Filed Pursuant to Rule 424(b)(3)
Registration No. 333-275443

Prospectus Supplement No. 1
(To Prospectus dated February 8, 2024)

Evoke Pharma, Inc.

This prospectus supplement updates, amends and supplements the prospectus dated February 8, 2024 (the "Prospectus"), which forms a part of our Registration Statement on Form S-1 (Registration No. 333-275443). Capitalized terms used in this prospectus supplement and not otherwise defined herein have the meanings specified in the Prospectus.

This prospectus supplement is being filed to update, amend and supplement the information included in the Prospectus with the information contained in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 14, 2024, which is set forth below.

This prospectus supplement is not complete without the Prospectus. This prospectus supplement should be read in conjunction with the Prospectus, which is to be delivered with this prospectus supplement, and is qualified by reference thereto, except to the extent that the information in this prospectus supplement updates or supersedes the information contained in the Prospectus. Please keep this prospectus supplement with your Prospectus for future reference.

Our common stock is listed on the Nasdaq Global Market under the symbol "EVOK." On March 13, 2024, the closing price of our common stock was $0.64.

Our business and investment in our common stock involve significant risks. These risks are described in the section titled "Risk Factors" beginning on page 9 of the Prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the accuracy or adequacy of the Prospectus or this prospectus supplement. Any representation to the contrary is a criminal offense.

The date of this prospectus supplement is March 14, 2024.

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, 2023

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 230 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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes Oxley Act (15 U.S.C. 7262 (b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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 $5.3 million, based on the closing price of the registrant's common stock on the Nasdaq Capital Market of $1.65 per share.

The number of outstanding shares of the registrant's common stock, par value $0.0001 per share, as of March 1, 2024 was 8,477,801.

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 2024 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, 2023.

EVOKE PHARMA, INC.

FORM 10-K — ANNUAL REPORT

For the Fiscal Year Ended December 31, 2023

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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, commercial activities to be conducted by Eversana Life Science Services, LLC, the pricing and reimbursement for Gimoti®™ (metoclopramide) nasal spray, future prescribing trends for Gimoti, future regulatory developments, research and development costs, the timing and likelihood of commercial success, the potential to develop future product candidates, plans and objectives of management for future operations, continued compliance with Nasdaq listing requirements and future results of current and anticipated products, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statement. The forward-looking statements are contained principally in the sections entitled "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business." In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "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™, 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 other trademarks, including 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.

Summary of Risks Related to our Business

Our business is subject to numerous risks and uncertainties, including those described in Part I, Item 1A, "Risk Factors." The principal risks and uncertainties affecting our business include the following:

- Our business is entirely dependent on the success of Gimoti, which may never generate sufficient sales to become profitable.
- We will require substantial additional funding and may be unable to raise capital when needed, which would force us to liquidate, dissolve or otherwise wind down our operations.

- 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.
- We have no internal sales, marketing or distribution capabilities currently and rely on Eversana, and may rely on other third parties, for the commercialization of Gimoti, and we and they may not be able to effectively market, sell and distribute Gimoti.
- We and Eversana will need to retain qualified sales and marketing personnel and collaborate in order to successfully commercialize Gimoti.
- Use of Gimoti or any future product candidates we may develop could be associated with side effects, adverse events or other properties or safety risks, which could delay or preclude approval, cause us to suspend or discontinue clinical trials, abandon a product candidate, limit the commercial profile of the approved labeling, or result in other significant negative consequences that could severely harm our business, prospects, operating results and financial condition.
- Any termination or suspension of, or delays in the completion of, the post-marketing pharmacokinetics PK trial of Gimoti or any other future clinical trials could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.
- Even though FDA has approved Gimoti for the relief of symptoms in adults with acute and recurrent diabetic gastroparesis, we will remain subject to significant post-marketing regulatory requirements and oversight.
- It will be difficult for us to profitably sell Gimoti if coverage and reimbursement are limited.
- We rely and will continue to rely on outsourcing arrangements for many of our activities, including commercialization activities and supply of Gimoti.
- 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.
- 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.
- 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.
- Our recurring losses from operations have raised substantial doubt regarding our ability to continue as a going concern.
- 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.

Item 1. Business

Overview

We are a specialty pharmaceutical company focused primarily on the development and commercialization of drugs to treat gastrointestinal ("GI") disorders and diseases. Since our inception, we have devoted our efforts to developing our sole product, Gimoti® (metoclopramide) nasal spray, the first and only nasally-administered product indicated for the relief of symptoms in adults with acute and recurrent diabetic gastroparesis. In June 2020, we received approval from the U.S. Food and Drug Administration ("FDA") for our 505(b)(2) New Drug Application for Gimoti (the "Gimoti NDA"). We launched commercial sales of Gimoti in the United States in October 2020 through our commercial partner, Eversana Life Science Services, LLC ("Eversana").

Diabetic gastroparesis is a GI disorder affecting millions of patients worldwide, in which food in an individual's stomach takes too long to empty resulting in a variety of serious GI symptoms and systemic metabolic complications. The gastric delay caused by gastroparesis can also compromise absorption of orally administered medications. In May 2023, we reported results from a study conducted by Eversana which showed diabetic gastroparesis patients taking Gimoti had significantly fewer physician office visits, emergency department visits, and inpatient hospitalizations compared to patients taking oral metoclopramide. This overall lower health resource utilization reduced patient and payor costs by approximately $15,000 during a six-month time period for patients taking Gimoti compared to patients taking oral metoclopramide.

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 frequency and degrees of severity.

In addition, we believe the increased use of GLP-1 (glucagon-like peptide-1) agonists could increase the number of people affected by gastroparesis. GLP-1 receptor agonists help glucose control through several mechanisms, including enhancement of glucose-dependent insulin secretion, slowed gastric emptying, and reduction of postprandial glucagon and food intake. Slow gastric emptying may potentially lead to symptoms similar to gastroparesis. Although definitive evidence attributing GLP-1 agonists specifically to causing gastroparesis is limited, a recent study published in the Journal of the American Medical Association found that use of GLP-1 agonists for weight loss compared with use of bupropion-naltrexone was associated with increased risk of pancreatitis, bowel obstruction and gastroparesis. While these adverse events from GLP-1 agonists have been rare, we believe it could have an impact on the gastroparesis market, considering the increased use, the large population expected to be treated and the incidence rate.

Patients with diabetic gastroparesis may experience impaired glucose control due to unpredictable gastric emptying and altered absorption of orally administered drugs, which may affect the severity of their signs and symptoms. Any combination of issues or 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 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.

In January 2020, we entered into a commercial services agreement with Eversana (as amended to date, the "Eversana Agreement") for the commercialization of Gimoti. Pursuant to the Eversana Agreement, Eversana commercializes and distributes Gimoti in the United States. Eversana also manages the marketing of Gimoti to targeted health care providers, as well as the sales and distribution of Gimoti in the United States. In 2020, we borrowed $5 million from Eversana pursuant to a revolving credit facility (the "Eversana Credit Facility") which expires on December 31, 2026, unless terminated earlier pursuant to its terms. As of December 31, 2023, there were approximately $63.5 million in cumulative unreimbursed commercialization costs under the agreement, to be payable only as net product profits are recognized, or upon certain termination events. For additional details regarding the Eversana Agreement and the Eversana Credit Facility, see "*Business – Commercialization – Commercial Services and Loan Agreements with Eversana*" below.

To date, we have only generated modest sales of Gimoti. We have incurred losses every year since our inception. These operating losses resulted from expenses incurred in connection with advancing Gimoti through development activities, from pre-commercialization and commercialization costs and from other general and administrative costs associated with operating our business. We expect to continue to incur operating losses until revenues from the sales of Gimoti exceed our expenses, if ever. 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 represent significant market opportunities. Our business strategy is to:

- *Successfully commercialize Gimoti in the United States.* Through our commercialization agreement with Eversana, we have built a commercial infrastructure to allow us to directly market Gimoti in the United States. 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. If Eversana terminates the

agreement, our plan moving forward to commercialize Gimoti is to initially employ a primarily digital marketing strategy. In addition, we may hire a select number of direct sales representatives to commercialize Gimoti.

- *Further development of Gimoti with a lower dosage strength to expand our market potential.* We are evaluating the design of a single dose PK clinical trial of Gimoti, based on an FDA post-marketing commitment. This trial will be designed to characterize dose proportionality of a lower dosage strength of Gimoti to accommodate patients that may require further dosage adjustments, with initiation timing pending additional feedback from the FDA.
- *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, including the potential to explore regulatory approval outside the United States.
- *In-license or acquire additional clinical or commercial stage product candidates for the treatment of GI diseases.* We may opportunistically in-license or acquire additional programs targeting GI diseases, leveraging our prior development experience.

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.

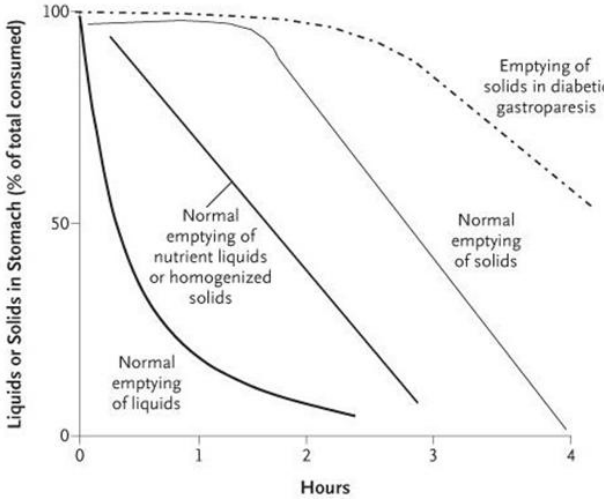
In 2004, the total cost of GI prescription drugs in the United States was $12.3 billion, and over half of this cost ($7.7 billion) was associated with drugs prescribed for gastroesophageal reflux disease, or GERD. Peptic ulcer disease, hepatitis C, irritable bowel syndrome, or IBS, and inflammatory bowel 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 2019, the American Diabetes Association estimated that diabetes affects approximately 37.3 million people of all ages in the United States, equating to about 11.3% 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, with approximately 3.0 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, pro-motility and anti-emetic treatment that we believe has the potential to significantly improve the standard of care for gastroparesis patients. With Gimoti being approved for the treatment of diabetic gastroparesis, patients and physicians now 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 developed Gimoti, a dopamine antagonist / mixed 5-HT3 antagonist / 5-HT4 agonist with pro-motility and anti-emetic effects, for the relief of symptoms associated with acute and recurrent diabetic gastroparesis. For over 40 years, the only FDA approved products for the treatment of diabetic gastroparesis had been an oral tablet and injection formulations of metoclopramide. Gimoti is a novel formulation of metoclopramide offering systemic delivery by nasal spray administration.

We developed 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 offers an alternative route of administration for 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.

Future Clinical Trials

We are evaluating the design of a single dose PK clinical trial of Gimoti, based on an FDA post-marketing commitment. This trial will be designed to characterize dose proportionality of a lower dosage strength of Gimoti to accommodate patients that may require further dosage adjustments, with initiation timing pending additional feedback from the FDA.

Commercialization

We are commercializing Gimoti in the United States through our partnership with Eversana. Our strategy is to establish Gimoti as the prescription product of choice for diabetic gastroparesis. Gimoti is initially being marketed to gastroenterologists, internal medicine specialists, primary care physicians and select health care providers. We have engaged Eversana to utilize its internal sales organization, along with additional commercial functions, for market access, marketing, distribution, and other related patient support services.

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 commercializes and distributes Gimoti in the United States. Eversana also manages the marketing of Gimoti to targeted health care providers, as well as the sales and distribution of Gimoti in 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. As of December 31, 2023, there were approximately $63.5 million in unreimbursed commercialization costs under the agreement ("Cumulative Deferred Costs"), to be payable only as net product profits are recognized, or upon certain termination events as described below.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.

On February 1, 2022, the Eversana Agreement was amended to extend the term from June 19, 2025 (five years from the date the FDA approved the Gimoti NDA) to December 31, 2026, unless terminated earlier pursuant to its terms. This amendment

also increased the percentage of net product profit retained by us and increased the proportion of costs that are reimbursed to Eversana to the extent Eversana has accumulated unreimbursed costs. We further amended the Eversana Agreement in November 2022 to provide the preexisting rights of both parties to terminate the agreement within 30 days of the first three annual anniversaries of commercial launch, if net sales of Gimoti did not meet certain annual thresholds, would be modified solely for 2022 such that either party could terminate the agreement by written notice to the other party by November 30, 2022. Neither party terminated the agreement by November 30, 2022.

Upon expiration or termination of the agreement, we will retain all profits from product sales and assume all corresponding commercialization responsibilities. Except as provided above with respect to 2022, 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; if the other party is in breach of certain regulatory compliance representations under the agreement; if we discontinue the development or production of Gimoti; if the net profit is negative for any two consecutive calendar quarters beginning with the first full calendar quarter 24 months following commercial launch (the "Net Profit Quarterly Termination Right"); if the cumulative net product profits fail to reach certain thresholds in the first three years following 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. As of December 31, 2023, either party had the right to exercise the Net Profit Quarterly Termination Right, which either party could have done until February 29, 2024, which was the end of the 60-day period following the end of the quarter. Each party will continue to have the option to exercise this termination right for the 60-day period following the end of future quarters so long as the net profit under the agreement remains negative for consecutive quarters.Either party may also terminate the Eversana Agreement upon a change of control of our ownership. In the event that we initiate such termination, we shall pay to Eversana a one-time payment equal to all of Eversana's unreimbursed costs (including the Cumulative Deferred Costs) plus a portion of Eversana's commercialization costs incurred in the 12 months prior to termination. 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. If Eversana initiates such a termination following a change of control, none of the Cumulative Deferred Costs incurred by Eversana will be due from Evoke. If Eversana terminates the agreement due to an uncured material breach by us, or if we terminate the Eversana Agreement in certain circumstances, including if we exercise the Net Profit Quarterly Termination Right, we have agreed to reimburse Eversana for its unreimbursed commercialization costs for the prior twelve-month period and certain other costs. In addition, Eversana may terminate the Eversana Agreement if we withdraw Gimoti from the market for more than 90 days. Upon expiration of the agreement, none of the Cumulative Deferred Costs incurred by Eversana will be due from Evoke. Upon expiration or termination of the agreement, we will retain all profits from product sales and assume all corresponding commercialization responsibilities.

In connection with the Eversana Agreement, we and Eversana have entered into the Eversana Credit Facility, pursuant to which Eversana agreed to provide a revolving credit facility of up to $5 million to us upon FDA approval of the Gimoti NDA, as well as certain other customary conditions. The Eversana Credit Facility terminates on December 31, 2026, unless terminated earlier pursuant to its terms. 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%, with such interest due at the end of the loan term. In June 2020 we borrowed $2 million and in December 2020 we borrowed the remaining $3 million under the Eversana Credit Facility.

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.

