatory approvals from the FDA, and any similar regulatory agencies;
- the timing and costs associated with manufacturing EVK-001 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 EVK-001;
- 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.

Off-Balance Sheet Arrangements

Through December 31, 2014, 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

Our most significant clinical trial expenditures are to CROs. The contracts with CROs generally are cancellable, with notice, at our option and do not have any cancellation penalties.

Our long-term debt obligation consists of amounts we are obligated to repay under our loan and security agreement with Square 1, of which we have drawn the full amount of $4.5 million as of December 31, 2014. We began making interest-only payments in January 2015. In November 2015, we will begin making the first of 24 monthly principal and interest payments, such that the loan balance will be fully repaid in November 2017. We expect to incur approximately $248,000, $184,000 and $57,000 of interest charges in 2015, 2016 and 2017.

In November 2013, we entered into an operating lease for office space in Solana Beach, California. The lease commenced on December 1, 2013 and will expire on December 31, 2015. Although rent payments did not commence until December 2013, we took possession of the facility in November 2013 to move into the facility. The lease contains annual rent increases and we received lease incentives in the form of rent abatements and a moving allowance. We recognize minimum rent payments, escalation clauses and lease incentive on a straight-line basis over the term of its operating lease. The difference between the minimum lease payments and the straight-line amount is accounted for as deferred rent. We also pay pass through costs and utility costs, which are expensed as incurred.

As of December 31, 2014, future minimum lease payments for our operating lease are $93,399 for the year ended December 31, 2015.

Item 7A. Quantitative and Qualitative Disclosure about Market Risk

Interest Rate Fluctuation Risk

Our cash and cash equivalents as of December 31, 2014 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, 2014 and 2013.

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 III 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, 2014 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, 2014.

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, 2014, 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, 2014 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 2015 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, 2014, 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:

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.

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, 2014 and 2013 and the related statements of operations, convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the two years in the period ended December 31, 2014. 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, 2014 and 2013, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2014, 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 4, 2015

56

Evoke Pharma, Inc.

Balance Sheets

	December 31, 2014	2013
Assets		
Current Assets:		
Cash and cash equivalents	$14,155,809	$24,196,691
Prepaid expenses	931,461	234,262
Other current assets	161,436	—
Total current assets	15,248,706	24,430,953
Other assets	53,023	555,505
Total assets	$15,301,729	$24,986,458
Liabilities and stockholders' equity		
Current Liabilities:		
Accounts payable and accrued expenses	$1,011,629	$284,915
Accrued compensation	697,245	557,399
Other current liabilities	12,313	—
Current portion of long-term debt	150,430	1,442,592
Total current liabilities	1,871,617	2,284,906
Other long-term liabilities	—	6,830
Long-term debt, net of current portion	4,241,448	1,511,461
Total liabilities	6,113,065	3,803,197
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.0001 par value; authorized shares — 5,000,000		
at December 31, 2014 and 2013; issued and outstanding shares —		
0 at December 31, 2014 and 2013	—	—
Common stock, $0.0001 par value; authorized shares — 50,000,000		
at December 31, 2014 and 2013; issued and outstanding shares —		
6,112,091 and 6,096,752 at December 31, 2014 and 2013, respectively	611	610
Additional paid-in capital	45,127,202	43,874,119
Accumulated deficit	(35,939,149)	(22,691,468)
Total stockholders' equity	9,188,664	21,183,261
Total liabilities and stockholders' equity	$15,301,729	$24,986,458

See accompanying notes.

57

Evoke Pharma, Inc.

Statements of Operations

	Year Ended December 31,	
	2014	2013
Operating expenses:		
Research and development	$9,991,855	$956,980
General and administrative	3,158,179	1,644,848
Total operating expenses	13,150,034	2,601,828
Loss from operations	(13,150,034)	(2,601,828)
Other income (expense):		
Interest income	10,187	7,248
Interest expense	(107,834)	(159,885)
Change in fair value of warrant liability	—	(82,000)
Total other expense	(97,647)	(234,637)
Net loss	$(13,247,681)	$(2,836,465)
Net loss per common share, basic and diluted	$(2.20)	$(1.20)
Weighted-average shares used to compute basic and diluted net loss per share	6,032,560	2,368,006

See accompanying notes.

