

Evoke Pharma Inc  
Form 10-K  
March 25, 2014  
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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
**WASHINGTON, DC 20549**

**Form 10-K**

(Mark One)

**ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the fiscal year ended December 31, 2013**

**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**  
**(State or Other Jurisdiction of**

**20-8447886**  
**(I.R.S. Employer**

**Incorporation or Organization)**

**Identification No.)**

**505 Lomas Santa Fe Drive, Suite 270**

**Solana Beach, California**  
**(Address of Principal Executive Offices)**

**92075**  
**(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**  
**Common Stock, par value \$0.0001 per share**

**Name of Each Exchange on Which Registered**  
**The NASDAQ Capital Market**

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

**None**

## Edgar Filing: Evoke Pharma Inc - Form 10-K

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

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

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K 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

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

As of March 20, 2014, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was approximately \$27,627,705, based on the closing price of the registrant's common stock on the NASDAQ Capital Market of \$10.34 per share.

The number of outstanding shares of the registrant's common stock, par value \$0.0001 per share, as of March 20, 2014 was 6,099,547.

### 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 2014 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, 2013.

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**EVOKE PHARMA, INC.**  
**FORM 10-K ANNUAL REPORT**  
**For the Fiscal Year Ended December 31, 2013**

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**PART I**

**Forward-Looking Statements and Market Data**

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. All statements other than statements of historical facts contained in this Annual Report on Form 10-K, including statements regarding our future results of operations and financial position, business strategy, prospective products, product approvals, 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, believe, 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, 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.

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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. We plan to initiate a Phase 3 trial of EVK-001 in female patients with symptoms associated with acute and recurrent diabetic gastroparesis in the first half of 2014. We anticipate receiving topline data from this trial in mid-2015. We will need to successfully complete this trial, as well as a thorough QT, or TQT, study, which is an evaluation of cardiac safety, 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. FDA approval of the NDA is required in order for us to commercially market EVK-001 in the United States. In addition, based on our discussions with the FDA, we plan to conduct a similar study for safety and efficacy in male patients with symptoms associated with acute and recurrent diabetic gastroparesis to assess the safety and efficacy of EVK-001 in men. We anticipate this trial will be conducted concurrently with the Phase 3 trial in women. The completion of the male companion trial is not required for submission of the NDA for EVK-001 for women; however, we expect to include safety data from this trial in our NDA submission for EVK-001.

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, our companion clinical trial in men and a TQT study of EVK-001 will be approximately \$15.0 million.

**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 preparing to initiate a Phase 3 trial of EVK-001 in female patients suffering from diabetic gastroparesis in the first half of 2014.

*Seek partnerships to accelerate and maximize the potential for EVK-001.* As we continue to generate data on EVK-001, we will seek 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 intend to evaluate 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 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.



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### ***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 with 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.



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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; although, 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, forward 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 2011, the American Diabetes Association estimated that diabetes affects approximately 26 million people of all ages in the United States, equating to about 8.3% 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 recent 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<sup>®</sup> 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, domperidone, 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.

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 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 blocks 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.

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We believe that if approved EVK-001 could also offer an alternative route of administration for female patients with severe symptoms of diabetic gastroparesis, who typically receive the intravenous formulation of metoclopramide. 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 (79% 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. Fewer than 150 subjects were enrolled across all studies included in the NDA for Reglan. 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.

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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)**

	<b>EVK-001 10 mg <i>p</i>-values</b>	<b>EVK-001 14 mg <i>p</i>-values</b>
<b>mGCSI-DD Total Score (per FDA guidance) (1)</b>		
All Subjects	0.1504	0.3005
Females	<b>0.0247</b>	<b>0.0215</b>
Males	0.4497	0.2174
<b>GCSI-DD Total Score (per trial protocol) (2)</b>		
All Subjects	0.2277	0.5266
Females	<b>0.0485</b>	<b>0.0437</b>
Males	0.4054	0.0972

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

- (1) The mGCSI-DD was comprised of 4 symptoms collected on a severity rating scale of 0 to 5. Baseline was 7 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 9 symptoms collected on a severity rating scale of 0 to 5. Baseline was 7 days prior to treatment or qualifying days during washout and Week 4 was days 21 to 27 of treatment.

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The table below summarizes the key data from the trial across all subjects and for female and male payments 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)**

<b>Time Point</b>	<b>Placebo (N=95)</b>	<b>Metoclopramide 10 mg IN (N=96)</b>	<b>Metoclopramide 14 mg IN (N=96)</b>
<b>ALL SUBJECTS</b>			
Baseline (1)			
N	95	96	96
Mean (SD)	2.8 (0.57)	2.9 (0.60)	2.8 (0.62)
Week 4			
N	95	96	96
Mean (SD)	1.8 (1.00)	1.6 (1.06)	1.7 (0.90)
Change from Baseline to Week 4			
N	95	96	96
Mean (SD)	-1.0 (0.89)	-1.2 (1.18)	-1.2 (0.94)
Difference of Least Square Means (95% CI)		-0.20 (-0.47, 0.07)	-0.14 (-0.42, 0.13)
Pairwise <i>p</i> -value vs. Placebo (2)		0.1504	0.3005
Difference of Least Square Means (95% CI)			0.06 (-0.22, 0.33)
Pairwise <i>p</i> -value vs. Metoclopramide 10 mg (2)			0.6830
<b>FEMALES</b>			
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 <i>p</i> -value vs. Placebo (2)		<b>0.0247</b>	<b>0.0215</b>
Difference of Least Square Means (95% CI)			-0.00 (-0.33, 0.32)



Pairwise <i>p</i> -value vs. Metoclopramide 10 mg (2)			0.9864
<b>MALES</b>			
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 <i>p</i> -value vs. Placebo (2)		0.4497	0.2174
Difference of Least Square Means (95% CI)			0.14 (-0.35, 0.63)
Pairwise <i>p</i> -value vs. Metoclopramide 10 mg (2)			0.5805

(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 analysis of covariance, or ANCOVA, model with effects for treatment group and baseline value as a covariate

**Table of Contents****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 ( $\geq 2\%$  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 2 Subjects in Any Treatment Group**

System Organ Class Preferred Term	All Subjects		
	Placebo (N = 95)	EVK-001 10 mg (N = 95)	EVK-001 14 mg (N = 95)
<b>Nervous System Disorders</b>			
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%)
<b>Gastrointestinal Disorders</b>			
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%)
<b>Respiratory, Thoracic, and Mediastinal Disorders</b>			
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%)
<b>Infections and Infestations</b>			
Upper respiratory tract infection	4 (4.2%)	0 (0.0%)	2 (2.1%)
Nasopharyngitis	1 (1.1%)	3 (3.2%)	1 (1.1%)
<b>General Disorders and Admin Site Conditions</b>			
Fatigue	1 (1.1%)	5 (5.3%)	6 (6.3%)
<b>Metabolism &amp; Nutrition Disorders</b>			
Hyperglycemia	1 (1.1%)	1 (1.1%)	3 (3.2%)
Hypoglycemia	1 (1.1%)	1 (1.1%)	3 (3.2%)
<b>Psychiatric Disorders</b>			
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.

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.

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**EVK-001 Phase 1 Clinical Trial**

**Mean Plasma Concentrations of Metoclopramide**

**(15 minute intervals 0-2h)**

*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 1,045 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, 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 intend to evaluate the same formulation in our proposed Phase 3 clinical trial. Similarly, the nasal spray pump used in our completed Phase 1 and Phase 2 clinical trials was identical and will also be used in our proposed 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 Planned Four-Week Phase 3 Clinical Trial in Female Subjects with Diabetic Gastroparesis*

Based on discussions with the FDA, we plan to conduct one Phase 3 trial in women, which we believe, if successful, will be sufficient for NDA submission. We plan to initiate 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 in the first half of 2014. 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.

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. We anticipate receiving topline data from this trial in mid-2015. Also based on discussions with FDA, and to assess safety in men, we plan to conduct a similar and concurrent companion study for safety and efficacy in diabetic men with gastroparesis. The trial design will include 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. We also plan to conduct the required TQT study of EVK-001 prior to NDA submission.

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**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 of 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.

**Table of Contents****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 preclinical research and clinical trials. We do not have any current contractual relationships for the manufacture of commercial supplies of EVK-001. If EVK-001 is approved by any regulatory agency, we intend to enter into agreements with third-party contract manufacturers for the commercial production at that time. 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 three other development candidates. All are in Phase 2 clinical development.

**Gastroparesis Treatment Development Pipeline**

<b>Product</b>	<b>Class</b>	<b>Route</b>	<b>Company</b>	<b>Status</b>
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EVK-001	dopamine antagonist /mixed	intranasal	Evoke Pharma	Phase 3
	5-HT3 antagonist 5-HT4 agonist			Ready
RM-131	ghrelin agonist	sub-cutaneous	Rhythm Pharmaceuticals	Phase 2a
GSK962040	motilin agonist	oral	GlaxoSmithKline	Phase 2a
TD-5108	5-HT4 receptor agonist	oral	Theravance	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 that 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.

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.

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.

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Tegaserod, another 5-HT<sub>4</sub> 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.