Gimoti Product Launch

The U.S. launch of Gimoti occurred in October 2020 through our commercial partner Eversana and its specialty pharmacy services. In February 2022, Eversana began to transition these services to vitaCare Prescription Services ("vitaCare"), a technology and services platform that helps physicians electronically prescribe Gimoti and helps patients navigate key access and adherence barriers for brand medications, and Thrifty White, a leading specialty pharmacy. Starting in July 2022, vitaCare, which was acquired by GoodRx.com, became the sole prescription intake system used for Gimoti. GoodRx then

wound down vitaCare's operations and as of November 2023, Gimoti pharmacy services have now been transitioned to ASPN Pharmacy ("ASPN"). The goal of this transition was to increase approval of Out-Of-Network prescription volume that is increasing across the platform. Although the transition has created some delay in managing patients and filling prescriptions, ASPN is now showing improved patient capture and conversion to reimbursed fills by insurers. We believe the ASPN platform offers a seamless path for filling a prescription, helps patients understand coverage and identify available savings opportunities, and facilitates communications between providers and payors.

The commercial strategy has focused on educating targeted healthcare professionals ("HCPs"), that are predominately gastroenterologists, about the clinical benefits of Gimoti. To date, the majority of prescriptions that have been enrolled in our patient reimbursement and distribution system have come from gastroenterologists. As of December 31, 2023, Eversana had 28 Gimoti dedicated sales representatives located throughout the U.S. In addition to the field sales team, Eversana telemarketing representatives field inbound calls and contact targeted physicians outside of the currently covered geographies. Sales representatives are communicating the benefits of Gimoti to HCPs, and ASPN Pharmacy manages prescription fulfillment. Gimoti is also being promoted through social media and digital promotion through patient support groups and other online resources.

HCP feedback regarding Gimoti has generally been positive. We believe this is due to the fact that patients diagnosed with gastroparesis have delayed gastric emptying resulting in unpredictable absorption of oral medications. The only products currently approved to treat diabetic gastroparesis in an outpatient setting are Gimoti and oral metoclopramide. This limited choice of treatments has led to notable interest in Gimoti. Because Gimoti is absorbed through the nasal passage and bypasses the potential issues associated with oral absorption, physicians have noted that Gimoti is appropriate for many of their patients. The primary messaging to physicians about the benefits of a non-oral treatment for diabetic gastroparesis remains the focus of our marketing strategy.

Gimoti also benefits from government program access initiatives. Certain Medicare Part D plans and Medicaid programs have begun to include Gimoti on their formularies. These access points allow HCPs to prescribe Gimoti to patients covered under these government programs and for Evoke's specialty pharmacy partners to seek reimbursement under those programs. Because no uniform policy of coverage and reimbursement for drugs exists among third-party payors in the U.S., coverage and reimbursement can differ significantly from payor to payor, including government healthcare programs and commercial payors.

Manufacturer Support/Co-pay Program

The ASPN prescription program offers benefits verification support and provides co-pay assistance to eligible patients. Co-pay assistance is available to commercially insured and cash paying patients, and varies in amount based on the patient's insurance plan. Government insured patients are not eligible for co-pay assistance due to legal restrictions.

Market Research

During June 2022, Eversana conducted an ATU (Awareness, Trial, and Usage) study, a quantitative survey to measure HCP awareness, trial, and product usage, for Gimoti. Responses from 142 HCPs were captured in June 2022. Survey respondents were split into the following groups: target gastroenterologists (n = 65); non-targeted gastroenterologists (n = 21); target PCPs (n= 20); and gastroenterologist-affiliated PAs/NPs (n = 36).

Key findings for the ATU study to measure HCP awareness, trial and product usage for Gimoti show that overall, 87% of all respondents indicated an intent to prescribe Gimoti. This includes 88% of target gastroenterologists, 86% of non-targeted gastroenterologists, 80% of target PCPs, and gastroenterologist-affiliated 92% of PAs/NPs.

Additionally, during October 2022, Eversana conducted an ATU study to measure patient awareness, trial, and product usage for Gimoti. Approximately 201 total patient responses were captured in October 2022. Survey respondents were split into groups drawn from non-diabetic (n = 50), type 1 diabetic (n = 26), and type 2 diabetic (n = 125), Areas of interest that were queried included diagnosis and experience, gastroparesis awareness, and treatments, usage and experience.
Key findings from the ATU study to measure patient awareness, trial, and product usage for Gimoti included:

- Patients reported a wide collection of issues associated with the disease;
- Besides diabetes, the top comorbidities were GERD, Chronic Pain/ Acute Pain, and Anxiety;
- Patients reported taking an average of between 6.3 to 9.1 medications each day, most of which were oral;
- Patients with type 1 diabetes and type 2 diabetes reported stomach pain as their top flare intensifying symptom and an average of 26.8 flares per year and 10.6 flares per year, respectively; and

- Patients reported 2.0 to 3.1 ER visits; 1.9 to 2.1 Urgent Care visits and 2.1 to 3.2 Hospital visits per year.

Gimoti scored better or equal on all treatment experience measurements (symptom improvements, side effects, ease of taking medication) than all other comparators (oral metoclopramide, liquid metoclopramide, domperidone and Motegrity).

- Gimoti 4.6 out of 7 for symptom improvement
- Gimoti 4.1 out of 7 for side effects
- Gimoti 5.0 out of 7 for ease of taking medication

Gimoti scored better in treating nausea and abdominal pain than all other comparators (oral metoclopramide, liquid metoclopramide, domperidone and Motegrity). Gimoti was the only product for which all respondents reported symptom improvement. In contrast, approximately 23 to 32% of respondents reported “no symptom improvement" with oral metoclopramide, liquid metoclopramide, domperidone or Motegrity.

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 ("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 31, 2025. 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.

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.

Gimoti competes 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 Gimoti, we are aware of the following development candidates, all of which are in clinical development.

Gastroparesis Treatment Development Pipeline

Product	Class	Route	Company	Status
Tradipitant	Neurokinin-1 (NK-1) receptor antagonist	oral	Vanda	NDA filed
Deudomperidone (CIN-102)	Dopamine 2/3 antagonist	oral	CinRx	Phase 2
PCS12852	5-HT4 receptor agonist	oral	Processa	Phase 2

Tradipitant is a NK-1 antagonist that has been tested in various other indications by Vanda Pharmaceuticals Inc. A Phase 3 clinical trial completed enrollment in the second half of 2021, and in February 2022 Vanda reported that the trial did not meet its primary endpoint. Although the Phase 3 trial did not meet its primary endpoint, Vanda submitted an NDA for tradipitant for the treatment of gastroparesis and the FDA has assigned a PDUFA target action date of September 18, 2024.

CIN-102 is a dopamine D2/D3 receptor antagonist that is a deuterated version of domperidone being developed by CinRx to treat gastroparesis. Domperidone is a molecule approved outside the U.S. to treat dyspepsia and nausea but has never received FDA approval due in part to its cardiovascular safety concerns around QT prolongation. A 60-person Phase 2 trial had been initiated with an estimated completion of the trial in March 2021 and as of March 13, 2024, no results have been reported. In January 2022, CinRx reported a cardiac safety trial was successfully completed, and in April 2023 announced the start of a 12-week, 400 subject Phase 2 study in patients with diabetic gastroparesis.

PCS12852 is a 5-HT4 reception agonist. A 25-person Phase 2a trial has been completed and Processa Pharmaceuticals announced positive results in December 2022. Processa has indicated it is finalizing the development plan for PCS12852 and is exploring licensing, partnering an/or collaborating opportunities.

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 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 consists of patents and patent applications, including the following U.S. patents and patent applications as of December 31, 2023:

- U.S. Patents 8,334,281; 11,020,361, 11,628,150, and 11,813,231 - Nasal Formulations of Metoclopramide. These patents are expected to expire no earlier than 2030, 2029, 2029, and 2029, respectively, and claim common priority with two pending US continuation applications (17/366,818 and 17/366,839), each of which, if granted, would be expected to expire no earlier than 2029. These four patents are listed in the FDA's list of Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the Orange Book.
- U.S. Non-Provisional Patent Application No. 17/381,464 – Treatment of Symptoms Associated with Female Gastroparesis. If granted, this patent would be expected to expire no earlier than 2032.
- U.S. Patent 11,517,545 – Treatment of Moderate and Severe Gastroparesis. This patent is expected to expire no earlier than 2038 and claims common priority with pending US continuation application 18/047,364 which, if granted, would be expected to expire no earlier than 2037.

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, Japanese, Russian 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. Two additional PTC patent applications have been filed related to more recent clinical trial findings; if granted, these would be expected to expire no earlier than 2043.

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 other trademarks, including 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.

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 were required to make additional milestone payments totaling up to $52 million. In March 2018, we 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, we would be required to make a single $5 million payment on the one-year anniversary after we receive FDA approval to market Gimoti. At the time of the Gimoti NDA approval by FDA, we recorded the $5 million payable owed to Mallinckrodt with a due date of June 19, 2021, along with a $5 million research and development expense. The $5 million milestone payment was paid in July 2021.

The remaining $47 million in milestone payments depended on Gimoti's commercial success. We were required to pay to Mallinckrodt a low single digit royalty percentage on net sales of Gimoti. As of December 31, 2023, we have paid Mallinckrodt approximately $134,000 for royalties on net sales of Gimoti. Our obligation to pay such royalties and milestones terminated due to the expiration of the last patent right covering Gimoti transferred under the asset purchase agreement.

Government Regulation

FDA Regulations

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.

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 certain 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, those currently set forth in the FDA's 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, and satisfactory completion of potential inspections of select clinical trial sites to assure compliance with GCP;
- 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, 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, among other things, 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:* The drug is administered to a large patient population 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 within the intended therapeutic indication following NDA approval. Such post-approval trials are typically referred to as Phase 4 studies.

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

Under federal law, the submission of most NDAs is subject to a substantial application user fee, and the manufacturer and/or sponsor under an approved NDA are also subject to annual 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 FDA's threshold determination that the NDA 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 NDAs for 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, 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 an NDA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, FDA may issue an approval letter or a Complete Response Letter, or CRL. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A CRL indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A CRL usually describes the specific deficiencies in the NDA identified by the FDA and may require additional clinical data, including additional clinical trials, or other significant and time-consuming requirements related to clinical trials, nonclinical

studies or manufacturing. If a CRL is issued, the sponsor must resubmit the NDA or, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the NDA does not satisfy the criteria for approval.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, FDA may approve the NDA with a Risk Evaluation and Mitigation Strategy, or REMS to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a medicine and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries, and other risk minimization tools. FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. FDA may also require one or more Phase 4 post- market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies.

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. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual program fees for any marketed products. FDA may also require post-approval studies and clinical trials if FDA finds that scientific data, including information regarding related drugs, deem such studies 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.

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.

In addition, 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 QSR requirements currently applicable to the device component of Gimoti. 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. 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.

Insurance Coverage and Reimbursement

Sales of our products depend, in part, on the extent to which our products are covered by third-party payors, such as commercial insurance, managed healthcare organizations and government health care programs. 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 Gimoti or any of our drug candidates or a decision by a third-party payor to not cover Gimoti or any of 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

We are subject to healthcare regulation and enforcement by the federal government and the states and foreign governments in which we conduct our business. These laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, and physician and other health care provider payment transparency 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. 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. 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 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 Physician Payment Transparency Act imposes reporting requirements on certain drug manufacturers for payments made by them to physicians (as defined by statute), non-physician practitioners including physician assistants and nurse practitioners, and teaching hospitals, as well as ownership and investment interests held by such 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.

Government Drug Price Reporting

Medicaid is a joint federal and state program for low-income and disabled beneficiaries. Under the Medicaid Drug Rebate Program, or MDRP, as a condition of having federal funds available for our covered outpatient drugs under Medicaid and under Medicare Part B, we have entered into an agreement with the Secretary of Health and Human Services to pay a rebate to state Medicaid programs for each unit of our covered outpatient drugs dispensed to a Medicaid beneficiary and paid for by the state Medicaid program. Medicaid rebates are based on pricing data we are required to report on a monthly and quarterly basis to the U.S. Centers for Medicare & Medicaid Services, or CMS, the federal agency that administers the MDRP and Medicare programs. For the MDRP, these data include the average manufacturer price, or AMP, for each drug and, in the case of innovator products, the Best Price, which represents the lowest price available from the manufacturer to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity in the United States in any pricing structure, calculated to include all applicable sales and associated rebates, discounts and other price concessions. If we become aware that our MDRP submissions for a prior period were incorrect or have changed as a result of recalculation of the pricing data, we must resubmit the corrected data for up to three years after those data originally were due. If we fail to provide information timely or are found to have knowingly submitted false information to CMS, we may be subject to civil monetary penalties and other sanctions, including termination from the MDRP.

Federal law requires that a manufacturer that participates in the MDRP also participate in the Public Health Service's 340B drug pricing program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B program is administered by the Health Resources and Services Administration, or HRSA and requires us to agree to charge statutorily defined covered entities no more than the 340B "ceiling price" for our covered outpatient drugs when used in an outpatient setting. 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients. The 340B ceiling price is calculated using a statutory formula, which is based on the AMP and rebate amount for the covered outpatient drug as calculated under the MDRP. In general, products subject to Medicaid price reporting and rebate liability are also subject to the 340B ceiling price requirement. We must report 340B ceiling prices to HRSA on a quarterly basis, and HRSA publishes them to 340B covered entities. HRSA has finalized regulations regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities for 340B-eligible drugs. HRSA has also finalized an administrative dispute resolution process through which 340B covered entities may pursue claims against participating manufacturers for overcharges.

In order to be eligible to have drug products paid for with federal funds under Medicaid and Medicare Part B and purchased by certain federal agencies and grantees, we must also participate in the U.S. Department of Veterans Affairs, or VA, Federal Supply Schedule, or FSS, pricing program. Under the VA/FSS program, we must report the Non-Federal Average Manufacturer Price, or Non-FAMP, for our covered drugs to the VA and charge certain federal agencies no more than the Federal Ceiling Price, which is calculated based on Non-FAMP using a statutory formula. These four agencies are the VA, the U.S. Department of Defense, the U.S. Coast Guard, and the U.S. Public Health Service (including the Indian Health

Service). We must also pay rebates on products purchased by military personnel and dependents through the TRICARE retail pharmacy program. If a manufacturer participating in the FSS program fails to provide timely information or is found to have knowingly submitted false information, the manufacturer may be subject to civil monetary penalties.

Individual states continue to consider and have enacted legislation to limit the growth of healthcare costs, including the cost of prescription drugs and combination products. A number of states have either implemented or are considering implementation of drug price transparency legislation. Requirements under such laws include advance notice of planned price increases, reporting price increase amounts and factors considered in taking such increases, wholesale acquisition cost information disclosure to prescribers, purchasers, and state agencies, and new product notice and reporting. Such legislation could limit the price or payment for certain drugs, and a number of states are authorized to impose civil monetary penalties or pursue other enforcement mechanisms against manufacturers for the untimely, inaccurate, or incomplete reporting of drug pricing information or for otherwise failing to comply with drug price transparency requirements

Healthcare Reform

Among policy makers and payors in the United States, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. In March 2010, the Patient Protection and Affordable Care Act, or ACA, 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 ACA contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement adjustments and fraud and abuse changes. Additionally, the ACA increases the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1%; expanded manufacturer Medicaid rebate liability to include utilization by beneficiaries enrolled in Medicaid managed care organizations; imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell “branded prescription drugs” to specified federal government programs; modified the AMP definition under the MDRP for drugs that are inhaled, infused, instilled, implanted or injected; 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.”

