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, 2019

or

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

For the transition period from _____ to _____

Commission file number: 001-36075

Evoke Pharma, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**20-8447886**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
420 Stevens Avenue, Suite 370 Solana Beach, California	**92075**
(Address of Principal Executive Offices)	**(Zip Code)**

858-345-1494

(Registrant's Telephone Number, Including Area Code)

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

Title of Each Class	**Trading Symbol(s)**	**Name of Each Exchange on Which Registered**
Common Stock, par value $0.0001 per share	**EVOK**	**The Nasdaq Capital Market**

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

None

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

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 every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). ☒ Yes ☐ No

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant as of the last business day of the registrant's most recently completed second fiscal quarter was approximately $13.2 million, based on the closing price of the registrant's common stock on the Nasdaq Capital Market of $0.625 per share.

The number of outstanding shares of the registrant's common stock, par value $0.0001 per share, as of February 29, 2020 was 24,431,914.

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 2020 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, 2019.

EVOKE PHARMA, INC.

FORM 10-K — ANNUAL REPORT

For the Fiscal Year Ended December 31, 2019

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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, such as the timing and results of any decision regarding the new drug application from the U.S. Food and Drug Administration, or FDA, including whether FDA will act by the Prescription Drug User Fee Act (PDUFA) target goal date for a decision of June 19, 2020, our plans to commercialize Gimoti, if approved, in partnership with Eversana, future regulatory developments, research and development costs, the timing and likelihood of success, plans and objectives of management for future operations, and future results of current and anticipated products. 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," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these terms or other similar expressions. Although we believe the expectations reflected in these forward-looking statements are reasonable, such statements are inherently subject to risk and we can give no assurances that our expectations will prove to be correct. Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements, which speak only as of the date of this Annual Report on Form 10-K. You should read this Annual Report on Form 10-K completely. As a result of many factors, including without limitation those set forth under "Risk Factors" under Item 1A of this Part I below, and elsewhere in this Annual Report on Form 10-K, our actual results may differ materially from those anticipated in these forward-looking statements. Except as required by applicable law, we undertake no obligation to update these forward-looking statements to reflect events or circumstances after the date of this report or to reflect actual outcomes. For all forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

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

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

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

Item 1. Business

Overview

We are a specialty pharmaceutical company focused primarily on the development of drugs to treat gastrointestinal, or GI, disorders and diseases. We are developing Gimoti, an investigational metoclopramide nasal spray for the relief of symptoms associated with acute and recurrent diabetic gastroparesis in women. Diabetic gastroparesis is a GI disorder afflicting millions of individuals worldwide and is characterized by slow or delayed gastric emptying and evidence of gastric retention in the absence of mechanical obstruction and can cause various serious digestive system symptoms and other complications. Metoclopramide tablets and injection are the only products currently approved in the United States to treat the symptoms associated with acute and recurrent diabetic gastroparesis. Gimoti is a novel nasal spray formulation of metoclopramide designed to provide systemic delivery of the molecule through the nasal mucosa.

In individuals with gastroparesis, food remains in the stomach for a longer time than normal, leading to a variety of GI symptoms and systemic metabolic complications. Gastroparesis frequently occurs in individuals with diabetes, but is also observed in patients with prior gastric surgery, a preceding infectious illness, pseudo-obstruction, collagen vascular disorders and anorexia nervosa. In some patients with gastroparesis, no cause can be identified, which is referred to as idiopathic gastroparesis. According to the American Motility Society Task Force on Gastroparesis, the prevalence of gastroparesis is estimated to be up to 4% of the United States population. Signs and symptoms of gastroparesis may include nausea, early satiety, bloating, prolonged fullness, upper abdominal pain, vomiting and retching. Patients may experience any combination of signs and symptoms with varying degrees of severity.

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

We believe nasal spray administration has the potential to provide our target population of female diabetic gastroparesis patients with a preferred treatment option over the tablet formulation for several important reasons: (1) unlike metoclopramide tablets which may be absorbed erratically due to gastroparesis itself, Gimoti is designed to bypass the digestive system to allow for more predictable absorption without needing to determine if a patient's stomach is functioning; (2) during episodes of vomiting, Gimoti may provide predictable drug absorption through the nasal mucosa; and (3) for gastroparesis patients experiencing nausea and are not wanting to swallow a pill or water, a nasal spray may be better tolerated than an oral medication.

We have evaluated Gimoti in a number of clinical trials in patients and subjects, including pharmacokinetic, or PK, trials, Phase 3 clinical efficacy and safety trials, Phase 2 clinical efficacy and safety trials, and a thorough electrocardiogram, or ECG, (QT/QTc) study. Based on the results of the pivotal comparative exposure PK trial and supporting data from the previous trials, we submitted a new drug application, or NDA, for Gimoti to the U.S. Food and Drug Administration, or FDA, on June 1, 2018. In August 2018, we received a Day-74 letter that stated that the NDA was sufficiently complete to permit a substantive review and set a target goal date under the Prescription Drug User Fee Act, or PDUFA, of April 1, 2019.

In March 2018, we announced that FDA granted our request for a small business waiver of the PDUFA fee of approximately $2.4 million for our 505(b)(2) NDA for Gimoti.

On March 1, 2019, we received a multi-disciplinary review letter, or DRL, from FDA, which provided preliminary notice of certain deficiencies identified during FDA's initial review of the Gimoti NDA. The DRL described concerns that insufficient data had been offered regarding certain product quality control and reproducibility for the commercially available sprayer device used with Gimoti, that there is a lack of adequate information to support sex-based efficacy claims and that the pharmacology data provided may not demonstrate bioavailability to the Listed Drug, Reglan Tablets 10 mg. On March 14, 2019, we submitted a response to the DRL to FDA, and on March 21, 2019, we met with FDA to obtain feedback on our responses.

On April 1, 2019, we received a complete response letter, or CRL, from FDA for the Gimoti NDA. The CRL, while citing fewer issues than the DRL, stated that FDA has determined it could not approve the NDA in its present form and provided recommendations to address the remaining approvability issues in an NDA resubmission. The approvability issues were related to clinical pharmacology and product quality/device quality. FDA did not request any new clinical data and did not raise any safety concerns.

The clinical pharmacology issue was specific to a low maximum observed plasma concentration, or C_{max}, in subjects representing less than 5% of the total administered Gimoti doses in the pivotal PK study. FDA stated the overall lower mean C_{max} was driven by the data from these few doses. We conducted an analysis excluding these aberrant doses, which showed that the PK study met the bioequivalence criteria for both men and women, although there is no assurance that FDA will agree with our conclusion. FDA recommended a root cause analysis to determine the origin of the PK variability and mitigation strategies to address their concern. Additionally, FDA requested data from three registration batches of commercial product to be manufactured at the proposed commercial manufacturing site, by the proposed commercial process and tested using validated analytical methods. These data were requested to provide additional support for the proposed acceptance criteria for droplet size distribution and other essential performance characteristics for the commercial product specifications.

On July 25, 2019, we completed a type A meeting with FDA to obtain FDA's feedback and agreement on our plan to address deficiencies cited in the CRL in support of a resubmission of the Gimoti NDA. The focus of the discussion was on topics noted in the CRL, including the root cause analysis of low drug exposure in the comparative bioavailability study and additional product quality/device quality control testing.

On December 19, 2019, based on FDA feedback received during the type A meeting, we resubmitted the Gimoti NDA to FDA. The resubmission provided the requested additional information intended to address the deficiencies cited in the CRL. To address the clinical pharmacology issues, the resubmission included an in-depth root cause analysis, as well as patient use and experience data from our clinical trials. To address product quality/device quality issues cited in the CRL, the resubmission included 3-month stability data from commercial scale registration batches that met all product specifications. We believe these data support the acceptance criteria for performance characteristics and device quality control we proposed in the Gimoti NDA. Additionally, as requested by FDA, the resubmission included data from an analysis of pump performance characteristics for the product used in the comparative

bioavailability study and the product from commercial scale registration batches. The results of this testing showed all products performed within specifications.

On January 17, 2020, we received a notice from FDA that it had accepted our NDA resubmission for review and set a target goal date for a decision under PDUFA of June 19, 2020.

On January 21, 2020, we entered into a commercial services agreement, or the Eversana Agreement, with Eversana Life Sciences Services, LLC, or Eversana, for the commercialization of Gimoti, if approved. Pursuant to the Eversana Agreement, Eversana will commercialize and distribute Gimoti in the United States, if approved by FDA. Eversana will manage the marketing of Gimoti to gastroenterologists and other targeted health care providers, as well as the sales and distribution of Gimoti to wholesalers, pharmacies and other customers within the United States. Eversana will also provide a $5 million revolving credit facility that we can access if FDA approves the Gimoti NDA. For additional details regarding the Eversana Agreement and the revolving credit facility, see "*Business—Commercialization—Commercial Services and Loan Agreements with Eversana*" below. On January 23, 2020, we and Novos Growth, LLC mutually agreed to terminate, effective immediately, a commercialization agreement entered into in January 2019.

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

Business Strategy

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

- *Pursue regulatory approval for Gimoti.* We submitted the Gimoti NDA to FDA on June 1, 2018 and, following receipt of a CRL, resubmitted the NDA to FDA in December 2019. On January 17, 2020, we received a notice from FDA that it had accepted our NDA resubmission for review and set a target goal date for a decision under PDUFA of June 19, 2020.

- *Seek partnerships to accelerate and maximize the potential for Gimoti.* We continue to evaluate partnering opportunities with pharmaceutical companies that have established development and sales and marketing capabilities to potentially enhance and accelerate the development and commercialization of Gimoti.

- *Continue to build capabilities to potentially commercialize Gimoti in the United States.* In addition to seeking partnering opportunities, we have begun to build our commercial infrastructure to allow us to directly market Gimoti in the United States, if approved by FDA. We have engaged Eversana to utilize its internal sales organization, along with other commercial functions, for market access, marketing, distribution, and other related patient support services.

- *Explore regulatory approval of Gimoti outside the United States*. We are seeking approval of Gimoti in the United States and will later evaluate the market opportunity in other countries.

The Gastrointestinal Market

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

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

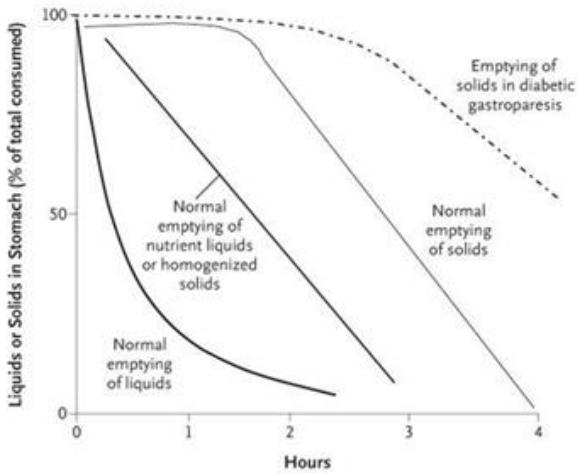
GI Motility Disorders

Motility disorders are some of the most common GI disorders. Motility disorders affect the orderly contractions or relaxation of the GI tract which move contents forward and prevent backward egress. This is important in the normal movement of food through the GI tract. Motility disorders are sometimes referred to as functional GI disorders to highlight that many abnormalities in stomach function can occur even when anatomic structures appear normal. Functional GI disorders affect the upper and lower GI tract and include

gastroparesis, GERD, functional dyspepsia, constipation and IBS. It has been estimated by the International Foundation for Functional Gastrointestinal Disorders that one in four people in the United States suffer from functional GI disorders, having signs and symptoms such as abdominal pain, nausea, constipation, diarrhea, bloating, decreased appetite, early satiety, swallowing difficulties, heartburn, vomiting and/or incontinence.

Gastroparesis

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



Camilleri M. New England Journal of Medicine 2007

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

In gastroparesis, the stomach does not perform these functions normally, causing characteristic flares of signs and symptoms that include nausea, early satiety, prolonged fullness, bloating, upper abdominal pain, vomiting and retching. As a result of these signs and symptoms, patients may limit their food and liquid intake leading to poor nutrition, dehydration and electrolyte disturbances, and have poor blood glucose control, ultimately requiring hospitalization. If left untreated or not adequately treated, gastroparesis causes significant acute and chronic medical problems, including additional diabetic complications resulting from poor glucose control.

Gastroparesis in the Hospital Setting

When patients experience a flare of their gastroparesis symptoms that cannot be adequately managed by oral medications, they may be hospitalized for hydration, parenteral nutrition, and correction of abnormal blood glucose or electrolyte levels. In this setting, intravenous metoclopramide is the first line of treatment. Typically, these diabetic patients with 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 and 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. According to a study conducted by Baylor College of Medicine and published in *Gastroenterology & Endoscopy* in December 2017, hospitalizations for gastroparesis have risen significantly since the early 1990s. This study noted that the number of hospitalizations increased from roughly 900 in 1994 to 16,400 in 2014, with median costs climbing from $6,000 to approximately $24,500 during the period. The number of people who visited the emergency department because of gastroparesis rose from 15,549 in 2006 to 39,470 in 2014, with an average annual increase of nearly 13% over that time.

Etiology

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

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

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

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

Prevalence

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

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

Unmet Needs in Gastroparesis Treatment

Market research and physician interviews demonstrate that existing treatment options for diabetic gastroparesis are inadequate and there is a high level of interest in effective outpatient options for managing patients with gastroparesis symptoms. The market is currently served by oral metoclopramide, intravenous metoclopramide, and the oral disintegrating tablet, or ODT, formulation of metoclopramide (Metozolv® ODT), with approximately 4.0 million prescriptions in the United States per year, according to IMS Health (2015).

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

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

Our Solution: Gimoti (Metoclopramide Nasal Spray)

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

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

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.

Clinical Trial Results

Comparative Exposure PK Trial

In October 2017, we announced positive topline results from the comparative exposure PK trial. The objective of the trial was to identify a dose of Gimoti that met the criteria for bioequivalence compared to the Listed Drug, Reglan Tablets 10 mg. after nasal and oral administration to healthy volunteers under fasted conditions.

The comparative exposure PK trial was an open label, 4-way crossover and enrolled 108 healthy male and female volunteers who each received one Reglan Tablet dose and three different doses of Gimoti in a random sequence. Following discussions at pre-NDA meetings with FDA, we selected a Gimoti dose based on criteria that included a 90% confidence interval for the ratio of AUC falling within the equivalence range of 80-125% of the Listed Drug, Reglan Tablets 10 mg. Though only one dose was needed to meet the dose selection criteria, the comparative exposure PK trial was designed to test three different doses of Gimoti. Based on results of the study, two of the three doses tested met the dose selection criteria for the pooled data in men and women. The C_{max} for Gimoti was slightly lower than the equivalence range, which we had anticipated and previously discussed with FDA as a likely outcome given the different route of administration and prior Gimoti PK trial results. Additionally, data showed the AUC and C_{max} increased in a dose-related manner across all three Gimoti doses tested. Relative to safety, all Gimoti doses were well tolerated with no serious or clinically significant adverse events reported following any of the doses.

Additional analysis of the PK data by sex revealed statistically significant differences in exposure between women and men given the same metoclopramide dose (both nasal and oral). Further analysis of results from the comparative exposure PK trial found statistically significantly lower AUC's in men compared to women. Similar sex-based differences were also observed irrespective of the route of metoclopramide administration (nasal, oral and IV) in one of our previous healthy volunteer studies.

In the most recent comparative exposure PK trial, results for women independently met equivalence criteria for $AUC_{0\text{-}inf}$ and $AUC_{0\text{-}t}$ at the Gimoti dose proposed in the NDA. We submitted the NDA for a female-only indication based on a dose in women with equivalent exposure to the Listed Drug, Reglan Tablets 10 mg. and submitted supporting efficacy and safety data from our Phase 2b and Phase 3 trials at doses similar or lower than the dose proposed in the NDA.

Phase 3 Clinical Trial

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

A total of 205 women (mean age 52.7 years, 88% with type 2 diabetes; 79% postmenopausal, 51% using insulin, mean duration of diabetes 12.9 years, mean baseline glycosylated hemoglobin (HbA1c) 7.5%) were randomized and 93% completed the study. The

primary endpoint for the intent-to-treat, or ITT, population was not statistically significant (p=0.881); however, in exploratory analyses, a treatment effect was seen at Weeks 1 to 3 for patients with higher baseline symptom scores (moderate to severe) in the ITT population (n=105) and for all four weeks for the per protocol population (see Table 1 below). There were also clinically and statistically significant improvements in nausea and abdominal pain, which are two of the more severe and debilitating symptoms of gastroparesis (see Table 2 below).

In July 2015, FDA issued a draft guidance document regarding the clinical evaluation of drugs for the treatment of gastroparesis, in which FDA states that in order to optimize the ability to demonstrate a treatment effect, clinical trials in this indication should enroll patients with higher symptom severity (moderate to severe). In August 2019, FDA issued a revised version of the draft guidance which continued to recommend enrollment of patients with higher symptom severity. The improvements observed in our exploratory analyses of our Phase 3 study focused on this subset of patients enrolled in the study. At the time the 2015 draft guidance was issued, our Phase 3 study, designed to include patients with a range of symptom severity, had been actively enrolling for more than a year. The overall efficacy results were not significant, due in large part to the patients with less severe symptoms who responded to placebo. Importantly, patients with more severe symptoms experienced a statistically-significant treatment effect with Gimoti, consistent with the recommendation in the draft guidance on clinical studies of gastroparesis.

Reports of treatment-emergent adverse events were similar in both groups (36% Gimoti and 35% placebo) and most were mild or moderate in severity. There were slightly more reports of nasal irritation in subjects receiving placebo than in subjects receiving Gimoti. In particular, there were no adverse events of special interest, such as the central nervous system effects observed (see Table 3 below).

These safety results were consistent with findings from previous Gimoti studies that showed the nasal formulation of metoclopramide has a favorable safety profile and is well-tolerated by healthy volunteers and patients with diabetic gastroparesis. There have been no reports of tardive dyskinesia among the more than 1,400 exposed healthy volunteers and patients over the metoclopramide nasal spray clinical development program.

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

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

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

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

1 LSMean from analysis of covariance, or ANCOVA

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

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

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

In December 2016, we announced the completion of a second pre-NDA meeting with FDA. The purpose of the meeting was to discuss efficacy and safety results from the Phase 3 clinical trial and submission strategies for an NDA. At the pre-NDA meeting FDA agreed that a comparative exposure PK trial was acceptable as a basis for submission of a Gimoti NDA. The comparative exposure PK trial will serve as a portion of the full 505(b)(2) data package to include prior efficacy and safety data developed by us and FDA's prior findings of safety and efficacy for the Listed Drug, Reglan Tablets 10 mg.

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

Male Companion Trial

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

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

Phase 2b Clinical Trial

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

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

We believe this Phase 2b trial is the largest ever conducted in a diabetic gastroparesis population for any approved metoclopramide dosage forms (oral tablet, orally disintegrating tablet and injection). Previous metoclopramide studies enrolled small numbers of subjects and did not evaluate treatment effects by gender. For example, fewer than 130 gastroparesis subjects were enrolled across all studies included in the NDA for the Listed Drug, Reglan Tablets 10 mg., a branded form of metoclopramide currently marketed in the United States by Ani Pharmaceuticals.

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

GI disorders present differently in males and females and responses to therapy vary by gender. There is general consensus among thought leaders in GI motility that women have a higher prevalence of symptoms, their neural and sensory pathways differ, and hormones, such as estrogen and progesterone, play a role. While the Gimoti Phase 2b trial is the first report of a gender- based difference in response to metoclopramide among subjects with diabetic gastroparesis, gender effects have been reported in drug

studies for other GI disorders, such as IBS. For example, products such as Lotronex® (alosetron), Zelnorm® (tegaserod) and Amitiza® (lubiprostone) were approved by FDA based on effectiveness in women, but not in men.

Phase 2b Trial Design

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

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

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

Phase 2b Efficacy Results

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

- The primary efficacy endpoint was the change from seven-day baseline to Week 4 of the treatment period in the mGCSI-DD total score (mean of four symptoms).

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

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

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

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

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

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

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

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

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

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

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

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

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

Phase 2b Safety Observations

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

Adverse events that occurred more commonly in both Gimoti 10 mg and 14 mg doses compared to placebo (≥2% difference between treated compared to placebo groups) were dysgeusia, headache, nasal discomfort, rhinorrhea, throat irritation, fatigue, hypoglycemia and hyperglycemia. The majority of adverse events were mild to moderate and transient in nature. The table below summarizes the key data from the trial across all subjects and for female and male subjects separately:

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

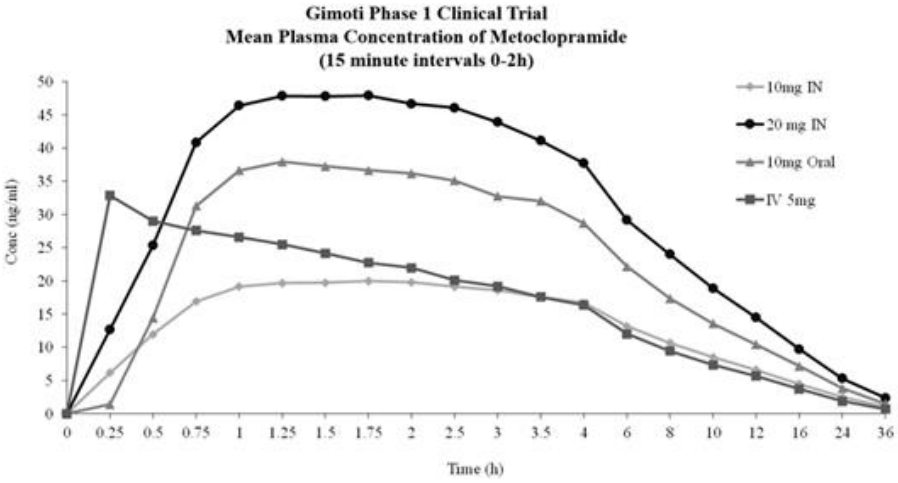
	All Subjects		
System Organ Class Preferred Term	**Placebo (N = 95)**	**Gimoti 10 mg (N = 95)**	**Gimoti 14 mg (N = 95)**
Nervous System Disorders			
Dysgeusia	4(4.2%)	12(12.6%)	13(13.7%)
Headache	4(4.2%)	7(7.4%)	8(8.4%)
Dizziness	2(2.1%)	3(3.2%)	3(3.2%)
Gastrointestinal Disorders			
Diarrhea	9(9.5%)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

Phase 1 Comparative Bioavailability Bridging Study

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

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

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



Thorough ECG (QT/QTc) Study

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

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

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

Prior Development

From 1985 to present, we, or our predecessors, have conducted numerous clinical studies to evaluate the safety and PK profile of nasal spray formulations of metoclopramide in healthy volunteers and the safety, efficacy, and PK profile of metoclopramide nasal spray in patients. More than 1,400 subjects have been exposed to nasal formulations of metoclopramide at doses ranging from 10 mg to 80 mg in these studies.