Evoke Pharma, Inc.

Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)

	Series A Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount	Shares	Amount			
Balance at December 31, 2012	12,195,068	$18,225,166	1,242,750	$ 124	$195,525	$(19,855,003)	$(19,659,354)
Stock-based compensation expense	—	—	—	—	145,966	—	145,966
Conversion of shares of preferred stock to common stock	(12,195,068)	(18,225,166)	2,439,002	244	18,224,922	—	18,225,166
Initial public offering of common stock at $12.00 per share, net of $3,859,052 of offering costs	—	—	2,415,000	242	25,120,706	—	25,120,948
Reclassification of warrant liability	—	—	—	—	187,000	—	187,000
Net loss	—	—	—	—	—	(2,836,465)	(2,836,465)
Balance at December 31, 2013	—	—	6,096,752	610	43,874,119	(22,691,468)	21,183,261
Stock-based compensation expense	—	—	—	—	1,102,087	—	1,102,087
Issuance of common stock upon exercise of warrant	—	—	2,795	—	—	—	—
Issuance of common stock upon exercise of stock option	—	—	5,250	—	1,522	—	1,522
Issuance of common stock from employee stock purchase plan	—	—	7,294	1	41,352	—	41,353
	—	—	—	—	108,122	—	108,122

Fair market value of issued warrant	—	—	—	—	—		
Net loss						(13,247,681)	(13,247,681)
Balance of December 31, 2014	—	—	6,112,091	$ 611	$45,127,202	$(35,939,149)	$9,188,664

See accompanying notes.

Evoke Pharma, Inc.

Statements of Cash Flows

	Year Ended December 31,	
	2014	2013
Operating activities		
Net loss	$(13,247,681)	$(2,836,465)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	1,102,087	145,966
Non-cash interest	59,982	23,261
Change in fair value of warrant liability	—	82,000
Deferred rent expense	5,483	6,830
Change in operating assets and liabilities:		
Prepaid expenses and other assets	(287,503)	(234,262)
Other assets	—	(555,505)
Accounts payable and accrued expenses	866,560	327,905
Net cash used in operating activities	$(11,501,072)	(3,040,270)
Financing activities		
Proceeds from bank line of credit	4,500,000	2,000,000
Payment on bank line of credit	(3,000,000)	—
Costs paid in connection with loan origination	(82,685)	—
Proceeds from issuance of common stock, net	42,875	25,120,948
Net cash provided by financing activities	1,460,190	27,120,948
Net increase (decrease) in cash and cash equivalents	(10,040,882)	24,080,678
Cash and cash equivalents at beginning of period	24,196,691	116,013
Cash and cash equivalents at end of period	$14,155,809	$24,196,691
Supplemental disclosure of cash flow information		
Interest paid	$58,790	$128,875
Non-cash financing activities		
Issuance of Series A Convertible Preferred Stock warrants	—	$49,000
Conversion of Series A Convertible Preferred Stock to common stock		
at the initial public offering	—	$18,225,166

See accompanying notes.

Evoke Pharma, Inc.

Notes to Financial Statements

1. Organization and Basis of Presentation

Evoke Pharma, Inc. (the "Company") was incorporated in the state of Delaware on January 29, 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 significant risks and uncertainties, including funding its operations beyond the completion of its ongoing Phase 3 clinical trial for EVK-001.

In its report on the Company's financial statements for the year ended December 31, 2014, our independent registered public accounting firm included an explanatory paragraph expressing substantial doubt regarding our ability to continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has experienced significant losses since its inception, including net losses of $13.2 million and $2.8 million for the years ended December 31, 2014 and 2013, respectively. As of December 31, 2014, the Company had an accumulated deficit of $35.9 million, approximately $14.2 million in cash and cash equivalents, and $4.5 million in borrowings under its bank credit facility. Substantially all the Company's net losses have resulted from costs incurred in connection with its research and development programs and its general and administrative costs to support operations. 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 at least the next several years. Over that period, the Company will need to raise additional debt or equity financing to fund its development. 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.