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA without specifically ruling on the constitutionality of the ACA.

Other legislative changes have been proposed and adopted since the ACA was enacted, including aggregate reductions of Medicare payments to providers, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through the first six months of 2032, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In addition, on March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminated the statutory cap on the Medicaid drug rebate beginning January 1, 2024. The rebate was previously capped at 100% of a drug's AMP.

The cost of prescription pharmaceuticals in the United States has also been the subject of considerable discussion. There have been 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. Most recently, on August 16, 2022, the Inflation Reduction Act of 2022 (IRA) was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services (HHS) to implement many of these provisions through guidance, as opposed to regulation, for the initial years. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. For that and other reasons, it is currently unclear how the IRA will be effectuated.

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 other transparency measures, and, in some cases, measures designed to encourage importation from other countries and bulk purchasing. It is possible that additional governmental action is taken in response to the COVID-19 pandemic. In addition, regional healthcare authorities and individual hospitals are increasingly

using bidding procedures to determine which drugs and suppliers will be included in their healthcare programs. Furthermore, there has been increased interest by third party payors and governmental authorities in reference pricing systems and publication of discounts and list prices.

Data Privacy and Security

We are subject to laws and regulations governing data privacy and the protection of health-related and other personal information. In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws, including HIPAA, and federal and state consumer protection laws and regulations (e.g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our partners. In addition, certain state and non-U.S. laws, such as the California Consumer Privacy Act, or the CCPA, the California Privacy Rights Act, or the CPRA, and the European Union General Data Protection Regulation, or the GDPR, govern the privacy and security of personal information, including health-related 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. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

Human Capital

Our human capital resources objectives include, as applicable, identifying, attracting, retaining and motivating our highly qualified management and our other employees, non-employee directors and consultants. The principal purposes of our long-term, equity-based incentive awards are to align the interests of our named executive officers and other employees, non-employee directors and consultants with the interests of our stockholders.

As of December 31, 2023, we had four 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 incorporated under the laws of the state of Delaware in January 2007. Our principal executive offices are located at 420 Stevens Avenue, Suite 230, 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 and commercialization 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. We use our website as a means of disclosing material non-public information and for complying with our disclosure obligations under Regulation FD. Investors should monitor such website, in addition to following our press releases, SEC filings and public conference calls and webcasts. 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 Regulatory Compliance and Commercialization of our Product, Gimoti

Our business is entirely dependent on the success of Gimoti, which may never generate sufficient sales to become profitable.

To date, we have devoted all of our research, development and clinical efforts and financial resources toward the development of our only product, Gimoti. Because our business is entirely dependent on the success of Gimoti, if we are unable to successfully commercialize this product, 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.

The future commercial success of Gimoti is subject to a number of risks, including the following:

- Gimoti competes with well-established products, including oral and intravenous forms of metoclopramide, the same active ingredient in the nasal spray for Gimoti;
- our reliance on Eversana to commercialize Gimoti;
- our ability, with Eversana, to hire, train and maintain a sales team for Gimoti;
- we may not be able to develop market demand for, and later increase sales of, Gimoti through our sales and marketing efforts;
- our ability to obtain adequate levels of coverage and reimbursement for Gimoti from commercial health plans and government health programs;
- we may not be able to maintain commercial manufacturing arrangements with third-party manufacturers or establish and maintain commercial-scale manufacturing capabilities;
- whether, and to the extent, GLP-1 agonists increase the number of patients diagnosed with diabetic gastroparesis, which remains speculative;
- contract manufacturers, suppliers and/or consultants may not meet appropriate timelines;
- our ability to successfully conduct a post-marketing commitment single dose pharmacokinetics, or PK, clinical trial of Gimoti to characterize dose proportionality of a lower dose strength of Gimoti, including the risk that FDA may disagree with the design of the clinical trial;
- patients taking Gimoti may suffer adverse effects for reasons that may or may not be related to Gimoti, which may adversely affect Gimoti's commercial profile; and
- we may not be able to obtain, maintain and enforce our patents and other intellectual property rights;

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

Our operations have consumed substantial amounts of cash since inception. We believe, based on our current operating plan, that our cash and cash equivalents as of December 31, 2023 of approximately $4.7 million, plus the estimated net proceeds of approximately $6.1 million from the offering we completed in February 2024, as well as cash flows from net sales of Gimoti, will be sufficient to fund our operations into the fourth quarter of 2024. This period could be shortened if there are any significant increases in planned spending on commercialization activities, including for marketing and manufacturing of Gimoti, and our selling, general and administrative costs to support operations, or as a result of any termination of the Eversana Agreement. As of December 31, 2023, we and Eversana each have the right to exercise the Net Profit Quarterly Termination Right and terminate the Eversana Agreement, which right either party may exercise for a 60-day period following the end of the quarter. We and Eversana will continue to have the option to exercise this termination right for the 60-day period following the end of future quarters so long as the net profit under the agreement remains negative for consecutive quarters. If the Net Profit Quarterly Termination Right is exercised, the outstanding principal and interest under the Eversana Credit Facility would be due within 90 days after the effective date of such termination. This would materially and adversely affect our near-term liquidity needs and cash runway. We anticipate that we 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 we will be able to raise additional funds on acceptable terms, or at all. Because our business is entirely dependent on the success of Gimoti, if we are unable to secure additional financing, successfully commercialize Gimoti or identify and execute on other commercialization 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 commercial success of Gimoti;
- the repayment of the outstanding principal and interest under the Eversana Credit Facility, approximately $6.6 million as of December 31, 2023, to be payable if we or Eversana exercise the Net Profit Quarterly Termination Right, or upon other certain termination events;
- the repayment of unreimbursed commercialization costs to Eversana, approximately $63.5 million as of December 31, 2023, to be payable only as net product profits are recognized, or upon certain termination events;
- the costs of commercialization activities, including costs associated with commercial manufacturing and distribution;
- competition with well-established products approved earlier by FDA, including oral and intravenous forms of metoclopramide, the same active ingredient in the nasal spray for Gimoti;
- our ability to manufacture sufficient quantities of Gimoti to meet demand, including whether our contract manufacturers, suppliers, and/or consultants are able to meet appropriate timelines;
- the progress and costs of the post-marketing commitment PK clinical trial of Gimoti to characterize dose proportionality of a lower dose strength of Gimoti and the costs of any additional clinical trials we may pursue to expand the indication of Gimoti;
- our ability to obtain, maintain and enforce our patents and other intellectual property rights and the costs incurred in doing so;
- claims by third parties that Gimoti and any other product candidates infringe their proprietary rights, which may result in liability for damages or prevent or delay our developmental and commercialization efforts;
- the terms and timing of any collaborative, licensing, co-promotion or other arrangements that we may establish;
- costs associated with any other product candidates that we may develop, in-license or acquire; and
- health epidemics and outbreaks or other natural or manmade disasters which could significantly disrupt our operations or the operations of third parties on whom we rely.

We are authorized to issue up to 50,000,000 shares of common stock. As of December 31, 2023, we had 3,343,070 shares of common stock outstanding and have reserved an aggregate of 1,317,451 shares of common stock for issuance under our equity incentive award plan and employee stock purchase plan. On February 13, 2024 we sold 5,134,731 common stock units (the “Common Stock Units”) at a public offering price of $0.68 per Common Stock Unit and, to certain investors, 5,894,680 pre-funded warrant units (the “PFW Units”) at a public offering price of $0.6799 per PFW Unit (the “February 2024 Offering”). Each Common Stock Unit consists of (i) one share of common stock, (ii) a Series A Warrant to purchase one share of common stock (the “Series A Warrant”), (iii) a Series B Warrant to purchase one share of common stock (the “Series B Warrant”), and (iv) a Series C Warrant to purchase one share of common stock (the “Series C Warrant,” and, together with the Series A Warrants and Series B Warrants, the "Common Warrants"). Each PFW Unit consists of (i) a pre-funded warrant to purchase one share of common stock ("the "Pre-Funded Warrants"), (ii) a Series A Warrant, (iii) a Series B Warrant, and (iv) a Series C Warrant. Given the number of Common Stock Units and PFW Units we sold in the February 2024 Offering, we have a very limited number of remaining unreserved and authorized shares available for issuance, which will impact our ability to raise additional funds in the future.

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 continue the commercialization of Gimoti or to otherwise continue as a going concern.

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

Currently, we have no internal sales, marketing or distribution capabilities, and we may not be able to effectively market and distribute the product. Eversana manages substantially all activities related to marketing, market access, distribution, sales team, patient reimbursement, and provides related support services. 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 Eversana will be effective in marketing and selling Gimoti, or that their personnel will be more effective than an internally developed sales organization.

Eversana may terminate our agreement under certain 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. In addition, upon certain termination events, we have agreed to reimburse Eversana for certain of its unreimbursed commercialization costs.

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 terminate 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 Gimoti or any future approved product, we will have difficulty commercializing the product, which would adversely affect our business and financial condition.

We and 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 provides sales representatives to promote Gimoti. These representatives are employees of Eversana and are hired and 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.

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 requires 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.

Revenues we receive from sales of Gimoti will largely depend upon the efforts of Eversana, which in many instances are not within our control. If we are unable to maintain the Eversana Agreement or to effectively establish alternative arrangements to market Gimoti or any other products, 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.

Use of Gimoti or any future product candidates we may develop could be associated with side effects, adverse events or other properties or safety risks, which could delay or preclude approval, cause us to suspend or discontinue clinical trials,

abandon a product candidate, limit the commercial profile of the approved labeling, or result in other significant negative consequences that could severely harm our business, prospects, operating results and financial condition.

If we or others identify undesirable side effects, or other previously unknown problems, with Gimoti, a number of potentially significant negative consequences could result, including:

- regulatory authorities may add new limitations for distribution and marketing of the product;
- regulatory authorities may require the addition of warnings in the product label or narrowing of the indication in the product label;
- FDA could suspend or withdraw approval of the product, or refuse to approve pending NDA supplements;
- FDA may require us to conduct additional clinical trials or costly post-marketing testing and surveillance to monitor the safety or efficacy of the product;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Moreover, if any future product candidates we may develop are associated with undesirable side effects in clinical trials or have characteristics that are unexpected, we may elect to abandon their development or limit their development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective, which may limit the commercial prospects for the product candidate, if approved. Undesirable side effects could cause us or regulatory authorities to interrupt, delay or halt clinical trials, result in a more restrictive label than proposed, or delay or cause the denial of regulatory approvals by FDA or comparable foreign regulatory authorities. The drug-related side effects could also affect patient recruitment for our clinical trials, or the ability of enrolled patients to complete the trials, or result in potential product liability claims. We may also be required to modify our plans for future studies based on findings in our ongoing clinical trials. Many compounds that initially showed promise in early-stage testing have later been found to cause side effects that prevented further development of the compound. In addition, regulatory authorities may draw different conclusions or require additional testing to confirm these determinations. Any of these occurrences may harm our business, financial condition and prospects significantly.

Undesirable side effects or other previously unknown problems could prevent us from achieving or maintaining market acceptance of Gimoti, or our future product candidates, if approved, and could substantially increase the costs of commercializing and developing such products or product candidates.

The results of the market research studies may not predict prescribing trends by doctors or acceptance by patients, and are not intended to reflect or imply actual prescriptions or sales to date.

A key element of our business strategy is utilizing market research to understand what people with diabetic gastroparesis and their healthcare providers are seeking to improve in diabetic gastroparesis therapy. This strategy underlies our product design, marketing and customer support approach. However, market research studies are based on interviews, focus groups, and online surveys involving people with diabetic gastroparesis and their healthcare providers, which represent only a small percentage of the overall diabetic gastroparesis market. As a result, their responses may not be reflective of the broader market and may not provide us and Eversana accurate insight into the needs and preferences of people with diabetic gastroparesis. In addition, we or Eversana may not be able perform analyses of the study data that yield meaningful results, or the conclusions we or Eversana draw from such analyses could be misleading or incorrect. Moreover, even if our market research has allowed us to better understand the needs and preferences of people with diabetic gastroparesis and their healthcare providers, there can be no assurance that such studies will predict prescribing trends by doctors or acceptance by patients.

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

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 experiencing severe or unexpected drug-related adverse effects;
- a facility manufacturing Gimoti, or any of its components, being ordered by FDA or other government or regulatory authorities to temporarily or permanently shut down due to violations of FDA's current Good

Manufacturing Practices, or other applicable requirements, or infections or cross-contaminations of 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 an IRB that require us to undertake corrective action, result in suspension or termination of one or more sites or the imposition of a clinical hold on the entire trial, or that prohibit us from using some or all of the data in support of our marketing applications;
- third-party contractors becoming debarred or suspended or otherwise penalized by 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
- an IRB 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 need to perform more or larger clinical trials than planned. For example, in connection with FDA's approval of Gimoti, we committed to conduct a PK trial to characterize dose proportionality of a lower dose strength compared to the current 15 mg dose strength, and complete the trial by September 2022. However, due to discussions with the FDA regarding trial design and difficulties caused by the COVID-19 pandemic at the time, we were unable to conduct the trial within the agreed-upon timeline. The timing of initiation of this trial is uncertain and is pending additional feedback from the FDA. Any failure by us to comply with reporting requirements applicable to this or any other post-marketing commitment could lead to FDA's withdrawal of approval, or have other negative consequences on us.

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.

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.

Disruptions at FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, 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, statutory, regulatory, and policy changes, FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect FDA's ability to perform routine functions. Average review times at FDA 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 or modifications to approved 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 FDA employees and stop critical activities.

Separately, in response to the COVID-19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. Even though the FDA has resumed standard inspection operations, any resurgence of the virus or emergence of new variants may lead to inspectional or administrative delays. If a prolonged government shutdown occurs, or if global health concerns prevent FDA or other regulatory authorities from conducting their regular

inspections, reviews, or other regulatory activities, it could significantly impact the ability of FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Even though FDA has approved Gimoti for the relief of symptoms in adults with acute and recurrent diabetic gastroparesis, we will remain subject to significant post-marketing regulatory requirements and oversight.

Any regulatory approvals that we may receive for Gimoti or any future product candidates will require the submission of reports to regulatory authorities and surveillance to monitor the safety and efficacy of the product, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post-approval study or risk management requirements. For example, the approved labeling for Gimoti includes a black box warning regarding the risks of tardive dyskinesia associated with metoclopramide, the active ingredient in Gimoti. FDA may also require a REMS in order to approve a product candidate, which could entail requirements for a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools.

In addition, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for Gimoti are subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as on-going compliance with current good manufacturing practices, or cGMPs, and GCPs for any clinical trials that we conduct post-approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by FDA and other regulatory authorities for compliance with cGMP regulations and standards. If we or a regulatory authority discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory authority may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. In addition, failure to comply with FDA and other comparable foreign regulatory requirements may subject our company to administrative or judicially imposed sanctions, including:

- delays in or the rejection of product approvals;
- restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials;
- restrictions on the products, manufacturers or manufacturing process;
- warning or untitled letters;
- civil and criminal penalties;
- injunctions;
- suspension or withdrawal of regulatory approvals;
- product seizures, detentions or import bans;
- voluntary or mandatory product recalls and publicity requirements;
- total or partial suspension of production; and
- imposition of restrictions on operations, including costly new manufacturing requirements.