## **Questcor Acquisition Agreement**

We acquired all worldwide rights, data, patents and other related assets associated with EVK-001 from Questcor in June 2007. We paid Questcor \$650,000 in the form of an upfront payment and will be required to make additional milestone payments totaling up to \$52,000,000. These milestones include up to \$5,000,000 in payments if EVK-001 achieves the following development targets:

\$500,000 upon the initiation of the first patient dosing in our planned Phase 3 clinical trial for EVK-001;

\$1,500,000 upon the FDA's acceptance for review of an NDA for EVK-001; and

\$3,000,000 upon the FDA's approval of EVK-001.

The remaining \$47,000,000 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 Questcor 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 FDCA, 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, or GLP, 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 practices, or GCP, 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, and for devices and device components, the Quality System Regulations, or QSR, and to assure that the facilities, methods and controls are adequate to preserve the drug'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 independent 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.



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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](http://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 a ten-month timeframe. A Priority Review designation is given to drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists. The goal for completing a Priority

Review is six months. 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 by the FDA for three additional months to consider certain information or obtain clarification regarding information already provided in the 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. In addition, for combination products, the FDA's review may include the participation of both the FDA's Center for Drug Evaluation and Research and the FDA's Center for Devices and Radiological Health, which may complicate or prolong the review.

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, for the device component of the product, QSR requirements 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 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.

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### *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 drugs 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, or the FDAAA, 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 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 FDAAA. 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 FDCA, 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 FDCA. 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



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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 FDCA, the filing of a patent infringement lawsuit within 45 days of their 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 and, if 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.

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### **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, the recently enacted Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the Health Care Reform Law, among other things, amends the intent requirement of the federal Anti-Kickback Statute and the criminal statute governing healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of these statutes or specific intent to violate them. In addition, the Health Care Reform Law 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 or federal civil money penalties statute. 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.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians and other healthcare providers. The Health Care Reform Law, 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 were required to begin collecting data on August 1, 2013 and submit reports to the government by March 31, 2014 and the 90<sup>th</sup> day of each subsequent 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.

### **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.

### **Employees**

We currently have seven full-time employees and several consultants in the regulatory, clinical, manufacturing and finance areas, which we engage on an as-needed, hourly basis. 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.

### **Financial Information about Segments**

We operate only in one business segment, which is the development of pharmaceutical products. See note [2] to our consolidated 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.

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**Research and Development**

We invested approximately \$957,000, \$1,166,000, and \$1,844,000 in research and development in the years ended December 31, 2013, 2012 and 2011, respectively.

**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](http://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](http://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.

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**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, which has not yet entered a Phase 3 clinical trial. 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 planned Phase 3 clinical trial of EVK-001, which we intend to commence in the first half of 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 clinical trials may not confirm the positive results of earlier clinical trials, particularly because we will utilize a modified patient report outcomes, or PRO, instrument for our planned 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 a 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 with Silicon Valley Bank and a prior lender. We believe, based on our current operating plan, that the net proceeds from our initial public offering and our existing cash and cash equivalents, together with interest thereon, will be sufficient to fund our operations for approximately the next 18 months as of December 31, 2013, although there can be no assurance in that regard. Because we expect our planned Phase 3 clinical trial of EVK-001 to commence in the first half of 2014 with an approximately 12-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.

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.



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***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 planned 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 currently plan to commence one Phase 3 clinical trial in female patients with symptoms associated with acute and recurrent diabetic gastroparesis in the first half of 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 planned 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 Gastroparesis Cardinal Symptom Index Daily Diary, or 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 Gastroparesis Symptom Assessment, or 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 planned 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 currently plan to commence one Phase 3 clinical trial in female patients with symptoms associated with acute and recurrent diabetic gastroparesis in the first half of 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 currently plan to conduct one Phase 3 trial in adult female subjects with diabetic gastroparesis, which we believe will be sufficient for NDA submission seeking an indication of treatment of symptoms associated with diabetic gastroparesis in women. We plan to initiate 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 in the first half of 2014. Although we believe successful results from this single Phase 3 clinical 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 plan to conduct a similar study for safety and efficacy in adult male subjects with diabetic gastroparesis. If we are unable to comply with the FDA's requirements, we will not be able to obtain approval for EVK-001 and our business will suffer.

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*Any termination or suspension of, or delays in the commencement or completion of, our planned 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 commencement or completion of our planned Phase 3 clinical trial for EVK-001 could significantly affect our product development costs. We do not know whether our planned trial will begin on time or be completed 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 failing to grant permission to proceed and placing the clinical trial on hold;

subjects failing to enroll or remain in our trial at the rate we expect;

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.

***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.

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*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 risk evaluation and mitigation strategy or REMS plan 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. 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 for metoclopramide drug products 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.

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.

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**Table of Contents*****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 planned Phase 3 clinical trial of EVK-001. We will be required to reach agreement on acceptable terms with the clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among trial sites. We will need assistance from our CRO in obtaining IRB approval at each clinical trial site and will rely on our CRO to recruit suitable patients to participate in the proposed trial.

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.

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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, DMD, MD, RAC, 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.

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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 Health Care Reform Law, 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 Health Care Reform Law, 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 Health Care Reform Law, 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 Health Care Reform Law 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. 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 Health Care Reform Law, 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 addition, the Health Care Reform Law 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 Health Care Reform Law 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 were required to begin data collection on August 1, 2013 and will be required to report such data to the government by March 31, 2014 and by the 90<sup>th</sup> calendar day of each year thereafter. 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.

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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 planned 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.





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***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.

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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.

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***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**

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 following the completion of our initial public offering, we expect to be able to fund our operations for approximately the next 18 months as of December 31, 2013. 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 planned 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 as we begin our Phase 3 clinical trial for EVK-001. Our net loss for the year ended December 31, 2013, was approximately \$2.8 million. As of December 31, 2013, we had an accumulated deficit of approximately \$22.7 million. Losses have resulted principally from costs incurred in our clinical trials, research and development programs and from our general and administrative expenses. 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 initiation, progress, costs, results of and timing of our clinical development program for EVK-001, including our planned 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 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 Questcor 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. 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.

If we are unable to obtain funding on a timely basis, if required, we will be unable to complete the planned 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.



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***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 \$3.0 million loan and security agreement with Silicon Valley Bank that is secured by a lien covering substantially all of our assets, excluding intellectual property. As of December 31, 2013, the outstanding principal balance of the Silicon Valley Bank loan was \$3.0 million. The loan agreement contains customary affirmative and negative covenants and events of default. The affirmative covenants include, among others, covenants requiring us to maintain our legal existence and governmental approvals, deliver certain financial reports and maintain insurance coverage. The negative covenants include, among others, restrictions on transferring collateral, changing our business, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions, making investments and creating other liens on our assets, in each case subject to customary exceptions. If we default under the loan agreement, the lender may accelerate all of our repayment obligations and take control of our pledged assets, potentially requiring us to renegotiate our agreement on terms less favorable to us or to immediately cease operations. Further, if we are liquidated, the lender's right to repayment would be senior to the rights of the holders of our common stock to receive any proceeds from the liquidation. The lenders 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, 2013, we had federal and state net operating loss carryforwards of approximately \$21.2 million and \$20.7 million, respectively, and federal research and development credits of approximately \$627,000 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.***

Prior to our initial public offering in September 2013, there was no public market for our common stock. An active trading market may never develop or be sustained. If an active trading market does not develop or is not sustained, it may be difficult to sell shares of our common stock at a price that is desirable or at all. In addition, an inactive market may impair our ability to raise capital by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration, which, in turn, could materially adversely affect our business. Since the commencement of trading in connection with our initial public offering in September 2013 through March 20, 2014, the sale price per share of our common stock on The NASDAQ Capital Market has ranged from a low of \$6.75 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 planned 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.

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***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 March 20, 2014, our executive officers, directors and greater than 5% stockholders, in the aggregate, owned approximately 56.2% 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 and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, our loan and security agreement with Silicon Valley Bank 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.***

The lock-up agreements pertaining to our initial public offering expired on March 23, 2014, which was 180 days after the date of the underwriting agreement pertaining to our initial public offering. Sales of a substantial number of shares of our common stock in the public market after the expiration of these lock-up agreements, 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.



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As of March 20, 2014, we had 6,099,547 shares of common stock outstanding. Of these shares, only the 2,415,000 shares of common stock sold by us in our initial public offering are freely tradable without restriction in the public market. However, Aegis Capital Corp., the representative of the underwriters for our initial public offering, may, in its sole discretion, permit our officers, directors and other stockholders who are subject to lock-up agreements to sell shares prior to the expiration of the lock-up agreements.

After the lock-up agreements expire, up to an additional 3,684,547 shares of common stock will be eligible for sale in the public market, of which 3,427,622 shares are held by directors, executive officers and other affiliates and will be subject to volume limitations under Rule 144 under the Securities Act of 1933, as amended, or 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, the lock-up agreements and Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

As of March 20, 2014, the holders of 2,984,752 shares of our common stock will be entitled to rights with respect to the registration of their shares under the Securities Act, subject to the lock-up agreements described above. In addition, holders of 84,000 shares of common stock issuable upon the exercise of warrants will be entitled to rights with respect to the registration of their shares under the Securities Act, subject to the lock-up agreements described above. 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 consolidated 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.



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*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.

**Table of Contents****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:

	<b>High</b>	<b>Low</b>
<b>Year Ended December 31, 2013</b>		
Fourth Quarter	\$ 14.25	\$ 6.75
Third Quarter	\$ 12.29	\$ 10.55

**Holders of Common Stock**

As of March 20, 2014, there were 43 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.