In the quarter ended June 30, 2014, the Company early adopted ASU No. 2014-10, Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation. Please refer to Note 2 for further details.

On June 13, 2013, the Company's board of directors approved an amendment to the restated certificate of incorporation to effect a one-for-five reverse stock split of the Company's common stock (the "Reverse Stock Split"). The amendment effecting the Reverse Stock Split was approved by the stockholders on August 29, 2013. The par value and the authorized shares of the common and convertible preferred stock were not adjusted as a result of the Reverse Stock Split. All issued and outstanding common stock and the conversion ratio of the convertible preferred stock have been retroactively adjusted to reflect this Reverse Stock Split for all periods presented. The Reverse Stock Split was effected on August 30, 2013.

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 patients for its clinical trials. If these CROs are unable to continue managing the clinical trials, or are unable to recruit the sufficient number of patients, the delays could adversely affect the completion of the trials and the timing of the filing of our new drug application with the U.S. Food and Drug Administration ("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.

Deferred Offering Costs

Deferred offering cost of approximately $138,000, which primarily consist of legal, accounting and filing fees relating to the Company's Form S-3 filed in November 2014, have been capitalized and are included in other current assets as of December 31, 2014 on the accompanying balance sheet. The deferred offering costs will be offset against the proceeds from the January 2015 offering described in Note 6.

Stock-Based Compensation

Stock-based compensation expense for stock option grants and employee stock purchase plan shares 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 employee stock purchase plan 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.

Prior to the Company's initial public offering ("IPO"), the Company 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 the Company faced at the time, the preferences of the Company's preferred stockholders and the lack of liquidity of the Company's common stock. Subsequent to the IPO, the exercise price of the stock options granted to employees and members of the board of directors of the Company was determined by the Company's closing market price on the date the stock options were 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, 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 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 EVK-001, 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. The Company does not have any current contractual relationships for the manufacture of commercial supplies of EVK-001. If EVK-001 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 70,625 and 103,750 weighted-average shares subject to repurchase from the weighted-average number of common shares outstanding for the year ended December 31, 2014 and 2013, respectively. 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 warrants for the purchase of common stock, options outstanding under the Company’s equity incentive plans and potential shares to be purchased under the Company’s employee stock purchase plan. 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,	
	2014	2013
Warrants to purchase common stock	118,881	106,000
Common stock options	683,500	624,750
Employee stock purchase plan	12,627	—
Total excluded securities	815,008	730,750

Recent Accounting Pronouncements

In June 2014, the Financial Accounting Standards Board ("FASB") issued an Accounting Standards Update ("ASU") No. 2014-10, Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation. This guidance removes the definition of a development stage entity from FASB's accounting standards codification, thereby removing the financial reporting distinction between development stage entities and other reporting entities from U.S. GAAP. In addition, the guidance eliminates the requirements for development stage entities to (1) present inception-to-date information in the statements of income, cash flows and stockholders' equity, (2) label the financial statements as those of a development stage entity, (3) disclose a description of the development stage activities in which the entity is engaged, and (4) disclose in the first year in which the entity is no longer a development stage entity that in prior years it had been in the development stage. The guidance becomes effective in the first annual period beginning after December 15, 2014, with an option for early adoption. The Company chose to early adopt this standard during the quarter ended June 30, 2014.