The occurrence of any event or penalty described above may inhibit our ability to commercialize Gimoti and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity. In addition, FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could impair our business. 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. 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 be subject to enforcement action, and we may not achieve or sustain profitability.

FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

FDA strictly regulates marketing, labeling, advertising and promotion of prescription drugs. These regulations include standards and restrictions for direct-to-consumer advertising, industry-sponsored scientific and educational activities, promotional activities involving the internet and off-label promotion. Any regulatory approval that FDA grants is limited to those specific diseases and indications for which a product is deemed to be safe and effective by FDA. For example, the FDA-approved label for Gimoti is limited to the relief of symptoms in adults with acute and recurrent diabetic gastroparesis.

While physicians in the United States may choose, and are generally permitted, to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those tested in clinical trials and approved by the regulatory authorities, our ability to promote the products is narrowly limited to those indications that are specifically approved by FDA. These "off-label" uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. For example, other formulations of metoclopramide, the active ingredient in Gimoti, have been approved for uses beyond those authorized in Gimoti's approved labeling, such as for the treatment of gastroesophageal reflux symptoms. We do not market or promote Gimoti for these uses.

Regulatory authorities in the United States generally do not regulate the behavior of physicians in their choice of treatments. Regulatory authorities do, however, restrict communications by pharmaceutical companies on the subject of off-label use. Although recent court decisions suggest that certain off-label promotional activities may be protected under the First Amendment, the scope of any such protection is unclear. If our promotional activities fail to comply with FDA's regulations or guidelines, we may be subject to warnings from, or enforcement action by, these authorities. In addition, our failure to follow FDA rules and guidelines relating to promotion and advertising may cause FDA to issue warning letters or untitled letters, bring an enforcement action against us, suspend or withdraw an approved product from the market, require a recall or institute fines or civil fines, or could result in disgorgement of money, operating restrictions, injunctions or criminal prosecution, any of which could harm our reputation and our business.

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 European Union, or 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 commercialization activities and supply of Gimoti.

As of December 31, 2023, we had four full-time employees and, as a result, we rely on outsourcing arrangements with third-party vendors for a significant portion of our activities, including commercial sales and marketing, data analysis, assistance with regulatory discussions, 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 commercialize Gimoti.

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 commercialization activities. 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 COVID-19 pandemic. 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 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, which competes 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.

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 Gimoti obsolete. We are aware of other product candidates in the gastroparesis pipeline in clinical development. Any of these product candidates could advance quickly through clinical development and, if approved, could attain faster and greater market acceptance than Gimoti. 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 commercialize Gimoti.

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 Chief Executive Officer, Matthew J. D'Onofrio, our President and Operating 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 commercialization of Gimoti.

In addition to the team at Eversana, we may need to hire and retain qualified personnel to pursue the 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.

We may need to grow our organization to pursue the commercialization of Gimoti and to potentially conduct additional unplanned development activities. As we 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.

If we fail to comply with reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We participate in governmental programs that impose drug price reporting, payment, and other compliance obligations on pharmaceutical manufacturers. Medicaid is a joint federal and state program that for low income and disabled beneficiaries. Under the Medicaid Drug Rebate Program, or MDRP, as a condition of having federal funds available for our covered outpatient drugs under Medicaid and under Medicare Part B, we have entered into an agreement with the Secretary of Health and Human Services to pay a rebate to state Medicaid programs for each unit of our covered outpatient drugs dispensed to a Medicaid beneficiary and paid for by the state Medicaid program. Medicaid rebates are based on pricing data that we are required to report on a monthly and quarterly basis to the U.S. Centers for Medicare & Medicaid Services, or CMS, the federal agency that administers the MDRP and Medicare programs. For the MDRP, these data include the average manufacturer price, or AMP, for each drug and, in the case of innovator products, the Best Price, which represents the lowest price available from the manufacturer to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity in the United States in any pricing structure, calculated to include all applicable sales and associated rebates, discounts and other price concessions. If we become aware that our MDRP submissions for a prior period were incorrect or have changed as a result of recalculation of the pricing data, we must resubmit the corrected data for up to three years after those data originally were due. If we fail to provide information timely or are found to have knowingly submitted false information to CMS, we may be subject to civil monetary penalties and other sanctions, including termination from the MDRP.

Federal law requires that any company that participates in the MDRP also participate in the Public Health Service's 340B drug pricing program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B program is administered by the Health Resources and Services Administration, or HRSA, and requires us to agree to charge statutorily defined covered entities no more than the 340B "ceiling price" for our covered drugs when used in an outpatient setting. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low income patients. The 340B ceiling price is calculated using a statutory formula, which is based on the AMP and rebate amount for the covered outpatient drug as calculated under the MDRP. In general, products subject to Medicaid price reporting and rebate liability are also subject to the 340B ceiling price requirement. We must report 340B ceiling prices to HRSA on a quarterly basis, and HRSA publishes them to 340B covered entities. HRSA has finalized regulations regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities for 340B eligible drugs. HRSA has also finalized an administrative dispute resolution process through which 340B covered entities may pursue claims against participating manufacturers for overcharges.

In order to be eligible to have drug products paid for with federal funds under Medicaid and Medicare Part B and purchased by certain federal agencies and grantees, we must also participate in the U.S. Department of Veterans Affairs, or VA, Federal Supply Schedule, or FSS, pricing program. Under the VA/FSS program, we must report the Non-Federal Average Manufacturer Price, or Non-FAMP, for our covered drugs to the VA and charge certain federal agencies no more than the Federal Ceiling Price, which is calculated based on Non FAMP using a statutory formula. These four agencies are the VA, the U.S. Department of Defense, the U.S. Coast Guard, and the U.S. Public Health Service (including the Indian Health Service). We must also pay rebates on products purchased by military personnel and dependents through the TRICARE retail pharmacy program. If a manufacturer participating in the FSS program fails to provide timely information or is found to have knowingly submitted false information, the manufacturer may be subject to civil monetary penalties.

Individual states continue to consider and have enacted legislation to limit the growth of healthcare costs, including the cost of prescription drugs and combination products. A number of states have either implemented or are considering implementation of drug price transparency legislation that may prevent or limit our ability to take price increases at certain

rates or frequencies. Requirements under such laws include advance notice of planned price increases, reporting price increase amounts and factors considered in taking such increases, wholesale acquisition cost information disclosure to prescribers, purchasers, and state agencies, and new product notice and reporting. Such legislation could limit the price or payment for certain drugs, and a number of states are authorized to impose civil monetary penalties or pursue other enforcement mechanisms against manufacturers for the untimely, inaccurate, or incomplete reporting of drug pricing information or for otherwise failing to comply with drug price transparency requirements. If we are found to have violated state law requirements, we may become subject to penalties or other enforcement mechanisms, which could have a material adverse effect on our business.

Pricing and rebate calculations vary across products and programs, are complex, and are often subject to interpretation by pharmaceutical manufacturers, governmental or regulatory agencies, and the courts, which can change and evolve over time. Such pricing calculations and reporting, along with any necessary restatements and recalculations, could increase costs for complying with the laws and regulations governing the MDRP and other governmental programs, and under the MDRP could result in an overage or underage in Medicaid rebate liability for past quarters. Price recalculations under the MDRP also may affect the ceiling price at which we are required to offer products under the 340B program. Civil monetary penalties can be applied if we are found to have knowingly submitted any false price or product information to the government, if we fail to submit the required price data on a timely basis, or if we are found to have charged 340B covered entities more than the statutorily mandated ceiling price. CMS could also terminate our Medicaid drug rebate agreement, in which case federal payments may not be available under Medicaid or Medicare Part B for our covered outpatient drugs. We cannot assure you that our submissions will not be found by CMS or other governmental agencies to be incomplete or incorrect.

Enacted and future legislation may increase the difficulty and cost for us to 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 restrict or regulate post-approval activities and affect our ability to profitably sell Gimoti.

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 commercialization of Gimoti, if any, may be.

In 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA, was signed into law. The ACA 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 ACA, among other things, increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively; modified the AMP definition under the MDRP for drugs that are inhaled, infused, instilled, implanted, or injected; imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell "branded prescription drugs" to specified federal government programs; 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, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA without specifically ruling on the constitutionality of the ACA.

There have been a number of recent regulatory and legislative initiatives designed to encourage generic competition for pharmaceutical products, including expedited review procedures for generic manufacturers and incentives designed to spur generic competition of branded drugs. In particular, FDA and Federal Trade Commission, or FTC, have been focused on brand companies' denial of drug supply to potential generic competitors for testing. In December 2019, the Creating and Restoring Equal Access to Equivalent Samples Act, or the CREATES Act, was enacted, which provides a legislatively defined private right of action under which eligible product developers can bring suit against companies who refuse to sell sufficient quantities of their branded products on commercially reasonable, market-based terms to support such eligible product developers' marketing applications. We cannot currently predict the specific outcome or impact on our business of such regulatory and legislative initiatives. However, it is our policy, which is in compliance with the CREATES Act, to evaluate requests for samples of our branded products, and to provide samples in response to *bona fide* requests from qualified third parties, including generic manufacturers, subject to specified conditions. During 2021, we received a request

for samples of Gimoti and we provided the requested samples in compliance with the requirements of the CREATES Act. No requests for Gimoti samples were received under the CREATES act in 2022.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers, which went into effect on April 1, 2013, and due to subsequent legislative amendments, will remain in effect through the first six months of 2032, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012, 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. In addition, on March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminated the statutory cap on the Medicaid drug rebate, beginning January 1, 2024. The rebate was previously capped at 100% of a drug's AMP.

The cost of prescription pharmaceuticals in the United States has been the subject of considerable discussion. There have been several Congressional inquiries and proposed and enacted legislation designed to, among other things, reform government program reimbursement methodologies. Most recently, on August 16, 2022, the Inflation Reduction Act of 2022 (IRA) was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services (HHS) to implement many of those provisions through guidance, as opposed to regulation, for the initial years. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. While the impact of the IRA on the pharmaceutical industry cannot yet be fully determined, it is likely to be significant.

In the coming years, additional legislative and regulatory changes could be made to governmental health programs that could significantly impact pharmaceutical companies and the success of our product.

Individual states in the United States have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, marketing cost disclosure and other transparency measures, and, in some cases, measures designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. Furthermore, there has been increased interest by third party payors and governmental authorities in reference pricing systems and publication of discounts and list prices. These reforms could reduce the ultimate demand for our products, if approved, or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

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. We expect that these healthcare reform measures that may be adopted in the future could result in more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our future product candidates, 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, and physician and other health care provider 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.

With the approval of Gimoti by FDA in June 2020, and our commencement of sales in the United States in October 2020, we are 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 non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists, anesthesiology assistants and certified nurse midwives), 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 are and may become subject to foreign, federal, and state data privacy and security laws and other requirements, and the actual or alleged failure to comply, or to protect our information technology 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, results of operations, financial condition and reputation to suffer.

The global data protection landscape is rapidly evolving, and we and our collaborators and third-party providers are and may become subject to federal, state and foreign data privacy and security laws and regulations and other requirements.

In the United States, numerous federal and state laws and regulations, including health information privacy laws, data breach notification laws, consumer protection laws that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our collaborators and third-party providers. For example, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA. Depending on the facts and circumstances, we could be subject to significant penalties if we violate HIPAA.

Even when HIPAA does not apply, the FTC and many state Attorneys General continue to enforce federal and state consumer protection laws against companies for online collection, use, dissemination and security practices that appear to be unfair or deceptive. According to the FTC, violating consumers' privacy rights or 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 FTC Act. 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.

Certain state laws also govern the privacy and security of health-related and other personal 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, the CCPA, as amended by the CPRA, collectively, the CCPA, requires covered businesses that process the personal information of California residents to, among other things: (i) provide certain disclosures to California residents regarding the business's collection, use, and disclosure of their personal information; (ii) receive and respond to requests from California residents to access, delete, and correct their personal information, or to opt out of certain disclosures of their personal information; and (iii) enter into specific contractual provisions with service providers that process California resident personal information on the business's behalf. Similar laws have been passed in other states, and are continuing to be proposed at the state and federal level, reflecting a trend toward more stringent privacy legislation in the United States. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging. Such laws may also be inconsistent with or restrict our collection, storage, transfer, use and disclosure of personal information, and may require changes to our data processing practices and policies, including the acceptance of more onerous obligations in our contracts or additional costs, and we may be unable to make such changes and modifications in a commercially reasonable manner, or at all. In the event that we are subject to or affected by HIPAA, the CCPA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our business, results of operation, and financial condition.

Similar laws and regulations exist in Europe and other jurisdictions, such as the GDPR, which went into effect in May 2018 and applies to any companies processing the personal data of individuals in the European Economic Area, or EEA, or in the context of their activities within the EEA. 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 undertaking, whichever is greater. The GDPR provides that EU and EEA 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. Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States, and the efficacy and longevity of current transfer mechanisms between the EU, and the United States remains uncertain. Case law from the Court of Justice of the European Union states that reliance on the standard contractual clauses, or SCCs - a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism - alone may not necessarily be sufficient in all circumstances and that transfers must be assessed on a case-by-case basis. On July 10, 2023, the European Commission adopted its Adequacy Decision in relation to the new EU-US Data Privacy Framework, or DPF, rendering the DPF effective as a GDPR transfer mechanism to U.S. entities self-certified under the DPF. We expect the existing legal complexity and

uncertainty regarding international personal data transfers to continue. In particular, we expect the DPF Adequacy Decision to be challenged and international transfers to the United States and to other jurisdictions more generally to continue to be subject to enhanced scrutiny by regulators. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the SCCs cannot be used, and/or start taking enforcement action, we could suffer additional costs, complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.

Further, from January 1, 2021, companies have to comply with the GDPR and also the UK General Data Protection Regulation, which, together with the amended UK Data Protection Act 2018, collectively the UK GDPR, retains the GDPR in UK national law. The UK GDPR mirrors the fines under the GDPR, e.g., fines up to the greater of £17.5 million or 4% of the annual global revenue of a noncompliant undertaking. On October 12, 2023, the UK Extension to the DPF came into effect (as approved by the UK Government), as a data transfer mechanism from the UK to U.S. entities self-certified under the DPF. As we continue to expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business.

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 as we commercialize Gimoti. 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, 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. The label for Gimoti contains 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 information technology system failures, cyberattacks, and other security incidents.

We collect and maintain information in digital form that is necessary to conduct our business, and we are increasingly dependent on information technology systems and infrastructure to operate our business. In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information, preclinical and clinical trial data, and personal information of our employees and contractors, or collectively, Confidential Information.