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**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 Silicon Valley Bank 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.

**Table of Contents****Item 6. Selected Financial Data.**

## SELECTED FINANCIAL DATA

You should read the following selected financial data 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, 2013, 2012, and 2011 and the period from January 29, 2007 (inception) to December 31, 2013, and the balance sheet data as of December 31, 2013 and 2012, 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,			Period From
	2013	2012	2011	January 29, 2007
				(Inception) to
				December 31, 2013
<b>Statement of Operations Data:</b>				
Operating Expenses				
Research and development	\$ 956,980	\$ 1,165,645	\$ 1,844,044	\$ 16,948,509
General and administrative	1,644,848	86,781	570,524	4,949,381
Purchase of in-process research and development				650,000
Total operating expenses	2,601,828	2,002,426	2,414,568	22,547,890
Loss from operations	(2,601,828)	(2,002,426)	(2,414,568)	(22,547,890)
Total other income (expense)	(234,637)	(15,102)	13,324	(143,578)
Net loss and comprehensive loss	\$ (2,836,465)	\$ (2,017,528)	\$ (2,401,244)	\$ (22,691,468)
Net loss per common share, basic and diluted <sup>(1)</sup>	\$ (1.20)	\$ (1.79)	\$ (2.18)	
Weighted-average shares used to compute basic and diluted net loss per share	\$ 2,368,006	\$ 1,124,000	\$ 1,102,625	

(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,	
	2013	2012
<b>Balance Sheet Data:</b>		
Cash and cash equivalent	\$ 24,196,691	\$ 116,013
Working capital (deficit)	22,146,047	(454,396)
Total assets	24,986,458	116,013
Current liabilities (including warrant liability)	2,284,906	570,409
Long-term debt, net of current portion	1,511,461	979,792
Series A Convertible preferred stock		18,225,166
Deficit accumulated during the development stage	(22,691,468)	(19,855,003)
Total stockholders equity (deficit)	21,183,261	(19,659,354)

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

*You should read the following discussion and analysis of our financial condition and results of operations 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. You should review the Risk Factors section of this Annual Report on Form 10-K for a discussion of important factors that could cause our actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.*

**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.

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. We plan to initiate a Phase 3 trial of EVK-001 in female patients with symptoms associated with acute and recurrent diabetic gastroparesis in the first half of 2014.

We have no products approved for sale, and we have not generated any revenue from product sales or other arrangements. We have primarily funded our operations through the sale of our convertible preferred stock, borrowings under our loan and security agreements and the sale of shares in our initial public offering, or IPO, in September 2013. We have incurred losses in each year since our inception. Our net losses were \$2.8 million and \$2.0 million for the years ended December 31, 2013 and 2012, respectively. As of December 31, 2013 and 2012, we had an accumulated deficit of \$22.7 million and \$19.9 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.

**Questcor Asset Purchase Agreement**

We acquired all worldwide rights, data, patents and other related assets associated with EVK-001 from Questcor Pharmaceuticals, Inc., or Questcor, in June 2007. We paid to Questcor \$650,000 in the form of an upfront payment, and will be required to make additional milestone payments totaling up to \$52,000,000. These milestones include up to \$5,000,000 in payments if EVK-001 achieves the following development targets:

\$500,000 upon the initiation of the first patient dosing in our planned Phase 3 clinical trial for EVK-001;

\$1,500,000 upon the FDA's acceptance for review of an NDA for EVK-001; and

\$3,000,000 million upon the FDA's approval of EVK-001.

The remaining \$47,000,000 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 Questcor 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 and Related Transactions

On September 30, 2013, we completed our IPO, whereby we sold 2,100,000 shares of common stock at \$12.00 per share. On October 8, 2013, the underwriters for our IPO exercised the over-allotment option to purchase an additional 315,000 shares of our common stock at \$12.00 per share. Net proceeds from the IPO, including the exercise of the over-allotment option, were determined as follows:

Gross proceeds (including over-allotment)	\$ 28,980,000
Underwriting discounts and commissions and non-accountable expense allowance	(2,344,875)
Total offering costs (excluding value of warrants granted to underwriter of \$470,000)	(1,514,177)
Net proceeds	\$ 25,120,948

Additionally, upon the closing of the IPO, certain related transactions occurred:

the conversion of all outstanding shares of our convertible preferred stock into 2,439,002 shares of our common stock;

retention payments in the amount of \$355,000 became payable to our executive officers. Such amount was recorded as expense on a straight-line basis from May 22, 2013 (the date of the Retention Agreements entered into with the executive officers) through December 24, 2013, the date at which the final payment was due based on continued employment. Since the terms of the payment required the occurrence of either a change in control of the Company or an equity financing, neither of which were considered probable to occur until they happen, a catch-up expense of \$202,857 was recorded at the time of our IPO. The executive officers remained with the Company through December 24, 2013 and received the full retention payment;

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the issuance of warrants to purchase 84,000 shares of our common stock to the representative of the underwriters of our IPO and certain of its affiliates. The warrants will become exercisable at a price of \$21.00 per share beginning on September 24, 2014 and will expire on September 24, 2018. The initial fair value of the warrants of \$470,000 was determined using the Black-Scholes option pricing model on the date of the IPO and recorded as a cost of the issuance of common stock from our IPO and charged to additional paid-in capital;

the conversion of warrants to purchase 110,000 shares of convertible preferred stock into warrants to purchase 22,000 shares of our common stock and the resultant reclassification of the \$187,000 warrant liability to additional paid-in capital; and

the filing of an amended and restated certificate of incorporation to authorize 50,000,000 shares of common stock and 5,000,000 shares of undesignated preferred stock.

## **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 contract research organizations, or 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 planned 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 the costs to complete our Phase 3 clinical trial in women, our companion clinical trial in men and a thorough QT study of EVK-001 will be approximately \$15.0 million. 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 and facility costs. 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 Income (Expense)***

Total other income (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 and preferred stock purchase right liability.



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**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 consolidated 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 contract manufacturing organizations 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 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.

### ***Estimated Fair Value of Convertible Preferred Stock Warrants***

Freestanding warrants for the purchase of convertible preferred stock that is either subject to a put right or redeemable are classified as liabilities on the balance sheet at their estimated fair value. At the end of each reporting period, changes in estimated fair value during the period are recorded as a component of other income (expense). We continued to adjust the carrying value of these warrants until the earlier of the exercise of the warrants or the completion of a liquidity event, including the completion of an IPO, at which time the liabilities were reclassified to additional paid-in capital. As of December 31, 2012 we had outstanding warrants exercisable to purchase 14,000 shares of our Series A convertible preferred stock. During January 2013, an additional 8,000 warrants to purchase our Series A convertible preferred stock were issued. We estimate the fair values of the convertible preferred stock warrants using the Black-Scholes option pricing model based on inputs as of the valuation measurement dates for the estimated fair value of the underlying convertible preferred stock, the remaining contractual terms of the warrants, risk-free interest rates, expected dividend rates and the estimated volatility of the price of the convertible preferred stock. The consummation of the IPO resulted in the conversion of our Series A convertible preferred stock into common stock. Upon such conversion, the preferred stock warrant liability was remeasured to fair value, reclassified to additional paid-in capital and is no longer subject to remeasurement.

### ***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.

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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 501,500 options in 2013 and no options in 2012.

**Other Information*****Net Operating Loss Carryforwards***

As of December 31, 2013, we had federal and California tax net operating loss carryforwards of approximately \$21.2 million and \$20.7 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, 2013, we also had federal and California research and development tax credit carryforwards of \$627,000 and \$459,000, 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, 2013 and 2012***

The following table summarizes the results of our operations for the fiscal years ended December 31, 2013 and 2012:

	Year Ended December 31,		Increase/ (Decrease)
	2013	2012	
Research and development	\$ 956,980	\$ 1,165,645	\$ (208,665)
General and administrative	1,644,848	836,781	808,067
Other income (expense):			
Interest income	7,248	1,690	5,558
Interest expense	(159,885)	(24,042)	(135,843)
Change in fair value of warrant liability	(82,000)	7,250	(89,250)
Total other income (expense)	(234,637)	(15,102)	(219,535)

*Research and Development Expenses.* Research and development expenses were approximately \$957,000 for the year ended December 31, 2013, compared to approximately \$1,165,000 for the year ended December 31, 2012. The decrease of approximately \$209,000 is primarily related to the decrease in executive compensation allocated to research and development as we worked to raise capital in 2013 and to the reversal of the 2012 bonus accrual due to the election by our board of directors in April 2013 to not pay 2012 bonuses in order to conserve cash.

*General and Administrative Expenses.* General and administrative expenses were approximately \$1,645,000 for the year ended December 31, 2013, compared to approximately \$837,000 for the year ended December 31, 2012. The increase of approximately \$808,000 is primarily related to a larger portion of our labor costs being allocated to general and administrative activities in 2013 in preparation for our IPO and the payment for the executive team's retention payments of \$355,000, offset by the reversal of the 2012 bonus accrual due to the election by our board of directors in April 2013 to not pay 2012 bonuses.