In June 2014, the FASB issued ASU 2014-12, Stock Compensation (Topic 718): Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could Be Achieved after the Requisite Service Period. This guidance requires that a performance target included in a share-based payment award that affects vesting and that could be achieved after the requisite service period be treated as a performance condition. Therefore, such performance target should not be reflected in estimating the grant-date fair value of the award. A reporting entity should apply existing guidance in Topic 718 as it relates to the award with performance conditions that affect vesting. That is, compensation cost should be recognized in the period in which it becomes probable that the performance condition would be achieved and should represent the compensation cost attributable to the period(s) for which the requisite service has already been rendered. If the performance target becomes probable of being achieved before the end of the requisite service period, the remaining unrecognized compensation cost should be recognized prospectively over the remaining requisite service period. The total amount of compensation cost recognized during and after the requisite service period should reflect the number of awards that are expected to vest and would be adjusted to reflect those awards that ultimately vest. Entities may apply the amendments in this Update either (a) prospectively to all awards granted or modified after the effective date or (b) retrospectively to all awards with performance targets that are outstanding as of the beginning of the earliest annual period presented in the financial statements and to all new or modified awards thereafter. If retrospective transition is adopted, the cumulative effect of applying this Update as of the beginning of the earliest annual period presented in the financial statements should be recognized as an adjustment to the opening retained earnings balance at that date. Additionally, if retrospective transition is adopted, an entity may use hindsight in measuring and recognizing the compensation cost. The guidance is effective for annual periods and interim periods within those annual periods beginning after December 15, 2015 with early adoption permitted. The Company is currently evaluating the impact of this guidance and expects to adopt the standard for the annual reporting period ended December 31, 2016.

In August 2014, the FASB issued ASU 2014-15 (Subtopic 205-40), Presentation of Financial Statements - Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. The guidance requires management to evaluate whether there are conditions and events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the financial statements are issued (or available to be issued when applicable). Management will be required to make this evaluation for both annual and interim reporting periods and will have to make certain disclosures if it concludes that substantial doubt exists or when its plans alleviate substantial doubt about the entity's ability to continue as a going concern. Substantial doubt exists when relevant conditions and events, considered in the aggregate, indicate that it is probable that the entity will be unable to meet its obligations as they become due within one year after the date that the financial statements are issued (or available to be issued). The term probable is used consistently with its use in ASC Topic 450, Contingencies. The guidance is effective for annual periods ending after December 15, 2016 and for interim reporting periods starting in the first quarter 2017, with early adoption permitted. The Company is currently evaluating the impact of this guidance and expects to adopt the standard for the annual reporting period ended December 31, 2016.

3. Debt

In June 2012, the Company entered into a $3 million loan and security agreement with Silicon Valley Bank (“SVB”), collateralized by the Company’s personal property. The agreement also contained non-financial covenants. By January 2013, the Company had been advanced the entire $3 million. Interest on advances under the agreement was at a fixed interest rate equal to 4.50%. Advances under the loan and security agreement had an interest-only period through December 31, 2013, and had a 24-month payback period that commenced in January 2014. On May 23, 2014, the Company repaid the outstanding principal and accrued interest of approximately $2.4 million to SVB. In addition, the Company expensed approximately $38,000 of unamortized debt discount costs upon the repayment of the loan. With such payoff, the SVB loan agreement and the documents entered into in connection therewith were deemed to be terminated. SVB’s security interest in substantially all of the Company’s assets was also terminated.

On May 28, 2014 (the “closing date”), the Company entered into a loan and security agreement (the “credit facility”) with Square 1 Bank (“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 a principal amount of up to $4.5 million.

In December 2014, the Company drew down the entire $4.5 million. The credit facility bears interest at a fixed annual rate of 5.50%. The Company is required to make interest-only payments through November 28, 2015 on the credit facility. The outstanding principal balance plus interest will begin amortizing at the end of the interest-only period, with monthly payments of principal and interest being made by the Company to Square 1 in consecutive monthly installments following November 28, 2015 until the credit facility matures on November 28, 2017. At the Company's option, it may prepay the outstanding principal balance of the credit facility before November 28, 2017 without penalty or premium.

The credit facility includes affirmative and negative covenants applicable to the Company and any subsidiaries it creates in the future. The affirmative covenants include, among others, covenants requiring the Company to maintain its legal existence and governmental approvals, deliver certain financial reports, maintain insurance coverage and meet certain covenants with respect to enrollment and results of its EVK-001 Phase 3 trial. After the Company receives positive results from the Phase 3 trial, if at all, it must either maintain a ratio of its cash at Square 1 to its cash burn over the preceding month of at least 3.00 to 1.00, or it must deliver evidence of a forthcoming financing or strategic partnership arrangement to Square 1, in each case in an amount satisfactory to Square 1. The negative covenants include, among others, restrictions on the Company's transferring collateral, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions, making investments, creating liens and selling assets, in each case subject to certain exceptions.