Despite the implementation of security measures, our information technology systems and those of our current and any future CROs and other contractors, consultants, and collaborators are vulnerable to attack, damage and interruption from computer viruses and malware (e.g., ransomware), malicious code, hacking, cyberattacks, phishing attacks and other social engineering schemes, and other means of unauthorized access, misconfigurations, bugs or other vulnerabilities, natural disasters, terrorism, war and telecommunication and electrical failures, employee theft or misuse, human error, fraud, denial or degradation of service attacks and sophisticated nation-state and nation-state-supported actors. For example, we have been the target of a cyberattack, which resulted in the misappropriation of an immaterial amount our funds, and we may be subject to further cyberattacks seeking to misappropriate our funds or otherwise disrupt our business.

Although we have implemented certain additional procedures to reduce the risk of another successful cyberattack, we cannot be sure that similar cyberattacks or failures will not occur in the future or that our and our third-party service providers', strategic partners', contractors', consultants', CROs' and collaborators' cybersecurity risk management program and processes, including policies, controls or procedures, will be fully implemented, complied with or effective in protecting our systems, networks and Confidential Information. Attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. As a result of the COVID-19 pandemic, we may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who continue to work remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence.

While we do not believe that we have 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 and commercialize Gimoti and conduct clinical trials, and similar events relating to their information technology 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, damage to, or inappropriate disclosure of our Confidential Information or applications, we could incur liability including litigation exposure, we could become the subject of regulatory investigation or enforcement action including penalties and fines, the costs associated with the investigation, remediation and potential notification of the breach to counter-parties and data subjects could be material, we could incur reputational damage and the further development and commercialization of our product candidate could be delayed, or otherwise adversely affected, any of which may adversely affect our business, results of operations or financial condition. Further, our insurance coverage may not be sufficient to cover the financial, legal, business or reputational losses that may result from an interruption or breach of our systems.

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

Our operations could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or manmade disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce our Gimoti. Our ability to obtain clinical supplies of Gimoti could be disrupted, if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

Our operations are located in Solana Beach, California near major earthquake faults and fire zones. The ultimate impact on us, our significant suppliers and our general infrastructure of being located near major earthquake faults and fire zones and being located 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.

In addition, upon a change of control of our ownership, either party may terminate the Eversana Agreement. In the event that we initiate such termination, we shall pay to Eversana a one-time payment equal to all of Eversana's unreimbursed costs plus a portion of Eversana's commercialization costs incurred in the 12 months prior to termination. 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. If Eversana initiates such a termination, none of the unreimbursed commercialization costs incurred by Eversana will be due from Evoke.

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 Gimoti's commercial sales. 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.

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, and we can offer no assurance that our efforts we will be successful, in which case our business may be materially and adversely affected.

For example, in 2022 we received a Paragraph IV certification notice letter from Teva Pharmaceuticals, Inc., or Teva, indicating that it has submitted to FDA an abbreviated new drug application, or ANDA, seeking approval to manufacture and sell a generic version of Gimoti (metoclopramide hydrochloride) nasal spray eq. 15 mg base/spray prior to the expiration of certain Orange Book-listed patents protecting Gimoti. In an ANDA, 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. The Teva ANDA initially contained a Paragraph IV certification with respect to two of our patents covering Gimoti, U.S. Patent Nos. 8,334,281, expiration date May 16, 2030; and 11,020,361, expiration date December 22, 2029. We initiated a patent infringement lawsuit against Teva (Civil Action No. 1:22-cv-02019) to defend our intellectual property rights protecting Gimoti. After we initiated litigation, Teva converted to a Paragraph III certification, which prevents FDA from approving Teva's ANDA until after the latest expiring patent expires in 2030. Consequently, the litigation against Teva has been dismissed. In addition, no future ANDA filer will be eligible to receive 180-day generic exclusivity for an ANDA that references Gimoti. This regulatory pathway is typically highly sought after by generic firms.

As illustrated by the now dismissed litigation against Teva, Evoke will vigorously defend and enforce our intellectual property rights protecting Gimoti. Although there is no currently pending litigation concerning our Gimoti patents, 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.

In addition, on June 1, 2023, the European Union Patent Package (EU Patent Package) regulations were implemented with the goal of providing a single pan-European Unitary Patent and a new European Unified Patent Court (UPC) for litigation involving European patents. As a result, all European patents, including those issued prior to ratification of the EU Patent Package, now by default automatically fall under the jurisdiction of the UPC, unless otherwise opted out. It is uncertain how the UPC will impact granted European patents in the biotechnology and pharmaceutical industries. Our European patents, and patent applications if issued, could be challenged in the UPC. During the first seven years of the UPC's existence, the UPC legislation allows a patent owner to opt its European patents out of the jurisdiction of the UPC. We may decide to opt out our future European patents from the UPC, but doing so may preclude us from realizing the benefits of the UPC. Moreover, if we do not meet all of the formalities and requirements for opt-out under the UPC, our future European patents could remain under the jurisdiction of the UPC. The UPC will provide our competitors with a new forum to centrally revoke our European patents, and allow for the possibility of a competitor to obtain pan-European injunction. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize our technology and our product candidates due to increased competition and, resultantly, on our business, financial condition, results of operations and prospects. The UPC and Unitary Patent are significant changes in European patent practice. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation in the UPC.

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.

Geo-political actions in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any current or future licensors and the maintenance, enforcement or defense of our issued patents or those of any current or future licensors. For example, the United States and foreign government actions related to Russia's invasion of Ukraine may limit or prevent filing, prosecution and maintenance of patent applications in Russia. Government actions may also prevent maintenance of issued patents in Russia. These actions could result in abandonment or lapse of our patents or patent applications, resulting in partial or complete loss of patent rights in Russia. If such an event were to occur, it could have a material adverse effect on our business. In addition, a decree was adopted by the Russian government in March 2022, allowing Russian companies and individuals to exploit inventions owned by patentees that have citizenship or nationality in, are registered in, or have a predominately primary place of business or profit-making activities in the United States and other countries that Russia has deemed unfriendly without consent or compensation. Consequently, we would not be able to prevent third parties from practicing our inventions in Russia or from selling or importing products made using our inventions in and into Russia. Accordingly, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

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. 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. 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, which we launched in October 2020.

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 as of December 31, 2023 of approximately $4.7 million, plus the estimated net proceeds of approximately $6.1 million from the offering we completed in February 2024, as well as cash flows from future net sales of Gimoti, will be sufficient to fund our operations into the fourth quarter of 2024. This period could be shortened if there are any significant increases in planned spending other than anticipated. We anticipate that 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, successfully commercialize Gimoti or identify and execute on 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 primarily related to funding commercialization activities for Gimoti, manufacturing commercial batches of Gimoti, and conducting the post-marketing commitment PK clinical trial of Gimoti. Our net loss for the year ended December 31, 2023, was approximately $7.8 million. As of December 31, 2023, we had an accumulated deficit of approximately $123.4 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 the commercial activities for Gimoti, including manufacturing commercial batches, conduct the post-marketing commitment PK clinical trial and any additional development activities should we seek additional indications, maintain, expand and protect our intellectual property portfolio and continue to fund general and administrative expenses and costs of being a public company. These costs will likely result in our incurring further significant losses until net sales from Gimoti exceed such costs, if ever.

Our ability to generate revenue and become profitable depends on our ability to successfully commercialize Gimoti, which we launched in October 2020 through our commercial partner Eversana. If we or Eversana fail to successfully launch Gimoti and grow and maintain sales, we may never generate significant revenues and our results of operations and financial position will be adversely affected, 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 commercialize Gimoti.

We may require additional capital in the future. The amount and timing of any expenditure needed to implement our development and commercialization programs will depend on numerous factors, including:

- the timing and costs related to commercialization activities for Gimoti by us and our commercial partner Eversana;
- the timing and costs to manufacture commercial batches of Gimoti;
- the market acceptance of Gimoti;
- the costs to conduct the post-marketing commitment PK clinical trial of Gimoti, including the timing and costs to manufacture product for such trial, and any additional development activities should we seek additional indications;
- the outcome, costs and timing of seeking and obtaining regulatory approvals from FDA, and any similar regulatory agencies for any new indications;
- our need and ability to hire additional management, development and scientific personnel, if necessary;
- 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 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;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems; and
- the costs necessary to fund general and administrative activities to support operations.

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 the items noted and, in any event, we may need to raise additional capital to complete such activities.

We may seek additional funding through collaboration agreements, public or private equity financings, debt financings or receivables financings. For example, in February 2024, we sold 5,134,731 common stock units (the "Common Stock Units"), at a public offering price of $0.68 per Common Stock Unit and, to certain investors, 5,894,680 pre-funded warrant units (the "PFW Units"), at a public offering price of $0.6799 per PFW Unit. Each Common Stock Unit consists of (i) one share of common stock, (ii) a Series A Warrant to purchase one share of common stock (the "Series A Warrant"), (iii) a Series B Warrant to purchase one share of common stock (the "Series B Warrant"), and (iv) a Series C Warrant to purchase one share of common stock (the "Series C Warrant"). Each PFW Unit consists of (i) a pre-funded warrant to purchase one share of common stock, (ii) a Series A Warrant, (iii) a Series B Warrant, and (iv) a Series C Warrant. After deducting underwriting discounts and commissions and offering expenses paid by us, the estimated net proceeds to us from this offering were approximately $6.1 million.

The Pre-Funded Warrants have an exercise price of $0.0001 per share. The Series A Warrants, Series B Warrants and the Series C Warrants have an exercise price of $0.68 per share. The Pre-Funded Warrants, Series A Warrants and Series B Warrants are exercisable immediately. The Series C Warrants are subject to a vesting schedule and may only be exercised to the extent and in proportion to a holder of the Series C Warrants exercising its corresponding Series B Warrants. The Series A Warrants will expire on February 13, 2029, which is five years from the date of issuance. The Series B Warrants will expire on November 13, 2024, which is nine months from the date of issuance. The Series C Warrants will also expire on November 13, 2024, provided that to the extent and in proportion to a holder of the Series C Warrants exercising its corresponding Series B Warrants included in the applicable unit, such Series C Warrant will expire on February 13, 2029.

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. 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, 2023, we had federal and state net operating loss carryforwards of approximately $105.8 million and $53.6 million, respectively, and federal and state research and development credits of approximately $2.4 million and $1.5 million, respectively, 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.

Risks Related to Ownership of Our Common Stock

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 24, 2023, we received a written notice from Nasdaq indicating that, based on our stockholders' equity of $2.1 million as of March 31, 2023, as reported in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, we were not in compliance with the minimum stockholders' equity requirement for continued listing on The Nasdaq Capital Market under Nasdaq Listing Rule 5550(b)(1) (the "Minimum Stockholders' Equity Requirement"). As required by Nasdaq, we submitted our plan to regain compliance with the Minimum Stockholders' Equity Requirement and Nasdaq granted us an extension until November 20, 2023 to regain compliance. Following notice on November 21, 2023 from Nasdaq that we had not met the Minimum Stockholders' Equity Requirement, we requested a hearing before the Nasdaq Hearings Panel (the "Hearings Panel") and on December 9, 2023, Nasdaq notified the Company that the hearing was scheduled for February 15, 2024. On February 7, 2024, we received a request from Nasdaq for us to provide additional pro forma financial information and future forecasts at the Hearings Panel in order to evidence compliance with the Minimum Stockholders' Equity Requirement. On February 15, 2024, we had the hearing before the Hearings Panel. There can be no assurance that the Hearings Panel will grant our request for continued listing or that we will be able to evidence compliance prior to the expiration of any extension that may be granted by the Hearings Panel. As of the date of this Annual Report, the Hearings Panel has not issued a ruling. Nasdaq has indicated in no event would such extension be granted, if at all, beyond May 20, 2024 under its rules. If the Hearings Panel does not grant our request for continued listing, we will be subject to delisting from The Nasdaq Capital Market. Even if the Hearings Panel grants an extension, there can be no assurances that we will regain compliance with the Minimum Stockholders' Equity Requirement to the satisfaction of Nasdaq currently or in any future periods, even applying the proceeds from the February 2024 Offering, or meet the other Nasdaq continued listing requirements. For example, we may be unable to demonstrate to Nasdaq that we will continue to meet the Minimum Stockholders' Equity Requirement through the current quarter or through December 31, 2024, based on the amount raised in the February 2024 Offering or our future revenue forecast assumptions, financing plans or otherwise. Further, even if we regain compliance with the Minimum Stockholders' Equity Requirement, we may not be able to maintain compliance which may cause Nasdaq to delist our shares.

In addition, on February 21, 2024, 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 under Nasdaq Listing Rule 5550(a)(2).

In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we were provided an initial period of 180 calendar days, or until August 19, 2024, to regain compliance. We will regain compliance under this rule if at any time before August 19, 2024, the bid price of our common stock closes at $1.00 per share or more for a minimum of ten consecutive business days. The Nasdaq letter had no immediate effect on the listing or trading of our common stock and such securities continue to trade on The Nasdaq Capital Market. We intend to monitor the bid price of our common stock and consider available options if our common stock does not trade at a level likely to result in us regaining compliance with Nasdaq's minimum bid price rule by August 19, 2024. If we do not regain compliance by August 19, 2024, we may be eligible for an additional 180 calendar day compliance period. To qualify, we would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market, with the exception of the bid price requirement, and would need to provide written notice of our intention to cure the deficiency during the second compliance period, by effecting a reverse stock split, if necessary. However, if it appears to the Nasdaq staff that we will not be able to cure the deficiency, or if we are otherwise not eligible, the Nasdaq staff would notify us that our securities would be subject to delisting. In the event of such a notification, we may appeal the Nasdaq staff's determination to delist our securities, but there can be no assurance the Nasdaq staff would grant our request for continued listing.

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. 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.

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

An active trading market may not be sustained. If an active trading market 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.

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;
- 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 COVID-19 pandemic;
- 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 Gimoti sales;
- additional clinical trials and related manufacturing and regulatory costs;
- 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 under the laws of the state of 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.

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.

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.

The global credit and financial markets have recently experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflict, including the conflict between Russia and Ukraine, terrorism or other geopolitical events. Sanctions imposed by the United States and other countries in response to such conflicts, including the one in Ukraine, may also adversely impact the financial markets and the global economy, and any economic countermeasures by affected countries and others could exacerbate market and economic instability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive an economic downturn, which could directly affect our ability to attain our operating goals on schedule and on budget.

The future issuance and sale of our common stock, including any shares issuable upon exercise of the outstanding Pre-Funded Warrants or Common Warrants, or the perception that such sales could occur, may depress our stock price and our ability to raise funds in new stock offerings.

We may from time-to-time issue additional shares of common stock at a discount from the current trading price of our common stock. As a result, our stockholders would experience immediate dilution upon the purchase of any shares of our common stock sold at such discount. In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities, preferred stock or common stock. The issuance and sale of shares of our common stock, including any shares issuable upon exercise of any Pre-Funded Warrants or Common Warrants, or the perception that such sales could occur, may lower the market price of our common stock and may make it more difficult for us to sell equity securities or equity-related securities in the future at a time and price that our management deems acceptable, or at all.

In addition, we must settle exercises of our outstanding Common Warrants in shares of our common stock. The issuance of shares of our common stock upon exercise of the Common Warrants will dilute the ownership interests of our stockholders, which could depress the trading price of our common stock. In addition, the market's expectation that exercises may occur could depress the trading price of our common stock even in the absence of actual exercises. Moreover, the expectation of exercises could encourage the short selling of our common stock, which could place further downward pressure on the trading price of our common stock.