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*Other Income (Expense).* Other income (expense) was approximately \$(235,000) for the year ended December 31, 2013 and primarily consisted of approximately \$(160,000) of interest expense and \$(82,000) related to the increase in the fair value of our outstanding warrant liability, and offset by approximately \$7,000 of interest income. Other income (expense) was approximately \$(15,000) for the year ended December 31, 2012 and primarily consisted of approximately \$(24,000) of interest expense related to advances under our loan and security agreement, offset by approximately \$2,000 of interest income and \$7,000 of other income related to the decrease in fair value of our outstanding warrant liability.

**Comparison of Years Ended December 31, 2012 and 2011**

The following table summarizes the results of our operations for the fiscal years ended December 31, 2012 and 2011:

	Year Ended December 31,		Increase/ (Decrease)
	2012	2011	
Research and development	\$ 1,165,645	\$ 1,844,044	\$ (678,399)
General and Administrative	836,781	570,524	266,257
Other income (expense):			
Interest income	1,690	10,696	(9,006)
Interest expense	(24,042)	(2,872)	(21,170)
Change in fair value of warrant liability	7,250	5,500	1,750
Total other income (expense)	(15,102)	13,324	(28,426)

*Research and Development Expenses.* Research and development expenses were approximately \$1,165,000 for the year ended December 31, 2012, compared to approximately \$1,844,000 for the year ended December 31, 2011. The decrease of approximately \$679,000 is primarily related to the decrease in development-related costs as we finalized the Phase 2 clinical trial for EVK-001 and engaged with the FDA for Phase 3 planning.

*General and Administrative Expenses.* General and administrative expenses were approximately \$837,000 for the year ended December 31, 2012, compared to approximately \$571,000 for the year ended December 31, 2011. The increase of approximately \$266,000 is primarily related to an increase in accruals for bonus payments to our officers in 2012.

*Other Income (Expense).* Other income (expense) was approximately \$(15,000) for the year ended December 31, 2012 and primarily consisted of approximately \$(24,000) of interest expense related to advances under our loan and security agreement, offset by approximately \$2,000 of interest income and \$7,000 of other income related to the decrease in fair value of our outstanding warrant liability. Other income (expense) was approximately \$13,000 for the year ended December 31, 2011 and primarily consisted of \$11,000 of interest income and \$5,000 related to the decrease in fair value of our outstanding warrant liability, offset by \$(3,000) of interest expense related to advances under our loan and security agreement.

**Liquidity and Capital Resources**

Since our inception in 2007, we have funded our operations primarily from the sale of equity securities and borrowings under our 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 net proceeds of \$3.0 million under our current loan and security agreement. During 2013, we completed our IPO and raised approximately \$25.1 million. We have incurred losses since inception and negative cash flows from operating activities. As of December 31, 2013, we had approximately \$24.2 million in cash and cash equivalents, working capital of approximately \$22.1 million and an

accumulated deficit of approximately \$22.7 million.

In June 2012, we entered into a \$3.0 million loan and security agreement with Silicon Valley Bank which is collateralized by our personal property. Interest on advances under the agreement is at a fixed interest rate equal to 4.50%. The loan and security agreement contains only non-financial covenants. Advances under the loan and security agreement had an interest-only period through December 31, 2013 and a 24-month payback period that commenced in January 2014. As of December 31, 2013, we had drawn down the entire \$3.0 million available under the agreement to fund working capital and have no credit available for future borrowings. In connection with the loan and security agreement, we issued a warrant to Silicon Valley Bank which is immediately exercisable for an aggregate of 12,000 shares of our common stock, at an exercise price of \$7.50 per share.

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:

initiate significant clinical trials associated with EVK-001, including our planned Phase 3 clinical trial that we plan to initiate in the first half of 2014;

hire additional staff, including clinical, scientific, operational, financial and management personnel;

to maintain, expand and protect our intellectual property portfolio; and

to continue to fund the additional accounting, legal, insurance and other costs associated with being a public company



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Though our current cash and cash equivalents is expected to be sufficient for us to complete our planned Phase 3 clinical trial of EVK-001, it 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, our companion clinical trial in men and a thorough QT study of EVK-001 will be approximately \$15.0 million. 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.

The following table summarizes of our cash flows for the years ended December 31, 2013, 2012 and 2011:

	Year Ended December 31		
	2013	2012	2011
Net cash used in operating activities	\$ (3,040,270)	\$ (1,749,863)	\$ (2,893,108)
Net cash provided by (used in) financing activities	27,120,948	1,000,000	(277,779)
Net increase (decrease) in cash and cash equivalents	\$ 24,080,678	\$ (749,863)	\$ (3,170,887)

*Operating Activities.* Net cash used in operating activities was approximately \$3,040,000, \$1,750,000 and \$2,893,000 for the years ended December 31, 2013, 2012 and 2011, respectively. In all periods the primary use of cash was to fund our net loss.

*Financing Activities.* Net cash provided by financing activities was approximately \$27,121,000 for the year ended December 31, 2013 compared to net cash provided by financing activities of \$1,000,000 for the year ended December 31, 2012. During the year ended December 31, 2013, our financing activity consisted of a \$2,000,000 advance on our current loan and security agreement to fund working capital requirements prior to completing our IPO where we sold 2,415,000 shares of our common stock for net proceeds of approximately \$25,121,000. In 2012, we took our initial advance of \$1,000,000 on our loan and security agreement. In 2011, we paid down our outstanding balances under our original loan and security agreement.

We believe that our existing cash and cash equivalents as of December 31, 2013, together with interest thereon, will be sufficient to meet our anticipated cash requirements for approximately 18 months. 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 initiation, progress, costs, results of and timing of our clinical development program for EVK-001, including our planned 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 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 Questcor 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, 2013, 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.

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Our long-term debt obligation consists of amounts we are obligated to repay under our loan and security agreement with Silicon Valley Bank, of which we have drawn the full amount of \$3.0 million as of January 31, 2013. In 2013, we made interest-only payments of \$128,875. In January 2014 we began making the first of 24 monthly principal and interest payments of \$131,024, such that the loan balance will be fully repaid in December 2015. We expect to incur a total of \$191,094 of interest charges in 2014 and 2015.

## **Table of Contents**

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, 2013, future minimum lease payments for our operating lease were \$75,603 and \$93,399 for the years ended December 31, 2014 and 2015, respectively. Prior to entering into the facility lease, we temporarily leased office space on a month-to-month basis and recognized the expense as incurred.

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

### ***Interest Rate Fluctuation Risk***

Our cash and cash equivalents as of December 31, 2013 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***

To date, all of our contractual obligations have been denominated in U.S. dollars. In the future, we may contract with organizations to manufacture drug product, active pharmaceutical ingredient, container closure system materials as well as CROs and investigational sites in foreign countries. We may therefore become subject to fluctuations in foreign currency rates in connection with these agreements.

### ***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, 2013 and 2012.

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

Our consolidated financial statements and the report of our independent registered public accounting firm are included in this report on the pages indicated in Item 15.

## **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), 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, 2013.

#### **Management's Annual Report on Internal Control Over Financial Reporting**

This Annual Report on Form 10-K does not include a report of management's assessment regarding internal control over financial reporting due to a transition period established by the rules of the SEC for newly public companies.

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**Changes in Internal Control Over Financial Reporting**

There have been no changes in our internal control over financial reporting during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Item 9B. Other Information**

None.

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**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 2014 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, 2013, 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](http://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.

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**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 Ernst & Young LLP, an independent registered public accounting firm, are included in this Annual Report on Form 10-K:

	<b>Page</b>
<u>Report of Independent Registered Public Accounting Firm</u>	46
<u>Balance Sheets</u>	47
<u>Statements of Operations and Comprehensive Loss</u>	48
<u>Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)</u>	49
<u>Statements of Cash Flows</u>	51
<u>Notes to Financial Statements</u>	52

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.



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**Report of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholders

Evoke Pharma, Inc.

We have audited the accompanying balance sheets of Evoke Pharma, Inc. (a development stage company), as of December 31, 2013 and 2012, and the related statements of operations and comprehensive loss, convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2013 and for the period from January 29, 2007 (inception) to December 31, 2013. 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. We were not engaged to perform an audit of the Company's 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 purposes 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, and 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, 2013 and 2012, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2013 and for the period from January 29, 2007 (inception) to December 31, 2013, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

San Diego, California

March 25, 2014

**Table of Contents****Evoke Pharma, Inc.****(A Development Stage Company)****Balance Sheets**

	<b>December 31,</b>	
	<b>2013</b>	<b>2012</b>
<b>Assets</b>		
Current Assets:		
Cash and cash equivalents	\$ 24,196,691	\$ 116,013
Prepaid expenses	234,262	
Total current assets	24,430,953	116,013
Other assets	555,505	
Total assets	\$ 24,986,458	\$ 116,013
<b>Liabilities, convertible preferred stock and stockholders equity (deficit)</b>		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 284,915	\$ 96,798
Accrued compensation	557,399	417,611
Warrant liability		56,000
Current portion of long-term debt	1,442,592	
Total current liabilities	2,284,906	570,409
Deferred rent expense	6,830	
Long-term debt, net of current portion	1,511,461	979,792
Total liabilities	3,803,197	1,550,201
Commitments and contingencies		
Series A convertible preferred stock, \$0.0001 par value; authorized shares 0 at December 31, 2013 and 12,305,068 at December 31, 2012; issued and outstanding shares 0 at December 31, 2013 and 12,195,068 at December 31, 2012; liquidation preference 0 at December 31, 2013 and \$18,292,602 at December 31, 2012		18,225,166
Stockholders equity (deficit):		
Preferred stock, \$0.0001 par value; authorized shares 5,000,000 at December 31, 2013 and 0 at December 31, 2012; issued and outstanding shares 0 at December 31, 2013 and 2012		
Common stock, \$0.0001 par value; authorized shares 50,000,000 at December 31, 2013 and 20,000,000 at December 31, 2012; issued and outstanding shares 6,096,752 at December 31, 2013 and 1,242,750 at December 31, 2012	610	124
Additional paid-in capital	43,874,119	195,525
Deficit accumulated during the development stage	(22,691,468)	(19,855,003)