The credit facility also includes events of default, the occurrence and continuation of which provide Square 1 with the right to exercise remedies against the Company and the collateral securing the term loans under the credit facility, including foreclosure against the Company's properties securing the credit facilities, including its cash. These events of default include, among other things, the Company's failure to pay any amounts due under the credit facility, a breach of covenants under the credit facility, the Company's insolvency, a material adverse change, the occurrence of any default under certain other indebtedness in an amount greater than $400,000 and a final judgment against the Company in an amount greater than $400,000.

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. The warrant expires ten years from its date of issuance. If the warrant has not been exercised prior to its expiration date, it will be deemed to automatically convert by "cashless" conversion. In the event that the Company is acquired, the warrant will be exercisable or deemed automatically converted, which shall be determined based upon whether the Company's successor assumes the obligations of the warrant.

The estimated fair value of the warrant issued to Square 1 was determined on the date of issuance using the Black-Scholes option-pricing valuation model with the following assumptions:

Risk free interest rate	2.17%
Expected warrant term	10 Years
Expected volatility of common stock	77.19%
Expected dividend yield	0.00%

The value determined for the warrant of $108,122 has been recorded as a debt discount, as well as to equity. The debt discount will be amortized to interest expense over the remaining term of the loan.

The Company incurred approximately $83,000 of loan origination costs related to this credit facility. Such costs have been capitalized and are being amortized to interest expense over the 42 month term of the credit facility.

Future maturities of long-term debt and interest payments under the credit facility as of December 31, 2014 are set forth below:

2015	436,375
2016	2,433,505
2017	2,119,935
Total minimum payments	4,989,815
Less amounts representing interest	(489,815)
Gross balance of outstanding debt	$4,500,000
Less debt discount [(1)]	(108,122)
Total carrying value	$4,391,878
Less current portion	(150,430)
Total carrying value, long-term portion	$4,241,448

(1) Represents the initial fair value of the detachable warrants to purchase common stock issued in connection with the term debt, net of amortization.

Total interest incurred under the loan and security agreements for the years ended December 31, 2014 and 2013 (excluding amortization of debt discount and loan origination costs) was $47,165 and $136,625, respectively.

4. Commitments

In November 2013, the Company entered into an operating lease for office space in Solana Beach, California. The lease commenced on December 1, 2013 and will expire on December 31, 2015. Although rent payments did not commence until December 2013, the Company took possession of the facility in November 2013 to move into the facility. The lease contains annual rent increases and the Company received lease incentives in the form of rent abatements and a moving allowance.

The Company recognizes minimum rent payments, escalation clauses and lease incentives on a straight-line basis over the term of its operating lease. Prior to entering into the facility lease, the Company temporarily leased office space on a month-to-month basis and recognized the expense as incurred.

Rent expense for 2014 and 2013 was $81,086 and $8,886, respectively. The difference between the minimum lease payments and the straight-line amount is accounted for as deferred rent. Deferred rent expense at December 31, 2014 and 2013 was $12,313 and $6,830, respectively. The Company also pays pass through costs and utility costs, which are expensed as incurred.

As of December 31, 2014, the Company has future minimum lease payments under its operating lease in 2015 of $93,399.

5. Technology Acquisition Agreement

In June 2007, the Company acquired all worldwide rights, data, patents and other related assets associated with EVK-001 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 EVK-001. 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 totaling up to $51.5 million. These milestones include up to $4.5 million in payments if EVK-001 achieves the following development targets:

$1.5 million upon the FDA’s acceptance for review of a new drug application for EVK-001; and
$3 million upon the FDA’s approval of EVK-001.

The remaining $47 million in milestone payments depend on EVK-001’s commercial success and will only apply if EVK-001 receives regulatory approval. In addition, the Company will be required to pay to Mallinckrodt a low single digit royalty on net sales of EVK-001. The Company’s obligation to pay such royalties will terminate upon the expiration of the last patent right covering EVK-001, 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, 2014 or 2013.