We may not receive any additional funds upon the exercise of the Pre-Funded Warrants or Common Warrants.

Each Pre-Funded Warrant may be exercised by way of a cashless exercise, meaning that the holder may not pay a cash purchase price upon exercise, but instead would receive upon such exercise the net number of shares of our common stock determined according to the formula set forth in the Pre-Funded Warrants. Accordingly, we may not receive any additional funds upon the exercise of the Pre-Funded Warrants.

Each Common Warrant (other than the Series B Warrant) may be exercised by way of a cashless exercise if at the time of exercise hereof there is no effective registration statement registering, or the prospectus contained therein is not available for the issuance of our common stock issuable upon exercise of the Common Warrants to the holder.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 1C. Cybersecurity Risk Management and Strategy

We have taken steps to develop and implement a cybersecurity risk management program intended to protect the confidentiality, integrity, and availability of our critical systems and information.

Our cybersecurity risk management program includes:

- the use of external service providers, where appropriate, to assess, test or otherwise assist with aspects of our security controls;
- risk assessments designed to help identify material cybersecurity risks to our critical systems, information, products, services, and our broader enterprise IT environment; and
- cybersecurity awareness training of our employees and senior management.

We have not identified risks from known cybersecurity threats, including as a result of any prior cybersecurity incidents, that have materially affected or are reasonably likely to materially affect us, including our operations, business strategy, results of operations, or financial condition. For more information, see the section titled “Risk Factor—Risks Related to our Business, including the Regulatory Compliance and Commercialization of our Product, Gimoti— Our business and operations would suffer in the event of information technology system failures, cyberattacks, and other security incidents.”

Cybersecurity Governance

Our Board considers cybersecurity risk as part of its risk oversight function and has delegated oversight of cybersecurity and other information technology risks to the Audit Committee ("the Audit Committee"). The Audit Committee oversees management’s implementation of our cybersecurity risk management program.

The Audit Committee receives annual reports from management on our cybersecurity risks. In addition, management updates the Committee, as necessary, regarding any material cybersecurity incidents, as well as any incidents with lesser impact potential.

The Audit Committee reports to the full Board regarding its activities, including those related to cybersecurity. The full Board also receives briefings from management on our cyber risk management program, as required. Board members may receive presentations on cybersecurity topics from external experts as part of the Board’s continuing education on topics that impact public companies.

Our management team, including our President and Chief Operating Officer, is responsible for assessing and managing our material risks from cybersecurity threats. The team has primary responsibility for our overall cybersecurity risk management program and supervises our retained external cybersecurity consultants. Our management team’s experience includes decades of experience in overseeing operations, including information technology functions, in the public company environment.

Our management team supervises efforts to prevent, detect, mitigate, and remediate cybersecurity risks and incidents through various means, which may include briefings from external consultants engaged by us; threat intelligence and other information obtained from governmental, public or private sources; and alerts and reports produced by security tools deployed in the IT environment.

Item 2. Properties

We occupy approximately 1,500 square feet of office space in Solana Beach, California under a lease that we entered into in October 2023. 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. However, from time to time, we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. Regardless of outcome, such proceedings or claims can have an adverse impact on us because of defense and settlement costs, diversion of resources and other factors, and there can be no assurances that favorable outcomes will be obtained.

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, 2024, there were five 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. Reserved

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 and commercialization of drugs to treat gastrointestinal, or GI, disorders and diseases. Since our inception, we have devoted our efforts to developing our sole product, Gimoti (metoclopramide) nasal spray, the first and only nasally-administered product indicated for the relief of symptoms in adults with acute and recurrent diabetic gastroparesis. In June 2020, we received approval from the U.S. Food and Drug Administration, or FDA, for our 505(b)(2) New Drug Application, or NDA, for Gimoti. We launched commercial sales of Gimoti in the United States in October 2020 through our commercial partner Eversana.

Diabetic gastroparesis is a GI disorder affecting millions of patients worldwide, in which food in an individual's stomach takes too long to empty resulting in a variety of serious GI symptoms and systemic metabolic complications. The gastric delay caused by gastroparesis can compromise absorption of orally administered medications. In May 2023, we reported results from a study conducted by Eversana which showed diabetic gastroparesis patients taking Gimoti had significantly fewer physician office visits, emergency department visits, and inpatient hospitalizations compared to patients taking oral metoclopramide. This overall lower health resource utilization reduced patient and payor costs by approximately $15,000 during a six-month time period for patients taking Gimoti compared to patients taking oral metoclopramide.

In January 2020, we entered into a commercial services agreement with Eversana, or the Eversana Agreement, for the commercialization of Gimoti. Pursuant to the Eversana Agreement, Eversana commercializes and distributes Gimoti in the United States. Eversana also manages the marketing of Gimoti to targeted health care providers, as well as the sales and distribution of Gimoti in the United States. Eversana also provided a $5 million revolving credit facility, or the Eversana Credit Facility, that became available upon FDA approval of the Gimoti NDA. In 2020 we borrowed $5 million under the Eversana Credit Facility, which expires on December 31, 2026, unless terminated earlier pursuant to its terms. As of December 31, 2023, there were approximately $63.5 million in cumulative unreimbursed commercialization costs under the agreement, to be payable only as net product profits are recognized, or upon certain termination events

We have primarily funded our operations through the sale of our convertible preferred stock prior to our initial public offering in September 2013, borrowings from loans and the sale of shares of our common stock on the Nasdaq Capital Market. We launched commercial sales of Gimoti in late October 2020 with Eversana and, to date, have generated modest sales.

We have incurred losses in each year since our inception. These operating losses resulted from expenses incurred in connection with advancing Gimoti through development activities, pre-commercial and commercialization activities, and other general and administrative costs associated with our operations. We expect to continue to incur operating losses until revenues from sales of Gimoti exceed our expenses, if ever. 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, 2023, we had cash and cash equivalents of approximately $4.7 million. Current cash on hand is intended to fund commercialization activities for Gimoti, including manufacturing Gimoti, conducting the post-marketing commitment single dose pharmacokinetics, or PK, clinical trial of Gimoti to characterize dose proportionality of a lower dose strength of Gimoti and any additional development activities should we seek additional indications, protecting our intellectual property portfolio and for other general and administrative costs to support our operations. Our operations have consumed substantial amounts of cash since inception. We believe, based on our current operating plan, that our existing cash and cash equivalents as of December 31, 2023, plus the estimated net proceeds of approximately $6.1 million from the offering we completed in February 2024, as well as cash flows from future net sales of Gimoti, will be sufficient to fund our operations into the fourth quarter of 2024. This period could be shortened if there are any significant increases in planned spending other than anticipated. We anticipate that we will be required to raise additional funds in order to continue as a going concern. 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., ("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 were required to make additional milestone payments totaling up to $52 million. In March 2018, we 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, we would be required to make a single $5 million payment on the one-year anniversary after we receive FDA approval to market Gimoti. At the time of the Gimoti NDA approval by FDA, we recorded the $5 million payable owed to Mallinckrodt, along with a $5 million research and development expense. The $5 million milestone payment was paid in July 2021.

The remaining $47 million in milestone payments depended on Gimoti's commercial success. We were also required to pay to Mallinckrodt a low single digit royalty percentage on net sales of Gimoti. As of December 31, 2023, we have paid Mallinckrodt approximately $134,000 for royalties on net sales of Gimoti. Our obligation to pay such royalties and milestones terminated due to the expiration of the last patent right covering Gimoti transferred under the asset purchase agreement.

Financial Operations Overview

Revenue Recognition

Our ability to generate revenue and become profitable depends on our ability to successfully commercialize Gimoti, which we launched in the United States through prescription in October 2020 through our commercial partner Eversana. If we or Eversana fail to successfully grow sales of Gimoti, we may never generate significant revenues and our results of operations and financial position will be adversely affected.

In accordance with Accounting Standards Codification, or ASC, 606, *Revenue from Contracts with Customers*, we recognize revenue when a customer obtains control of promised goods in an amount that reflects the consideration we expect to receive in exchange for the goods provided. Customer control is determined upon the customer's physical receipt of the product. To determine revenue recognition for arrangements within the scope of ASC 606, we perform the following five steps: identify the contracts with the customer; identify the performance obligations in the contract; determine the transaction price; allocate the transaction price to the performance obligations in the contract; and recognize revenue when (or as) it satisfies a performance obligation. At contract inception, we assess the goods promised within each contract and determine those that are performance obligations and assess whether each promised good is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when the customer obtains control of the product.

Product revenues are recorded net of sales-related adjustments, wherever applicable, including patient support programs, rebates, and other sales related discounts. The Company uses judgment to estimate variable consideration. The Company is subject to rebates under Medicaid and Medicare programs. The rebates for these programs are determined based on statutory provisions. The Company estimates Medicaid and Medicare rebates based on the expected number of claims and related cost associated with the customer transaction.

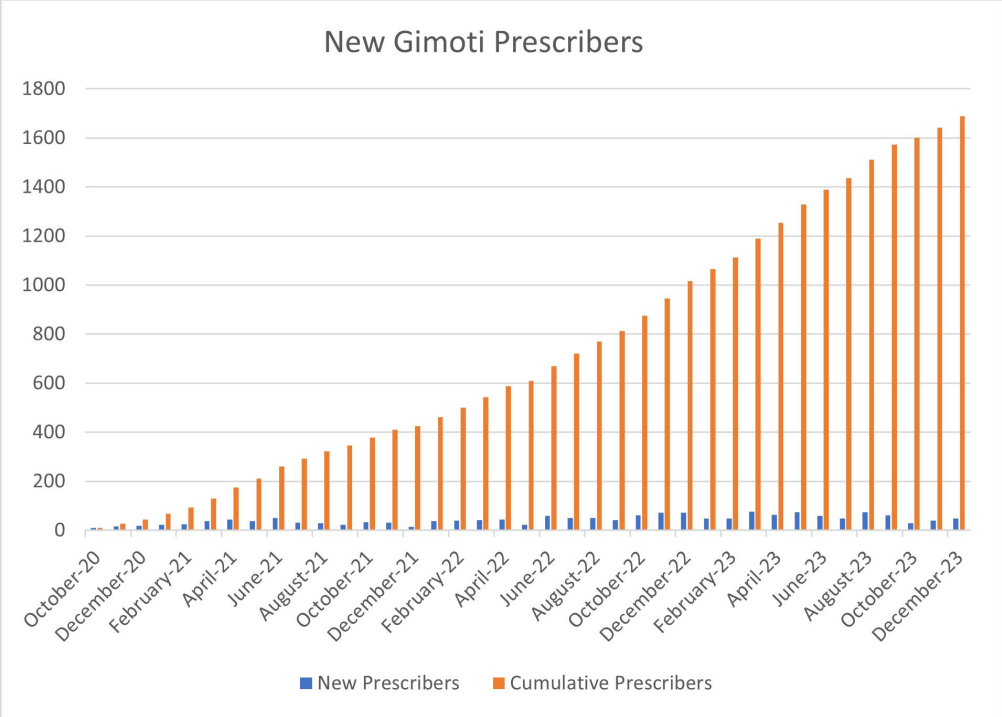
The Company also makes estimates about co-payment assistance to commercially insured patients meeting certain eligibility requirements, as well as to uninsured patients. Co-payment assistance is recorded as an offset to gross revenue at the time revenue from the product sale is recognized based on expected and actual program participation.

Co-pay liabilities are estimated using prescribing data available from customers. Actual amounts of consideration ultimately received may differ from our estimates. If actual results in the future vary from estimates, we will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known. Liabilities for Medicare and Medicaid rebates, as well as co-pay assistance, are classified as accounts payable and accrued expenses in the balance sheets.

Sales of Gimoti Metrics

Gimoti prescriptions, prescribers, and other metrics revenues continue to increase. Net product sales during the year ended December 31, 2023 were approximately $5.2 million compared to net product sales of approximately $2.5 million during the year ended December 31, 2022, an increase of approximately 107%. We began a pilot program with vitaCare Prescription Services, or vitaCare, in February 2022, and fully transitioned to vitaCare in July 2022 which was the exclusive prescription intake system used for Gimoti. As of November 2023, Gimoti pharmacy services were transitioned to ASPN Pharmacy ("ASPN"). This transition was to improve the approval of the Out-Of-Network prescriptions that were increasing across the platform and in conjunction with a transition away from pharmacy services by vitaCare. Although these transitions have created some slowing in managing patients and filling prescriptions, we believe ASPN is now processing inbound prescriptions at a pace that is showing improved patient capture and conversion to reimbursed fills by insurers. The ASPN platform offers a seamless path for filling a prescription, helps patients understand coverage and identify available savings opportunities, and facilitates communications between providers and payors.

There were approximately 1,429 new inbound prescriptions into the vitaCare and ASPN reimbursement centers during the quarter ended December 31, 2023, a 6.7% increase compared to the prior quarter. Patients who have an opportunity to refill the product (that is, patients who have completed their current supply and have additional refills on their prescription) received a refill approximately 79% of the time. We believe some patients choose not to refill their prescriptions due to remission of symptoms. Cumulatively, new prescribers increased 7.4% during the fourth quarter ended December 31, 2023.



The ASPN team accesses the Medicare and Medicaid systems to facilitate product reimbursement submissions for patients seeking treatment. For the year ended December 31, 2023, these government programs made up approximately 33.6% of the filled prescriptions for Gimoti. From the commercial launch of Gimoti through December 31, 2023, the majority of patients have been between the ages of 31 and 65 years old. The vast majority of patients are female and were being treated by a gastroenterologist.

The feedback from the sales organization continues to be positive with regard to physician interest. Although face to face visits by sales team members are more commonplace than during the pandemic, there are offices that continue to not allow face to face meetings apart from designated meeting times. However, when meetings with gastroenterology teams do occur, they generally generate prescriptions and fills. Furthermore, we have detected a pattern within larger gastroenterology teams

that the first physician adopting the use of Gimoti has led other physicians within the same practice to begin prescribing Gimoti as well.

Key Opinion Leaders, or KOLs, are actively presenting data regarding the safety profile for Gimoti. Data presented at Digestive Disease Week indicated a far lower incidence of tardive dyskinesia, or TD, than previously published. This retrospective data was generated from a US based database with over 80 million patient lives. The outcome showed a 0.1% incidence of TD for gastroparesis patients taking any form of metoclopramide

At the May 2023 Digestive Disease Week conference, a head-to-head (oral v. nasal metoclopramide), real world evidence data in 514 patients was presented. Gimoti reduced the likelihood of visiting a physician's office, going to an emergency room (60% reduction), and had fewer inpatient admissions (68% reduction) compared to oral metoclopramide. This was elevated to the top plenary presentation for the conference by the gastroenterology selection committee for the conference. To our knowledge, this study is the first such head-to-head data ever to be presented regarding the product and a clear support for improved outcomes for patients using Gimoti. This data was further validated in October 2023 at the American College of Gastroenterology conference, when the related cost data showed a $15,000 savings for those patients taking Gimoti compared to oral metoclopramide over the six-month index period. This data was also elevated to the plenary presentation by the American College of Gastroenterology selection committee. These data have recently been provided to our commercialization field force to inform physicians and payers of the potential benefits seen in these real-world trials.