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Total stockholders equity (deficit)	21,183,261	(19,659,354)
Total liabilities, convertible preferred stock and stockholders equity (deficit)	\$ 24,986,458	\$ 116,013

*See accompanying notes.*

Table of Contents**Evoke Pharma, Inc.****(A Development Stage Company)****Statements of Operations and Comprehensive Loss**

	Year Ended December 31,			Period From January 29, 2007
	2013	2012	2011	(Inception) to December 31, 2013
Operating expenses:				
Research and development	\$ 956,980	\$ 1,165,645	\$ 1,844,044	\$ 16,948,509
General and administrative	1,644,848	836,781	570,524	4,949,381
Purchase of in-process research and development				650,000
<b>Total operating expenses</b>	<b>2,601,828</b>	<b>2,002,426</b>	<b>2,414,568</b>	<b>22,547,890</b>
Loss from operations	(2,601,828)	(2,002,426)	(2,414,568)	(22,547,890)
Other income (expense):				
Interest income	7,248	1,690	10,696	221,100
Interest expense	(159,885)	(24,042)	(2,872)	(365,827)
Change in fair value of preferred stock purchase right				(188,587)
Change in fair value of warrant liability	(82,000)	7,250	5,500	(54,264)
Grant income				244,000
<b>Total other income (expense)</b>	<b>(234,637)</b>	<b>(15,102)</b>	<b>13,324</b>	<b>(143,578)</b>
<b>Net loss and comprehensive loss</b>	<b>\$ (2,836,465)</b>	<b>\$ (2,017,528)</b>	<b>\$ (2,401,244)</b>	<b>\$ (22,691,468)</b>
<b>Net loss per common share, basic and diluted</b>	<b>\$ (1.20)</b>	<b>\$ (1.79)</b>	<b>\$ (2.18)</b>	
Weighted-average shares used to compute basic and diluted net loss per share	2,368,006	1,124,000	1,102,625	

*See accompanying notes.*

Table of Contents**Evoke Pharma, Inc.****(A Development Stage Company)****Statements of Convertible Preferred Stock and Stockholders Equity (Deficit)**

	Series A Convertible Preferred Stock		Common Stock		Additional	Deficit	Total
	Shares	Amount	Shares	Amount	Paid-In Capital	During the Development Stage	Shareholders Equity (Deficit)
Balance at January 29, 2007 (inception)		\$		\$	\$	\$	\$
Issuance of restricted common stock for cash to founders at \$0.005 per share			916,000	92	4,488		4,580
Issuance of Series A convertible preferred stock at \$1.50 per share for cash and the conversion of \$250,000 of bridge notes and \$42,538 of accrued interest, net of issuance costs of \$218,037	4,195,067	6,074,501					
Initial fair value of preferred stock purchase rights issued in connection with Series A financing		(848,257)					
Estimated fair value of exercised purchase right of		80,819					

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\$0.04 per share							
Issuance of common stock upon exercise of stock options			266,750	26	77,332		77,358
Stock-based compensation expense					5,458		5,458
Net loss						(2,009,591)	(2,009,591)
Balance at December 31, 2007							
	4,195,067	5,307,063	1,182,750	118	87,278	(2,009,591)	(1,922,195)
Issuance of Series A convertible preferred stock at \$1.50 per share for cash, net of issuance costs of \$1,855	4,000,000	5,998,145					
Estimated fair value of purchase rights upon completion of final preferred stock investment		956,025					
Stock-based compensation expense					16,184		16,184
Net loss						(3,227,664)	(3,227,664)
Balance at December 31, 2008							
	8,195,067	12,261,233	1,182,750	118	103,462	(5,237,255)	(5,133,675)
Stock-based compensation expense					17,803		17,803
Net loss						(5,159,638)	(5,159,638)
Balance at December 31, 2009							
	8,195,067	12,261,233	1,182,750	118	121,265	(10,396,893)	(10,275,510)
Issuance of Series A convertible preferred stock at \$1.50 per share for cash, net of issuance costs of \$36,069	4,000,001	5,963,933					
Issuance of common stock			60,000	6	23,994		24,000

upon exercise of stock options							
Stock-based compensation expense					15,056		15,056
Net loss						(5,039,338)	(5,039,338)
Balance at December 31, 2010	12,195,068	18,225,166	1,242,750	124	160,315	(15,436,231)	(15,275,792)

**Table of Contents****Statements of Convertible Preferred Stock and Stockholders Equity (Deficit)****(Continued)**

	Series A Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Deficit	
	Shares	Amount	Shares	Amount		Accumulated	Total
						During the	Shareholders
						Development	Equity
						Stage	(Deficit)
Balance at December 31, 2010	12,195,068	18,225,166	1,242,750	124	160,315	(15,436,231)	(15,275,792)
Stock-based compensation expense					22,705		22,705
Net loss						(2,401,244)	(2,401,244)
Balance at December 31, 2011	12,195,068	18,225,166	1,242,750	124	183,020	(17,837,475)	(17,654,331)
Stock-based compensation expense					12,505		12,505
Net loss						(2,017,528)	(2,017,528)
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

*See accompanying notes.*

Table of Contents**Evoke Pharma, Inc.****(A Development Stage Company)****Statements of Cash Flows**

	Year Ended December 31,			Period From
	2013	2012	2011	January 29,
				2007
				(Inception) to
				December 31,
				2013
<b>Operating activities</b>				
Net loss	\$ (2,836,465)	\$ (2,017,528)	\$ (2,401,244)	\$ (22,691,468)
Adjustments to reconcile net loss to net cash used in operating activities:				
Stock-based compensation expense	145,966	12,505	22,705	235,677
Non-cash interest	23,261	4,042	2,426	129,327
Change in fair value of purchase right liability				188,587
Change in fair value of warrant liability	82,000	(7,250)	(5,500)	54,264
Deferred rent expense	6,830			6,830
Change in operating assets and liabilities:				
Prepaid expenses and other assets	(234,262)	39,459	76,353	(234,262)
Other assets	(555,505)			(555,505)
Accounts payable and accrued expenses	327,905	218,909	(587,848)	842,314
Net cash used in operating activities	(3,040,270)	(1,749,863)	(2,893,108)	(22,024,236)
<b>Financing activities</b>				
Proceeds from convertible promissory note				250,000
Proceeds from bank line of credit and loan advances	2,000,000	1,000,000		5,500,000
Payment on bank line of credit			(277,779)	(2,500,000)
Proceeds from issuance of common stock, net	25,120,948			25,125,528
Proceeds from issuance of preferred stock and purchase rights, net				17,744,041
Proceeds from exercise of stock options				101,358
Net cash provided by (used in) financing activities	27,120,948	1,000,000	(277,779)	46,220,927
Net increase (decrease) in cash and cash equivalents	24,080,678	(749,863)	(3,170,887)	24,196,691
Cash and cash equivalents at beginning of period	116,013	865,876	4,036,763	

Cash and cash equivalents at end of period	\$ 24,196,691	\$ 116,013	\$ 865,876	\$ 24,196,691
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**Supplemental disclosures of cash flow information**

Interest paid	\$ 128,875	\$ 20,000	\$ 1,346	\$ 228,751
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**Non-cash financing activities**

Conversion of convertible promissory note and accrued interest to Series A Convertible Preferred Stock	\$	\$	\$	\$ 292,538
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Issuance of Series A Convertible Preferred Stock warrants	\$ 49,000	\$ 24,250	\$	\$ 108,486
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Conversion of Series A Convertible Preferred Stock to common stock at the initial public offering	\$ 18,225,166	\$	\$	\$ 18,225,166
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*See accompanying notes.*

**Table of Contents****Evoke Pharma, Inc.****(A Development Stage Company)****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 (inception). 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. Accordingly, the Company is considered to be in the development stage.

As reflected in the accompanying financial statements, the Company has a limited operating history and the sales and income potential of the Company's business are unproven. The Company has experienced net losses since its inception and, as of December 31, 2013 and 2012, had an accumulated deficit of \$22,691,468 and \$19,855,003, respectively. The Company had a working capital (deficit) of \$22,146,047 and \$(454,396) as of December 31, 2013 and 2012, respectively.

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.

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.