Initial Public Offering

In September 2013, the Company completed the IPO whereby it issued and sold 2,100,000 shares of common stock at a public offering price of $12.00 per share. Concurrently with the completion of the IPO, all outstanding shares of convertible preferred stock were converted into 2,439,002 shares of the Company's common stock. In addition, warrants to purchase 84,000 shares of the Company's common stock were issued to the representative of the underwriters of the Company's IPO and certain of its affiliates. The warrants became exercisable at a price of $21.00 per share beginning on September 24, 2014 and will expire on September 24, 2018. Finally, warrants to purchase 110,000 shares of convertible preferred stock were converted into warrants to purchase 22,000 shares of the Company's common stock and upon this conversion became classified as equity. In October 2013, the underwriters for the IPO exercised an option to purchase 315,000 additional shares of the Company's common stock at $12.00 per share. Total net proceeds from the IPO, after deducting underwriter discounts, commissions and other offering expenses of $3.9 million, were $25.1 million.

Common Stock

As of December 31, 2014, there were 6,112,091 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.

On November 13, 2014, the Company entered into an At Market Sales Agreement ("Sales Agreement") with MLV & Co. LLC ("MLV"), pursuant to which the Company may sell from time to time, at its option, up to an aggregate of $6.6 million of shares of common stock through MLV, as sales agent. The sales of shares of the Company's common stock made through this equity program are made in "at-the-market" offerings as defined in Rule 415 of the Securities Act. As of December 31, 2014, the Company had not issued any shares of its common stock pursuant to the Sales Agreement. In January 2015, the Company sold 25,000 shares of common stock at a weighted average price per share of $6.74 pursuant to the Sales Agreement and received net proceeds of approximately $163,000, net of commissions and fees. The Company intends to use the net proceeds to continue to fund its ongoing Phase 3 clinical trial and for general corporate purposes. The Company currently has the capacity to issue up to approximately $6.4 million of additional shares of common stock pursuant to the Sales Agreement.

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. Although sales of the Company's common stock have taken place pursuant to the Sales Agreement, there can be no assurance that MLV 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. Under current SEC regulations, at any time during which the aggregate market value of the Company's common stock held by non-affiliates, or public float, is less than $75.0 million, the amount the Company can raise through primary public offerings of securities in any twelve-month period using shelf registration statements, including sales under the Sales Agreement, is limited to an aggregate of one-third of the Company's public float. As of November 11, 2014, the Company's public float was 2.9 million shares, the value of which was $20.0 million based upon the closing price of the Company's common stock of $6.86 on such date. The value of one-third of the Company's public float calculated on the same basis was $6.6 million.

In addition, the Company will not be able to make future sales of common stock pursuant to the Sales Agreement unless certain conditions are met, which include the accuracy of representations and warranties made to MLV under the Sales Agreement. Furthermore, MLV 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 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 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, 2013	106,000	$ 18.20	5.13
Issued	22,881	$ 5.90	10.00
Exercised	(10,000)	$ 7.50	3.10
Expired/Forfeited	—	—	—
Outstanding at December 31, 2014	118,881	$ 16.73	5.35

Stock Options

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, 2014, 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. As a result of such calculation, the Company increased the number shares reserved for issuance under the 2013 Plan by 243,870 shares. As of December 31, 2014, 188,370 options remain available for future grant under the 2013 Plan. On January 1, 2015, the Company further increased the number of shares reserved for issuance under the 2013 Plan by 244,484 shares, making 432,854 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 64,000 and 501,500 shares of common stock in 2014 and 2013, respectively. The exercise price of all options granted during the years ended December 31, 2014 and 2013 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:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2013	624,750	$ 7.61	8.41	$ 869,490
Granted	64,000	$ 7.65	9.35	—
Exercised	(5,250)	$ 0.29	2.70	$ 33,810
Expired/Forfeited	—	—	—	—
Outstanding at December 31, 2014	683,500	$ 7.67	8.45	$ 649,000
Vested and expected to vest at December 31, 2014	683,500	$ 7.67	8.45	$ 649,000
Exercisable at December 31, 2014[(1)]	259,081	$ 5.47	7.65	$ 631,231

(1) Includes awards with early exercise provisions that permit optionee to exercise unvested options.