Research and Development Expenses

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

- clinical and regulatory-related costs;
- expenses incurred under agreements with contract research organizations, or CROs;
- manufacturing and stability testing costs and related supplies and materials used in clinical trials; 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. Since FDA approval of Gimoti in June 2020, research and development costs have decreased and shifted to commercialization and selling costs. In 2021, we initiated planning, and are in discussion with FDA related to the design, for an FDA post-marketing commitment single dose PK clinical trial of Gimoti to characterize dose proportionality of a lower dosage strength of Gimoti to accommodate patients that may require further dosage adjustments. We are unable to estimate with any certainty the costs we will incur related to this trial, or the regulatory review of such lower dosage of Gimoti, though such costs may be significant and will substantially increase research and development expenses once this trial is initiated. We may also incur additional costs to the extent we pursue additional clinical trials to expand the indication of Gimoti. Clinical development timelines, the probability of success and development costs can differ materially from expectations.

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

- per subject trial costs;
- the number of sites included in the trials;
- 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; and
- the duration of patient follow-up.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of salaries and related benefits, including stock-based compensation. Other selling, 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 selling, general and administrative expenses will increase in the future as we continue to progress with the commercialization of Gimoti and we reimburse Eversana from the net profits attained from the sales of Gimoti.

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.

Revenue Recognition

Our ability to generate revenue and become profitable depends on our ability to successfully commercialize Gimoti, which was launched in the United States through prescription in October 2020 through our commercial partner Eversana. If we or Eversana fail to successfully launch Gimoti and grow and maintain sales, we may never generate significant revenues and our results of operations and financial position will be adversely affected.

In accordance with Accounting Standards Codification, or ASC, 606, *Revenue from Contracts with Customers*, we recognize revenue when a customer obtains control of promised goods in an amount that reflects the consideration we expect to receive in exchange for the goods provided. Customer control is determined upon the customer's physical receipt of the product.

Product revenues are recorded net of sales-related adjustments, wherever applicable, including patient support programs, rebates, and other sales related discounts. We use judgment to estimate variable consideration. We are subject to rebates under Medicaid and Medicare programs. The rebates for these programs are determined based on statutory provisions. We estimate Medicaid and Medicare rebates based on the expected number of claims and related cost associated with the customer transaction.

We also make estimates about co-payment assistance to commercially insured patients meeting certain eligibility requirements, as well as to uninsured patients. Co-payment assistance is recorded as an offset to gross revenue at the time revenue from the product sale is recognized based on expected and actual program participation.

Co-pay liabilities are estimated using prescribing data available from customers. Actual amounts of consideration ultimately received may differ from our estimates. If actual results in the future vary from estimates, we will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known. Liabilities for Medicare and Medicaid rebates, as well as co-pay assistance, are classified as accounts payable and accrued expenses in the balance sheets.

Other Information

Net Operating Loss Carryforwards

As of December 31, 2023, we had federal and state net operating loss carryforwards of approximately $105.8 million and $53.6 million, respectively. The federal and state 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 $43.9 million do not expire and will carry forward indefinitely. As of December 31, 2023, we also had federal and California research and development tax credit carryforwards of $2.4 million and $1.5 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. Pursuant to U.S. tax legislation enacted in December 2017, 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, 2023 and 2022

The following table summarizes the results of our operations for the fiscal years ended December 31, 2023 and 2022:

	Year Ended December 31,		Increase/(Decrease)
	2023	**2022**	
Net product sales	$ 5,180,630	$ 2,508,645	$ 2,671,985
Cost of Goods Sold	$ 201,879	$ 370,394	$ (168,515)
Research and development expense	$ 181,907	$ 300,789	$ (118,882)
Selling general and administrative expense	$ 12,227,735	$ 9,623,599	$ 2,604,136

Net Product Sales. Net product sales for the year ended December 31, 2023 compared to the year ended December 31, 2022 increased by approximately $2.7 million. The increase in product sales during 2023 is due to increased product adoption as commercialization efforts continue, and a greater number of physicians within larger gastroenterology teams prescribing Gimoti after first-physician adoption.

Cost of Goods Sold. Cost of goods sold for the year ended December 31, 2023 compared to the year ended December 31, 2022 decreased by approximately $169,000. The decrease in cost of goods sold during 2023 is due to a reduction in royalty costs of $128,000 due to expiration of the royalty agreement, and a decrease in stability costs of $17,000 and obsolescence expense of approximately $14,000.

Research and Development Expenses. Research and development expenses for the year ended December 31, 2023 compared to the year ended December 31, 2022 decreased by approximately $0.1 million. Costs incurred in 2023 included approximately $170,000 related to stability testing and approximately $12,000 for wages, taxes and employee insurance, including approximately $3,000 of stock-based compensation expense. Costs incurred in 2022 included approximately $261,000 related to stability testing and approximately $37,000 for wages, taxes and employee insurance, including approximately $11,000 of stock-based compensation expense.

Selling, General and Administrative Expenses. Selling, general and administrative expenses for the year ended December 31, 2023 compared to the year ended December 31, 2022 increased by approximately $2.6 million. Costs incurred in 2023 primarily included approximately $4.3 million for wages, taxes, and employee insurance, including approximately $1.1 million of stock-based compensation expense, approximately $5.1 million for marketing and Eversana profit sharing, approximately $2.4 million for legal, accounting, directors and officers liability insurance and other costs associated with being a public company, and $172,000 for facility-related expenses.

Costs incurred in 2022 primarily included approximately $3.8 million for wages, taxes and employee insurance, including approximately $1.4 million of stock-based compensation expense, approximately $2.6 million for legal, accounting, directors and officers liability insurance and other costs associated with being a public company, approximately $2.8 million for marketing, royalties and Eversana profit sharing, and $188,000 for facility-related expenses.

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.

In connection with the Eversana Agreement, we entered into the Eversana Credit Facility, pursuant to which Eversana agreed to provide a revolving credit facility of up to $5 million to us upon FDA approval of the Gimoti NDA, as well as certain other customary conditions. The Eversana Credit Facility terminates on December 31, 2026, unless terminated earlier pursuant to its terms. 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%, with such interest due at the end of the loan term. In 2020 we borrowed $5 million from the Eversana Credit Facility.

In February 2024, we sold 5,134,731 common stock units (the "Common Stock Units"), at a public offering price of $0.68 per Common Stock Unit and, to certain investors, 5,894,680 pre-funded warrant units (the "PFW Units"), at a public offering price of $0.6799 per PFW Unit. Each Common Stock Unit consists of (i) one share of common stock, (ii) a Series A Warrant to purchase one share of common stock (the "Series A Warrant"), (iii) a Series B Warrant to purchase one share of common stock (the "Series B Warrant"), and (iv) a Series C Warrant to purchase one share of common stock (the "Series C Warrant"). Each PFW Unit consists of (i) a pre-funded warrant to purchase one share of common stock, (ii) a Series A Warrant, (iii) a Series B Warrant, and (iv) a Series C Warrant. After deducting underwriting discounts and commissions and offering expenses paid by us, the estimated net proceeds to us from this offering were approximately $6.1 million.

The Pre-Funded Warrants have an exercise price of $0.0001 per share. The Series A Warrants, Series B Warrants and the Series C Warrants have an exercise price of $0.68 per share. The Pre-Funded Warrants, Series A Warrants and Series B Warrants are exercisable immediately. The Series C Warrants are subject to a vesting schedule and may only be exercised to the extent and in proportion to a holder of the Series C Warrants exercising its corresponding Series B Warrants. The Series A Warrants will expire on February 13, 2029, which is five years from the date of issuance. The Series B Warrants will expire on November 13, 2024, which is nine months from the date of issuance. The Series C Warrants will also expire on November 13, 2024, provided that to the extent and in proportion to a holder of the Series C Warrants exercising its corresponding Series B Warrants included in the applicable unit, such Series C Warrant will expire on February 13, 2029.

We concluded that there is substantial doubt about 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 issuance of the financial statements could materially limit our ability to raise additional funds through the issuance of new debt or equity securities or otherwise. We have incurred significant losses since our inception and have never been profitable, and it is possible we will never achieve profitability. We believe, based on our current operating plan, that our cash and cash equivalents as of December 31, 2023 of approximately $4.7 million, plus the estimated net proceeds of approximately $6.1 million from the offering we completed in February 2024, as well as future cash flows from net sales of Gimoti, will be sufficient to fund our operations into the fourth quarter of 2024. This period could be shortened if there are any significant increases in planned spending on commercialization activities, including for marketing and manufacturing of Gimoti, and our selling, general and administrative costs to support operations, including as a result of any termination of the Eversana Agreement. As of December 31, 2023, Eversana and Evoke each had the right to exercise the Net Profit Quarterly Termination Right, which either party could have done until February 29, 2024, which was the end of the 60-day period following the end of the quarter. Each party will continue to have the option to exercise this termination right for the 60-day period following the end of future quarters so long as the net profit under the agreement remains negative for consecutive quarters. If the Net Profit Quarterly Termination Right is exercised, the outstanding principal and interest under the Eversana Credit Facility would be due within 90 days after the effective date of such termination. This would materially and adversely affect our near-term liquidity needs and cash runway. We anticipate we will be required to raise additional funds in order to continue as a going concern. 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.

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.

On December 29, 2021, 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 June 27, 2022, to regain compliance. The letter states that Nasdaq will provide written notification that we have achieved compliance with its rules if at any time before June 27, 2022, the bid price of our common stock closes at $1.00 per share or more for a minimum of ten consecutive business days. 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.

On April 27, 2022, our stockholders granted the board of directors the authority to effect a reverse stock split of our outstanding common stock. On May 23, 2022, we effected a 1-for-12 reverse stock split of the shares of our common stock, or the Reverse Stock Split. The par value and the authorized shares of the common stock were not adjusted as a result of the Reverse Stock Split. All of our issued and outstanding common stock, warrants to purchase common stock, and options to purchase common stock have been adjusted to reflect the Reverse Stock Split.

On June 7, 2022, we received notice from Nasdaq stating that the closing price of our common stock has been $1.00 per share or greater for the prior ten consecutive business days and that we had regained compliance with the minimum $1.00 per share requirement.

On May 24, 2023, we received a written notice from Nasdaq indicating that, based on our stockholders' equity of $2.1 million as of March 31, 2023, as reported in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, we were not in compliance with the minimum stockholders' equity requirement for continued listing on The Nasdaq Capital Market under Nasdaq Listing Rule 5550(b)(1), or the Minimum Stockholders' Equity Requirement. As required by Nasdaq, we submitted our plan to regain compliance with the Minimum Stockholders' Equity Requirement and Nasdaq granted us an extension until November 20, 2023 to regain compliance. Following notice on November 21, 2023 from Nasdaq that we had not met the Minimum Stockholders' Equity Requirement, we requested a hearing before the Nasdaq Hearings Panel, or the Hearings Panel, and on December 9, 2023, Nasdaq notified the Company that the hearing was scheduled for February 15, 2024. On February 15, 2024, we had the hearing before the Hearings Panel. There can be no assurance that the Hearings Panel will grant our request for continued listing or that we will be able to evidence compliance prior to the expiration of any extension that may be granted by the Hearings Panel. As of the date of this Annual Report, the Hearings Panel has not issued a ruling.

On February 21, 2024, 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 August 19, 2024, to regain compliance. The letter states that Nasdaq will provide written notification that we have achieved compliance with its rules if at any time before August 19, 2024, the bid price of our common stock closes at $1.00 per share or more for a minimum of ten consecutive business days. 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 expect to continue to incur expenses as we:

- continue the commercial activities for Gimoti;
- manufacture Gimoti;
- conduct the post-marketing commitment single dose PK clinical trial of Gimoti and any additional development activities should we seek additional indications;
- maintain, expand and protect our intellectual property portfolio; and
- continue to fund the 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, 2023 and 2022:

	Year Ended December 31,		Increase/(Decrease)
	2023	2022	
Net cash used in operating activities	$ (4,984,977)	$ (6,595,987)	$ 1,611,010
Net cash (used)/ provided by financing activities	$ (119,296)	$ 7,294,976	$ (7,414,272)
Net (decrease)/increase in cash and cash equivalents	$ (5,104,273)	$ 698,989	$ (5,803,262)

Operating Activities. The primary use of our cash has been to fund our commercial sales of Gimoti and clinical research, prepare our NDA, manufacture Gimoti, and other general operations. The cash used in operating activities during the year ended December 31, 2023 and 2022 was primarily related to commercialization activities for Gimoti. We expect that cash used in operating activities during 2024 will be consistent with 2023 results because growing sales will offset costs incurred due to commercialization activities, including manufacturing Gimoti, and the planned post-marketing commitment to conduct a single dose PK clinical trial of Gimoti to characterize dose proportionality of a lower dose strength of Gimoti.

Financing Activities. During the year ended December 31, 2023, cash used by financing activities of $0.1 million was due to payment of costs related to the February 2024 public offering of our stock. During the year ended December 31, 2022, we received net proceeds of approximately $7.3 million from the sale of 621,697 shares of common stock pursuant to the ATM Sales Agreement.

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

- the costs of commercialization activities, including costs associated with commercial manufacturing;
- the commercial success of Gimoti, including competition with well-established products approved earlier by FDA, including oral and intravenous forms of metoclopramide, the same active ingredient in the nasal spray for Gimoti;
- our ability to manufacture sufficient quantities of Gimoti to meet demand, including whether our contract manufacturers, suppliers, and/or consultants are able to meet appropriate timelines;
- the progress and costs of the post-marketing commitment to conduct a single dose PK clinical trial of Gimoti to characterize dose proportionality of a lower dose strength of Gimoti and the costs of any additional clinical trials we may pursue to expand the indication of Gimoti;
- our ability to obtain, maintain and enforce our patents and other intellectual property rights, and the costs incurred to do so;
- the terms and timing of any collaborative, licensing, co-promotion or other arrangements that we may establish;
- costs associated with any other product candidates that we may develop, in-license or acquire; and
- the impact of the COVID-19 pandemic on us or on third parties on whom we rely;

Off-Balance Sheet Arrangements

Through December 31, 2023, 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, December 2019, December 2020, February 2022, and August 2022 and expired on October 31, 2023. In October 2023, we entered into a new operating lease for office space in Solana Beach that expires on October 31, 2024. We also pay pass through costs and utility costs, which are expensed as incurred.

As of December 31, 2023, future minimum lease payments for our facility lease are approximately $63,000.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

As a smaller reporting company, we are not required to provide the information required by this Item.

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 Operating 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, 2023 we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Operating 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 Operating Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2023.

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 Operating 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 our assets that could have a material effect on the financial statements.