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

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

We evaluated the current formulation of Gimoti with the same nasal spray pump in six completed clinical trials enrolling a total of 746 healthy volunteers and patients with diabetic gastroparesis. Phase 1 (39 and 108), thorough ECG (54), Phase 2 (287), Phase 3 (205) and Companion (53).

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

Intellectual Property and Proprietary Rights

Overview

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

Our business success will depend significantly on our ability to:

- secure, maintain and enforce patent and other proprietary protection for our core technologies, inventions and know-how;
- obtain and maintain licenses to key third-party intellectual property owned by such third parties;
- preserve the confidentiality of our trade secrets; and
- operate without infringing upon valid, enforceable third-party patents and other rights.

Patent Portfolio

Our patent portfolio includes the following U.S. patents and patent applications as of February 29, 2020:

- U.S. Patent 6,770,262—Nasal Administration of Agents for the Treatment of Gastroparesis. This patent is expected to expire no earlier than 2021.
- U.S. Patent 8,334,281—Nasal Formulations of Metoclopramide. This patent is expected to expire no earlier than 2030 and has a pending Continuation application (U.S. Non-Provisional Patent Application No. 16/181,841).
- U.S. Non-Provisional Patent Application No. 16/016,246 —Treatment of Symptoms Associated with Female Gastroparesis. If granted, this patent is not expected to expire earlier than 2032.
- U.S. Non-Provisional Patent Application No. 16/469,092 – Treatment of Moderate and Severe Gastroparesis. If granted, this patent is not expected to expire earlier than 2037.

We have also been granted European and Canadian patents for the method of use of metoclopramide via nasal delivery for gastroparesis. These patents are expected to expire no earlier than 2021. We have also been granted European and Canadian patents for pharmaceutical compositions comprising metoclopramide. These patents are expected to expire no earlier than 2029. We have also been granted European and Mexican patents for the use of intranasal metoclopramide for treating diabetic gastroparesis in human females. These patents are expected to expire no earlier than 2032. Additional patent applications have been filed in the United States and abroad related to more recent clinical trial findings.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidate are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Other Intellectual Property Rights

We currently have a registered trademark for EVOKE PHARMA and a trademarked product name for GIMOTI in the United States.

Confidential Information and Inventions Assignment Agreements

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

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

Commercialization

We plan to commercialize Gimoti in the United States through partnerships with companies that have established commercialization capabilities. Our strategy for Gimoti, if approved by FDA, will be to establish Gimoti as the prescription product of choice for diabetic gastroparesis in women. If the product candidate is approved, our expectation is that Gimoti would initially be marketed to GI and internal medicine specialists, primary care physicians and select health care providers. We have engaged Eversana to utilize its internal sales organization, along with other commercial functions, for market access, marketing, distribution, and other related patient support services. On January 23, 2020, we and Novos Growth, LLC mutually agreed to terminate, effective immediately, our commercialization agreement entered into in January 2019.

Commercial Services and Loan Agreements with Eversana

On January 21, 2020, we entered into the Eversana Agreement for the commercialization of Gimoti. Pursuant to the Eversana Agreement, Eversana will commercialize and distribute Gimoti in the United States, if approved by FDA. Eversana will manage the marketing of Gimoti to gastroenterologists and other targeted health care providers, as well as the sales and distribution of Gimoti to wholesalers, pharmacies and other customers within the United States.

Under the terms of the Eversana Agreement, we maintain ownership of the Gimoti NDA, as well as legal, regulatory, and manufacturing responsibilities for Gimoti. Eversana will utilize its internal sales organization, along with other commercial functions, for market access, marketing, distribution and other related patient support services. We will record sales for Gimoti and retain more than 80% of net product profits once the parties' costs are reimbursed. Eversana will receive reimbursement of its commercialization costs pursuant to an agreed upon budget and a percentage of product profits in the mid-to-high teens. Net product profits are the net sales (as defined in the Eversana Agreement) of Gimoti, less (i) reimbursed commercialization costs, (ii) manufacturing and administrative costs set at a fixed percentage of net sales, and (iii) third party royalties. During the term of the Eversana Agreement, Eversana agreed to not market, promote, or sell a competing product in the United States.

The term of the Eversana Agreement is from January 21, 2020 until five years from the date, if any, that FDA approves the Gimoti NDA. Upon expiration or termination of the agreement, we will retain all profits from product sales and assume all corresponding commercialization responsibilities. Within 30 days after each of the first three annual anniversaries of commercial launch, either party may terminate the agreement if net sales of Gimoti do not meet certain annual thresholds. Either party may terminate the agreement: for the material breach of the other party, subject to a 60-day cure period; in the event an insolvency, petition of the other party is pending for more than 60 days; upon 30 days written notice to the other party if Gimoti is subject to a safety recall; the other party is in breach of certain regulatory compliance representations under the agreement; we discontinue the development or production of Gimoti; Gimoti is not commercially launched within nine months of FDA approval, if any, or the net profit is negative for any two consecutive calendar quarters beginning with the first full calendar quarter 24 months following commercial launch; or if there is a change in applicable laws that makes operation of the services as contemplated under the agreement illegal or commercially impractical. Either party may also terminate the Eversana Agreement upon a change of control of our ownership, subject, in the event that we initiate such termination, to a one-time payment equal to between two times and one times annualized service fees paid by us under the Eversana Agreement, with such amount based on which year after commercial launch the change of control occurs. Such payment amount would be reduced by the amount of previously reimbursed commercialization costs and profit split paid for the related prior twelve month period and any revenue which occurred prior to the termination yet to be collected. In addition, Eversana may terminate the Eversana Agreement if Gimoti is not approved by FDA by December 31, 2020 (provided Eversana gives us notice of such termination no later than March 1, 2021), or if we withdraw Gimoti from the market for more than 90 days. We may also terminate the agreement if the parties are unable to agree to a commercialization plan and budget within 75 days of the date of the Eversana Agreement.

In addition, in connection with the Eversana Agreement, we and Eversana have entered into a credit facility, or the Eversana Credit Facility, pursuant to which Eversana has agreed to provide a revolving credit facility of up to $5.0 million to us if FDA approves the Gimoti NDA, as well as certain other customary conditions. The Eversana Credit Facility is secured by all of our personal property other than our intellectual property. Under the terms of the Eversana Credit Facility, we cannot grant an interest in our intellectual property to any other person. Each loan under the Eversana Credit Facility will bear interest at an annual rate equal to 10.0%.

We may prepay any amounts borrowed under the Eversana Credit Facility at any time without penalty or premium. The maturity date of all amounts, including interest, borrowed under the Eversana Credit Facility will be 90 days after the expiration or earlier termination of the Eversana Agreement. The Eversana Credit Facility also includes events of default, the occurrence and continuation of which provide Eversana with the right to exercise remedies against us and the collateral securing the loans under the Eversana Credit Facility, including our cash. These events of default include, among other things, our failure to pay any amounts due under the Eversana Credit Facility, an uncured material breach of the representations, warranties and other obligations under the Eversana Credit Facility, the occurrence of insolvency events and the occurrence of a change in control.

Manufacturing

We do not own or operate manufacturing facilities for the production of Gimoti, nor do we have plans to develop our own manufacturing operations in the foreseeable future. We currently depend on third-party contract manufacturers for all of our required raw materials, drug substance and finished product for our product development and clinical trials. We currently use a third-party consultant, which we engage on an as-needed, hourly basis, to manage product development and manufacturing contractors.

In November 2017, we entered into a Manufacturing Services Agreement with Patheon UK Limited, or Patheon, a wholly-owned subsidiary of Thermo Fisher, Inc., pursuant to which Patheon has agreed to manufacture commercial quantities of Gimoti. Under the terms of the agreement, we are required to purchase a certain percentage of our requirements for our Gimoti product intended for commercial sale, provided certain terms and conditions are met. The initial term of the agreement commenced in November 2017 and will continue in effect until December 31st of the year that is five years from the date Gimoti first receives approval for marketing from FDA or any other foreign regulatory agencies competent to grant marketing approvals for pharmaceutical products. This initial term shall be automatically renewed for additional one-year terms, unless either party provides written notice of its intention to terminate the agreement upon notice within a specified time prior to the end of the then current term. Either party may terminate the agreement effective immediately upon written notice to the other in the event that (i) the other party dissolves, is declared insolvent or bankrupt by a court of competent jurisdiction, (ii) a voluntary petition of bankruptcy is filed in any court of competent jurisdiction, or (iii) the agreement is assigned for the benefit of creditors. We may terminate the agreement upon specified prior written notice if any governmental or regulatory authority, including, but not limited to, FDA, takes any action, or raises any objection, that prevents us from importing, exporting, purchasing, or selling Gimoti. Patheon or we may terminate the agreement upon specified prior written notice to the other party if Patheon or we, as applicable, assigns any of our rights under the agreement to an assignee that is (i) not a credit worthy substitute for the assigning party; or (ii) a competitor of assigning party. Moreover, either party may terminate the agreement upon written notice to the other party where the other party has failed to remedy a material breach of any of its representations, warranties, or other obligations under the agreement within a specified period of time following receipt of a written notice of the breach, subject to specified terms and conditions.

In May 2016, we entered into a Master Supply Agreement with Cosma S.p.A., or Cosma, pursuant to which Cosma will be the exclusive commercial supplier of metoclopramide for the manufacture of Gimoti. Under the supply agreement, Cosma will supply metoclopramide pursuant to purchase orders which we may deliver to Cosma from time to time, and there is no minimum supply requirement. In the event Cosma discontinues supply of metoclopramide for any reason, including by reason of a force majeure event, or materially changes the metoclopramide specifications, then we may require Cosma to supply up to a two years' supply of the metoclopramide based on our purchase orders over the preceding two years. The term of the supply agreement is three years, which term shall be automatically extended (1) for an additional period equivalent to the time elapsing from May 2016 to the date of the first commercial launch of Gimoti and (2) for successive one-year periods thereafter, unless terminated earlier. Either party may terminate the supply agreement on 180 days' written notice to the other party or on a 30 days' written notice to the other party for such party's material uncured breach.

In September 2019, we announced the manufacturing of commercial scale lots of Gimoti as required by FDA in the CRL. With the completion of this large-scale production of Gimoti, and pump performance testing and previously submitted CMC datasets, we believe we have demonstrated Gimoti meets all of the appropriate specifications. The additional CMC datasets from the latest commercial scale manufacturing were provided in the NDA submission in December 2019.

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

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

Gastroparesis Treatment Development Pipeline

Product	Class	Route	Company	Status
Gimoti	dopamine antagonist /mixed 5-HT3 antagonist 5-HT4 agonist	nasal	Evoke Pharma	NDA Submitted
Relamorelin/RM-131	ghrelin agonist	sub-cutaneous	Rhythm/Allergan	Phase 3
Velusetrag/TAK-954	5-HT4 receptor agonist	oral	Theravance/Takeda	Phase 2
Tradipitant	NK-1 antagonist	oral	Vanda	Phase 2/3
Renzapride	5-HT4 agonist/ 5-HT3 antagonist	oral	Endologic	Phase 2
NG-101	D2/D3 antagonist	Oral	Neurogastrx	Phase 1

Relamorelin, also called RM-131, is a small-peptide analog of ghrelin, a hormone produced in the stomach that stimulates GI activity. The compound is being developed for GI motility disorders and has shown efficacy in surgical and opiate-induced ileus in animal models due to a direct prokinetic effect. In October 2016, a Phase 2b study failed to reach statistical significance. Following the trial results, Allergan plc. executed its option to acquire Rhythm Holding Company, LLC. Relamorelin Phase 3 clinical trials are targeting complete enrollment in late 2021.

Velusetrag, also called TAK-954, is a 5-HT4 receptor agonist compound under development for the treatment of gastroparesis by Takeda Pharmaceuticals in collaboration with Theravance Biopharma, Inc. In August 2018, Theravance announced that its Phase 2 study failed to reach statistical significance in the two higher doses tested, but did show statistical significance in the lower dose tested. We believe no additional clinical trials are currently planned or ongoing.

Tradipitant is a NK-1 antagonist that has been tested in various other indications by Vanda Pharmaceuticals Inc. In December 2018, a Phase 2 study reached statistical significance for the primary endpoint for treatment of nausea. Vanda proposed a 12-month open-label extension trial for patients who completed the Phase 2 clinical trial of tradipitant. This trial is currently subject to an FDA partial clinical hold. A Phase 3 clinical trial is targeting complete enrollment by mid-2020.

Renzapride, a 5-HT4 agonist and 5HT-3 antagonist, has been studied in more than 5,000 patients including one Phase 3 trial for the treatment of constipation-dominant irritable bowel syndrome (IBS-C). Renzapride demonstrated a small but statistically significant benefit in the Phase 3 study in IBS-C, however, the prior owner of the product decided to not continue to pursue development of the drug for this indication. The drug was well tolerated and showed no evidence of cardiotoxicity. A pilot Phase 2 study in patients with diabetic gastroparesis showed that doses of 0.5 mg, 1.0 mg and 2.0 mg, once-daily, showed significant improvement in gastric emptying in a dose-dependent manner. This endpoint does not meet the July 2015 and August 2019 FDA draft guidance for gastroparesis recommending measurement of symptoms associated with gastroparesis. We believe no additional clinical trials are currently planned or ongoing.

Neurogastrx is currently developing NG-101. NG-101 is a selective and peripherally restricted dopamine D2/D3 receptor antagonist to treat gastroparesis. It is approved in countries outside the U.S. in other indications. We believe no additional clinical trials are currently planned or ongoing.

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

Technology Acquisition Agreement

In June 2007, we acquired all worldwide rights, data, patents and other related assets associated with Gimoti from Questcor pursuant to an asset purchase agreement. We paid Questcor $650,000 in the form of an upfront payment and $500,000 in May 2014 as a milestone payment based upon the initiation of the first patient dosing in our Phase 3 clinical trial for Gimoti. In August 2014, Mallinckrodt, plc, or Mallinckrodt, acquired Questcor. As a result of that acquisition, Questcor transferred its rights included in the asset purchase agreement with us to Mallinckrodt. In addition to the payments previously made to Questcor, we may be required to make additional milestone payments totaling up to $52 million. In March 2018, we amended the asset purchase agreement with Mallinckrodt to defer development and approval milestone payments, such that rather than paying two milestone payments based on FDA acceptance for review of the NDA and final product marketing approval, we would be required to make a single $5 million payment on the one-year anniversary after we receive FDA approval to market Gimoti.

The remaining $47 million in milestone payments depend on Gimoti’s commercial success and will only apply if Gimoti receives regulatory approval. In addition, we will be required to pay to Mallinckrodt a low single digit royalty on net sales of Gimoti. Our obligation to pay such royalties will terminate upon the expiration of the last patent right covering Gimoti, which is expected to occur in 2032, subject to possible extension should any additional, later expiring, licensed patents be granted.

Government Regulation

FDA Review and Approval Process

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

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

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

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

Further, an IRB covering each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and informed consent information for subjects before the trial commences at that site, and it must monitor the study until completed. FDA, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk or for failure to comply with the IRB's or regulatory requirements, or for other reasons, or FDA or IRB may impose other conditions.

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

- *Phase 1:* The drug is initially introduced into healthy human subjects or patients and tested for safety, dose tolerance, absorption, metabolism, distribution and excretion and, if possible, to gain an early indication of its effectiveness.
- *Phase 2:* The drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted indications and to determine dose tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more extensive Phase 3 clinical trials.

- *Phase 3:* These are commonly referred to as pivotal studies. When Phase 2 evaluations demonstrate that a dose range of the product appears to be effective and has an acceptable safety profile, Phase 3 trials are undertaken in large patient populations to further evaluate dosage, to obtain additional evidence of clinical efficacy and safety in an expanded patient population at multiple, geographically-dispersed clinical trial sites, to establish the overall risk-benefit relationship of the drug and to provide adequate information for the labeling of the drug.

- *Phase 4:* In some cases, FDA may condition approval of an NDA for a product candidate on the sponsor's agreement to conduct additional clinical trials to further assess the drug's safety and effectiveness after NDA approval. Such post-approval trials are typically referred to as Phase 4 studies.

The results of product development, pre-clinical studies and clinical trials are submitted to FDA as part of an NDA. NDAs must also contain extensive information relating to the product's pharmacology, 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 program fees. FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information and is subject to payment of additional user fees. The resubmitted application is also subject to review before FDA accepts it for filing.

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

FDA may refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. FDA is not bound by the recommendation of an advisory committee, but it considers such recommendations carefully when making decisions.

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

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

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

Post-Approval Requirements

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

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved products are required to register their establishments with FDA and state agencies, and are subject to periodic unannounced inspections by FDA and these state

agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and generally require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

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

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

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

The Food and Drug Administration Amendments Act of 2007 gave FDA the authority to require a Risk Evaluation and Mitigation Strategy, or REMS, from manufacturers to ensure that the benefits of a drug outweigh its risks. In determining whether a REMS is necessary, FDA must consider the size of the population likely to use the drug, the seriousness of the disease or condition to be treated, the expected benefit of the drug, the duration of treatment, the seriousness of known or potential adverse events, and whether the drug is a new molecular entity. If FDA determines a REMS is necessary, the drug sponsor must agree to the REMS plan at the time of approval. A REMS may be required to include various elements, such as a medication guide or patient package insert, a communication plan to educate health care providers of the drug's risks, limitations on who may prescribe or dispense the drug, or other measures that FDA deems necessary to assure the safe use of the drug. In addition, the REMS must include a timetable to assess the strategy at 18 months, three years, and seven years after the strategy's approval. FDA may also impose a REMS requirement on a drug already on the market if FDA determines, based on new safety information, that a REMS is necessary to ensure that the drug's benefits continue to outweigh its risks.

In March 2009, FDA informed drug manufacturers that it will require a REMS for metoclopramide drug products. FDA's authority to take this action is based on risk management and post market safety provisions within the Food and Drug Administration Amendments Act. The REMS consists of a Medication Guide, elements to assure safe use (including an education program for prescribers and materials for prescribers to educate patients), and a timetable for submission of assessments of at least six months, 12 months, and annually after the REMS is approved. In 2011, FDA determined that maintaining the Medication Guide as a part of the approved labeling is adequate to address the public health concern and meets the regulatory standards. We followed current labeling procedures and included a medication guide at the time of the NDA submission for Gimoti. Based on feedback from FDA, we proposed elements of a REMS to be included in the NDA submission. At this time the elements of the REMS for Gimoti are unclear as there are varying levels of requirements that may include a Medication Guide, similar to the Reglan Tablet, and other elements, such as a communication plan and an implementation plan, designed to ensure safe use, as well as a timetable for submission of post-marketing assessments after the REMS is approved.

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

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

Section 505(b)(2) New Drug Applications

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

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

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

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

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

Manufacturing Requirements

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

Other Regulatory Requirements

We are also subject to various laws and regulations regarding laboratory practices, the experimental use of animals, and the use and disposal of hazardous or potentially hazardous substances in connection with our research. In each of these areas, as above, FDA has broad regulatory and enforcement powers, including, among other things, the ability to levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products, and withdraw approvals, any one or more of which could have a material adverse effect on us.

Coverage and Reimbursement

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

Other Healthcare Laws

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

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

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

The federal criminal false claims laws prohibit, among other things, knowingly and willfully making, or causing to be made, a false statement or representation of a material fact for use in determining the right to any benefit or payment under a federal health care program. A violation of these laws may constitute a felony or misdemeanor and may result in fines or imprisonment.

The federal Civil Monetary Penalties Law prohibits, among other things, the offering or transferring of remuneration to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular supplier of Medicare or Medicaid payable items or services. Noncompliance with such beneficiary inducement provision of the federal Civil Monetary Penalties Law can result in civil money penalties for each wrongful act, assessment of three times the amount claimed for each item or service and exclusion from the federal healthcare programs.

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

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians and other healthcare providers. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the Affordable Care Act, among other things, imposes new reporting requirements on certain drug manufacturers for payments made by them to physicians, certain other health care professionals beginning in 2022, 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 significant civil monetary penalties for any payments, transfers of value or ownership or investment interests that are not timely, accurately and completely reported in an annual submission. Drug manufacturers are required to submit reports to the government by the 90th day of each calendar year. Certain states also mandate implementation of commercial compliance programs, impose restrictions on drug manufacturer marketing practices and/or require the tracking and reporting of marketing expenditures and pricing information, as well as gifts, compensation and other remuneration to physicians.

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

Healthcare Reform

In March 2010, the Affordable Care Act, which substantially changed the way healthcare is financed by both governmental and private insurers in the United States, was signed into law and significantly affected the pharmaceutical industry. The Affordable Care Act contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement adjustments and fraud and abuse changes. Additionally, the Affordable Care Act increases the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1%; imposes a non-deductible annual fee on pharmaceutical manufacturers or importers who sell “branded prescription drugs” to specified federal government programs; and addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, and we expect there will be additional challenges and amendments to the Affordable Care Act in the future. For example, on December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, ruled that the individual mandate is a critical and inseverable feature of the Affordable Care Act, and therefore, because it was repealed as part of the Tax Cuts and Jobs Act, the remaining provisions of the Affordable Care Act are invalid as well. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the district court’s decision that the individual mandate was unconstitutional, but remanded the case back to the District Court to determine whether the remaining provisions of the Affordable Care Act are invalid as well. It is unclear how these decisions, subsequent appeals, if any, and other efforts to challenge, repeal or replace the Affordable Care Act will impact the law.

Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted, including aggregate reductions of Medicare payments to providers of 2% per fiscal year and reduced payments to several types of Medicare providers. Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. Individual states in the United States have also become increasingly active in implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Data Privacy and Security

We may also be subject to U.S. federal and state and foreign health information privacy, security and data breach notification laws, which may govern the collection, use, disclosure and protection of health-related and other personal information. In the U.S., HIPAA imposes privacy, security and breach reporting obligations with respect to individually identifiable health information upon “covered entities” (health plans, health care clearinghouses and certain health care providers), and their respective business associates, individuals or entities that create, received, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HIPAA mandates the reporting of certain breaches of health information to the United States Department of Health and Human Services, or HHS, affected individuals and if the breach is large enough, the media. Entities that are found to be in violation of HIPAA as the result of a breach of unsecured protected health information, a complaint about privacy practices or an audit by HHS, may be subject to significant civil, criminal and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance. Even when HIPAA does not apply, according to the Federal Trade Commission, or FTC, failing to take appropriate steps to keep consumers’ personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act, or the FTCA, 15 U.S.C. § 45(a). The FTC expects a company’s data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it

holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. The FTC's guidance for appropriately securing consumers' personal information is similar to what is required by the HIPAA Security Rule.

In addition, certain states govern the privacy and security of health information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. For example, California recently enacted legislation, the California Consumer Privacy Act, or CCPA, which went into effect January 1, 2020. The CCPA, among other things, creates new data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to opt out of certain disclosures of their information. The CCPA also creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. Although the law includes limited exceptions, including for "protected health information" maintained by a covered entity or business associate, it may regulate or impact our processing of personal information depending on the context.

In Europe, the General Data Protection Regulation, or GDPR, went into effect in May 2018 and imposes stringent data protection requirements for controllers and processors of personal data of persons within the European Union, or EU. The GDPR applies to any company established in the EU as well as to those outside the EU if they collect and use personal data in connection with the offering of goods or services to individuals in the EU or the monitoring of their behavior. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. In addition, the United Kingdom leaving the EU could also lead to further legislative and regulatory changes. It remains unclear how the United Kingdom data protection laws or regulations will develop in the medium to longer term and how data transfer to the United Kingdom from the EU will be regulated, especially following the United Kingdom's departure from the EU on January 31, 2020 without a deal. However, the United Kingdom has transposed the GDPR into domestic law with the Data Protection Act 2018, which remains in force following the United Kingdom's departure from the EU.

Employees

As of February 29, 2020, we had five full-time employees and several consultants in the regulatory, clinical, manufacturing and finance areas. None of our employees are represented by a collective bargaining arrangement, and we believe our relationship with our employees is good.

About Evoke

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

Financial Information about Segments

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

Available Information

We file electronically with the Securities and Exchange Commission, or SEC, our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended. We make available copies of these reports, free of charge, on our website at *www.evokepharma.com*, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. The SEC maintains a website that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. The address of that website is www.sec.gov. The information in or accessible through the SEC and our website are not incorporated into, and are not considered part of, this report. Further, our references to the URLs for these websites are intended to be inactive textual references only.

Item 1A. Risk Factors

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

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

Our business is entirely dependent on the success of Gimoti, which failed to achieve the primary endpoint of symptom improvement in a Phase 3 clinical trial in female patients with symptoms associated with diabetic gastroparesis. While we have resubmitted our Gimoti NDA based on the results of our completed comparative exposure PK trial, FDA may not agree that we have adequately addressed the issues raised in its CRL from our initial Gimoti NDA submission and we cannot be certain that we will be able to obtain regulatory approval for, or successfully commercialize, Gimoti.

To date, we have devoted all of our research, development and clinical efforts and financial resources toward the development of Gimoti, our patented nasal delivery formulation of metoclopramide for the relief of symptoms associated with acute and recurrent diabetic gastroparesis in adult women. Gimoti is our only product candidate. In July 2016, we announced topline results from our Phase 3 clinical trial that evaluated the efficacy and safety of Gimoti in women with symptoms associated with diabetic gastroparesis. In this study, Gimoti did not achieve its primary endpoint of symptom improvement in the Intent-to-Treat, or ITT, group at Week 4.

In December 2016, we announced the completion of a pre-NDA meeting with FDA, in which FDA agreed that a comparative exposure PK trial was acceptable as a basis for submission of a Gimoti NDA. Data from the comparative exposure PK trial served as a portion of the 505(b)(2) data package and included prior efficacy and safety data developed by us and FDA's prior findings of safety and efficacy for the Listed Drug, Reglan Tablets 10 mg. In October 2017, we announced positive topline results from the comparative exposure PK trial. In addition, based on feedback received from FDA at an additional pre-NDA meeting, we proposed a REMS and post-approval safety trial as part of the NDA we submitted for Gimoti to FDA on June 1, 2018. In August 2018, we received a Day-74 letter that stated that the NDA was sufficiently complete to permit a substantive review and set a target goal date for a decision under PDUFA of April 1, 2019.

On March 1, 2019, we received a DRL from FDA, which provided preliminary notice of certain deficiencies identified during FDA's initial review of the Gimoti NDA. The DRL described concerns with the information provided in the NDA, including concerns that insufficient data had been offered regarding certain product quality control and reproducibility specific to the commercially available sprayer device used with Gimoti, that there is a lack of adequate information to support sex-based efficacy claims and that the pharmacology data provided may not demonstrate bioavailability to the Listed Drug, Reglan Tablets 10 mg. On March 14, 2019, we submitted a response to the DRL to FDA, and on March 21, 2019, we met with FDA to obtain feedback on our responses.

On April 1, 2019, we received a CRL from FDA for our Gimoti NDA. The CRL, while citing fewer issues than the DRL, stated that FDA determined it could not approve the NDA in its present form and provided recommendations to address the remaining approvability issues in an NDA resubmission. The approvability issues were related to clinical pharmacology and product quality/device quality.

The clinical pharmacology issue was specific to a low C_{max} in subjects representing less than 5% of the total administered Gimoti doses in the pivotal PK study. FDA stated the overall lower mean C_{max} was driven by the data from these few doses. We conducted an analysis excluding these aberrant doses, which showed that the PK study met the bioequivalence criteria for both men and women, although there is no assurance that FDA will agree with our conclusion. FDA recommended a root cause analysis to determine the origin of the PK variability and mitigation strategies to address their concern. Additionally, FDA requested data from three registration batches of commercial product to be manufactured at the proposed commercial manufacturing site, by the proposed commercial process and tested using validated analytical methods. These data were requested to provide additional support for the proposed acceptance criteria for droplet size distribution and other essential performance characteristics for the commercial product specifications.

On July 25, 2019, we completed a type A meeting with FDA to obtain FDA's feedback and agreement on our plan to address deficiencies cited in the CRL in support of a resubmission of the Gimoti NDA. The focus of the discussion was on topics noted in the CRL, including the root cause analysis of low drug exposure in the comparative bioavailability study and additional product quality/device quality control testing.

On December 19, 2019, based on FDA feedback received during the type A meeting, we resubmitted the Gimoti NDA to FDA. The resubmission provided the requested additional information intended to address the deficiencies cited in the CRL. To address the clinical pharmacology issues, the resubmission included an in-depth root cause analysis, as well as patient use and experience data from our clinical trials. To address product quality/device quality issues cited in the CRL, the resubmission included 3-month stability data from commercial scale registration batches that met all product specifications. We believe these data support the acceptance

criteria for performance characteristics and device quality control we proposed in the Gimoti NDA. Additionally, as requested by FDA, the resubmission included data from an analysis of pump performance characteristics for the product used in the comparative bioavailability study and the product from commercial scale registration batches. The results of this testing showed all products performed within specifications. However, FDA may determine that our root cause analysis and additional patient data and/or the stability data, including our proposed acceptance criteria for performance characteristics and device quality, do not adequately address the issues raised in the CRL, and/or support approval of the NDA, and may later require us to conduct additional human clinical trials prior to approval.

On January 17, 2020, we received a notice from FDA that it had accepted our NDA resubmission for review and set a target goal date for a decision under PDUFA of June 19, 2020. However, the review process and the PDUFA target action date may be extended if FDA requests or we otherwise provide additional information or clarification regarding information already provided in the submission. FDA's review goals are subject to change, and the duration of FDA's review may depend on the number and type of other NDAs that are submitted to FDA around the same time period.

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

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

- we may not be able to provide acceptable evidence of safety and efficacy for Gimoti, including as a result of the proposed duration of use for Gimoti being shorter as compared to the maximum approved dosing duration for the referenced Listed Drug, Reglan Tablets 10 mg;
- the results of our clinical trials may not meet the level of statistical or clinical significance or other bioequivalence parameters required by FDA for marketing approval, including C_{max} falling below the equivalence range in the comparative exposure PK trial;
- FDA may not agree with the analysis of our clinical trial results, including our analysis of results of the PK trial and our root cause analysis to determine the origin of the PK variability raised by FDA in the CRL;
- later developments with FDA that may be inconsistent with our recent type A meeting;
- we may be required to undertake additional clinical trials and other studies of Gimoti before we receive approval of the NDA we resubmitted;
- we may not have sufficient financial and other resources to complete clinical development for Gimoti;
- if approved, Gimoti will compete with well-established products already approved for marketing by FDA, including oral and intravenous forms of metoclopramide, the same active ingredient in the nasal spray for Gimoti;
- our reliance on Eversana and any other third party to commercialize Gimoti, if approved;
- we may not be able to maintain commercial manufacturing arrangements with third-party manufacturers or establish and maintain commercial-scale manufacturing capabilities;
- contract manufacturers, suppliers and/or consultants may not meet appropriate timelines;
- FDA may disagree with the design of any future clinical trials, if any are necessary;
- subjects in our clinical trials may die or suffer other adverse effects for reasons that may or may not be related to Gimoti, such as dysgeusia, headache, diarrhea, nasal discomfort, tremor, myoclonus, somnolence, rhinorrhea, throat irritation, and fatigue; and
- we may not be able to obtain, maintain and enforce our patents and other intellectual property rights.

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

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

Our operations have consumed substantial amounts of cash since inception. On January 17, 2020, we received a notice from FDA that it had accepted our NDA resubmission for review and set a target goal date for a decision under PDUFA of June 19, 2020. We believe, based on our current operating plan, that our existing cash and cash equivalents will be sufficient to fund our operations through the PDUFA target goal date and into the third quarter of 2020. If Gimoti is approved by FDA, additional funds will become

available from the Eversana Credit Facility which we believe, based on our current operating plan, will provide sufficient cash to fund our operations into 2021 excluding any potential future Gimoti product revenue. This period could be shortened if there are any significant increases in planned spending other than anticipated. Even with the Eversana Credit Facility, we will be required to raise additional funds in order to continue as a going concern. There can be no assurance that we will be able to raise additional funds on acceptable terms, or at all, to further develop Gimoti, if required, and receive FDA approval of the Gimoti NDA. Because our business is entirely dependent on the success of Gimoti, if we are unable to secure additional financing or identify and execute on other development or strategic alternatives for Gimoti or our company, we will be required to curtail all of our activities and may be required to liquidate, dissolve or otherwise wind down our operations. Any of these events could result in a complete loss of your investment in our securities.

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 potential for FDA to delay the PDUFA target goal date due to FDA's internal resource constraints or other reasons;
- the need for, and the progress, costs and results of, any additional clinical trials of Gimoti that may be required by FDA, including any pre-approval or post-approval trials FDA or other regulatory agencies may require evaluating the efficacy or safety of Gimoti;
- the costs involved for additional data collection and analysis to respond to FDA questions related to the NDA;
- the outcome, costs and timing of seeking and obtaining regulatory approvals from FDA, and any similar regulatory agencies;
- the costs and timing of completion of outsourced commercial manufacturing supply arrangements for Gimoti;
- the costs required to commercialize Gimoti, including expenses incurred under our commercialization agreement with Eversana;
- the commercial success of Gimoti, if approved;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights associated with Gimoti;
- the terms and timing of any collaborative, licensing, co-promotion or other arrangements that we may establish; and
- costs associated with any other product candidates that we may develop, in-license or acquire.

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

Topline data may not accurately reflect the complete results of a particular study or trial.

We may publicly disclose topline or interim data from time to time, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. For example, while we believe that the AUC measurement was the most clinically relevant PK parameter for our comparative exposure PK trial, FDA may disagree or may emphasize other data such as C_{max} falling below the equivalence range of the Listed Drug, Reglan Tablets 10 mg. Any contrary views by FDA would impact our dose selection and FDA's review of the NDA. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular drug, drug candidate or our business. If the topline data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and

commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition. Further, although we reported positive topline data for the PK trial, FDA may still require the conduct of additional efficacy or safety trials.

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

We have submitted an NDA for Gimoti, but have not received regulatory approval to market any product candidates in any jurisdiction. We are not permitted to market Gimoti in the United States until we receive approval of an NDA for Gimoti in a particular indication from FDA. To date, we have completed a Phase 1 bioavailability and pharmacokinetics trial, a comparative exposure PK trial, a Phase 3 clinical trial in female subjects, a companion Phase 3 clinical trial in male subjects, a Thorough ECG (QT/QTc) study, a Phase 2b clinical trial and we acquired the results from a separate Phase 2 clinical trial in diabetic subjects with gastroparesis. In the Phase 2b clinical trial that we performed ourselves, which concluded in 2011, Gimoti failed to meet the primary endpoint for the trial. Although an overall improvement in symptoms was observed in Gimoti-treated subjects with diabetic gastroparesis compared to placebo in this Phase 2b clinical trial, the difference was not statistically significant due to a high placebo response among male subjects. The earlier Phase 2 clinical trial performed by Questcor was a multicenter, randomized, open-label, parallel design study. This head-to-head study compared the efficacy and safety of two doses of metoclopramide nasal spray, 10 mg and 20 mg, with FDA-approved 10 mg metoclopramide tablet. Although data from the earlier Phase 2 clinical trial was referenced in the Gimoti NDA, the open-label study design limits the importance of the efficacy results in the NDA.

We completed our Phase 3 clinical trial in female subjects with symptoms associated with acute and recurrent diabetic gastroparesis and announced in July 2016 that Gimoti did not achieve its primary endpoint of symptom improvement at Week 4. While we submitted the results from the comparative exposure PK trial as a portion of the 505(b)(2) NDA submission that included prior efficacy and safety data developed by us along with FDA's prior findings of safety and efficacy for the Listed Drug, Reglan Tablets 10 mg., there is no guarantee that regulators will agree with our assessment of the clinical trials for Gimoti conducted to date, including the comparative exposure PK trial. In addition, we have only limited experience in filing the applications necessary to gain regulatory approvals and expect to rely on consultants and third-party contract research organizations to assist us in this process. FDA and other regulators have substantial discretion in the approval process and may decide that our data are insufficient for approval and require additional clinical trials, or preclinical or other studies.

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

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

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

In July 2015, and again in August 2019, FDA published draft guidance intended to assist sponsors in the clinical development of drugs for the treatment of diabetic and idiopathic gastroparesis clinical trials, *Gastroparesis: Clinical Evaluation of Drugs for Treatment – Guidance for Industry*. We believe that the FDA draft guidance is consistent with the advice FDA provided to us regarding trial design and study endpoints for our completed Phase 3 trials. In addition, the FDA draft guidance explicitly states that there is an urgent medical need for development of safe and effective drugs to treat patients with gastroparesis and acknowledges that "patients with diabetic gastroparesis may experience further derangement of glucose control because of unpredictable gastric emptying and altered absorption of orally administered hypoglycemic drugs." FDA draft guidance, however, does not create or confer any rights for or on any person and do not operate to bind FDA or the public, and FDA may ultimately disagree with our interpretation regarding the meaning or applicability of any published Guidance documents.

We conducted a Phase 3 trial in adult female subjects with diabetic gastroparesis, which failed to reach its primary endpoint. However, following our second pre-NDA meeting with FDA in December 2016, FDA agreed that a comparative exposure PK trial, along with prior efficacy and safety data from other completed Gimoti studies, would be appropriate for NDA submission seeking an indication of treatment of symptoms associated with diabetic gastroparesis in women. Although the results from the comparative exposure PK trial along with the prior data were sufficient to submit an NDA for Gimoti in June 2018, it is possible FDA will require additional clinical testing before approval of the NDA. In addition, based on discussions with FDA, we also conducted a similar study for safety and efficacy in adult male subjects with diabetic gastroparesis. A portion of the safety and efficacy data from this trial was submitted as a part of the NDA. If we are unable to comply with FDA's requirements, we will not be able to obtain approval for Gimoti and our ability to generate revenue will be materially impaired.

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

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

- FDA placing a clinical trial on hold;
- subjects failing to remain in our trial at the rate we expect (for example, due to variable patient frequency and severity of disease and variability in gastric emptying testing);
- subjects choosing an alternative treatment for the indication for which we are developing Gimoti, or participating in competing clinical trials;
- subjects experiencing severe or unexpected drug-related adverse effects;
- a facility manufacturing Gimoti, or any of its components, being ordered by FDA or other government or regulatory authorities to temporarily or permanently shut down due to violations of FDA's cGMP or other applicable requirements, or infections or cross-contaminations of a product candidate in the manufacturing process;
- any changes to our manufacturing process that may be necessary or desired;
- third-party clinical investigators losing their license or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, good clinical practice and regulatory requirements, or other third parties not performing data collection and analysis in a timely or accurate manner;
- inspections of clinical trial sites by FDA or the finding of regulatory violations by FDA or IRB that require us to undertake corrective action, result in suspension or termination of one or more sites or the imposition of a clinical hold on the entire trial, or that prohibit us from using some or all of the data in support of our marketing applications;
- third-party contractors becoming debarred or suspended or otherwise penalized by FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or any of the data produced by such contractors in support of our marketing applications; or
- one or more IRBs refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing its approval of the trial.

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

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

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

We submitted an NDA for Gimoti in June 2018. Under PDUFA, FDA is subject to a two-tiered system of review times - standard review and priority review. For drugs that are not new molecular entities that are subject to standard review, such as Gimoti, FDA has a goal to complete its review of the NDA and respond to the applicant within ten months from the date of receipt of an NDA. In its Day-74 filing communication letter, FDA assigned a target goal date for a decision under PDUFA of April 1, 2019 for the Gimoti NDA. On April 1, 2019, we received a CRL from FDA for our NDA. The CRL stated that FDA could not approve the NDA in its present form and provided recommendations to address the remaining approvability issues in an NDA resubmission.

On July 25, 2019, we completed a type A meeting with FDA to obtain FDA's feedback and agreement on our plan to address deficiencies cited in the CRL in support of a resubmission of the Gimoti NDA. The focus of the discussion was on topics noted in the CRL, including the root cause analysis of low drug exposure in the comparative bioavailability study and additional product quality/device quality control testing.

On December 19, 2019, based on FDA feedback received during the type A meeting, we resubmitted the Gimoti NDA to FDA. The resubmission provided the requested additional information intended to address the deficiencies cited in the CRL. To address the

clinical pharmacology issues, the resubmission included an in-depth root cause analysis, as well as patient use and experience data from our clinical trials. To address product quality/device quality issues cited in the CRL, the resubmission included 3-month stability data from commercial scale registration batches that met all product specifications and support the proposed acceptance criteria for performance characteristics and device quality control. Additionally, as requested by FDA, the resubmission included data from an analysis of pump performance characteristics for the product used in the comparative bioavailability study and the product from commercial scale registration batches. The results of this testing showed all products performed within specifications. In addition, FDA may determine that our root cause analysis and additional patient data and/or the stability data do not adequately address the issues raised in the CRL, or support approval of the NDA, and may later require us to conduct additional human clinical trials prior to approval.

On January 17, 2020, we received a notice from FDA that it had accepted our NDA resubmission for review and set a target goal date for a decision under PDUFA of June 19, 2020.

The duration of FDA's review of any resubmitted NDA may depend on the number and type of other NDAs that are submitted with FDA around the same time period. In addition, FDA may refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. FDA is not bound by the recommendation of an advisory committee, but it considers such recommendations carefully when making decisions.

We cannot provide any assurance as to whether or when we will obtain regulatory approval to commercialize Gimoti. We cannot, therefore, predict the timing of any future revenue. Because Gimoti is our only product candidate this risk is particularly significant for us. We cannot commercialize Gimoti until the appropriate regulatory authorities have reviewed and approved marketing applications for this product candidate. We cannot assure you that the regulatory agencies will complete their review processes in a timely manner or that we will obtain regulatory approval for Gimoti. In addition, we may experience delays or the application may be rejected based upon additional government regulation from future legislation or administrative action or changes in FDA policy during the period of product development, clinical trials and FDA regulatory review. For example, in 2009 following an FDA review of metoclopramide spontaneous safety reports, FDA required a boxed warning be added to the metoclopramide product label concerning the chance of tardive dyskinesia, or TD, for patients taking these products. FDA requires a boxed warning (sometimes referred to as a "Black Box" Warning) for products that have shown a significant risk of severe or life-threatening adverse events. Recently, the European Medicines Agency's Committee on Medicinal Products for Human Use, or CHMP, has reviewed and has proposed labeling changes for marketed metoclopramide products in the EU 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 EU. There can be no assurance as to whether FDA will re-review approved metoclopramide product labels as a result of any such regulatory actions in the EU or otherwise. If marketing approval for Gimoti is delayed, limited or denied, our ability to market the product candidate, and our ability to generate product sales, would be adversely affected.

In addition, in a written communication, FDA responded to our request for proprietary name review by conditionally accepting our proposed proprietary brand name, Gimoti. However, FDA issued the CRL even though it had previously approved this proprietary name. FDA typically conducts a rigorous review of proposed product names, including an evaluation of potential for confusion with the names of other products, which could lead to identification of the wrong medication or other prescribing, ordering, dispensing, administration, or monitoring errors. FDA may also object to a product name if it believes the name functions to overstate the efficacy, minimize the risk, broaden the proposed indication, make unsubstantiated superiority claims, or is otherwise false or misleading. If FDA objects to the product name Gimoti as part of its NDA resubmission review process, we may be required to adopt an alternative name for our product candidate. If we adopt an alternative name, we would lose the benefit of our existing trademark applications for Gimoti and may be required to expend significant additional resources in an effort to identify a suitable product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our product candidate.

We have no internal sales, marketing or distribution capabilities currently and will rely on Eversana and other third parties for the commercialization of Gimoti, and we and they may not be able to effectively market, sell and distribute Gimoti, if approved.