**Initial Public Offering and Related Transactions**

On September 30, 2013, the Company completed its Initial Public Offering (IPO) whereby it sold 2,100,000 shares of common stock at a price of \$12.00 per share. On October 8, 2013, the underwriters for the Company's IPO purchased the over-allotment option for an additional 315,000 shares of the Company's common stock at \$12.00 per share. Net proceeds from the IPO, including the exercise of the over-allotment option, were determined as follows:

Gross proceeds (including over-allotment)	\$ 28,980,000
Underwriting discounts and commissions and non-accountable expense allowance	(2,344,875)

Total offering costs (excluding value of warrants granted to underwriter of \$470,000)	(1,514,177)
Net proceeds	\$ 25,120,948

Additionally, upon the closing of the IPO, certain transactions occurred based on a successful completion of the IPO:

the conversion of all outstanding shares of convertible preferred stock into 2,439,002 shares of the Company's common stock;

retention payments in the amount of \$355,000 became payable to the Company's executive officers. Such amount was recorded as expense on a straight-line basis from May 22, 2013 (the date of the retention agreements entered into with the executive officers) through December 24, 2013, the date at which the final payment was due based on continued employment. Since the terms of the payment required the occurrence of either a change in control of the Company, or an equity financing, neither of which were considered probable to occur until they happen, a catch-up expense of \$202,857 was recorded at the time of the Company's IPO. The executive officers remained with the Company through December 24, 2013 and received the full retention payment;

the issuance of warrants to purchase 84,000 shares of the Company's common stock to the representative of the underwriters of the Company's IPO and certain of its affiliates. The warrants will become exercisable at a price of \$21.00 per share beginning on September 24, 2014 and will expire on September 24, 2018. The \$470,000 initial fair value of the warrants was determined using the Black-Scholes option pricing model and recorded as a cost of the Company's IPO and charged to additional paid-in capital;

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The fair value of the issued warrants was estimated using the Black-Scholes option pricing model with the following assumptions:

Assumed risk-free interest rate	1.44%
Assumed volatility	71%
Expected warrant life	5 Years
Expected dividend yield	0.0%

the conversion of warrants to purchase 110,000 shares of convertible preferred stock into warrants to purchase 22,000 shares of the Company's common stock, and the final remeasurement of fair value and reclassification of the \$187,000 warrant liability to additional paid-in capital; and

the filing of an amended and restated certificate of incorporation to authorize 50,000,000 shares of common stock and 5,000,000 shares of undesignated preferred stock.

**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 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 accounts payable and accrued expenses 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. The carrying amount of the warrant liability represents fair 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.

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.

### **Preferred Stock Warrant Liability**

Warrants for shares that are puttable and warrants for shares that are contingently redeemable are classified as liabilities on the accompanying balance sheets and carried at their estimated fair value. At the end of each reporting period, any changes in fair value are recorded as a component of other income (expense). At the completion of the IPO, the Company adjusted the carrying value of the warrants and reclassified the liability to additional paid-in capital.

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**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, 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 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 the Company's limited historical data as a public company, the estimated volatility is calculated based upon the historical volatility of the Company 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. The Company granted 501,500 options in 2013 and no options in 2012.

**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 clinical research organizations, or 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. Service providers invoice us 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 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.



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 preclinical research and clinical trials. We do not have any current contractual relationships for the manufacture of commercial supplies of EVK-001. If EVK-001 is approved by any regulatory agency, we intend to enter into agreements with third-party contract manufacturers for the commercial production at that time. We currently utilize a third-party consultant, which we engage on an as-needed, hourly basis, to manage our 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.

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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.

**Comprehensive Income (Loss)**

ASC 220, *Comprehensive Income*, defines comprehensive income (loss) as a change in equity during a period from transactions and other events and circumstances from non-owner sources. Net loss and comprehensive loss were the same for all periods presented.

**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 103,750, 118,750 and 140,125 weighted-average shares subject to repurchase from the weighted-average number of common shares outstanding for the year ended December 31, 2013, 2012 and 2011, 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 convertible preferred stock, warrants for the purchase of convertible preferred stock, warrants for the purchase of common stock, and options outstanding under the Company's equity incentive plans. 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 summarizes the weighted-average anti-dilutive securities excluded from the calculation of diluted net loss per share (in common equivalent shares):

	Year Ended December 31,		
	2013	2012	2011
Convertible preferred stock outstanding		2,439,002	2,439,002
Warrants for convertible preferred stock		14,000	10,000
Warrants for common stock	106,000		
Common stock options	624,750	123,250	123,250
	730,750	2,576,252	2,572,252

**Recent Accounting Pronouncements**

In February 2013, the Financial Accounting Standards Board issued an accounting standard update to require reclassification adjustments from other comprehensive income to be presented either in the financial statements or in the notes to the financial statements. This accounting standard became effective for the Company beginning in the first quarter of 2013, and its adoption did not have any impact on the Company's financial statements.

In July 2013, the FASB issued Accounting Standards Update No. 2013-11, *presentation of an unrecognized tax benefit when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists* (ASU 2013-11). The guidance is effective prospectively for fiscal years, and interim periods within those years, beginning

after December 15, 2013, with an option for early adoption. The Company intends to adopt this guidance during the first quarter of 2014, and does not believe the adoption of this standard will have a material impact on the Company's consolidated financial statements.

### **3. Fair Value Measurements**

The following tables present information about the Company's financial liabilities measured at fair value on a recurring basis as of December 31, 2013 and 2012 and indicate the fair value hierarchy of the valuation techniques utilized by the Company to determine such fair value. The Company had no financial liabilities as of December 31, 2013. As a basis for categorizing inputs, the Company uses a three-tier fair value hierarchy, which prioritizes the inputs used to measure fair value from market based assumptions to entity specific assumptions:

**Level 1:** Observable inputs such as quoted prices in active markets;

**Level 2:** Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly; and

**Level 3:** Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

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The Company's Level 3 financial liabilities consisted of warrant liabilities related to warrants to purchase preferred stock. All warrants were measured at fair value utilizing the Black-Scholes option pricing model.

The fair value of the outstanding preferred stock warrants at December 31, 2012 was estimated using the Black-Scholes option pricing model with the following assumptions:

	December 31, 2012	
Assumed risk-free-interest rate	0.25%	1.78%
Assumed volatility		80%
Expected warrant life	2.08	9.50 years
Expected dividend yield		0.0%

Liabilities measured at fair value on a recurring basis as of December 31, 2012 are as follows:

	Fair Value Measurements at Reporting Date Using			
	Quoted Prices			
	in			
	Active			
	Markets			
	for			
	Identical	Significant	Other	Significant
	Assets	Observable	Inputs	Unobservable
	(Level	(Level	(Level	Inputs
	1)	2)	3)	(Level 3)
	Balance as of			
	December 31,			
	2012			
<b>Liabilities:</b>				
Preferred stock warrant liability	\$ 56,000	\$	\$	\$ 56,000
<b>Total liabilities</b>	<b>56,000</b>	<b>\$</b>	<b>\$</b>	<b>\$ 56,000</b>

The following table is a reconciliation of all the Company's liabilities measured using significant unobservable inputs (Level 3) for the years ended December 31, 2013 and 2012:

	Warrant Liability
Fair value measurement at December 31, 2011	\$ 39,000
Warrants issued in connection with loan and security agreement	24,250
Change in fair value of warrant liability	(7,250)
Fair value measurement at December 31, 2012	56,000
	49,000

Warrants issues in connection with loan and security agreement	
Change in fair value of warrant liability	82,000
Reclassification to additional paid-in capital at initial public offering	(187,000)
Fair value measurement at December 31, 2013	\$

#### 4. Debt

In June 2012, the Company entered into a \$3.0 million loan and security agreement collateralized by the Company's personal property. Interest on advances under the agreement is at a fixed interest rate equal to 4.50%. The loan and security agreement contains only non-financial covenants. Advances under the loan and security agreement have an interest-only period through December 31, 2013 and a 24-month payback period commences in January 2014. The Company was advanced \$1 million and \$2 million in July 2012 and January 2013, respectively. As such, as of December 31, 2013 and 2012, the Company had \$0 and \$2.0 million, respectively, in available credit under the loan and security agreement.

In connection with the loan and security agreement, a warrant was issued for shares of Series A Convertible Preferred Stock that is exercisable in whole, or in part, at any time until the expiration date of June 1, 2022. During July 2012, the Company drew down \$1.0 million under the loan and security agreement and the warrant became exercisable for 4,000 shares of Series A Convertible Preferred Stock at an exercise price of \$7.50 per share. During January 2013, the Company drew down the remaining \$2.0 million under the loan and security agreement and the warrant became exercisable for an additional 8,000 shares of Series A Convertible Preferred Stock at an exercise price of \$7.50 per share.

The initial \$24,250 fair value of the 4,000 warrant shares earned in July 2012 and the initial \$49,000 fair value of the 8,000 warrant shares earned in January 2013 were recorded as a debt discount and are amortized to interest expense over the term of the loan using the effective interest method. As of December 31, 2013 and 2012, the Company had unamortized debt discount of \$45,947 and \$20,208, respectively, related to the initial fair value of the warrants.

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The initial fair value of warrants earned in 2013 and 2012 was estimated using the Black-Scholes option pricing model with the following assumptions:

	January 2013	July 2012
Assumed risk-free interest rate	1.86%	1.43%
Assumed volatility	80%	80%
Expected warrant life	9.5 Years	10 Years
Expected dividend yield	0.0%	0.0%

The aggregate advances under the loan and security agreement and unamortized discount as of December 31, 2013 and 2012 are as follows:

	December 31, 2013	December 31, 2012
Aggregate advances under loan and security agreement	\$ 3,000,000	\$ 1,000,000
Less unamortized discount	(45,947)	(20,208)
Long-term debt, net of debt discount	2,954,053	979,792
Current portion of unamortized discount	23,260	
Current portion of long-term debt	(1,465,852)	
Long-term debt, net of current portion	\$ 1,511,461	\$ 979,792

Maturities of long-term debt as of December 31, 2013, are as follows:

	2014	\$ 1,572,285
	2015	1,572,285
Total minimum payments		3,144,570
Less amount representing interest		(144,570)
Total outstanding debt		3,000,000
Less current portion		(1,465,852)
Long-term portion		\$ 1,534,148

Total interest incurred under the loan and security agreement for the years ended December 31, 2013 and 2012 (excluding amortization of debt discount) was \$136,625 and \$20,000, respectively.