Except for the stock options exercised, the intrinsic values above represent the aggregate value of the total pre-tax intrinsic value based upon a common stock price of $5.90 and $7.45 at December 31, 2014 and 2013, respectively, and the contractual exercise prices. The intrinsic value for the stock option exercise is based upon a common stock price of $6.73 on the date of exercise.

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 ("Repurchase Option"). 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 and 230,500 were vested as of December 31, 2014 and 2013, respectively.

The total intrinsic value of stock options exercised was $33,810 and $0 for the years ended December 31, 2014 and 2013, respectively. There was one option exercised in 2014 and no options exercised during 2013.

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

	Shares	Weighted Average Grant Date Fair Value Per Share
Nonvested at December 31, 2013	534,210	$ 8.84
Granted	64,000	$ 4.76
Vested	(173,791)	$ 7.96
Expired/Forfeited	—	—
Nonvested at December 31, 2014	424,419	$ 9.02

Stock-Based Compensation

Stock-based compensation expense includes charges related to stock option grants and employee stock purchases under the Company's Employee Stock Purchase Plan (the "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, 2014:

The weighted average grant date fair value per share of employee stock options granted during the years ended December 31, 2014 and 2013, was $4.76 and $6.33, respectively.

	Year Ended December 31,	
	2014	2013
Risk free interest rate	1.66% - 1.77%	1.75% - 1.8%
Expected option term	5.5 - 6.0 years	6.0 years
Expected volatility of common stock	71.06% - 73.21%	70.8% - 79.4%
Expected dividend yield	0.00%	0.00%

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 January 1, 2014. During 2014, 7,294 shares of common stock were issued under the ESPP. As of December 31, 2014, 52,706 shares remain available for future issuance under the ESPP. On January 1, 2015, the Company further increased the number of shares reserved for future issuance under the ESPP by 30,000 shares, making 82,706 shares available 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, 2014:

	Year Ended December 31,	
	2014	2013
Risk free interest rate	0.05% - 0.08%	—
Expected term	6.0 months	—
Expected volatility of common stock	69.32% - 73.21%	—
Expected dividend yield	0.00%	—

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:

	Year Ended December 31,	
	2014	2013
Research and development	$410,150	$39,638
General and administrative	691,937	106,328
Total stock-based compensation expense	$1,102,087	$145,966

As of December 31, 2014, there was approximately $2,323,000 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 1.32 years.

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance consists of the following at December 31, 2014 and 2013:

	December 31,	
	2014	2013
Stock options issued and outstanding	683,500	624,750
Authorized for future option grants	188,370	8,500
Warrants to purchase common stock	118,881	106,000
Authorized for employee stock purchase plan	52,706	30,000
Total common stock reserved for future issuance	1,043,457	769,250

7. 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 year ended December 31, 2014, the Company adopted Safe Harbor 401(k) provisions and payments of approximately $20,000 will be contributed to the accounts of certain employees in order to maintain the Plan's compliance with Internal Revenue Service regulations.

8. 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 our subjective assumptions and judgments can materially affect amounts recognized in our 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 sheets at December 31, 2014 and 2013. 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, 2014 and 2013:

	December 31,	
	2014	2013
	(%)	(%)
Federal statutory rate	34.0	34.0
Change in valuation allowance	(1.6)	(2.5)
State income taxes, net of federal effect	5.8	5.8
Research and development credits	5.0	4.3
Removal of net operating loss and other credits	(41.2)	(39.5)

Stock compensation and other permanent items	(2.0)	(2.1)
Effective income tax rate	0.0	0.0

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 $13.2 million and a research and development credit of approximately $1.6 million generated through December 31, 2014 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, 2014 and 2013 are as follows:

	December 31,	
	2014	2013
Acquired technology	$317,000	$147,000
Stock compensation expense	223,000	67,000
Accruals and other	105,000	223,000
Total deferred tax assets		