Currently, we have no internal sales, marketing or distribution capabilities. If Gimoti ultimately receives regulatory approval, we may not be able to effectively market and distribute the product candidate. We have engaged Eversana to manage substantially all activities related to marketing, market access, distribution, sales team, patient reimbursement, and provide related support services. Eversana may be unable to identify and retain suitable candidates to fill our direct sales force needs, on our expected launch timeframe or otherwise. To the extent we and Eversana are not successful in retaining qualified sales and marketing personnel, we may not be able to effectively market Gimoti. Further, there can be no assurance that the capabilities of the Eversana will be effective in marketing and selling Gimoti, or that their personnel will be more effective than an internally developed sales organization. In addition, Eversana may terminate our agreement, including the obligation to provide a line of credit, and can terminate the agreement under certain additional circumstances, including failure to make payments when due, if we are in material breach of the agreement and fail to remedy the breach following notice, if we enter into bankruptcy, or if we are excluded from participation in certain federal governmental programs or have similar actions taken against us. If we and Eversana fail to hire, train, retain and manage qualified

sales personnel, market our product successfully or on a cost-effective basis or otherwise terminates our relationship, our ability to generate revenue will be limited and we will need to identify and retain an alternative organization, or develop our own sales and marketing capability. In such an event, we would have to invest significant amounts of financial and management resources to develop internal sales, distribution and marketing capabilities. This could involve significant delays and costs, including the diversion of our management's attention from other activities. We may also need to retain additional consultants or external service providers to assist us in sales, marketing and distribution functions, and may be unsuccessful in retaining such services on acceptable financial terms or at all.

If we do perform sales, marketing and distribution functions ourselves, we could face a number of additional related risks, including:

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

If we are unsuccessful in building and managing a sales and marketing infrastructure internally or through a third-party partner for any approved product, we will have difficulty commercializing the product, which would adversely affect our business and financial condition.

We and our contract sales force provider, Eversana, will need to retain qualified sales and marketing personnel and collaborate in order to successfully commercialize Gimoti.

In January 2020, we entered into the Eversana Agreement, pursuant to which Eversana will provide a minimum number of sales representatives to promote Gimoti upon its commercial launch, if any. These representatives would be employees of Eversana and would be hired and be managed by Eversana. To the extent Eversana is not successful in retaining qualified sales and marketing personnel, we may not be able to effectively market Gimoti, if approved.

We and Eversana each have the right to terminate the Eversana Agreement subject to certain conditions, as described above under "*Business—Commercialization—Commercial Services and Loan Agreements with Eversana*." While our agreement with Eversana would require sales representatives to undergo onboarding and training, we cannot be sure that Eversana's efforts will be successful or generate sufficient awareness or demand for Gimoti, if approved.

Any revenues we receive from sales of Gimoti will largely depend upon the efforts of Eversana, which in many instances will not be within our control. If we are unable to maintain the Eversana Agreement or to effectively establish alternative arrangements to market our products, if any, our business could be adversely affected. In addition, despite our arrangement with Eversana, we still may not be able to cover all of the prescribing physicians for gastroparesis at the same level of reach and frequency as our competitors, and we ultimately may need to further expand our selling efforts in order to effectively compete.

Changes in funding for FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business.

The ability of FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years the U.S. government has shut down several times and certain regulatory agencies, such as FDA, have had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

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

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

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

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

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

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

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

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

FDA has the authority to require a REMS as a condition of approval of an NDA or following approval, which may impose further requirements or restrictions on the distribution or use of an approved drug, such as limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria and requiring treated patients to enroll in a registry. In March 2009, FDA informed drug manufacturers that it will require a REMS for metoclopramide drug products, including a Medication Guide, elements to assure safe use (including an education program for prescribers and materials for prescribers to educate patients), and a timetable for submission of assessments of at least six months, 12 months, and annually after the REMS is approved. In addition, FDA requested we include a proposal for a risk mitigation strategy in the NDA submission. We proposed elements of a REMS and a post-approval safety trial within the NDA for Gimoti. At this time, the elements of the REMS that FDA will require for Gimoti are uncertain as there are varying levels of requirements that may include a Medication Guide, similar to the Listed Drug, Reglan Tablets 10 mg., and other elements, such as a communication plan and an implementation plan, designed to ensure safe use, as well as a timetable for submission of post-marketing assessments after the REMS is approved.

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

FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the current administration may impact our business and industry. Namely, several recent executive actions, including the issuance of a number of Executive Orders, could impose significant burdens on, or otherwise materially delay, FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these executive actions, including the Executive Orders, will be implemented, and the extent to which they will impact FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

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

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

- demonstration of clinical efficacy and safety compared to other more-established products;
- the limitation of our targeted patient population to women-only;
- limitations or warnings contained in any FDA-approved labeling, including the potential boxed warning on all metoclopramide product labels concerning the chance of TD for patients taking these products, or any limitations with respect to metoclopramide product labels in the EU;
- 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, Eversana's, or any future collaborators' sales and marketing strategies and execution;
- our ability to obtain and maintain sufficient third-party coverage and reimbursement from government health care programs, including Medicare and Medicaid, private health insurers and other third-party payors; and
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage.

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

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

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

As of February 29, 2020, we had only five full-time employees and, as a result, we rely on outsourcing arrangements with third-party vendors for a significant portion of our activities, including pre-commercial sales and marketing, data analysis, assistance with ongoing regulatory discussions and submissions supporting the Gimoti NDA, manufacturing, and the functions required of being a public company. Any failure of our third-party vendors to continue their support could adversely affect our ability to respond to issues raised by FDA's review of the NDA and our ability to commercialize Gimoti, if approved.

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. We do not own or operate manufacturing facilities for the production of any component of Gimoti, including metoclopramide, the nasal spray device or associated bottle, nor do we have plans to develop our own manufacturing operations in the foreseeable future. We currently depend on third-party contract manufacturers for all of our required raw materials, drug substance and drug product for our clinical trials and pre-commercialization activities, and will continue to rely on such third parties for commercial production if Gimoti is approved for marketing. We are currently using, and relying on, single suppliers and single manufacturers for starting materials, the final drug substance and nasal spray delivery device for Gimoti, including Cosma as the sole-source supplier of metoclopramide and Thermo Fisher Scientific Inc., as the sole manufacturer of Gimoti. 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.

If we change to other manufacturers in the future, FDA and comparable foreign regulators must approve these manufacturers' facilities and processes prior to use, which could require new clinical studies, testing and compliance inspections, and the new manufactures would have to be educated in, or demonstrate successful technology transfer of, the processes necessary for the production of Gimoti.

In addition, our reliance on third-party vendors 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.

Any performance failure on the part of our third-party manufacturers could delay commercialization and we may be required to replace such manufacturers, and we may be unable to replace them on a timely basis or at all. Further, our third-party manufacturers may experience manufacturing difficulties due to resource constraints or as a result of natural disasters, labor disputes, unstable political environments, or public health emergencies such as the recent coronavirus (Covid-19) outbreak. If our third-party manufacturers were to encounter any manufacturing difficulties or delays due to these factors, our ability to provide Gimoti for treatment of patients if approved by FDA, would be jeopardized.

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

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

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

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

- collaborate with others to effectively market, sell and distribute Gimoti.

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

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

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and commercial personnel. We are highly dependent upon our senior management team composed of three individuals: David A. Gonyer, R.Ph., our President and Chief Executive Officer, Matthew J. D'Onofrio, our Executive Vice President and Chief Business Officer, and Marilyn Carlson, D.M.D., M.D., our Chief Medical Officer. The loss of services of any of these individuals could delay or prevent the successful development of Gimoti or the commercialization of this product candidate, if approved.

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

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

Because we only had five full-time employees as of February 29, 2020, we may need to grow our organization to pursue the potential commercialization of Gimoti and to potentially conduct additional unplanned development activities. As we seek to commercialize Gimoti, we will need to expand our regulatory, finance, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various strategic partners, suppliers and other third parties. Future growth will impose significant added responsibilities on members of management and require us to retain additional internal capabilities. Our future financial performance and our ability to commercialize Gimoti and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train and integrate additional management, clinical and regulatory, financial, administrative and sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company.

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

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

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

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

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act. For example, the Tax Cuts and Jobs Act, or Tax Act, was enacted, which, among other things, removes penalties for not complying with Affordable Care Act's individual mandate to carry health insurance. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, ruled that the individual mandate is a critical and inseverable feature of the Affordable Care Act, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the Affordable Care Act are invalid as well. On December 18, 2019, the U.S. Court of Appeals for

the 5th Circuit upheld the District Court's decision that the individual mandate was unconstitutional but remanded the case back to the District Court to determine whether the remaining provisions of the Affordable Care Act are invalid as well. It is unclear how these decisions, subsequent appeals, if any, and other efforts to challenge, repeal or replace the Affordable Care Act will impact the law. We cannot predict the ultimate content, timing or effect of any healthcare reform legislation or the impact of potential legislation on us.

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. These changes include aggregate reductions to Medicare payments to providers of two percent per fiscal year, which went into effect on April 1, 2013, and due to subsequent legislative amendments, will remain in effect through 2029, unless additional Congressional action is taken and the American Taxpayer Relief Act of 2012 which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Recently there has also been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted legislation designed to, among other things, reform government program reimbursement methodologies. Individual states in the United States have also become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. These 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 or our commercialization partners market products in a manner that violates healthcare laws, we may be subject to civil or criminal penalties.

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

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are several statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution, the exceptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability. Further a person or entity does not need to have actual knowledge of these statutes or specific intent to violate them in order to have committed a violation.

Federal civil and criminal false claims laws, including the False Claims Act, 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. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act. 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.

Federal civil monetary penalties laws impose civil fines for, among other things, the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state healthcare program, unless an exception applies.

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

Federal price reporting laws require manufactures to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/or discounts on approved products.

Federal and state consumer protection and unfair competition laws broadly regulate marketplace activities and activities that potentially harm consumers.

Once our products are approved and we commence sales in the United States, we will also be required to comply with 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), certain other health care professionals beginning in 2022, and teaching hospitals, and applicable manufacturers and group purchasing organizations to report annually to the government ownership and investment interests held by physicians (as defined above) and their immediate family members. Manufacturers are required to report such data to the government by the 90th calendar day of each year. There are also several states with similar laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information, and/or require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers.

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

We may be subject to foreign, federal, and state data privacy and security laws, and failure to protect our information systems against security breaches, service interruptions, or misappropriation of data could disrupt operations, compromise sensitive data, and expose us to liability, possibly causing our business and reputation to suffer.

We may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by HITECH and its implementing regulations, imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's security standards directly applicable to business associates, independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. Even when HIPAA does not apply, according to the Federal Trade Commission, or FTC, failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act, or FTCA, 15 U.S.C § 45(a). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. The FTC's guidance for appropriately securing consumers' personal information is similar to what is required by the HIPAA Security Rule.

Certain state laws also govern the privacy and security of health information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. For example, California recently enacted legislation, the California Consumer Privacy Act, or CCPA, which went into effect January 1, 2020. The CCPA, among other things, creates new data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to opt out of certain disclosures of their information. The CCPA also creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. Although the law includes limited exceptions, including for "protected health information" maintained by a covered entity or business associate, it may regulate or impact our processing of personal information depending on the context.

Similar healthcare laws and regulations exist in the EU and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers and requirements regarding the collection, distribution, use, security, and storage of personally identifiable information and other data relating to individuals, including the EU General Data Protection Regulation 2016/679, or GDPR, which went into effect in May 2018. The GDPR applies to any company established in the EU as well as to those outside the EU if they collect and use personal data in connection with the offering of goods or services to individuals in the EU or the monitoring of their behavior. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4%

of the annual global revenues of the noncompliant company, whichever is greater. The GDPR provides that EU member states may introduce further conditions, including limitations, to the processing of genetic, biometric or health data, which could limit our ability to collect, use and share personal data, or could cause our compliance costs to increase, ultimately having an adverse impact on our business. In addition, the United Kingdom leaving the EU could also lead to further legislative and regulatory changes. It remains unclear how the United Kingdom data protection laws or regulations will develop in the medium to longer term and how data transfer to the United Kingdom from the EU will be regulated, especially following the United Kingdom's departure from the EU on January 31, 2020 without a deal. However, the United Kingdom has transposed the GDPR into domestic law with the Data Protection Act 2018, which remains in force following the United Kingdom's departure from the EU.

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

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

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

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

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

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

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

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

Despite the implementation of security measures, our internal computer systems and those of our current and any future CROs and other contractors and consultants and collaborators are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development program for Gimoti and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties to manufacture Gimoti and conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or

security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidate could be delayed, or otherwise adversely affected.

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

Our operations could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or manmade disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce our Gimoti. Our ability to obtain clinical supplies of Gimoti could be disrupted, if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption. For example, in December 2019, a novel strain of coronavirus (Covid-19), has resulted in business closures and a limit on travel, as well as creating uncertainty in the broader economy and financial markets. At this point, the extent to which Covid-19, and any measures taken by governments of the countries affected, may impact our results is uncertain and cannot be predicted.

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, or public health emergency.

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

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

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

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

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

We may be unable to maintain sufficient product liability insurance.

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

Risks Relating to Our Intellectual Property

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

We place considerable importance on obtaining patent protection for new technologies, products and processes because our commercial success will depend, in large part, on obtaining patent protection for new technologies, products and processes,

successfully defending these patents against third-party challenges and successfully enforcing our patents against third-party competitors. To that end, we have acquired and will file applications for patents covering formulations containing or uses of Gimoti or our proprietary processes as well as other intellectual property important to our business. One of our patent families related to Gimoti was acquired from Questcor, which was acquired by Mallinckrodt in August 2014. The method of use patents in this patent family were 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 as we would have if we had been the owners of the patents and application and had control over the drafting and prosecution.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain and involves complex legal and factual questions for which legal principles remain unresolved. 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. In recent years patent rights have been the subject of significant litigation, in particular due to *inter partes* review, introduced by the America Invents Act of 2012, which allows for quicker patent challenges decided by the U.S. Patent and Trademark Office's, or USPTO, Patent Trial and Appeal Board rather than a lay jury. 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.

With respect to challenges to the validity of our patents, for example, there might be invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on a product candidate. Even if a defendant does not prevail on a legal assertion of invalidity and/or unenforceability, our patent claims may be construed in a manner that would limit our ability to enforce such claims against the defendant and others. The cost of defending such a challenge, particularly in a foreign jurisdiction, and any resulting loss of patent protection could have a material adverse impact on one or more of our product candidates and our business.

Enforcing our intellectual property rights against third parties may also cause such third parties to file other counterclaims against us, which could be costly to defend, particularly in a foreign jurisdiction, and could require us to pay substantial damages, cease the sale of certain products or enter into a license agreement and pay royalties (which may not be possible on commercially reasonable terms or at all). Any efforts to enforce our intellectual property rights are also likely to be costly and may divert the efforts of our scientific and management personnel.

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

Third parties may seek approval to market their own products similar to or otherwise competitive with our product candidates. In these circumstances, we may need to defend or assert our patents, including by filing lawsuits alleging patent infringement. The outcome following legal assertions of invalidity and unenforceability is unpredictable. In any of these types of proceedings, a court or agency with jurisdiction may find our patents invalid or unenforceable. Even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives. Even after they have issued, our patents and any patents that we license may be challenged, narrowed, invalidated or circumvented. If our patents are invalidated or otherwise limited or will expire prior to the commercialization of our product candidates, other companies may be better able to develop products that compete with ours, which could adversely affect our competitive business position, business prospects and financial condition. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. The following are examples of litigation and other adversarial proceedings or disputes that we could become a party to involving our patents or patents licensed to us:

- we may initiate litigation or other proceedings against third parties to enforce our patent and trade secret rights;
- third parties may initiate litigation or other proceedings seeking to invalidate patents owned by or licensed to us or to obtain a declaratory judgment that their product or technology does not infringe our patents or patents licensed to us;

- third parties may initiate opposition or reexamination proceedings challenging the validity or scope of our patent rights, requiring us to participate in such proceedings to defend the validity and scope of our patents;

- there may be a challenge or dispute regarding inventorship or ownership of patents or trade secrets currently identified as being owned by or licensed to us;

- the USPTO may initiate an interference between patents or patent applications owned by or licensed to us and those of our competitors, requiring us to participate in an interference proceeding to determine the priority of invention, which could jeopardize our patent rights; or

- third parties may seek approval to market similar versions of our future approved products prior to expiration of relevant patents owned by or licensed to us, requiring us to defend our patents, including by filing lawsuits alleging patent infringement.

These lawsuits and proceedings would be costly and could affect our results of operations and divert the attention of our managerial and scientific personnel. Adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our licensors can. There is a risk that a court or administrative body would decide that our patents are invalid or not infringed or trade secrets not misappropriated by a third party's activities, or that the scope of certain issued claims must be further limited. An adverse outcome in a litigation or proceeding involving our own patents or trade secrets could limit our ability to assert our patents or trade secrets against these or other competitors, affect our ability to receive royalties or other licensing consideration from any licensees, and may curtail or preclude our ability to exclude third parties from making, using and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. We may not be able to prevent, alone or with our licensors, infringement or misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of our common shares. The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- third parties may seek approval to market similar versions of our future approved products prior to expiration of relevant patents owned by or licensed to us, requiring us to defend our patents, including by filing lawsuits alleging patent infringement.

- others may be able to develop a platform that is similar to, or better than, ours in a way that is not covered by the claims of our patents;

- others may be able to make products that are similar to our product candidates but that are not covered by the claims of our patents;

- we might not have been the first to make the inventions covered by patents or pending patent applications or we might not have been the first to file patent applications for these inventions;

- any patents that we obtain may not provide us with any competitive advantages or may ultimately be found invalid or unenforceable; or

- we may not develop additional proprietary technologies that are patentable or that afford meaningful trade secret protection.

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

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

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

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

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

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

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

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

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

Changes in patent laws or patent jurisprudence could diminish the value of patents in general, thereby impairing our ability to protect our products.

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. Changes in either the patent laws or in the interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. We cannot predict the breadth of claims that may be allowed or found to be enforceable in our patents, in our strategic partners' patents or in third-party patents. The United States has enacted and is currently implementing wide-ranging patent reform legislation. Further, recent U.S. Supreme Court rulings have either narrowed the scope of patent protection available in certain circumstances or weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the validity, scope and value of patents, once obtained.

For our U.S. patent applications containing a priority claim after March 16, 2013, there is a greater level of uncertainty in the patent law. In September 2011, the Leahy-Smith America Invents Act, also known as the America Invents Act, or AIA, was signed into law. The AIA includes a number of significant changes to U.S. patent law, including provisions that affect the way patent applications will be prosecuted and may also affect patent litigation.

The AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have an adverse effect on our business. An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties disclosing or claiming the same invention. A third party that has filed, or does file a patent application in the USPTO after March 16, 2013 but before us, could be

awarded a patent covering a given invention, even if we had made the invention before it was made by the third party. This requires us to be cognizant going forward of the time from invention to filing of a patent application.

Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and providing opportunities for third parties to challenge any issued patent in the USPTO. This applies to all of our U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal court necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action.

Depending on decisions by the U.S. Congress, the U.S. federal courts, the USPTO or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that may weaken our and our licensors' ability to obtain new patents or to enforce existing patents we and our licensors or partners may obtain in the future.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our current or future products, if any, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Recent United States Supreme Court cases have narrowed the scope of what is considered patentable subject matter, for example, in the areas of software and diagnostic methods involving the association between treatment outcome and biomarkers. This could impact our ability to patent certain aspects of our technology in the United States.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Additionally, the requirements for patentability may differ in certain countries, particularly developing countries. For example, unlike other countries, China has a heightened requirement for patentability, and specifically requires a detailed description of medical uses of a claimed drug. In India, unlike the United States, there is no link between regulatory approval of a drug and its patent status. In addition to India, certain countries in Europe and developing countries, including China, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensors may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license.

Risks Related to Our Financial Position and Need for Capital

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

Our recurring losses from operations raise substantial doubt about our ability to continue as a going concern, and as a result, management concluded that there is substantial doubt about our ability to continue as a going concern. Our independent registered public accounting firm also included an explanatory paragraph in its report on our financial statements as of and for the year ended December 31, 2019 with respect to this uncertainty. This doubt about our ability to continue as a going concern could materially limit our ability to raise additional funds through the issuance of new debt or equity securities or otherwise. In addition, 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. Future reports on our financial statements may also include an explanatory paragraph with respect to our ability to continue as a going concern. We have incurred significant losses since our inception and have never been profitable, and it is possible we will never achieve profitability. We have devoted our resources to developing Gimoti, but it cannot be marketed until regulatory approvals have been obtained.

Our operations have consumed substantial amounts of cash since inception. On January 17, 2020, we received a notice from FDA that it had accepted our NDA resubmission for review and set a target goal date for a decision under PDUFA of June 19, 2020. We believe, based on our current operating plan, that our existing cash and cash equivalents will be sufficient to fund our operations through the PDUFA target goal date and into the third quarter of 2020. If Gimoti is approved by FDA, additional funds will become available from the Eversana Credit Facility which we believe, based on our current operating plan, will provide sufficient cash to fund our operations into 2021 excluding any potential future Gimoti product revenue. This period could be shortened if there are any significant increases in planned spending other than anticipated. Even with the Eversana Credit Facility, we will be required to raise additional funds in order to continue as a going concern. There is no assurance that other financing will be available on acceptable terms, or at all, when needed to allow us to continue as a going concern. There can be no assurance that we will be able to further develop Gimoti, if required. Because our business is entirely dependent on the success of Gimoti, if we are unable to secure additional financing or identify and execute on other development or strategic alternatives for Gimoti or our company, we will be required to curtail all of our activities and may be required to liquidate, dissolve or otherwise wind down our operations. Any of these events could result in a complete loss of your investment in our securities.

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

We have incurred significant operating losses since we were founded in 2007 and expect to incur significant losses for the next several years related to completing development for Gimoti, and seeking regulatory approval from FDA to manufacture and commercialize Gimoti. Our net loss for the year ended December 31, 2019, was approximately $7.1 million. As of December 31, 2019, we had an accumulated deficit of approximately $85.7 million. Losses have resulted principally from costs incurred in our clinical trials, research and development programs and from our general and administrative expenses, especially since we became a public company in September 2013. In the future, we intend to continue to conduct research and development, clinical testing, regulatory compliance activities as needed and, if Gimoti is approved, sales and marketing activities that, together with anticipated general and administrative expenses, will likely result in our incurring further significant losses for the next several years.

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

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

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

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

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

We may seek additional funding through collaboration agreements, public or private equity financings, debt financings or receivables financings. For example, we currently may sell from time to time, at our option, up to an aggregate of $16.0 million of shares of our common stock through B. Riley FBR, Inc., or FBR, as sales agent pursuant to a sales agreement, or FBR Sales Agreement. Sales pursuant to the FBR Sales Agreement are registered pursuant to a shelf registration statement on Form S-3 which was declared effective by the SEC on December 28, 2017. As of February 29, 2020, we had sold approximately $10.9 million of shares of our common stock pursuant to the FBR Sales Agreement. However, there can be no assurance that FBR will be successful in consummating future sales based on prevailing market conditions or in the quantities or at the prices that we deem appropriate.