**5. 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 2013, 2012, 2011 and the period from January 29, 2007 (inception) to December 31, 2013 was \$8,886, \$5,000, \$12,000, and \$57,686, 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, 2013 and 2012 was \$6,830 and \$0, respectively. We also pay pass through costs and utility costs, which are expensed as incurred.

As of December 31, 2013, future minimum lease payments for our operating lease are as follows:

2014	\$ 75,603
2015	93,399
<b>Total</b>	<b>\$ 169,002</b>

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**6. Acquisition of Technology**

In June 2007, the Company purchased from Questcor Pharmaceuticals, Inc. ( Questcor ) all rights and patents to a development program for the Company s EVK-001 product candidate, for an upfront payment of \$650,000 which was expensed as in-process research and development. In addition to the upfront payment, the Company will be required to make additional milestone payments totaling up to \$52,000,000. These milestones include up to \$5,000,000 in payments if EVK-001 achieves the following development targets:

\$500,000 upon the initiation of the first patient dosing in the Company s planned Phase 3 clinical trial for EVK-001;

\$1,500,000 upon the U.S. Food and Drug Administration s (the FDA ) acceptance for review of a new drug application for EVK-001; and

\$3,000,000 upon the FDA s approval of EVK-001.

The remaining \$47,000,000 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 Questcor 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.

**7. Convertible Preferred Stock, Common Stock and Stockholders Equity (Deficit)**

**Convertible Preferred Stock**

The Company s convertible preferred stock has been classified as temporary equity in the accompanying balance sheets instead of in stockholders equity (deficit) in accordance with authoritative guidance for the classification and measurement of potentially redeemable securities. Upon certain change in control events that are outside of the Company s control, including liquidation, sale or transfer of control of the Company, holders of the convertible preferred stock were able to cause its redemption.

During June and October 2007, the Company sold an aggregate of 4,000,000 shares of Series A Convertible Preferred Stock at \$1.50 per share for gross proceeds of \$6,000,000 in cash. In addition, \$250,000 in convertible promissory notes issued in an earlier bridge financing and \$42,538 in accrued interest thereon converted into 195,067 shares of Series A Convertible Preferred Stock. In connection with the Series A Convertible Preferred Stock issuance, \$848,257 of the proceeds were allocated to the preferred stock purchase right liability, and the Company incurred \$218,037 of offering costs.

As part of the October 2007 Series A Convertible Preferred Stock transaction, the preferred stock purchase right liability for the second closing was revalued with the \$4,132 increase in fair value recorded as other expense on the statement of operations and the then fair value of \$80,819 was reclassified to Series A Convertible Preferred Stock. At December 31, 2007, the preferred stock purchase right liability for the third closing was revalued with the \$68,955 increase in fair value recorded as other expense on the statement of operations.



During November 2008, the Company sold an additional 4,000,000 shares of Series A Convertible Preferred Stock for gross proceeds of \$6,000,000 in cash. In connection with this financing, the Company incurred \$1,855 of offering costs. As part of the Series A Convertible Preferred Stock transaction, the preferred stock purchase right liability for the third closing was revalued with the \$115,500 increase in fair value recorded as other expense on the statement of operations and the then fair value of \$956,025 was reclassified to Series A Convertible Preferred Stock.

During June 2010, the Company sold an additional 4,000,001 shares of Series A Convertible Preferred Stock for gross proceeds of \$6,000,002 in cash. In connection with this financing, the Company incurred \$36,069 of offering costs.

The holders of the Series A Convertible Preferred Stock were entitled to receive noncumulative dividends at a rate of \$0.12 per share per annum. The preferred stock dividends were payable when and if declared by the board of directors. As of December 31, 2012 and June 30, 2013, the board of directors had not declared any dividends. The Series A Convertible Preferred Stock dividends were payable in preference and in priority to any dividends on common stock. At the time of the conversion of the Series A Convertible Preferred Stock, no dividends had been declared.

The holders of the Series A Convertible Preferred Stock were entitled to receive liquidation preferences at the rate of \$1.50 per share, plus all declared and unpaid dividends. Liquidation payments to the holders of Series A Convertible Preferred Stock had priority and were made in preference to any payments to the holders of common stock.

The shares of Series A Convertible Preferred Stock were convertible into one share of common stock for each five shares of preferred stock, at the option of the holder, subject to certain anti-dilutive adjustments. Each share of Series A Convertible Preferred Stock was automatically converted into common stock immediately upon the earlier of (i) the Company's sale of its common stock in a firm commitment underwritten public offering pursuant to a registration statement under the Securities Act of 1933, as amended, in which the per share price is at least \$22.50 (as adjusted), and the gross cash proceeds are at least \$25,000,000 or (ii) the date specified by written consent or agreement of the holders of not less than 66.66% of the then outstanding shares of Series A Convertible Preferred Stock.

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The holders of Series A Convertible Preferred Stock were entitled to one vote for each share of common stock into which such Series A Convertible Preferred Stock could then be converted; and with respect to such vote, such holder had full voting rights and powers equal to the voting rights and powers of the holders of common stock.

The holders of the Series A Convertible Preferred Stock with greater than 250,000 shares were entitled to elect one member each to the Company's board of directors.

As of December 31, 2013, there were no shares of Series A Convertible Preferred Stock issued or outstanding as all shares, totaling 2,439,002 of Series A Convertible Preferred Stock, converted to 2,439,002 shares of common stock immediately prior to the completion of the IPO.

Under the Company's amended and restated certificate of incorporation as of December 31, 2013, the Company is authorized to issue 5,000,000 shares of preferred stock with a \$0.0001 par value.

**Common Stock**

As of December 31, 2013, there were 6,096,752 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.

**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, 2012 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 of December 31, 2013, 8,500 options remain available for future grant under the 2013 Plan.

Options granted under the 2007 Plan and 2013 Plan have terms ranging from seven to ten years from the date of grant and generally vest over a three to four year period. The exercise price of all options granted during the years ended December 31, 2013, 2012 and 2011 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	Weighted Average	Aggregate Intrinsic
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		Exercise Price	Remaining Contractual Term (Years)	Value
Outstanding at December 31, 2012	123,250	\$ 0.40	7.84	\$ 578
Granted	501,500	\$ 9.39	9.88	
Exercised				
Canceled/Forfeited				
Outstanding at December 31, 2013	624,750	\$ 7.61	8.41	\$ 869,490
Exercisable at December 31, 2013 (1)	90,540	\$ 0.39	5.01	\$ 638,881
Vested or expected to vest at December 31, 2013	624,750	\$ 7.61	8.41	\$ 869,490

(1) Includes awards with early exercise provisions that permit optionee to exercise unvested options. The intrinsic values above represent the aggregate value of the total pre-tax intrinsic value based upon a common stock price of \$7.45 and \$0.40 at December 31, 2013 and 2012, respectively, and the contractual exercise prices.

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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 326,750 stock options exercised, 230,500 and 215,500 were vested as of December 31, 2013 and 2012, respectively.

The total intrinsic value of stock options exercised was \$0 for the years ended December 31, 2013, 2012 and 2011, respectively, as there were no options exercised during these years.

**Stock-Based Compensation**

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 three years ended December 31, 2013:

	Year Ended December 31,		
	2013	2012	2011
<b>Stock Options</b>			
Risk free interest rate	1.75% - 1.8%		2.33%
Expected option term	6.0 years		5.0 years
Expected volatility of common stock	70.8% - 79.4%		80.0%
Expected dividend yield	%		%

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 assumed dividend yield was based on the Company never paying cash dividends and having no expectation of paying cash dividends in the foreseeable future. The weighted average expected term of options 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 weighted average grant date fair value per share of employee stock options granted during the years ended December 31, 2013, 2012 and 2011 was \$6.33, \$0 and \$0.05, respectively.

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,	Period from January 29, 2007 (Inception)
-------------------------	---

	2013	2012	2011	to December 31, 2013
Research and development	\$ 39,638	\$ 10,004	\$ 15,360	\$ 93,435
General and administrative	106,328	2,501	7,345	142,243
<b>Total stock-based compensation expense</b>	<b>\$ 145,966</b>	<b>\$ 12,505</b>	<b>\$ 22,705</b>	<b>\$ 235,678</b>

As of December 31, 2013 and 2012, there was approximately \$3,055,000 and \$26,000, respectively, 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 1.84 and 2.0 years, respectively.

### **Employee Stock Purchase Plan**

On June 13, 2013, the Company's board of directors adopted the Employee Stock Purchase Plan (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 common stock through payroll deductions of up to 20% of their eligible compensation. A total of 30,000 shares of common stock will initially be reserved for issuance under the ESPP. In addition, the number of shares of common

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stock available for issuance under the ESPP will be annually increased on the first day of each fiscal year during the term of the ESPP, beginning with the 2014 fiscal year, by an amount equal to the least 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. No shares of common stock have been issued under the ESPP.