Under current SEC regulations, at any time during which the aggregate market value of our common stock held by non-affiliates, or public float, is less than $75 million, the amount we can raise through primary public offerings of securities in any twelve-month period using shelf registration statements, including sales under the FBR Sales Agreement, is limited to an aggregate of one-third of our public float. As of February 29, 2020, our public float was approximately $34.2 million and we had the capacity to issue up to approximately $5.1 million of additional shares of common stock pursuant to the FBR Sales Agreement. If our public float decreases, the amount of securities we may sell under our Form S-3 shelf registration statement will also decrease. In addition, FBR is permitted to terminate the FBR Sales Agreement in its sole discretion upon ten days' notice, or at any time in certain circumstances, including the occurrence of an event that would be reasonably likely to have a material adverse effect on our assets, business, operations, earnings, properties, condition (financial or otherwise), prospects, stockholders' equity or results of operations.

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

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

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

Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change" (generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period), the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. As a result of our 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, 2019, we had federal and state net operating loss carryforwards of approximately $74.5 million and $47.7 million, respectively, and federal research and development credits of approximately $2.3 million which could be limited if we experience an "ownership change." Furthermore, under U.S. tax legislation enacted in December 2017, although the treatment of tax losses generated before December 31, 2017 has generally not changed, tax losses generated in calendar year 2018 and beyond do not expire, but may only offset 80% of our taxable income. This change may require us to pay federal income taxes in future years despite generating a loss for federal income tax purposes in prior years.

U.S. tax legislation may materially adversely affect our financial condition, results of operations and cash flows.

U.S. tax legislation enacted in December 2017 has significantly changed the U.S. federal income taxation of U.S. corporations, including by reducing the U.S. corporate income tax rate, limiting interest deductions, adopting elements of a territorial tax system, imposing a one-time transition tax on all undistributed earnings and profits of certain U.S.-owned foreign corporations, revising the rules governing net operating losses and the rules governing foreign tax credits, and introducing new anti-base erosion provisions. Many of these changes are effective immediately, without any transition periods or grandfathering for existing transactions. The legislation is unclear in many respects and could be subject to potential amendments and technical corrections, as well as interpretations and implementing regulations by the Treasury and Internal Revenue Service, any of which could lessen or increase certain adverse impacts of the legislation. In addition, it is unclear how these U.S. federal income tax changes will affect state and local taxation, which often uses federal taxable income as a starting point for computing state and local tax liabilities.

While some of the changes made by the tax legislation may adversely affect us in one or more reporting periods and prospectively, other changes may be beneficial on a going forward basis. We urge our investors to consult with their legal and tax advisors with respect to such legislation.

Risks Related to Ownership of Our Common Stock

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

Prior to our initial public offering in September 2013, there was no public market for our common stock. An active trading market may never develop or be sustained. If an active trading market does not develop or is not sustained, it may be difficult to sell shares of our common stock at a price that is desirable or at all. In addition, an inactive market may impair our ability to raise capital by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration, which, in turn, could materially adversely affect our business. Since the commencement of trading in connection with our initial public offering in September 2013 through February 29, 2020, the sale price per share of our common stock on the Nasdaq Capital Market has ranged from a low of $0.50 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:

- regulatory developments in the United States and foreign countries;
- the timing, progress and results of any additional trials we may conduct, and the results of trials of our competitors or those of other companies in our market sector;
- announcements of the failure to obtain regulatory approval or receipt of another CRL from FDA;
- 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;
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters, such as earthquakes, typhoons, floods and fires, or public health emergencies or pandemics, such as the recent coronavirus (Covid-19) outbreak;
- market conditions in the pharmaceutical and biotechnology sectors and issuance of securities analysts' reports or recommendations;
- sales of our stock by insiders and 5% stockholders;
- trading volume of our common stock;
- general economic, industry and market conditions other events or factors, many of which are beyond our control;
- additions or departures of key personnel; and
- intellectual property, product liability or other litigation against us.

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

Our quarterly operating results may fluctuate significantly.

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

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

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

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

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

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

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

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

We have never declared or paid any cash dividend on our common stock and do not currently intend to do so for the foreseeable future. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business. In addition, any future debt financing arrangement may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Any return to stockholders will therefore be limited to the appreciation of their stock. Therefore, the success of an investment in shares of our common stock will depend upon any future appreciation in their value. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which our stockholders have purchased their shares.

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

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

As of February 29, 2020, we had 24,431,914 shares of common stock outstanding. All of these shares are freely tradable without restriction in the public market, except for 3,037,375 shares that are held by directors, executive officers and other affiliates that are subject to volume limitations under Rule 144 under the Securities Act. In addition, shares of common stock that are either subject to outstanding options or reserved for future issuance under our employee benefit plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules and Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

As of February 29, 2020, the holders of 1,509,789 shares of our common stock are entitled to reasonable best efforts registration rights with respect to the registration of their shares under the Securities Act. 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 will continue to incur significant costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, we have incurred and will continue to incur significant legal, accounting and other expenses under the Sarbanes-Oxley Act and the Dodd-Frank Wall Street Reform and Consumer Protection Act, as well as rules adopted by the SEC and the Nasdaq Stock Market. These rules impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls, changes in corporate governance practices, proxy access and "say on pay" votes. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

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

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

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

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

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

Our common stock is listed on the Nasdaq Capital Market. In order to maintain our listing, we must meet minimum financial and other requirements, including requirements for a minimum amount of capital, a minimum closing bid price per share of $1.00 and continued business operations so that we are not characterized as a "public shell company."

On May 15, 2019, we received a letter from Nasdaq indicating that, for the last thirty consecutive business days, the bid price for our common stock had closed below the minimum $1.00 per share requirement for continued listing on the Nasdaq Capital Market.

In accordance with Nasdaq listing rules, we were provided an initial period of 180 calendar days, or until November 11, 2019, to regain compliance. The Nasdaq letter had no immediate effect on the listing or trading of our common stock and the common stock continued to trade on the Nasdaq Capital Market.

We did not regain compliance with Nasdaq listing rules by November 11, 2019, but Nasdaq provided an additional 180 calendar day compliance period. On November 29, 2019, we received notification from Nasdaq that we regained compliance with the minimum bid price requirement for continued listing on the Nasdaq Capital Market.

In the event that our common stock is delisted from the Nasdaq Capital Market and is not eligible for quotation or listing on another market or exchange, trading of our common stock could be conducted only in the over-the-counter market or on an electronic bulletin board established for unlisted securities such as the Pink Sheets or the OTC Bulletin Board. In such event, it could become more difficult to dispose of, or obtain accurate price quotations for, our common stock, and there would likely also be a reduction in our coverage by securities analysts and the news media, which could cause the price of our common stock to decline further. Also, it may be difficult for us to raise additional capital if we are not listed on a major exchange.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 2. Properties

We occupy approximately 3,000 square feet of office space in Solana Beach, California under a lease that we entered into in December 2016. The lease was amended in September 2018 and December 2019 to extend the expiration date through December 2020. We believe that our facility is adequate to meet our needs and that, if necessary, additional space can be leased to accommodate any future growth on commercially reasonable terms.

Item 3. Legal Proceedings

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

Item 4. Mine Safety Disclosures

Not applicable.

PART II

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

Market Information

Our common stock is traded on the Nasdaq Capital Market under the symbol "EVOK."

Holders of Common Stock

As of February 29, 2020, there were 16 holders of record of our common stock.

Dividend Policy

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

Unregistered Sales of Equity Securities

None.

Issuer Repurchases of Equity Securities

None.

Securities Authorized for Issuance Under Equity Compensation Plans

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

Item 6. Selected Financial Data.

The following selected financial data should be read in conjunction with our financial statements and the related notes thereto appearing elsewhere in this Annual Report on Form 10-K and in the section of this Annual Report on Form 10-K entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations." We have derived the statements of operations data for the years ended December 31, 2019 and 2018 and the balance sheet data as of December 31, 2019 and 2018, 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,	
	2019	**2018**
Statement of Operations Data:		
Research and development expense	$ 3,416,466	$ 4,095,014
General and administrative expense	$ 3,737,987	$ 3,919,671
(Gain) from change in fair value of warrant liability	—	$ (433,392)
Net loss	$ (7,125,655)	$ (7,566,080)
Net loss per common share, basic and diluted(1)	$ (0.32)	$ (0.46)
Weighted-average shares outstanding, basic and diluted	22,296,089	16,602,422

(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,	
	2019	**2018**
Balance Sheet Data:		
Cash and cash equivalents	$ 5,663,833	$ 5,319,004
Working capital	$ 4,230,456	$ 4,013,769
Total assets	$ 6,395,628	$ 5,659,773
Current liabilities	$ 2,015,083	$ 1,634,453
Accumulated deficit	$ (85,730,390)	$ (78,604,735)
Total stockholders' equity	$ 4,380,545	$ 4,025,320

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

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

Overview

We are a specialty pharmaceutical company focused primarily on the development of drugs to treat gastrointestinal, or GI, disorders and diseases. We are developing Gimoti, an investigational metoclopramide nasal spray for the relief of symptoms associated with acute and recurrent diabetic gastroparesis in women. Diabetic gastroparesis is a GI disorder afflicting millions of individuals worldwide and is characterized by slow or delayed gastric emptying and evidence of gastric retention in the absence of mechanical obstruction and can cause various serious digestive system symptoms and other complications. Metoclopramide tablets and injection are the only products currently approved in the United States to treat the symptoms associated with acute and recurrent diabetic gastroparesis. Gimoti is a novel nasal spray formulation of metoclopramide designed to provide systemic delivery of the molecule through the nasal mucosa. We submitted an NDA for Gimoti to FDA on June 1, 2018 and received a Day-74 FDA filing communication letter in August 2018. The letter stated that the NDA was sufficiently complete to permit a substantive review and set a target goal date for a decision under PDUFA of April 1, 2019.

On March 1, 2019, we received a DRL from FDA, which provided preliminary notice of certain deficiencies identified during FDA's initial review of the Gimoti NDA. The DRL described concerns that insufficient data had been offered regarding certain product quality control and reproducibility for the commercially available sprayer device used with Gimoti, that there is a lack of adequate information to support sex-based efficacy claims and that the pharmacology data provided may not demonstrate bioavailability to the Listed Drug, Reglan Tablets 10 mg. On March 14, 2019, we submitted a response to the DRL to FDA, and on March 21, 2019, we met with FDA to obtain feedback on our responses.

On April 1, 2019, we received a CRL from FDA for our NDA. The CRL, while citing fewer issues than the DRL, stated that FDA has determined it could not approve the NDA in its present form and provided recommendations to address the two remaining approvability issues in an NDA resubmission. The approvability issues were related to clinical pharmacology and product quality/device quality. FDA did not request any new clinical data and did not raise any safety concerns.

The clinical pharmacology issue was specific to a low C_{max} in subjects representing less than 5% of the total administered Gimoti doses in the pivotal PK study. FDA stated the overall lower mean C_{max} was driven by the data from these few doses. We conducted an analysis excluding these aberrant doses, which showed that the PK study met the bioequivalence criteria for both men and women, although there is no assurance that FDA will agree with our conclusion. FDA recommended a root cause analysis to determine the origin of the PK variability and mitigation strategies to address their concern. Additionally, FDA requested data from three registration batches of commercial product to be manufactured at the proposed commercial manufacturing site, by the proposed commercial process and tested using validated analytical methods. These data were requested to provide additional support for the proposed acceptance criteria for droplet size distribution and other essential performance characteristics for the commercial product specifications.

On July 25, 2019, we completed a type A meeting with FDA to obtain FDA's feedback and agreement on our plan to address deficiencies cited in the CRL in support of a resubmission of the Gimoti NDA. The focus of the discussion was on topics noted in the CRL, including the root cause analysis of low drug exposure in the comparative bioavailability study and additional product quality/device quality control testing.

On December 19, 2019, based on FDA feedback received during the type A meeting, we resubmitted the Gimoti NDA to FDA. The resubmission provided the requested additional information intended to address the deficiencies cited in the CRL. To address the clinical pharmacology issues, the resubmission included an in-depth root cause analysis, and patient use and experience data from our clinical trials. To address product quality/device quality issues cited in the CRL, the resubmission included 3-month stability data from commercial scale registration batches that met all product specifications and support the proposed acceptance criteria for performance characteristics and device quality control. Additionally, as requested by FDA, the resubmission included data from an analysis of pump performance characteristics for the product used in the comparative bioavailability study and the product from commercial scale registration batches. The results of this testing showed all products performed within specifications.

On January 17, 2020, we received a notice from FDA that it had accepted our NDA resubmission for review and set a target goal date for a decision under PDUFA of June 19, 2020.

On January 21, 2020, we entered into the Eversana Agreement for the commercialization of Gimoti, if approved. Pursuant to the Eversana Agreement, Eversana will commercialize and distribute Gimoti in the United States, if approved by FDA. Eversana will manage the marketing of Gimoti to gastroenterologists and other targeted health care providers, as well as the sales and distribution of Gimoti to wholesalers, pharmacies and other customers within the United States. Eversana will also provide a $5 million revolving

credit facility that we can access if FDA approves Gimoti. On January 23, 2020, we and Novos Growth, LLC mutually agreed to terminate, effective immediately, a commercialization agreement entered into in January 2019.

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

As of December 31, 2019, we had cash and cash equivalents of approximately $5.7 million. Current cash on hand is intended to fund interactions with FDA on the NDA resubmission for Gimoti, and potentially manufacturing commercial batches of Gimoti. In addition, cash will be needed to fund pre-commercialization and pre-approval activities for Gimoti, including preparing for marketing and commercial manufacturing of Gimoti, and general and administrative costs to support operations. Our operations have consumed substantial amounts of cash since inception. We believe, based on our current operating plan, that our existing cash and cash equivalents will be sufficient to fund our operations through the target goal date for a decision under PDUFA and into the third quarter of 2020. If Gimoti is approved by FDA, additional funds will become available from the Eversana Credit Facility which we believe, based on our current operating plan, will provide sufficient cash to fund our operations into 2021 excluding any potential future Gimoti product revenue. This period could be shortened if there are any significant increases in planned spending other than anticipated. Even with the Eversana Credit Facility, we will be required to raise additional funds in order to continue as a going concern. There can be no assurance that we will be able to further develop Gimoti, if required, and resubmit and receive FDA approval of the Gimoti NDA. Because our business is entirely dependent on the success of Gimoti, if we are unable to secure additional financing or identify and execute on other development or strategic alternatives for Gimoti or our company, we will be required to curtail all of our activities and may be required to liquidate, dissolve or otherwise wind down our operations. Any of these events could result in a complete loss of your investment in our securities.

Technology Acquisition Agreement

In June 2007, we acquired all worldwide rights, data, patents and other related assets associated with Gimoti from Questcor Pharmaceuticals, Inc., or Questcor, pursuant to an asset purchase agreement. We paid Questcor $650,000 in the form of an upfront payment and $500,000 in May 2014 as a milestone payment based upon the initiation of the first patient dosing in our Phase 3 clinical trial for Gimoti. In August 2014, Mallinckrodt, plc, or Mallinckrodt, acquired Questcor. As a result of that acquisition, Questcor transferred its rights included in the asset purchase agreement with us to Mallinckrodt. In addition to the payments previously made to Questcor, we may be required to make additional milestone payments totaling up to $52 million. In March 2018, we amended the asset purchase agreement with Mallinckrodt to defer development and approval milestone payments, such that rather than paying two milestone payments based on FDA acceptance for review of the NDA and final product marketing approval, we would be required to make a single $5 million payment one year after we receive FDA approval to market Gimoti.

The remaining $47 million in milestone payments depend on Gimoti's commercial success and will only apply if Gimoti receives regulatory approval. In addition, we will be required to pay to Mallinckrodt a low single digit royalty on net sales of Gimoti. Our obligation to pay such royalties will terminate upon the expiration of the last patent right covering Gimoti, which is expected to occur in 2032, subject to possible extension should any additional, later expiring, licensed patents be granted.

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 the development of Gimoti. The process of conducting clinical trials necessary to obtain regulatory approval is costly and time consuming. While we resubmitted the NDA for Gimoti in December 2019, the successful development and commercialization of Gimoti is still highly uncertain, in part due to our receipt of the CRL from FDA. We are unable to estimate with any certainty the costs we will incur in the continued development and regulatory review of Gimoti, though such costs may be significant. Clinical development timelines, the probability of success and development costs can differ materially from expectations. We may never succeed in achieving marketing approval for our product candidate.

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

- per patient trial costs;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible subjects;
- the number of subjects that participate in the trials;
- the number of doses that subjects receive;
- the cost of comparative agents used in trials;
- the drop-out or discontinuation rates of subjects;
- potential additional safety monitoring or other studies requested by regulatory agencies;
- the duration of patient follow-up; and
- the efficacy and safety profile of the product candidate.

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

General and Administrative Expenses

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

Other Income

Other income consists primarily of changes in the fair value of the warrant liability, which represents the change in the fair value of common stock warrants from the date of issuance to the end of the reporting period. The warrant liability was revalued each reporting period until March 2018, when we entered into warrant amendments, or the Warrant Amendments, with each of the holders of our outstanding warrants to purchase common stock issued on July 25, 2016 and August 3, 2016, or the Warrants. We previously used the Black Scholes valuation model to value the related warrant liability at each reporting date. As a result of the Warrant Amendments, the Warrants are no longer required to be accounted for as a liability and are no longer required to be revalued at each reporting period.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which we have prepared in accordance with generally accepted accounting principles in the United States, or GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported 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.

Stock-Based Compensation

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

We grant stock options to purchase common stock to employees and members of the board of directors with exercise prices equal to our closing market price on the date the stock options are granted. The risk-free interest rate assumption was based on the yield of an

applicable rate for U.S. Treasury instruments with maturities similar to those of the expected term of the award being valued. The weighted-average expected term of options and employee stock purchases was calculated using the simplified method as prescribed by accounting guidance for stock-based compensation. This decision was based on the lack of relevant historical data due to our limited historical experience. In addition, due to our limited historical data, the estimated volatility was calculated based upon our historical volatility and, if necessary, supplemented with historical volatility of comparable companies in the biotechnology industry whose share prices are publicly available for a sufficient period of time. The assumed dividend yield was based on our history of never paying cash dividends and having no expectation of paying cash dividends in the foreseeable future. We granted options to purchase 829,500 and 886,000 shares of common stock in 2019 and 2018, respectively. In addition, in June 2019, we effected a one-time option exchange, wherein employees were offered the opportunity to exchange certain outstanding stock options for the grant of a lesser number of replacement stock options. The participants received three new stock options for every four stock options tendered for exchange. As a result, 2,456,999 stock options were exchanged for 1,842,746 replacement options.

Warrant Accounting

In March 2018, we entered into the Warrant Amendments with each of the holders of our Warrants. As a result of the Warrant Amendments, the Warrants are no longer classified as a liability on the Company's balance sheet, were adjusted to fair value as of the date of the Warrant Amendments, and were reclassified to additional paid-in capital, a component of stockholders' equity.

Prior to the Warrant Amendments, the Warrants were classified as warrant liability and recorded at fair value. These Warrants contained a feature that could have required the transfer of cash in the event a change of control occurred without the authorization of our board of directors, and therefore, were classified as a liability in accordance with the Financial Accounting Standards Board, or FASB, Accounting Standards Codification 480, *Distinguishing Liabilities from Equity*.

This warrant liability was subject to remeasurement at each reporting date and we recognized any change in the fair value of the warrant liability in the statement of operations. We continued to adjust the carrying value of the warrants for changes in the estimated fair value until the date of the Warrant Amendments.

Other Information

Net Operating Loss Carryforwards

As of December 31, 2019, we had federal and California tax net operating loss carryforwards of approximately $74.5 million and $47.7 million, respectively. The federal and California net operating loss carryforwards will begin to expire in 2027 and 2028, respectively, unless previously utilized. The portion of federal net operating losses created after 2017 of approximately $12.6 million do not expire and will carry forward indefinitely. As of December 31, 2019, we also had federal and California research and development tax credit carryforwards of $2.3 million and $1.4 million, respectively. The federal research and development tax credit carryforwards will begin to expire in 2027 unless previously utilized. The California research and development tax credit will carry forward indefinitely. Furthermore, under the U.S. tax legislation enacted in December 2017, although the treatment of tax losses generated before December 31, 2017 has generally not changed, tax losses generated in calendar year 2018 and beyond do not expire, but may only offset 80% of our taxable income. This change may require us to pay federal income taxes in future years despite generating a loss for federal income tax purposes in prior years.

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.

Results of Operations

Comparison of Years Ended December 31, 2019 and 2018

The following table summarizes the results of our operations for the fiscal years ended December 31, 2019 and 2018:

	Year Ended December 31,		Increase/
	2019	2018	(Decrease)
Research and development expense	$ 3,416,466	$ 4,095,014	$ (678,548)
General and administrative expense	$ 3,737,987	$ 3,919,671	$ (181,684)
Other income	$ 28,798	$ 448,605	$ (419,807)

Research and Development Expenses. Research and development expenses for the year ended December 31, 2019 compared to the year ended December 31, 2018 decreased by approximately $679,000. During 2019, we incurred expenses primarily related to responding to requests for additional information from FDA related to our Gimoti NDA filing and manufacturing registration batches of Gimoti, while during 2018 we prepared and filed the Gimoti NDA with FDA and had ongoing communication with FDA related to the NDA. Costs incurred in 2019 included approximately $2.2 million for wages, taxes and employee insurance, including approximately $710,000 of stock-based compensation expense, approximately $945,000 related to manufacturing, and approximately

$286,000 related to responding to FDA questions on the NDA and CRL. Costs incurred in 2018 included approximately $2.4 million for wages, taxes and employee insurance, including approximately $674,000 of stock-based compensation expense, approximately $1.3 million of NDA preparation costs, and approximately $399,000 related to manufacturing costs.

General and Administrative Expenses. General and administrative expenses for the year ended December 31, 2019 compared to the year ended December 31, 2018 decreased by approximately $182,000. Costs incurred in 2019 primarily included approximately $1.7 million for wages, taxes and employee insurance, including approximately $664,000 of stock-based compensation expense, approximately $1.6 million for legal, accounting, directors and officers liability insurance and other costs associated with being a public company, approximately $165,000 for facility-related costs and approximately $132,000 for outside consultants. Costs incurred in 2018 primarily included approximately $2.0 million for wages, taxes and employee insurance, including approximately $866,000 of stock-based compensation expense, approximately $1.5 million for legal, accounting, directors and officers liability insurance and other costs associated with being a public company and approximately $159,000 for facility-related costs.