**Common Stock Reserved for Future Issuance**

Common stock reserved for future issuance consists of the following at December 31, 2013 and 2012:

	December 31,	
	2013	2012
Conversion of preferred stock		2,439,002
Stock options issued and outstanding	624,750	123,250
Authorized for future option grants	8,500	
Warrants for convertible preferred stock		14,000
Warrants for common stock	106,000	
Authorized for Employee Stock Purchase Plan	330,000	
<b>Total common stock reserved for future issuance</b>	<b>1,069,250</b>	<b>2,576,252</b>

**8. Employee Benefit Plan**

The Company has established a defined contribution 401(k) plan (the Plan) for all employees who are at least 21 years of age. Employees are eligible to participate in the Plan beginning one year following 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.

**9. Income Taxes**

On January 1, 2009, the Company adopted authoritative guidance relating to the accounting for uncertainty in income taxes. The guidance clarified the recognition threshold and measurement attributes for financial statement disclosure of tax positions taken, or expected to be taken, on a tax return. The impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more likely than not to be sustained upon audit by the relevant taxing authority. An uncertain tax position will not be recognized if it has a less than 50% likelihood of being sustained. On the date of adoption, there were no unrecognized tax benefits. Further, there is no unrecognized tax benefit included in the Company's balance sheets at December 31, 2013 and 2012 that would, if recognized, affect the Company's effective tax rate.

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, 2013 and 2012. The Company is subject to taxation in the United States and state jurisdictions, and as of December 31, 2013, 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.

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

	December 31,		
	2013	2012	2011
	(%)	(%)	(%)
Federal statutory rate	34.0	34.0	34.0
Change in valuation allowance	(2.5)	(4.9)	(0.2)
State income taxes, net of federal effect	5.8	5.8	5.8
Research and development credits	4.3	1.5	4.2
Removal of net operating loss and other credits	(39.5)	(36.4)	(43.9)
Other	(2.1)	(0.0)	0.1
<b>Effective income tax rate</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>

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 \$8.4 million and a research and development credit of approximately \$931,000.

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generated through December 31, 2013 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, 2013 and 2012 are as follows:

	December 31,	
	2013	2012
Deferred tax assets:		
Acquired technology	\$ 147,000	\$ 164,000
Other, net	290,000	203,000
Total deferred tax assets	437,000	367,000
Less valuation allowance	(437,000)	(367,000)
Net deferred tax assets	\$	\$

At December 31, 2013, the Company has federal and state net operating loss carryforwards of approximately \$21.2 million and \$20.7 million, respectively. The federal and state loss carryforwards begin to expire in 2027 and 2017, respectively, unless previously utilized. The Company also has federal and state research tax credit carryforwards of approximately \$627,000 and \$459,000, respectively. The federal research credit carryforwards will begin expiring in 2027 unless previously utilized. The state research credit will carry forward indefinitely.

**10. Subsequent Events**

For the purposes of the financial statements as of December 31, 2013 and the year then ended, the Company has evaluated subsequent events through March 25, 2014, the date the audited annual financial statements were issued. The Company has concluded that no subsequent event has occurred that requires disclosure.

**11. Summarized Quarterly Data (Unaudited)**

The following financial information reflects all adjustments, which include only normal recurring adjustments, which are, in the opinion of management, necessary for a fair statement of the consolidated financial results of the interim periods. Summarized quarterly data for the years ended December 31, 2013 and 2012 are as follows:

	For the Quarters Ended			
	March 31,	June 30,	September 30,	December 31,
2013				
Research and development expense	\$ 110,981	\$ 130,846	\$ 78,731	\$ 636,423
General and administrative expense	221,049	72,578	406,862	944,359
Net loss	(493,992)	(239,871)	(485,904)	(1,616,698)



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Net loss per share, basic and diluted <sup>(1)</sup>	(0.44)	(0.21)	(0.41)	(0.27)
Weighted average shares outstanding, basic and diluted	1,133,375	1,137,125	1,190,212	5,971,236
2012				
Research and development expense	\$ 297,285	\$ 213,010	\$ 337,003	\$ 318,347
General and administrative expense	205,137	147,328	140,746	343,570
Net loss	(500,158)	(358,666)	(486,254)	(672,450)
Net loss per share, basic and diluted <sup>(1)</sup>	(0.45)	(0.32)	(0.43)	(0.60)
Weighted average shares outstanding, basic and diluted	1,118,375	1,122,125	1,125,875	1,129,625

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

**Table of Contents****SIGNATURES**

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

EVOKE PHARMA, INC.

Date: March 25, 2014

By: /s/ David A. Gonyer  
David A. Gonyer  
President and Chief Executive Officer

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

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ David A. Gonyer David A. Gonyer, R.Ph.	President, Chief Executive Officer and Director (principal executive officer)	March 25, 2014
/s/ Matthew J. D. Onofrio Matthew J. D. Onofrio	Executive Vice President, Chief Business Officer, Treasurer and Secretary (principal financial and accounting officer)	March 25, 2014
/s/ Cam L. Garner Cam L. Garner	Chairman of the Board of Directors	March 25, 2014
/s/ Todd C. Brady, M.D., Ph.D. Todd C. Brady, M.D., Ph.D.	Director	March 25, 2014
/s/ Scott L. Glenn Scott L. Glenn	Director	March 25, 2014
/s/ Malcolm R. Hill, Pharm. D. Malcolm R. Hill, Pharm. D.	Director	March 25, 2014
/s/ Ann D. Rhoads Ann D. Rhoads	Director	March 25, 2014
/s/ Kenneth J. Widder, M.D. Kenneth J. Widder, M.D.	Director	March 25, 2014

**Table of Contents****Exhibit Index**

<b>Exhibit Number</b>	<b>Description of Exhibit</b>
1.1 (1)	Underwriting Agreement
3.1 (2)	Amended and Restated Certificate of Incorporation of the Company
3.2 (2)	Amended and Restated Bylaws of the Company
4.1 (3)	Form of the Company's Common Stock Certificate
4.2 (4)	Investor Rights Agreement dated as of June 1, 2007
4.3 (4)	Warrant dated February 7, 2007 issued by the Company to Square 1 Bank
4.4 (4)	Warrant dated June 1, 2012 issued by the Company to Silicon Valley Bank
4.5 (3)	Form of Warrant Agreement dated September 30, 2013 issued by the Company to the representative of the underwriters and certain of its affiliates in connection with the closing of the Company's initial public offering.
10.1 (4)	Form of Indemnity Agreement for Directors and Officers
10.2 (5)#	Amended and Restated Employment Agreement, effective as of June 7, 2013, between the Company and David A. Gonyer
10.3 (5)#	Amended and Restated Employment Agreement, effective as of June 7, 2013, between the Company and Matthew D. Onofrio
10.4 (4)	2007 Equity Incentive Plan, as amended, and form of option agreement thereunder
10.5 (1)	2013 Equity Incentive Award Plan and form of option agreement thereunder
10.6 (5)	2013 Employee Stock Purchase Plan
10.7 (5)#	Amended and Restated Retention Letter, dated May 22, 2013, between the Company and David A. Gonyer
10.8 (5)#	Amended and Restated Retention Letter, dated May 22, 2013, between the Company and Matthew D. Onofrio
10.9 (1)	Non-Employee Director Compensation Policy
10.10 (6)	Asset Purchase Agreement, dated as of June 1, 2007, between the Company and Questcor Pharmaceuticals, Inc.
10.11 (4)	Loan and Security Agreement, dated as of June 1, 2012, between Company and Silicon Valley Bank
10.12	Second Amendment to Master Services Agreement, dated as of November 25, 2013, between the Company and SynteractHCR, Inc.
10.13	Standard Office Lease, dated as of November 26, 2013, between the Company and Beckman/Lomas, LLC
10.14 (7)#	Employment Agreement, effective as of December 1, 2013, between the Company and Marilyn R.

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10.15	Third Amendment to Master Services Agreement, dated as of January 29, 2014, between the Company and SynteractHCR, Inc.
23.1	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934
31.2	Certification of Chief Financial Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934
32.1*	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2*	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

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- (1) Incorporated by reference to the Company's Amendment No. 4 to Registration Statement on Form S-1 filed with the SEC on August 30, 2013.
  - (2) Incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on September 30, 2013.
  - (3) Incorporated by reference to the Company's Amendment No. 3 to Registration Statement on Form S-1 filed with the SEC on August 16, 2013.
  - (4) Incorporated by reference to the Company's Registration Statement on Form S-1 filed with the SEC on May 24, 2013.
  - (5) Incorporated by reference to the Company's Amendment No. 1 to Registration Statement on Form S-1 filed with the SEC on June 14, 2013.
  - (6) Incorporated by reference to the Company's Amendment No. 2 to Registration Statement on Form S-1 filed with the SEC on July 3, 2013.
  - (7) Incorporated by reference to the Company's Current Report on Form 8-K filed on December 2, 2013.  
Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment pursuant to Rule 406 under the Securities Act of 1933.
- # Management contract or compensatory plan or arrangement.
- \* These certifications are being furnished solely to accompany this annual report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and are not to be incorporated by reference into any filing of Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.