Other Income. Other income for the year ended December 31, 2019 compared to the year ended December 31, 2018 decreased by approximately $420,000 due primarily to no longer being required to revalue the Warrants. Since the date of the Warrant Amendments in March 2018, the Warrants were no longer classified as a liability on our balance sheet, were adjusted to fair value and were reclassified to additional paid-in capital, a component of stockholders' equity. Prior to the amendment, the Warrants were accounted for as a liability and were required to be revalued at each reporting period.

Liquidity and Capital Resources

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

In November 2017, we filed a shelf registration statement with the SEC. The shelf registration statement includes a prospectus for the at-the-market offering to sell up to an aggregate of $16.0 million of shares of our common stock through FBR as a sales agent, pursuant to the FBR Sales Agreement. We did not sell any shares of common stock through the FBR Sales Agreement during 2017. During the year ended December 31, 2018, we sold 1,985,054 shares of common stock at a weighted-average price per share of $2.38 pursuant to the FBR Sales Agreement and received proceeds of approximately $4.6 million, net of commissions and fees. During the year ended December 31, 2019, we sold 7,004,381 shares of common stock at a weighted-average price per share of $0.89 pursuant to the FBR Sales Agreement and received proceeds of approximately $6.1 million, net of commission and fees. From January 1, 2020 through February 29, 2020, we have not sold any additional shares of common stock pursuant to the FBR Sales Agreement.

Under current SEC regulations, if at the time we file our Annual Report on Form 10-K our public float is less than $75 million, and for so long as our public float remains less than $75 million, the amount we can raise through primary public offerings of securities in any twelve-month period using shelf registration statements is limited to an aggregate of one-third of our public float, which is referred to as the baby shelf rules. As of February 29, 2020, our public float was approximately $34.2 million, based on 21,394,539 shares of outstanding common stock held by non-affiliates and at a price of $1.60 per share, which was the last reported sale price of our common stock on the Nasdaq Capital Market on January 16, 2020. As a result of our public float being below $75 million, we will be limited by the baby shelf rules until such time as our public float exceeds $75 million, which means we only have the capacity to sell shares up to one-third of our public float under shelf registration statements in any twelve-month period. If our public float decreases, the amount of securities we may sell under our Form S-3 shelf registration statement will also decrease. As of February 29, 2020, we had the capacity to issue up to approximately $5.1 million of additional shares of common stock pursuant to the FBR Sales Agreement.

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

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

In July 2016, we completed an at-the-market offering of 1,804,512 shares of common stock and a concurrent private placement of warrants to purchase shares of our common stock. The aggregate gross proceeds from the sale of the common stock and warrants were $4.5 million, and the net proceeds after deduction of commissions and fees were approximately $4.0 million.

In August 2016, we completed an at-the-market offering of 3,244,120 shares of common stock and a concurrent private placement of warrant to purchase shares of our common stock. The aggregate gross proceeds from the sale of the common stock and warrants were $10.0 million, and the net proceeds after deduction of commissions and fees were approximately $9.2 million.

In March 2018, we entered into the Warrant Amendments with each of the remaining holders of our outstanding Warrants from the

July 2016 and August 2016 financings. As a result of the Warrant Amendments, all of the remaining Warrants to purchase 2,449,129 shares of our common stock are no longer required to be classified as liabilities. The value of the amended Warrants was adjusted to the fair value immediately prior to the Warrant Amendments, resulting in a gain of approximately $433,000 in the statement of operations, and approximately $3.3 million was reclassified from warrant liability to additional paid-in capital, a component of stockholders' equity.

Management concluded that there is substantial doubt about our ability to continue as a going concern. Our independent registered public accounting firm also included an explanatory paragraph in their report on our financial statements as of and for the year ended December 31, 2019 with respect to our ability to continue as a going concern. This doubt about our ability to continue as a going concern for at least twelve months from the date of the financial statements could materially limit our ability to raise additional funds through the issuance of new debt or equity securities or otherwise. Future reports on our financial statements may also include an explanatory paragraph with respect to our ability to continue as a going concern. We have incurred significant losses since our inception and have never been profitable, and it is possible we will never achieve profitability. On January 17, 2020, we received a notice from FDA that it had accepted our NDA resubmission for review and set a target goal date for a decision under PDUFA of June 19, 2020. We believe, based on our current operating plan, that our existing cash and cash equivalents will be sufficient to fund our operations through the PDUFA target goal date and into the third quarter of 2020. If Gimoti is approved by FDA, additional funds will become available from the Eversana Credit Facility which we believe, based on our current operating plan, will provide sufficient cash to fund our operations into 2021 excluding any potential future Gimoti product revenue. This period could be shortened if there are any significant increases in planned spending other than anticipated. Even with the Eversana Credit Facility, we will be required to raise additional funds in order to continue as a going concern. There can be no assurance that we will be able to further develop Gimoti, if required, and receive FDA approval of the Gimoti NDA. Because our business is entirely dependent on the success of Gimoti, if we are unable to secure additional financing or identify and execute on other development or strategic alternatives for Gimoti or our company, we will be required to curtail all of our activities and may be required to liquidate, dissolve or otherwise wind down our operations. Any of these events could result in a complete loss of your investment in our securities.

These estimates of cash runway could be shortened if there are any significant increases in planned spending on responding to the issues raised by FDA in the CRL, pre-commercialization and pre-approval activities, including hiring a sales force, preparing for marketing and manufacturing of Gimoti, and our general and administrative costs to support operations. There is no assurance that other financing will be available when needed to allow us to continue as a going concern. The perception that we may not be able to continue as a going concern may cause others to choose not to deal with us due to concerns about our ability to meet our contractual obligations.

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

- respond to any requests or issues raised by FDA in its review of the CRL and conduct additional development activities, if required;
- continue the pre-approval and pre-commercialization activities for Gimoti;
- continue the preparation of the commercial manufacturing process;
- maintain, expand and protect our intellectual property portfolio; and
- continue to fund the additional accounting, legal, insurance and other costs associated with being a public company.

The following table summarizes our cash flows for the years ended December 31, 2019 and 2018:

	Year Ended December 31,	
	2019	**2018**
Net cash used in operating activities	$ (5,762,093)	$ (6,978,560)
Net cash provided by financing activities	$ 6,106,922	$ 4,618,297
Net increase (decrease) in cash and cash equivalents	$ 344,829	$ (2,360,263)

Operating Activities. The primary use of our cash has been to fund our clinical research, prepare our NDA, manufacture Gimoti, and other general operations. The cash used in operating activities during 2019 was primarily related to ongoing communication with FDA related to the NDA and the CRL, and manufacturing registration batches of Gimoti. The cash used in operating activities during 2018 was primarily related to the preparation of the NDA and ongoing communication with FDA related to the NDA. We expect that cash used in operating activities will increase in 2020 due to pre-approval and pre-commercialization activities, as well as commercialization activities should FDA approve the NDA for Gimoti.

Financing Activities. During the year ended December 31, 2019, we received net proceeds of approximately $6.1 million from the sale of 7,004,381 shares of common stock pursuant to the FBR Sales Agreement. During the year ended December 31, 2018 we received net proceeds of approximately $4.6 million from the sale of 1,985,054 shares of common stock pursuant to the FBR Sales Agreement.

In addition, during the year ended December 31, 2018, we received proceeds of approximately $47,000 from the sale of 28,869 shares of common stock through our ESPP. We did not sell any shares through our ESPP during 2019.

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

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

Off-Balance Sheet Arrangements

Through December 31, 2019, we have not entered into and did not have any relationships with unconsolidated entities or financial collaborations, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purpose.

Contractual Obligations and Commitments

In December 2016, we entered into an operating lease for office space in Solana Beach, California. The lease commenced on January 1, 2017, was extended in September 2018 and December 2019, and has an expiration date of December 31, 2020. We also pay pass through costs and utility costs, which are expensed as incurred.

As of December 31, 2019, future minimum lease payments for our facility lease are approximately $146,000.

In accordance with the technology acquisition with Mallinckrodt, we may be required to make milestone payments totaling up to $52 million. The first $5 million would be required on the one-year anniversary of our receipt of approval from FDA to market Gimoti. The remaining $47 million in milestone payments depend on Gimoti's commercial success and will only apply if Gimoti receives regulatory approval. In addition, we will be required to pay a low single digit royalty on net sales of Gimoti. Our obligation to pay such royalties will terminate upon the expiration of the last patent right covering Gimoti, which is expected to occur in 2032, subject to possible extension should any additional, later expiring, licensed patents be granted.

Item 7A. Quantitative and Qualitative Disclosure about Market Risk

Interest Rate Fluctuation Risk

Our cash and cash equivalents as of December 31, 2019 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.

Foreign Currency Exchange Risk

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

Inflation Risk

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation has had a material effect on our business, financial condition or results of operations during the years ended December 31, 2019 and 2018.

Item 8. Financial Statements and Supplementary Data

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

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

None.

Item 9A. Controls and Procedures

Conclusions Regarding the Effectiveness of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the timelines specified in the SEC'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 SEC Rule 13a-15(b), as of December 31, 2019 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, 2019.

Management's Report on Internal Control Over Financial Reporting

Internal control over financial reporting refers to the process designed by, or under the supervision of, our Chief Executive Officer and Chief Business Officer, and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles, and includes those policies and procedures that: (1) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

Internal control over financial reporting cannot provide absolute assurance of achieving financial reporting objectives because of its inherent limitations. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human failures. Internal control over financial reporting also can be circumvented by collusion or improper management override. Because of such limitations, there is a risk that material misstatements

may not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

Management is responsible for establishing and maintaining adequate internal control over our financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act. Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Business Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting. Management has used the framework set forth in the report entitled "Internal Control — Integrated Framework (2013 Framework)" published by the Committee of Sponsoring Organizations of the Treadway Commission to evaluate the effectiveness of our internal control over financial reporting. Based on its evaluation, management has concluded that our internal control over financial reporting was effective as of December 31, 2019, the end of our most recent fiscal year.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting identified in management's evaluation pursuant to Rules 13a-15(d) or 15d-15(d) of the Exchange Act during the quarter ended December 31, 2019 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Information required by this item will be contained in our definitive proxy statement to be filed with the Securities and Exchange Commission in connection with our 2019 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, 2019, under the headings “Election of Directors,” “Corporate Governance and Other Matters,” and “Executive Officers,” and is incorporated herein by reference.

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

Item 11. Executive Compensation

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

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

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

Item 13. Certain Relationships, Related Transactions and Director Independence

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

Item 14. Principal Accounting Fees and Services

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

PART IV

Item 15. Exhibits, Financial Statement Schedules

(a) *Documents filed as part of this report.*

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

2. *Financial Statement Schedules.*

None.

3. *Exhibits.*

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

(b) See Exhibit Index.

(c) See Item 15(a)(2) above.

Item 16. Form 10-K Summary

None.

Report of Independent Registered Public Accounting Firm

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

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Evoke Pharma, Inc. (the "Company") as of December 31, 2019 and 2018, the related statements of operations, stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2019, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2019, in conformity with accounting principles generally accepted in the United States of America.

Going Concern Uncertainty

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations and has not generated revenues or positive cash flows from operations. These factors raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ BDO USA, LLP

We have served as the Company's auditor since 2014.

San Diego, California

March 12, 2020

Evoke Pharma, Inc.

Balance Sheets

	December 31,	
	2019	**2018**
Assets		
Current Assets:		
Cash and cash equivalents	$ 5,663,833	$ 5,319,004
Prepaid expenses	581,706	329,218
Total current assets	6,245,539	5,648,222
Operating lease right-of-use asset	138,538	—
Other assets	11,551	11,551
Total assets	$ 6,395,628	$ 5,659,773
Liabilities and stockholders' equity		
Current Liabilities:		
Accounts payable and accrued expenses	$ 1,033,383	$ 476,202
Accrued compensation	843,162	1,158,251
Operating lease liability	138,538	—
Total current liabilities	2,015,083	1,634,453
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.0001 par value; authorized shares — 5,000,000 at December 31, 2019 and 2018; issued and outstanding shares — 0 at December 31, 2019 and 2018	—	—
Common stock, $0.0001 par value; authorized shares — 50,000,000 at December 31, 2019 and 2018; issued and outstanding shares — 24,431,914 and 17,427,533 at December 31, 2019 and 2018, respectively	2,443	1,743
Additional paid-in capital	90,108,492	82,628,312
Accumulated deficit	(85,730,390)	(78,604,735)
Total stockholders' equity	4,380,545	4,025,320
Total liabilities and stockholders' equity	$ 6,395,628	$ 5,659,773

See accompanying notes.

Evoke Pharma, Inc.

Statements of Operations

	Year Ended December 31,	
	2019	**2018**
Operating expenses:		
Research and development	$ 3,416,466	$ 4,095,014
General and administrative	3,737,987	3,919,671
Total operating expenses	7,154,453	8,014,685
Loss from operations	(7,154,453)	(8,014,685)
Other income:		
Interest income	28,798	15,213
Gain from change in fair value of warrant liability	—	433,392
Total other income	28,798	448,605
Net loss	$ (7,125,655)	$ (7,566,080)
Net loss per share of common stock, basic and diluted	$ (0.32)	$ (0.46)
Weighted-average shares used to compute basic and diluted net loss per share	22,296,089	16,602,422

See accompanying notes.

Evoke Pharma, Inc.

Statements of Stockholders' Equity

	Common Stock		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance at December 31, 2017	15,413,610	$ 1,541	$73,202,863	$ (71,038,655)	$ 2,165,749
Stock-based compensation expense	—	—	1,539,469	—	1,539,469
Issuance of common stock from employee stock purchase plan	28,869	3	47,054	—	47,057
Issuance of common stock, net	1,985,054	199	4,571,041	—	4,571,240
Reclassification of warrant liability due to warrant amendment	—	—	3,267,885	—	3,267,885
Net loss	—	—	—	(7,566,080)	(7,566,080)
Balance at December 31, 2018	17,427,533	1,743	82,628,312	(78,604,735)	4,025,320
Stock-based compensation expense	—	—	1,373,958	—	1,373,958
Issuance of common stock, net	7,004,381	700	6,106,222	—	6,106,922
Net loss	—	—	—	(7,125,655)	(7,125,655)
Balance at December 31, 2019	24,431,914	$ 2,443	$90,108,492	$ (85,730,390)	$ 4,380,545

See accompanying notes.

Evoke Pharma, Inc.

Statements of Cash Flows

	Year Ended December 31,	
	2019	**2018**
Operating activities		
Net loss	$ (7,125,655)	$ (7,566,080)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	1,373,958	1,539,469
Change in fair value of warrant liability	—	(433,392)
Change in operating assets and liabilities:		
Prepaid expenses and other assets	(116,676)	(78,172)
Accounts payable and accrued expenses	106,280	(440,385)
Net cash used in operating activities	(5,762,093)	(6,978,560)
Financing activities		
Proceeds from issuance of common stock, net	6,106,922	4,618,297
Net cash provided by financing activities	6,106,922	4,618,297
Net increase (decrease) in cash and cash equivalents	344,829	(2,360,263)
Cash and cash equivalents at beginning of period	5,319,004	7,679,267
Cash and cash equivalents at end of period	$ 5,663,833	$ 5,319,004
Non-cash financing activities		
Reclassification of warrant liability to equity due to amendment of warrants	—	$ 3,267,885

See accompanying notes.

1. Organization and Basis of Presentation

Evoke Pharma, Inc. (the "Company") was incorporated in the state of Delaware in January 2007. The Company is a 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 developing its sole product candidate, Gimoti™, and has not realized revenues from its planned principal operations. The Company filed a 505(b)(2) New Drug Application ("NDA") for Gimoti with the U.S. Food and Drug Administration ("FDA") on June 1, 2018, and on April 1, 2019, the Company received a Complete Response Letter ("CRL") from FDA for the NDA. The CRL stated that FDA has determined it cannot approve the NDA in its present form and provided recommendations to address the two remaining approvability issues in an NDA resubmission. The approvability issues are related to clinical pharmacology and product quality/device quality. FDA did not request any new clinical data and did not raise any safety concerns.

On July 25, 2019, the Company completed a type A meeting with FDA to obtain FDA's feedback and agreement on the Company's plan to address deficiencies cited in the CRL in support of a resubmission of the Gimoti NDA. The focus of the discussion was on topics noted in the CRL, including the root cause analysis of low drug exposure in the comparative bioavailability study and additional product quality/device quality control testing.

On December 19, 2019, based on FDA feedback received during the type A meeting, the Company resubmitted the Gimoti NDA to FDA. The resubmission provided the requested additional information intended to address the deficiencies cited in the CRL. To address the clinical pharmacology issues, the resubmission included an in-depth root cause analysis, as well as patient use and experience data from the Company's clinical trials. To address product quality/device quality issues cited in the CRL, the resubmission included 3-month stability data from commercial scale registration batches that met all product specifications. We believe these data support the acceptance criteria for performance characteristics and device quality control we proposed in the Gimoti NDA. Additionally, as requested by FDA, the resubmission included data from an analysis of pump performance characteristics for the product used in the comparative bioavailability study and the product from commercial scale registration batches. The results of this testing showed all products performed within specifications.

On January 17, 2020, the Company received a notice from FDA that it had accepted the Company's NDA resubmission for review and set a target goal date for a decision under the Prescription Drug User Fee Act ("PDUFA") of June 19, 2020.

The Company does not anticipate realizing revenues until FDA approves the NDA and the Company begins commercializing Gimoti, which events may never occur. The Company's activities are subject to the significant risks and uncertainties associated with any specialty pharmaceutical company that has substantial expenditures for research and development, including funding its operations.

Going Concern

The Company has incurred recurring losses and negative cash flows from operations since inception and expects to continue to incur net losses for the foreseeable future until such time, if ever, that it can generate significant revenues from the sale of Gimoti. Although the Company ended 2019 with approximately $5.7 million in cash and cash equivalents, the Company anticipates that it will continue to incur losses from operations due to pre-approval and pre-commercialization activities, including interactions with FDA on the Company's NDA submission for Gimoti, responding to approvability issues raised in the CRL received from FDA, and potentially manufacturing commercial batches of Gimoti, and for general and administrative costs to support operations. As a result, the Company believes that there is substantial doubt about its ability to continue as a going concern for one year after the date these financial statements are issued. The financial statements do not include any adjustments that may result from the outcome of this uncertainty.

The determination as to whether the Company can continue as a going concern contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. In its report on the Company's financial statements for the year ended December 31, 2019, the Company's independent registered public accounting firm included an explanatory paragraph expressing substantial doubt regarding the Company's ability to continue as a going concern.

The Company's net losses may fluctuate significantly from quarter to quarter and year to year. The Company believes, based on its current operating plan, that its existing cash and cash equivalents will be sufficient to fund its operations through the target goal date for a decision under PDUFA and into the third quarter of 2020. If Gimoti is approved by FDA, additional funds will become available from the revolving credit facility (the "Eversana Credit Facility") with Eversana Life Sciences Services, LLC ("Eversana"), as disclosed in Note 8, which we believe, based on our current operating plan, will provide sufficient cash to fund the Company's operations into 2021 excluding any potential future Gimoti product revenue. This period could be shortened if there are any significant increases in planned spending other than anticipated. Even with the Eversana Credit Facility, the Company will be required to raise additional funds through debt, equity or other forms of financing, such as potential collaboration arrangements, to fund future operations and continue as a going concern.

There can be no assurance that additional financing will be available when needed or on acceptable terms. If the Company is not able to secure adequate additional funding, the Company may be forced to make reductions in spending, extend payment terms with suppliers, and/or suspend or curtail planned programs. Any of these actions could materially harm the Company's business, results of operations, financial condition and future prospects. There can be no assurance that the Company will be able to further develop Gimoti, if required, and receive FDA approval of the Gimoti NDA. Because the Company's business is entirely dependent on the success of Gimoti, if the Company is unable to secure additional financing or identify and execute on other development or strategic alternatives for Gimoti or the company, the Company will be required to curtail all of its activities and may be required to liquidate, dissolve or otherwise wind down its operations.

Notice of Delisting

On May 15, 2019, the Company received a letter from Nasdaq indicating that, for the last thirty consecutive business days, the bid price for the Company's common stock had closed below the minimum $1.00 per share requirement for continued listing on the Nasdaq Capital Market.

In accordance with Nasdaq listing rules, the Company was provided an initial period of 180 calendar days, or until November 11, 2019, to regain compliance. The Nasdaq letter had no immediate effect on the listing or trading of the Company's common stock and the common stock continued to trade on the Nasdaq Capital Market.

The Company did not regain compliance with Nasdaq listing rules by November 11, 2019, but Nasdaq provided an additional 180 calendar day compliance period. On November 29, 2019, the Company received notification from Nasdaq that the Company regained compliance with the minimum bid price requirement for continued listing on the Nasdaq Capital Market.

2. Summary of Significant Accounting Policies

Use of Estimates

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

Segment Reporting

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

Cash and Cash Equivalents

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

Fair Value of Financial Instruments

The carrying amounts of all financial instruments, including accounts payable and accrued expenses, and employee-related liabilities, are considered to be representative of their respective fair values because of the short-term nature of those instruments.

Concentrations of Risk

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

The Company relies on contract research organizations ("CROs") and consultants to assist with ongoing regulatory discussions and submissions supporting the NDA. If the CROs and consultants are unable to continue their support, this could adversely affect FDA's review of the NDA.

In addition, the Company relies on third-party manufacturers for the production of Gimoti. If the third-party manufacturers are unable to continue manufacturing Gimoti, or if the Company loses one of its sole source suppliers used in its manufacturing processes, the Company may not be able to meet any development needs or commercial supply demand for Gimoti, if approved by FDA, and the development and/or commercialization of Gimoti could be materially and adversely affected.

The Company also relies on third-party sales and marketing organizations for the management of the pre-commercial launch preparation for Gimoti, as well as for a dedicated sales team to sell Gimoti, if approved by FDA. If such third-party organizations are unable to continue managing the launch preparation, or serving as a dedicated sales team, the commercialization of Gimoti could be materially and adversely affected.

Warrant Accounting

In March 2018, the Company entered into warrant amendments (the "Warrant Amendments") with each of the holders of the Company's outstanding warrants to purchase common stock issued on July 25, 2016 and August 3, 2016 (the "Warrants"). As a result of the Warrant Amendments, the Warrants are no longer classified as a liability on the Company's balance sheet, were adjusted to fair value as of the date of the Warrant Amendments, and were reclassified to additional paid-in capital, a component of stockholders' equity.

Prior to the Warrant Amendments, the Warrants were classified as warrant liability and recorded at fair value. These Warrants contained a feature that could have required the transfer of cash in the event a change of control occurred without the authorization of the Company's board of directors, and therefore, were classified as a liability in accordance with the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 480, *Distinguishing Liabilities from Equity*.

This warrant liability was subject to remeasurement at each reporting date and the Company recognized any change in the fair value of the warrant liability in the statement of operations. The Company continued to adjust the carrying value of the warrants for changes in the estimated fair value until the date of the Warrant Amendments.

Stock-Based Compensation

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

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

Research and Development Expenses

Research and development costs are expensed as incurred and primarily include compensation and related benefits, stock-based compensation expense and costs paid to third-party contractors for product development activities and drug product materials. 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.

Service providers typically invoice the Company monthly in arrears for services performed. In accruing service fees, the Company estimates the time period over which services were performed and the level of effort expended in each period. If the Company does not identify costs that have begun to be incurred, or if the Company underestimates or overestimates the level of services performed or the costs of these services, actual expenses could differ materially from estimates. To date, the Company has not experienced significant changes in estimates of accrued research and development expenses after a reporting period. However, due to the nature of estimates, no assurance can be made that changes to the estimates will not be made in the future as the Company becomes aware of additional information about the status or conduct of clinical studies and other research activities.

The Company does not own or operate manufacturing facilities for the production of Gimoti, nor does it plan to develop its own manufacturing operations in the foreseeable future. The Company currently depends on third-party contract manufacturers for all of its required raw materials, drug substance and finished product for its pre-commercial product development. The Company has agreements with Cosma S.p.A. to supply metoclopramide for the manufacture of Gimoti, and with Thermo Fisher Scientific Inc., who acquired Patheon UK Limited, for product development and manufacturing of Gimoti. The Company currently utilizes third-party consultants, which it engages on an as-needed, hourly basis, to manage product development and manufacturing contractors.

Income Taxes

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

The Company's policy related to accounting for uncertainty in income taxes prescribes a recognition threshold and measurement attributed criteria for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax

return. For those benefits to be recognized, a tax position must be more likely than not to be sustained upon examination by taxing authorities.

Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of common stock outstanding for the period, without consideration for common stock equivalents and adjusted for the weighted-average number of common stock outstanding that are subject to repurchase. Since the Company's repurchase right lapsed upon the filing of the NDA in June 2018, the Company no longer has any common stock subject to repurchase. As such, to account for the time the common stock was subject to repurchase, the Company excluded 18,791 shares from the weighted-average number of common stock outstanding for the year ended December 31, 2018. Diluted net loss per share is calculated by dividing the net loss by the weighted-average number of common share equivalents outstanding for the period determined using the treasury-stock method. Dilutive common stock equivalents are comprised of shares subject to repurchase, warrants to purchase common stock, options to purchase common stock under the Company's equity incentive plans and potential shares to be purchased under the ESPP. For the periods presented, the following table sets forth the outstanding potentially dilutive securities that have been excluded from the calculation of diluted net loss per share because to do so would be anti-dilutive:

	Year Ended December 31,	
	2019	**2018**
Common stock subject to repurchase	—	18,791
Warrants to purchase common stock	2,713,561	2,713,561
Common stock options	3,114,371	3,017,624
Employee stock purchase plan	25,000	10,785
Total excluded securities	5,852,932	5,760,761

Recent Accounting Pronouncements

In February 2016, the FASB issued Accounting Standards Update ("ASU") No. 2016-02, *Leases* (Topic 842). The new standard establishes a right-of-use ("ROU") model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. The Company adopted this standard effective January 1, 2019, as required. The Company determines if an arrangement is a finance lease, operating lease or short-term lease at inception. The Company elected the "package of practical expedients," which permits the Company not to reassess prior conclusions about lease identifications, lease classification and initial direct costs. The Company also elected not to separate lease and non-lease components when certain conditions are met. As discussed in Note 3, the Company's only significant lease is its facility lease, which expires on December 31, 2020, and is classified as an operating lease.

3. Commitments

In December 2016, the Company entered into an operating lease for office space in Solana Beach, California. The lease commenced on January 1, 2017, was extended in September 2018 and December 2019, and has an expiration date of December 31, 2020. According to ASU No. 2016-02, the Company recognized an operating lease ROU asset and liability based on the present value of the future minimum lease payments over the lease term at the commencement date, using the Company's assumed incremental borrowing rate, and then amortizes the ROU assets over the lease term. The Company applies a discount rate to the minimum lease payments within the lease agreement to determine the value of right-of-use assets and lease liabilities. Unless the rate implicit in the lease is determinable, ASU No. 2016-02 requires the use of the rate of interest that a lessee would have to pay to borrow on a collateralized basis over a similar term for a similar amount to the lease payments in a similar economic environment. The Company noted that the implicit rate in the lease was not determinable and calculated its incremental borrowing rate primarily based on the Company's assumed borrowing rate of 12%. On January 1, 2019, the Company recorded an operating lease ROU asset and liability of approximately $136,000 based on the present value of the remaining minimum lease payments. During the year ended December 31, 2019, changes in operating lease ROU asset and payments of the lease liability were included in prepaid expenses and other assets and accounts payable and other current liabilities, respectively, on the statement of cash flows.

Upon amendment and renewal of the term of the lease in December 2019, the Company updated the operating lease ROU asset and liability based on the present value of the future minimum lease payments over the lease term at the commencement date of the lease amendment and recorded an operating lease ROU asset and liability of approximately $139,000.

Rent expense for the years ended December 31, 2019 and 2018 was approximately $145,000 and $139,000, respectively. The Company also pays pass through costs and utility costs, which are expensed as incurred.

As of December 31, 2019, the Company has future minimum lease payments under its facility lease in 2020 of approximately $146,000.

4. Technology Acquisition Agreement

In June 2007, the Company acquired all worldwide rights, data, patents and other related assets associated with Gimoti from Questcor Pharmaceuticals, Inc. ("Questcor") pursuant to an Asset Purchase Agreement. The Company paid Questcor $650,000 in the form of an upfront payment and $500,000 in May 2014 as a milestone payment based upon the initiation of the first patient dosing in the Company's Phase 3 clinical trial for Gimoti. In August 2014, Mallinckrodt, plc ("Mallinckrodt") acquired Questcor. As a result of that acquisition, Questcor transferred its rights included in the Asset Purchase Agreement with the Company to Mallinckrodt. In addition to the payments previously made to Questcor, the Company may also be required to make additional milestone payments totaling up to $52 million. In March 2018, the Company and Mallinckrodt amended the Asset Purchase Agreement to defer development and approval milestone payments, such that, rather than paying two milestone payments based on FDA acceptance for review of the NDA and final product marketing approval, the Company would be required to make a single $5 million payment on the one-year anniversary after the Company receives FDA approval to market Gimoti.

The remaining $47 million in milestone payments depend on Gimoti's commercial success and will only apply if Gimoti receives regulatory approval. In addition, the Company will be required to pay Mallinckrodt a low single digit royalty on net sales of Gimoti. The Company's obligation to pay such royalties will terminate upon the expiration of the last patent right covering Gimoti, which is expected to occur in 2032, subject to possible extension should any additional, later expiring, licensed patents be granted.

5. Preferred Stock, Common Stock and Stockholders' Equity

Preferred Stock

Under the Company's amended and restated certificate of incorporation, the Company is authorized to issue 5,000,000 shares of preferred stock with a $0.0001 par value. No shares of preferred stock were outstanding as of December 31, 2019 or 2018.

Common Stock

As of December 31, 2019, there were 24,431,914 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.

As of December 31, 2019, the holders of 1,509,789 shares of the Company's common stock are entitled to reasonable best efforts registration rights with respect to the registration of their shares under the Securities Act of 1933, as amended ("Securities Act."). Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined in Rule 144 under the Securities Act.

At the Market Equity Offering Program

In November 2017, the Company filed a shelf registration with the SEC on Form S-3. The shelf registration statement includes a prospectus for the at-the-market offering to sell up to an aggregate of $16.0 million of shares of the Company's common stock through B. Riley FBR, Inc. ("FBR") as a sales agent (the "FBR Sales Agreement"). During the year ended December 31, 2018, the Company sold 1,985,054 shares of common stock at a weighted-average price per share of $2.38 pursuant to the FBR Sales Agreement and received proceeds of approximately $4.6 million, net of commissions and fees. During the year ended December 31, 2019, the Company sold 7,004,381 shares of common stock at a weighted-average price per share of $0.89 pursuant to the FBR Sales Agreement and received proceeds of approximately $6.1 million, net of commissions and fees. From January 1, 2020 through February 29, 2020, the Company has not sold any shares of common stock pursuant to the FBR Sales Agreement.

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

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

Warrants

The Company has issued warrants to purchase common stock to banks that have previously loaned funds to the Company, as well as to representatives of the underwriters of the Company's public offerings and certain of their affiliates.

In March 2018, the Company entered into the Warrant Amendments with each of the holders of the Company's outstanding Warrants acquired as a part of the Company's financings which closed in July and August 2016. As a result of the Warrant Amendments, all of the remaining Warrants to purchase 2,449,129 shares of the Company's common stock were no longer required to be classified as liabilities. The value of the amended Warrants was adjusted to the fair value immediately prior to the Warrant Amendments, resulting

in a net gain of approximately $433,000 in the statement of operations for 2018, and approximately $3.3 million was reclassified from warrant liability to additional paid-in capital.

In September 2018, warrants to purchase 84,000 shares of the Company's common stock, issued to representatives of the underwriters in connection with the Company's initial public offering in September 2013, expired and have been cancelled.

At December 31, 2019 and 2018, there were warrants outstanding to purchase 2,713,561 shares of the Company's common stock with a weighted average exercise price of $2.91. At December 31, 2019, the weighted average remaining contractual term of the outstanding warrants is 2.04 years.

Equity Incentive Award Plans

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

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

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

In April 2018, the Company's stockholders approved another amendment and restatement of the 2013 Plan (the "Restated Plan") to increase the number of shares of common stock authorized for issuance under the 2013 Plan by 1,500,000 shares, to an aggregate of 6,286,425 shares, and to extend the term of the 2013 Plan to February 2028. In addition, beginning on January 1, 2019, the number of shares available for issuance will be annually increased on the first day of each fiscal year by that number of shares equal to the least of (a) four percent of the outstanding shares of common stock on the last day of the immediately preceding calendar year, and (b) such other amount determined by the Company's board of directors. Notwithstanding the foregoing, the number of shares of common stock that may be issued or transferred pursuant to incentive stock options under the Restated Plan may not exceed an aggregate of 8,000,000 shares.

In June 2019, the Company effected a one-time option exchange, wherein employees were offered the opportunity to exchange certain outstanding stock options for the grant of a lesser number of replacement stock options. The participants received three new stock options for every four stock options tendered for exchange. As a result, 2,456,999 stock options were exchanged for 1,842,746 replacement stock options. The replacement stock options have a four-year vesting schedule and an exercise price of $0.62 per share, which was the closing price of the Company's common stock on the date of the option exchange. All other terms of the replacement stock options remain the same as the original stock options that were exchanged. As a result of this transaction, the Company will recognize approximately $84,000 of additional stock-based compensation expense over the four-year vesting term of the exchanged options.

As a result of the annual increases since the 2013 Plan originated, and the increase of stock options reserved under the Restated Plan approved by the Company's stockholders through April 2018, the Company has increased the number shares reserved for issuance under the 2013 Plan by 4,073,526 shares. As of December 31, 2019, 1,587,155 options remain available for future grant under the 2013 Plan. On January 1, 2020, the Company further increased the number of shares reserved for issuance under the 2013 Plan by 977,277 shares, making 2,564,432 options available for future grant under the 2013 Plan.

Options granted under the 2007 Plan and 2013 Plan have ten-year terms from the date of grant and generally vest over a one to four year period. The Company granted options to purchase 829,500 and 886,000 shares of common stock in 2019 and 2018, respectively. The exercise price of all options granted during the years ended December 31, 2019 and 2018 was equal to the market value per share of the Company's common stock on the date of grant.

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

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2018	3,017,624	$ 3.11	7.68	$ 382,160
Granted/Exchanged	2,672,246	$ 1.20	9.36	—
Exercised	—	—	—	—
Expired/Forfeited/Exchanged	(2,575,499)	$ 2.82	7.48	—
Outstanding at December 31, 2019	3,114,371	$ 1.71	8.32	$ 2,143,756
Vested and expected to vest at December 31, 2019	3,114,371	$ 1.71	8.32	$ 2,143,756
Exercisable at December 31, 2019	1,230,605	$ 3.17	6.70	$ 392,604

The intrinsic values above represent the aggregate value of the total pre-tax intrinsic value based upon a common stock price of $1.62 and $2.48 at December 31, 2019 and 2018, respectively, and the contractual exercise price.

The weighted average grant date fair value per share of employee stock options granted during the years ended December 31, 2019 and 2018, was $0.91 and $1.86, respectively.

There were no options exercised in 2019 and 2018.

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

	Shares	Weighted Average Grant Date Fair Value Per Share
Nonvested at December 31, 2018	1,117,407	$ 2.44
Granted	2,672,246	$ 1.20
Vested	(494,674)	$ 1.53
Expired/Forfeited/Exchanged	(1,411,213)	—
Nonvested at December 31, 2019	1,883,766	$ 0.75

Employee Stock Purchase Plan

In June 2013, the Company's board of directors adopted the ESPP, and the Company's stockholders approved the ESPP on August 29, 2013. The ESPP became effective on the day prior to the effectiveness of the IPO. The ESPP permits participants to purchase the Company's common stock at 85% of the fair market value through payroll deductions of up to 20% of their eligible compensation. A total of 30,000 shares of common stock were initially reserved for issuance under the ESPP. In addition, the number of shares of common stock available for issuance under the ESPP has been annually increased on the first day of each fiscal year during the term of the ESPP by an amount equal to the lesser of: (i) 30,000 shares; (ii) one percent of the outstanding shares of common stock as of the last day of the immediately preceding fiscal year; or (iii) such other amount as the Company's board of directors may determine.

In May 2017, the Company's stockholders approved an amendment and restatement of the Company's ESPP to increase the number of shares of common stock reserved under the ESPP by 100,000 shares (to an aggregate of 1,250,000 shares), to increase the annual evergreen provision from 30,000 shares to 100,000 shares, and to extend the term of the ESPP into 2027. The Company increased the number shares reserved for issuance under the ESPP by 420,000 shares since the inception of the ESPP. As of December 31, 2019, 263,065 shares remain available for future issuance under the ESPP. On January 1, 2020, the Company further increased the number of shares reserved for future issuance under the ESPP by 100,000 shares, making 363,065 shares available for future issuance under the ESPP after that increase.

Payroll withholdings from the Company's employees of approximately $47,000 resulted in the issuance of 28,869 shares of common stock through its ESPP during the year ended December 31, 2018. No shares of common stock were issued through the ESPP during 2019.

Stock-Based Compensation

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

The estimated fair value of each stock 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 option grants during the years ended December 31, 2019 and 2018:

	Year Ended December 31,	
	2019	**2018**
Risk free interest rate	1.80% - 2.55%	2.66% - 2.85%
Expected option term	4.27 - 6.0 years	5.5 - 6.0 years
Expected volatility of common stock	90.34% - 112.58%	90.15% - 92.30%
Expected dividend yield	0.0%	0.0%

The estimated fair value of the shares to be acquired under the ESPP was determined on the initiation date of each six-month purchase period using the Black-Scholes option-pricing valuation model with the following weighted-average assumptions for ESPP shares to be purchased during the years ended December 31, 2019 and 2018 as follows:

	Year Ended December 31,	
	2019	**2018**
Risk free interest rate	1.89% - 2.52%	1.85% - 2.29%
Expected term	0.5 years	0.5 years
Expected volatility of common stock	130.36% - 170.68%	45.24% - 58.76%
Expected dividend yield	0.0%	0.0%

The Company recognized non-cash stock-based compensation expense to employees and directors in its research and development and its general and administrative functions during the years ended December 31, 2019 and 2018 as follows:

	Year Ended December 31,	
	2019	**2018**
Research and development	$ 710,155	$ 673,525
General and administrative	663,803	865,944
Total stock-based compensation expense	$ 1,373,958	$ 1,539,469

As of December 31, 2019, there was approximately $2.1 million of unrecognized compensation costs related to outstanding employee and board of director options, which are expected to be recognized over a weighted-average period of 1.24 years.

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance consists of the following at December 31, 2019 and 2018:

	December 31,	
	2019	**2018**
Stock options issued and outstanding	3,114,371	3,017,624
Authorized for future option grants	1,587,155	986,801
Warrants to purchase common stock	2,713,561	2,713,561
Authorized for employee stock purchase plan	263,065	163,065
Total common stock reserved for future issuance	7,678,152	6,881,051

6. Fair Value Measurements

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

As noted in Notes 2 and 5, due to the Warrant Amendments in March 2018, the warrant liability was reclassified to additional paid-in capital. Prior to the Warrant Amendments, the Company utilized a valuation hierarchy for disclosure of the inputs to the valuations used to measure fair value. This hierarchy prioritized the inputs into three broad levels as follows: Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities. Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument. Level 3 inputs are unobservable inputs based on the Company's own assumptions used to measure assets and liabilities at fair value. A financial asset or liability's classification within the hierarchy is determined based on the lowest level input that is significant to the fair value measurement.

The Company had no assets or liabilities classified as Level 1 or Level 2. The warrant liability, prior to the Warrant Amendments of the warrants, was classified as Level 3.

The following table presents a reconciliation of the Company's warrant liability measured at fair value on a recurring basis using significant unobservable inputs (Level 3) for the year ended December 31, 2018:

	December 31, 2018
Beginning balance of warrant liability	$ 3,701,277
Change in fair value upon re-measurement	(433,392)
Reclassification to Additional Paid-in Capital due to warrant exercise	—
Reclassification to Additional Paid-in Capital due to warrant amendment	(3,267,885)
Ending balance of warrant liability	$ -

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

7. Employee Benefit Plan

The Company has established a defined contribution 401(k) plan (the "Plan") for all employees who are at least 21 years of age. Employees are eligible to participate in the Plan beginning on the date of employment. Under the terms of the Plan, employees may make voluntary contributions as a percentage of compensation. The Company's contributions to the Plan are discretionary, and no contributions have been made by the Company to date. For the years ended December 31, 2019 and 2018, the Company adopted Safe Harbor 401(k) provisions. No contributions were required to be made to the accounts of employees for the years ended December 31, 2019 and 2018 in order to maintain the Plan's compliance with Internal Revenue Service regulations.

8. Commercial Services and Loan Agreements with Eversana

On January 21, 2020, the Company entered into a commercial services agreement (the "Eversana Agreement") with Eversana for the commercialization of Gimoti. Pursuant to the Eversana Agreement, Eversana will commercialize and distribute Gimoti in the United States, if approved by FDA. Eversana will manage the marketing of Gimoti to gastroenterologists and other targeted health care providers, as well as the sales and distribution of Gimoti to wholesalers, pharmacies and other customers within the United States.

Under the terms of the Eversana Agreement, the Company maintains ownership of the Gimoti NDA, as well as legal, regulatory, and manufacturing responsibilities for Gimoti. Eversana will utilize its internal sales organization, along with other commercial functions, for market access, marketing, distribution and other related patient support services. The Company will record sales for Gimoti and retain more than 80% of net product profits once the parties' costs are reimbursed. Eversana will receive reimbursement of its commercialization costs pursuant to an agreed upon budget and a percentage of product profits in the mid-to-high teens. Net product profits are the net sales (as defined in the Eversana Agreement) of Gimoti, less (i) reimbursed commercialization costs, (ii) manufacturing and administrative costs set at a fixed percentage of net sales, and (iii) third party royalties. During the term of the Eversana Agreement, Eversana agreed to not market, promote, or sell a competing product in the United States.

The term of the Eversana Agreement is from January 21, 2020 until five years from the date, if any, that FDA approves the Gimoti NDA. Upon expiration or termination of the agreement, the Company will retain all profits from product sales and assume all corresponding commercialization responsibilities. Within 30 days after each of the first three annual anniversaries of commercial launch, either party may terminate the agreement if net sales of Gimoti do not meet certain annual thresholds. Either party may terminate the agreement: for the material breach of the other party, subject to a 60-day cure period; in the event an insolvency, petition of the other party is pending for more than 60 days; upon 30 days written notice to the other party if Gimoti is subject to a safety recall; the other party is in breach of certain regulatory compliance representations under the agreement; the Company discontinues the

development or production of Gimoti; Gimoti is not commercially launched within nine months of FDA approval, if any, or the net profit is negative for any two consecutive calendar quarters beginning with the first full calendar quarter 24 months following commercial launch; or if there is a change in applicable laws that makes operation of the services as contemplated under the agreement illegal or commercially impractical. Either party may also terminate the Eversana Agreement upon a change of control of the Company's ownership, subject, in the event that the Company initiates such termination, to a one-time payment equal to between two times and one times annualized service fees paid by the Company under the Eversana Agreement, with such amount based on which year after commercial launch the change of control occurs. Such payment amount would be reduced by the amount of previously reimbursed commercialization costs and profit split paid for the related prior twelve month period and any revenue which occurred prior to the termination yet to be collected. In addition, Eversana may terminate the Eversana Agreement if Gimoti is not approved by FDA by December 31, 2020 (provided Eversana gives the Company notice of such termination no later than March 1, 2021), or if the Company withdraws Gimoti from the market for more than 90 days. The Company may also terminate the agreement if the parties are unable to agree to a commercialization plan and budget within 75 days of the date of the Eversana Agreement.

In addition, in connection with the Eversana Agreement, the Company and Eversana have entered into the Eversana Credit Facility, pursuant to which Eversana has agreed to provide a revolving Credit Facility of up to $5.0 million to the Company upon FDA approval of the Gimoti NDA, if any, as well as certain other customary conditions. The Eversana Credit Facility is secured by all of the Company's personal property other than the Company's intellectual property. Under the terms of the Eversana Credit Facility, the Company cannot grant an interest in the Company's intellectual property to any other person. Each loan under the Eversana Credit Facility will bear interest at an annual rate equal to 10.0%.

The Company may prepay any amounts borrowed under the Eversana Credit Facility at any time without penalty or premium. The maturity date of all amounts, including interest, borrowed under the Eversana Credit Facility will be 90 days after the expiration or earlier termination of the Eversana Agreement. The Eversana Credit Facility also includes events of default, the occurrence and continuation of which provide Eversana with the right to exercise remedies against the Company and the collateral securing the loans under the Eversana Credit Facility, including the Company's cash. These events of default include, among other things, the Company's failure to pay any amounts due under the Eversana Credit Facility, an uncured material breach of the representations, warranties and other obligations under the Eversana Credit Facility, the occurrence of insolvency events and the occurrence of a change in control.

On January 23, 2020, the Company and Novos Growth, LLC mutually agreed to terminate, effective immediately, a commercialization agreement entered into in January 2019.

9. Income Taxes

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

The Company's policy is to recognize interest and/or penalties related to income tax matters in income tax expense. The Company had no accrual for interest and penalties on the balance sheet at December 31, 2019. The Company has an uncertain tax position of $2.0 million related to California net operating losses at December 31, 2019. The Company is subject to taxation in the United States and state jurisdictions, and the Company's tax years beginning 2007 to date are subject to examination by taxing authorities.

Deferred income taxes result from temporary differences between the tax basis of assets and liabilities and their reported amounts in the financial statements that will result in taxable or deductible amounts in future years. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in years in which those temporary differences are expected to be recovered or settled. As changes in tax laws or rates are enacted, deferred tax assets and liabilities are adjusted through income tax expense.

A reconciliation of the federal statutory income tax rate and the effective income tax rate is as follows for the years ended December 31, 2019 and 2018:

	December 31,	
	2019 (%)	2018 (%)
Federal statutory rate	21	21
Change in valuation allowance	(4)	(1)
State income taxes, net of federal effect	7	—
Warrant liability FMV adjustment	—	1
Research and development credits	3	4
Removal of net operating losses and other credits	(27)	(22)
Impact of state tax rate change	4	—
Stock compensation and other permanent items	(4)	(3)
Effective income tax rate	—	—

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 $19.0 million and a research and development credit of approximately $3.5 million generated through December 31, 2019 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, 2019 and 2018 are as follows:

	December 31,	
	2019	2018
Deferred tax assets:		
Acquired technology	$ 80,000	$ 81,000
Stock compensation expense	846,000	574,000
Lease liability	39,000	—
Accruals and other	237,000	244,000
Total deferred tax assets	$ 1,202,000	$ 899,000
Deferred tax liabilities:		
Right of use asset	(39,000)	—
Total deferred tax liabilities	(39,000)	—
Less valuation allowance	(1,163,000)	(899,000)
Net deferred tax assets (liabilities)	—	—

At December 31, 2019, the Company has federal and California net operating loss carryforwards of approximately $74.5 million and $47.7 million, respectively. The federal and California net operating loss carryforwards begin to expire in 2027 and 2028, respectively, unless previously utilized. The portion of federal net operating losses created after 2017 of approximately $12.6 million do not expire and will carry forward indefinitely. The Company also has federal and California research tax credit carryforwards of approximately $2.3 million and $1.4 million, respectively. The federal research credit carryforwards will begin expiring in 2027 unless previously utilized. The California research credit will carry forward indefinitely. Furthermore, under U.S. tax legislation enacted in December 2017, although the treatment of tax losses generated before December 31, 2017 has generally not changed, tax losses generated in calendar year 2018 and beyond do not expire, but may only offset 80% of the Company's taxable income. This change may require us to pay federal income taxes in future years despite generating a loss for federal income tax purposes in prior years.

There were no changes to unrecognized tax benefits in 2019 and 2018. As such, the balance of unrecognized tax benefits (excluding interest and penalties) was approximately $2.0 million at December 31, 2019 and 2018.

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

10. Subsequent Events

For the purposes of the financial statements as of December 31, 2019 and the year then ended, the Company has evaluated subsequent events through the date the audited annual financial statements were issued. The Company has concluded that no subsequent event has occurred that required disclosure in the financial statements other than what has been disclosed.

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 financial results of the interim periods. Summarized quarterly data for the years ended December 31, 2019 and 2018 are as follows:

	For the Quarters Ended			
	March 31,	**June 30,**	**September 30,**	**December 31,**
2019				
Research and development expense	$ 746,882	$ 1,205,599	$ 822,444	$ 641,541
General and administrative expense	$ 1,223,013	$ 918,139	$ 814,218	$ 782,617
Net loss	$ (1,965,266)	$ (2,114,096)	$ (1,628,065)	$ (1,418,228)
Net loss per common share, basic and diluted (1)	$ (0.11)	$ (0.09)	$ (0.07)	$ (0.06)
Weighted average shares outstanding, basic and diluted	17,484,318	23,258,567	24,128,060	24,313,411
2018				
Research and development expense	$ 1,385,366	$ 1,388,791	$ 625,497	$ 695,360
General and administrative expense	$ 1,032,245	$ 917,305	$ 897,060	$ 1,073,061
Gain from change in fair value of warrant liability	$ 433,392	—	—	—
Net loss	$ (1,982,786)	$ (2,303,193)	$ (1,519,468)	$ (1,760,633)
Net loss per common share, basic and diluted (1)	$ (0.13)	$ (0.14)	$ (0.09)	$ (0.10)
Weighted average shares outstanding, basic and diluted	15,427,037	16,425,468	17,129,649	17,427,533

(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.

Exhibit Index

Exhibit Number	Description of Exhibit
3.1(2)	Amended and Restated Certificate of Incorporation of the Company
3.2(2)	Amended and Restated Bylaws of the Company
4.1(3)	Form of the Company's Common Stock Certificate
4.2(4)	Investor Rights Agreement dated as of June 1, 2007
4.3(4)	Warrant dated June 1, 2012 issued by the Company to Silicon Valley Bank
4.4(10)	Form of Warrant issued by the Company to certain investors under the Securities Purchase Agreement between the Company and such investors dated July 25, 2016
4.5(11)	Form of Warrant issued by the Company to certain investors under the Securities Purchase Agreement between the Company and such investors dated August 3, 2016
4.6 (13)	Form of Amendment to Common Stock Purchase Warrant, amending certain of the warrants dated July 25, 2016 and August 3, 2016
4.7 (18)	Form of Amendment to Common Stock Purchase Warrant, amending certain of the warrants dated July 25, 2016 and August 3, 2016
4.9	Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934
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(4)#	2007 Equity Incentive Plan, as amended, and form of option agreement thereunder
10.4(1)#	2013 Equity Incentive Award Plan and form of option agreement thereunder
10.5(6)#	2013 Employee Stock Purchase Plan restated effective May 3, 2017
10.6(5)#	Amended and Restated Retention Letter, dated May 22, 2013, between the Company and David A. Gonyer
10.7(5)#	Amended and Restated Retention Letter, dated May 22, 2013, between the Company and Matthew D'Onofrio
10.8(7)†	Asset Purchase Agreement, dated as of June 1, 2007, between the Company and Questcor Pharmaceuticals, Inc.
10.9(8)#	Employment Agreement, effective as of December 1, 2013, between the Company and Marilyn R. Carlson
10.10(9)#	Non-Employee Director Compensation Policy, as Amended and Restated Effective January 28, 2016
10.11(10)	Form of Securities Purchase Agreement dated as of July 20, 2016 by and between the Company and certain investors party thereto
10.12(10)	Engagement Letter dated as of July 19, 2016 by and between the Company and Rodman & Renshaw, a unit of H.C. Wainwright & Co., LLC
10.13(11)	Form of Securities Purchase Agreement dated as of July 29, 2016 by and between the Company and certain investors party thereto
10.14(11)	Engagement Letter dated as of July 29, 2016 by and between the Company and Rodman & Renshaw, a unit of H.C. Wainwright & Co., LLC
10.15(14)	Standard Office Lease, dated as of December 19, 2016, between the Company and SB Corporate Centre III-IV, LLC
10.16(14)#	Amendment to Amended and Restated Employment Agreement, effective as of January 25, 2017 between the Company and Matthew D'Onofrio
10.17(14)#	Amendment to Employment Agreement, effective as of January 25, 2017, between the Company and Marilyn R. Carlson

Exhibit Number	Description of Exhibit
10.18(16)†	Manufacturing Services Agreement dated November 7, 2017, between the Company and Patheon UK Limited
10.19(21)	At Market Issuance Sales Agreement, dated as of April 15, 2016, between the Company and B. Riley FBR, Inc. (as successor by merger to FBR Capital Markets & Co.)
10.20(15)	Amendment No. 1 to At Market Issuance Sales Agreement, effective as of November 14, 2017, between the Company and B. Riley FBR, Inc.
10.21(12)†	Master Supply Agreement dated as of May 11, 2016 by and between the Company and Cosma S.p.A.
10.22(19)	Amendment to Asset Purchase Agreement entered into by and between the Company and Mallinckrodt ARD Inc. dated March 21, 2018
10.23(17)	2013 Equity Incentive Award Plan, as amended and restated, effective February 7, 2018
10.24(20)	First Amendment to Standard Office Lease dated September 27, 2018 between the Company and SB Corporate Centre III-IV, LLC.
10.25(20)#	Non-Employee Director Compensation Policy, as Amended and Restated Effective February 6, 2019
10.26	Second Amendment to Standard Office Lease dated December 6, 2019 between the Company and SB Corporate Centre III IV, LLC
23.1	Consent of BDO USA, LLP, Independent Registered Public Accounting Firm
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934
31.2	Certification of Chief Financial Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934
32.1*	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2*	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

(1) 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 Appendix A to the Company's Definitive Proxy Statement on Schedule 14A filed with the SEC on March 22, 2017.
(7) 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.
(8) Incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on December 2, 2013.
(9) Incorporated by reference to the Company's Annual Report on Form 10-K filed with the SEC on March 10, 2016.
(10) Incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on July 20, 2016.
(11) Incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on August 1, 2016.
(12) Incorporated by reference to the Company's Quarterly Report on Form 10-Q filed with the SEC on August 15, 2016.
(13) Incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on December 16, 2016.

(14) Incorporated by reference to the Company's Annual Report on Form 10-K filed with the SEC on March 15, 2017.
(15) Incorporated by reference to the Company's Registration Statement on Form S-3 filed with the SEC on November 14, 2017.
(16) Incorporated by reference to the Company's Annual Report on Form 10-K filed with the SEC on March 7, 2018.
(17) Incorporated by reference to Appendix A to the Company's Definitive Proxy Statement on Schedule 14A filed with the SEC on March 16, 2018.
(18) Incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on April 4, 2018.
(19) Incorporated by reference to the Company's Quarterly Report on Form 10-Q filed with the SEC on May 14, 2018.
(20) Incorporated by reference to the Company's Annual Report on Form 10-K filed with the SEC on March 6, 2019.
(21) Incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on April 15, 2016.
† Confidential treatment has been granted as applicable for portions of this exhibit. These portions have been omitted from the filed version of this exhibit and filed separately with the SEC.
# 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.

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 12, 2020

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.

Signature	Title	Date
/s/ David A. Gonyer David A. Gonyer, R.Ph.	President, Chief Executive Officer and Director (principal executive officer)	March 12, 2020
/s/ Matthew J. D'Onofrio Matthew J. D'Onofrio	Executive Vice President, Chief Business Officer, Treasurer and Secretary (principal financial and accounting officer)	March 12, 2020
/s/ Cam L. Garner Cam L. Garner	Chairman of the Board of Directors	March 12, 2020
/s/ Todd C. Brady, M.D., Ph.D. Todd C. Brady, M.D., Ph.D.	Director	March 12, 2020
/s/ Malcolm R. Hill, Pharm. D. Malcolm R. Hill, Pharm. D.	Director	March 12, 2020
/s/ Ann D. Rhoads Ann D. Rhoads	Director	March 12, 2020
/s/ Kenneth J. Widder, M.D. Kenneth J. Widder, M.D.	Director	March 12, 2020

Exhibit 4.9

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

Evoke Pharma, Inc. (we, us and our) has one class of securities registered pursuant to Section 12 of the Securities Exchange Act of 1934, as amended: our common stock.

Description of Common Stock

General

The following summary of the terms of our common stock is based upon our amended and restated certificate of incorporation and amended and restated bylaws. The summary is not complete, and is qualified in its entirety by reference to our amended and restated certificate of incorporation and amended and restated bylaws, which are filed as exhibits to our most recent Annual Report on Form 10-K and are incorporated by reference herein. We encourage you to read our amended and restated certificate of incorporation, our amended and restated bylaws and the applicable provisions of the Delaware General Corporation Law (DGCL) for additional information.

Under our amended and restated certificate of incorporation, the total number of shares of all classes of stock that we have authority to issue is 55,000,000, consisting of 50,000,000 shares of common stock, $0.0001 par value per share, and 5,000,000 shares of preferred stock, $0.0001 par value per share.

Common Stock

Voting rights

Under the terms of our amended and restated certificate of incorporation, holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders, including the election of directors, and do not have cumulative voting rights. Accordingly, the holders of a majority of the outstanding shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they so choose, other than any directors that holders of any preferred stock we may issue may be entitled to elect.

Dividend rights

Subject to preferences that may be applicable to any then outstanding preferred stock, holders of common stock are entitled to receive ratably those dividends, if any, as may be declared by the board of directors out of legally available funds.

Liquidation rights

In the event of our liquidation, dissolution or winding up, the holders of common stock will be entitled to share ratably in the assets legally available for distribution to stockholders after the payment of or provision for all of our debts and other liabilities, subject to the prior rights of any preferred stock then outstanding.

Rights and preferences

Holders of common stock have no preemptive or conversion rights or other subscription rights and there are no redemption or sinking funds provisions applicable to the common stock. The rights, preferences and privileges of holders of common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

Fully paid and nonassessable

All outstanding shares of common stock are duly authorized, validly issued, fully paid and nonassessable.

Anti-Takeover Effects of Delaware Law and Our Certificate of Incorporation and Bylaws

Some provisions of Delaware law, our amended and restated certificate of incorporation and our amended and restated bylaws contain provisions that could make the following transactions more difficult: an acquisition of us by means of a tender offer; an acquisition of us by means of a proxy contest or otherwise; or the removal of our incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interest or in our best interests, including transactions which provide for payment of a premium over the market price for our shares.

These provisions, summarized below, are intended to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of the increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

Undesignated Preferred Stock

The ability of our board of directors, without action by the stockholders, to issue up to 5,000,000 shares of undesignated preferred stock with voting or other rights or preferences as designated by our board of directors could impede the success of any attempt to change control of us. These and other provisions may have the effect of deferring hostile takeovers or delaying changes in control or management of our company.

Stockholder Meetings

Our amended and restated bylaws provide that a special meeting of stockholders may be called only by our chairperson of the board, chief executive officer or president, or by a resolution adopted by a majority of our board of directors.

Requirements for Advance Notification of Stockholder Nominations and Proposals

Our amended and restated bylaws establish advance notice procedures with respect to stockholder proposals to be brought before a stockholder meeting and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of directors.

Elimination of Stockholder Action by Written Consent

Our amended and restated certificate of incorporation and amended and restated bylaws eliminate the right of stockholders to act by written consent without a meeting.

Staggered Board

Our board of directors is divided into three classes. The directors in each class serve for a three-year term, one class being elected each year by our stockholders. This system of electing and removing directors may tend to discourage a third-party from making a tender offer or otherwise attempting to obtain control of us, because it generally makes it more difficult for stockholders to replace a majority of the directors.

Removal of Directors

Our amended and restated certificate of incorporation provides that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than 66 2/3% of the total voting power of all of our outstanding voting stock then entitled to vote in the election of directors.

Stockholders Not Entitled to Cumulative Voting

Our amended and restated certificate of incorporation does not permit stockholders to cumulate their votes in the election of directors. Accordingly, the holders of a majority of the outstanding shares of our common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they choose, other than any directors that holders of our preferred stock may be entitled to elect.

Delaware Anti-Takeover Statute

We are subject to Section 203 of the DGCL, which prohibits persons deemed to be “interested stockholders” from engaging in a “business combination” with a publicly held Delaware corporation for three years following the date these persons become interested stockholders unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. Generally, an “interested stockholder” is a person who, together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation’s voting stock. Generally, a “business combination” includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. The existence of this provision may have an anti-takeover effect with respect to transactions not approved in advance by the board of directors.

Amendment of Charter Provisions

The amendment of any of the above provisions, except for the provision making it possible for our board of directors to issue preferred stock, would require approval by holders of at least 66 2/3% of the total voting power of all of our outstanding voting stock.

The provisions of Delaware law, our amended and restated certificate of incorporation and our amended and restated bylaws could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in the composition of our board and management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

Listing

Our common stock is listed for trading on The Nasdaq Capital Market under the symbol “EVOK.”

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company, LLC.

SECOND AMENDMENT TO LEASE

This Second Amendment to Lease (this "Amendment") is made, for reference purposes only, December 6, 2019, by and between SB CORPORATE CENTRE Ill-IV, LLC, a Delaware limited liability company ("Landlord"), and EVOKE PHARMA, INC., a Delaware corporation ("Tenant"), with reference to the following facts:

RECITALS

A. Landlord and Tenant are parties to that certain Office Lease Agreement dated as of December 19, 2016, as amended by that certain First Amendment to Lease dated as of September 27, 2018 (collectively, as amended, the "Lease") for that certain premises located at 420 Stevens Avenue, Suite 370, Solana Beach, California 92075, consisting of approximately 3,031 Rentable Square Feet of commercial office space (the "Premises").

B. The parties desire to amend the Lease as set forth in this Amendment.

C. All capitalized terms used in this Amendment, unless specifically defined herein, shall have the same meaning as the capitalized terms used in the Lease.

NOW, THEREFORE, for valuable consideration, the receipt and adequacy of which are expressly acknowledged, Landlord and Tenant agree as follows:

AGREEMENT

1. Extension Term. The term of the Lease for the Premises is set to expire on December 31, 2019. By virtue of this Amendment, Landlord and Tenant hereby agree that the term of the Lease for the Premises shall be extended to and including December 31, 2020 (the "Expiration Date"), subject to the terms and conditions contained herein and the Lease. For the purposes of this Amendment, the period of time between and including January 1, 2020 (the "Extended Term Effective Date") and the Expiration Date shall be referred to herein as, the "Extension Term". Furthermore, any and all previously granted and unexercised options to extend the term of the Lease shall be null and void and of no further force or effect.

2. Rent. Tenant shall pay Basic Monthly Rent to Landlord for the Premises in advance on or before the first day of every calendar month, without any set-off or deduction, pursuant to the current rate as set forth in the Lease. However, as of the Extended Term Effective Date, Tenant's Basic Monthly Rent for the Premises shall be as follows during the Extension Term:

Lease Period	Basic Monthly Rent Approximate Rate per RSF per Month	Actual Total per Month
1/1/2020-12/31/2020	$4.01	$12,154.3

3. Tenant Certification. By execution of this Amendment, Tenant hereby certifies that as of the date hereof, neither Tenant nor Landlord is in default of the performance of its obligations pursuant to the Lease, and Tenant has no claim, defense, or offset with respect to the Lease.

4. Real Estate Brokers. Tenant represents and warrants to Landlord that it has not authorized or employed, or acted by implication to authorize or employ, with any real estate broker or sales person to act for it in connection with this Amendment or dealt with any real estate broker or sales person in connection with this Amendment other than RE:Align, Inc. Tenant also agrees to indemnify, defend and hold harmless Landlord from and against any and all claims by any real estate broker or salesman whom the Tenant authorized or employed, or acted by implication to authorize or employ, to act for Tenant in connection with this Amendment, or with any broker or sales person with whom Tenant dealt in connection with this Amendment other than RE:Align, Inc.

5. Confirmation. Except, as and to the extent modified by this Amendment, all provisions of the Lease shall remain in full force and effect. In the event of a conflict between the terms of the Lease and the terms of this Amendment, the terms in this Amendment shall control.

6. Counterparts. This Amendment may be executed in any number of counterparts, including counterparts transmitted by facsimile or electronic mail, each of which shall be deemed an original for all purposes, and all counterparts shall constitute one and the same instrument.

7. **Electronic Signatures.** Landlord and Tenant consent to the use of electronic signatures on this Amendment and all documents relating to the Lease and this Amendment, and any amendments to any of the foregoing (collectively, the "Lease Documents"). Landlord and Tenant agree that any electronic signatures appearing on the Lease Documents are the same as handwritten signatures for the purposes of validity, enforceability and admissibility, and that any electronically signed Lease Document shall, for all purposes of the Lease Documents and applicable law, be deemed to be "written" or "in writing", to have been executed, and to constitute an original written record when printed, and shall be fully admissible in any legal proceeding. For purposes hereof, "electronic signature" shall have the meaning set forth in the Uniform Electronic Transactions Act, as the same may be amended from time to time.

IN WITNESS WHEREOF, Landlord and Tenant agree to the foregoing as evidenced by affixing their signatures below.

LANDLORD:	TENANT:
SB CORPORATE CENTRE III-IV, LLC, a Delaware limited liability company	EVOKE PHARMA, INC. a Delaware corporation
By: American Assets Trust Management, LLC a Delaware limited liability company, as Agent	By: s/Matt D'Onofrio
By: s/Adam Wyll Executive V.P. and COO	Name: Matt D'Onofrio
By: s/Steven M. Center V.P. of Office Properties	Title: CBO
Dated: December 6, 2019	Dated: December 6, 2019

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Evoke Pharma, Inc.
Solana Beach, California

We hereby consent to the incorporation by reference in Registration Statements on Form S-3 (No. 333-221556) and Form S-8 (Nos. 333-224897, 333-219960, 333-211302 and 333-191518) of Evoke Pharma, Inc. (the "Company") of our report dated March 12, 2020, relating to the financial statements, which appears in this Form 10-K. Our report contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

/s/ BDO USA, LLP

San Diego, California
March 12, 2020

Exhibit 31.1

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

I, David A. Gonyer, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 12, 2020

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

Exhibit 31.2

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

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

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

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

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

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

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

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

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

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

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

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

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

Date: March 12, 2020

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

Exhibit 32.1

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

In connection with the Annual Report on Form 10-K of Evoke Pharma, Inc. (the "Company") for the period ended December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, David A. Gonyer, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 12, 2020

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

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

Exhibit 32.2

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

In connection with the Annual Report on Form 10-K of Evoke Pharma, Inc. (the "Company") for the period ended December 31, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Matthew J. D'Onofrio, Executive Vice President, Chief Business Officer, Treasurer and Secretary of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 12, 2020

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

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