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

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 Operating 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, 2023, 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, 2022 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

From time to time, our officers (as defined in Rule 16a-1(f) of the Exchange Act) and directors may enter into Rule 10b5-1 or non-Rule 10b5-1 trading arrangements (as each such term is defined in Item 408 of Regulation S-K). During the three months ended December 31, 2023, none of our officers or directors adopted, modified or terminated any such trading arrangements.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

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 2024 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, 2023, 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, P.C., 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

Shareholders and Board of Directors
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, 2023 and 2022, the related statements of operations, stockholders' equity (deficit), and cash flows for each of the years then ended, 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, 2023 and 2022, and the results of its operations and its cash flows for each of the years then ended**,** 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 and negative cash flows from operations since inception. 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.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Revenue under the Eversana Agreement

As described in Notes 2 and 7 to the financial statements, the Company's product Gimoti is commercialized through the Company's commercial partner. The Company recognizes revenue when a customer obtains control of promised goods in an amount that reflects the consideration the Company expects to receive in exchange for goods provided.

We identified the auditing of revenue under the Eversana Agreement as a critical audit matter. The principal consideration that led to our determination is evaluating the sales quantity information of prescriptions processed by service providers that is used for recording revenue transactions. Auditing the Company's revenue was especially challenging due to the nature of audit evidence and the extent of audit effort required to address this matter.

The primary procedures we performed to address this critical audit matter included:

- Confirming the sales quantity of prescriptions processed with certain service providers that fulfill orders and comparing that to information provided by Eversana.
- Evaluating the sales quantity of prescriptions processed through verification of beginning and ending inventory balances and testing the movement of inventory during the year to ensure quantities of prescriptions processed agree to sales quantity information provided by Eversana.

/s/ BDO USA, P.C.

We have served as the Company's auditor since 2014.
San Diego, California
March 14 , 2024

Evoke Pharma, Inc.

Balance Sheets

	December 31,	
	2023	**2022**
Assets		
Current Assets:		
Cash and cash equivalents	$ 4,739,426	$ 9,843,699
Accounts receivable	673,071	624,832
Prepaid expenses	885,040	952,954
Inventory	481,840	289,378
Other current assets	47,532	11,551
Total current assets	6,826,909	11,722,414
Deferred offering costs	241,637	-
Operating lease right-of-use asset	-	129,074
Total assets	$ 7,068,546	$ 11,851,488
Liabilities and stockholders' equity (deficit)		
Current Liabilities:		
Accounts payable and accrued expenses	$ 1,711,778	$ 934,312
Accrued compensation	1,324,010	591,158
Operating lease liability	-	129,074
Total current liabilities	3,035,788	1,654,544
Long-term Liabilities:		
Note payable	5,000,000	5,000,000
Accrued interest payable	1,612,295	1,112,295
Total long-term liabilities	6,612,295	6,112,295
Total liabilities	9,648,083	7,766,839
Commitments and contingencies (Note 3)		
Stockholders' equity (deficit):		
Preferred stock, $0.0001 par value; authorized shares — 5,000,000 at December 31, 2023 and 2023; issued and outstanding shares — 0 at December 31, 2023 and 2022 respectively	-	-
Common stock, $0.0001 par value; authorized shares — 50,000,000 at December 31, 2023 and 2022; issued and outstanding shares — 3,343,070 at December 31, 2023 and 2022, respectively	334	334
Additional paid-in capital	120,859,567	119,731,458
Accumulated deficit	(123,439,438)	(115,647,143)
Total stockholders' equity (deficit)	(2,579,537)	4,084,649
Total liabilities and stockholders' equity (deficit)	$ 7,068,546	$ 11,851,488

See accompanying notes.

Evoke Pharma, Inc.

Statements of Operations

	Year Ended December 31,	
	2023	**2022**
Net product sales	$ 5,180,630	$ 2,508,645
Operating expenses:		
Cost of goods sold	201,879	370,394
Research and development	181,907	300,789
Selling, general and administrative	12,227,735	9,623,599
Total operating expenses	12,611,521	10,294,782
Loss from operations	(7,430,891)	(7,786,137)
Other income (expense):		
Interest income	138,596	62,007
Interest expense	(500,000)	(500,000)
Total other income (expense)	(361,404)	(437,993)
Net loss	$ (7,792,295)	$ (8,224,130)
Net loss per share of common stock, basic and diluted	$ (2.33)	$ (2.62)
Weighted-average shares used to compute basic and diluted net loss per share	3,343,070	3,143,626

See accompanying notes.

Evoke Pharma, Inc.

Statements of Stockholders' Equity (Deficit)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount			
Balance at December 31, 2021	2,721,373	$ 272	$ 110,977,835	$ (107,423,013)	$ 3,555,094
Stock-based compensation expense	-	-	1,458,709	-	1,458,709
Issuance of common stock from ATM, net of costs of $148,993	621,697	62	7,294,914	-	7,294,976
Net loss	-	-	-	(8,224,130)	(8,224,130)
Balance at December 31, 2022	3,343,070	334	119,731,458	(115,647,143)	4,084,649
Stock-based compensation expense	-	-	1,128,109	-	1,128,109
Net loss	-	-	-	(7,792,295)	(7,792,295)
Balance at December 31, 2023	3,343,070	$ 334	$ 120,859,567	$ (123,439,438)	$ (2,579,537)

See accompanying notes.

Evoke Pharma, Inc.

Statements of Cash Flows

	Year Ended December 31,	
	2023	**2022**
Operating activities		
Net loss	$ (7,792,295)	$ (8,224,130)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash lease expense	129,074	37,025
Stock-based compensation expense	1,128,109	1,458,709
Change in operating assets and liabilities:		
Accounts receivable	(48,239)	(329,639)
Prepaid expenses and other assets	31,932	(29,208)
Inventory	(192,462)	(103,843)
Accounts payable and accrued expenses	655,126	60,284
Accrued compensation	732,852	71,840
Accrued interest payable	500,000	500,000
Operating lease liabilities	(129,074)	(37,025)
Net cash used in operating activities	(4,984,977)	(6,595,987)
Financing activities		
Proceeds from issuance of common stock from ATM	-	7,443,969
Payment of ATM offering costs	-	(148,993)
Cash paid for offering costs	(119,296)	-
Net cash (used)/provided by financing activities	(119,296)	7,294,976
Net (decrease)/ increase in cash and cash equivalents	(5,104,273)	698,989
Cash and cash equivalents at beginning of period	9,843,699	9,144,710
Cash and cash equivalents at end of period	$ 4,739,426	$ 9,843,699
Non-cash financing activities		
Public offering costs included in accounts payable and accrued expenses	$ 122,340	$ -
Operating lease right-of-use asset obtained in exchange for operating lease liabilities	$ -	$ 153,671

See accompanying notes.

Evoke Pharma, Inc.

Notes to Financial Statements

1. Organization and Basis of Presentation

Evoke Pharma, Inc. (the "Company") was incorporated under the laws of 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 its efforts to developing its sole product, Gimoti (metoclopramide) nasal spray, the first and only nasally-administered product indicated for the relief of symptoms in adults with acute and recurrent diabetic gastroparesis. On June 19, 2020, the Company received approval from the U.S. Food and Drug Administration ("FDA") for its 505(b)(2) New Drug Application ("NDA") for Gimoti. The Company launched U.S. commercial sales of Gimoti in October 2020 through its commercial partner Eversana Life Science Services, LLC ("Eversana").

The Company's activities are subject to the significant risks and uncertainties associated with any specialty pharmaceutical company that has launched its first commercial product, including market acceptance of the product and the potential need to obtain additional funding for its operations.

Going Concern

The financial statements have been prepared assuming the Company will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has 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. The Company ended 2023 with approximately $4.7 million in cash and cash equivalents, plus the estimated net proceeds of approximately $6.1 million from the offering we completed in February 2024 as described in the subsequent event note. The Company anticipates that it will continue to incur losses from operations due to commercialization activities, including manufacturing Gimoti, conducting the post-marketing commitment single-dose pharmacokinetics ("PK") clinical trial of Gimoti to characterize dose proportionality of a lower dose strength of Gimoti, and for other general and administrative costs to support the Company's operations. Additionally, if Eversana were to terminate the Commercial Services and Loan Agreement as described in Note 7, the principal and interest on the Loan, $6.6 million as of December 31, 2023, becomes due in 90 days. 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 Company's net losses may fluctuate significantly from quarter to quarter and year to year. The Company anticipates that it 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 commercialization activities. 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 successfully commercialize Gimoti. Because the Company's business is entirely dependent on the success of Gimoti, if the Company is unable to secure additional financing, successfully commercialize Gimoti or identify and execute on 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 and Reverse Stock Split

On December 29, 2021, the Company 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, the Company was provided an initial period of 180 calendar days, or until June 27, 2022, to regain compliance. The letter stated that Nasdaq will provide written notification that the Company has achieved compliance with its rules if at any time before June 27, 2022 the bid price of the Company's common stock closes at $1.00 per share or more for a minimum of ten consecutive business days. 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.

On April 27, 2022, the Company's stockholders granted the board of directors the authority to effect a reverse stock split of the Company's outstanding common stock. On May 23, 2022 the Company effected a 1-for-12 reverse stock split of the shares of the Company's common stock (the "Reverse Stock Split"). The par value and the authorized shares of the common

stock were not adjusted as a result of the Reverse Stock Split. All of the Company's issued and outstanding common stock, warrants to purchase common stock, and options to purchase common stock have been retroactively adjusted to reflect the Reverse Stock Split for all periods presented.
On June 7, 2022, the Company received notice from Nasdaq stating that the closing price of the Company's common stock had been at $1.00 per share or greater for the prior ten consecutive business days and that the Company had regained compliance with the minimum $1.00 per share requirement.

On May 24, 2023, the Company received a written notice from Nasdaq indicating that, based on the Company's stockholders' equity of $2.1 million as of March 31, 2023, as reported in the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, the Company was not in compliance with the minimum stockholders' equity requirement for continued listing on The Nasdaq Capital Market under Nasdaq Listing Rule 5550(b)(1) (the "Minimum Stockholders' Equity Requirement"). As required by Nasdaq, the Company submitted its plan to regain compliance with the Minimum Stockholders' Equity Requirement and Nasdaq granted the Company an extension until November 20, 2023 to regain compliance. Following notice on November 21, 2023 from Nasdaq that the Company had not met the Minimum Stockholders' Equity Requirement, the Company requested a hearing before the Nasdaq Hearings Panel (the "Hearings Panel") and on December 9, 2023, Nasdaq notified the Company that the hearing was scheduled for February 15, 2024. On February 15, 2024, the Company had the hearing before the Hearings Panel. There can be no assurance that the Hearings Panel will grant our request for continued listing or that we will be able to evidence compliance prior to the expiration of any extension that may be granted by the Hearings Panel. As of the date of this Annual Report, the Hearings Panel has not issued a ruling.

On February 21, 2024, 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 August 19, 2024, to regain compliance. The letter states that Nasdaq will provide written notification that the Company has achieved compliance with its rules if at any time before August 19, 2024, the bid price of the Company's common stock closes at $1.00 per share or more for a minimum of ten consecutive business days. 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.

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 revenues and 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 ("CODM") 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. The Company's cash equivalents are classified as Level 1 inputs within the fair value hierarchy.

Fair Value of Financial Instruments

The carrying amounts of all financial instruments, including accounts receivable and accounts payable and accrued expenses, are considered to be representative of their respective fair values because of the short-term nature of those instruments. The carrying value of other short-term and long-term borrowings approximates fair value based upon interest rates the Company believes it can currently obtain for similar debt, which is a Level 2 input within the fair value hierarchy.

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 activities. If the CROs and consultants are unable to continue their support, this could adversely affect the Company's operations.

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, and the development and/or commercialization of Gimoti could be materially and adversely affected.

The Company also relies on a dedicated third-party sales team to sell Gimoti. If such third-party organization is unable to continue serving as a dedicated sales team, the commercialization of Gimoti could be materially and adversely affected.

Accounts Receivable and Allowance for Credit Losses

Accounts receivable are recorded net of allowance for credit losses. The Company evaluates the collectability of accounts receivable based on a combination of factors, including specific circumstances that may impair a customer's ability to pay and historical payment patterns. The allowance for credit losses was zero at December 31, 2023 and December 31, 2022, and no bad debt expense was recorded for the years ended December 31, 2023 and December 31, 2022.

Inventory

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 depends on third-party contract manufacturers for all of its required raw materials, drug substance and finished product for its commercial manufacturing. The Company has agreements with Cosma S.p.A. to supply metoclopramide for the manufacture of Gimoti, and with Thermo Fisher Scientific Inc., through its subsidiary Patheon UK Limited, for the manufacturing of Gimoti. The Company currently utilizes third-party consultants, which it engages on an as-needed, hourly basis, to manage the manufacturing contractors.

Subsequent to FDA approval, the Company began manufacturing Gimoti for commercialization and began capitalizing inventory at that time. The Company's inventory consisted of approximately $361,000 and $239,000 of raw materials at December 31, 2023 and December 31, 2022, respectively, and approximately $121,000 and $50,000 of finished goods inventory at December 31, 2023 and December 31, 2022, respectively. Inventories are stated at the lower of cost (first-in first-out basis) or net realizable value. The Company's raw materials inventory is held at its third-party suppliers and its work-in-process and finished goods inventory is held at its manufacturer and at Eversana. The Company records such inventory as consigned inventory.

Deferred Offering Costs

Deferred offering costs represent legal, accounting and other direct costs related to the public offering that was completed in February 2024. All deferred offering costs were reclassified to additional paid-in capital in February 2024. The Company recorded approximately $242,000 and zero deferred offering costs as a non-current asset in the accompanying balance sheets as of December 31, 2023 and 2022, respectively.

Revenue Recognition

The Company's ability to generate revenue and become profitable depends on its ability to successfully commercialize Gimoti, which was launched in the United States in October 2020 through the Company's commercial partner Eversana. If the Company or Eversana fail to successfully grow and maintain sales of Gimoti, the Company may never generate significant revenues and its results of operations and financial position will be adversely affected.

In accordance with Accounting Standards Codification ("ASC") 606, *Revenue from Contracts with Customers*, the Company recognizes revenue when a customer obtains control of promised goods in an amount that reflects the consideration the Company expects to receive in exchange for the goods provided. Customer control is determined upon the customer's physical receipt of the product. To determine revenue recognition for arrangements within the scope of ASC 606, the Company performs the following five steps: identify the contracts with the customer; identify the performance obligations in the contract; determine the transaction price; allocate the transaction price to the performance obligations in the contract; and recognize revenue when (or as) it satisfies a performance obligation. At contract inception, the Company assesses the goods promised within each contract and determines those that are performance obligations and assesses whether each promised

good is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when the customer obtains control of the product.

Product revenues are recorded net of sales-related adjustments, wherever applicable, including patient support programs, rebates, and other sales related discounts. The Company uses judgment to estimate variable consideration. The Company is subject to rebates under Medicaid and Medicare programs. The rebates for these programs are determined based on statutory provisions. The Company estimates Medicaid and Medicare rebates based on the expected number of claims and related cost associated with the customer transaction. Medicaid and Medicare rebates of $46,000 were recorded as accounts payable and accrued expenses on the balance sheet as of December 31, 2023, and $13,000 was recorded as a reduction to Accounts Receivable as of December 31, 2022.

Co-payment assistance is recorded as an offset to gross revenue at the time revenue from the product sale is recognized based on expected and actual program participation. Co-pay liabilities are estimated using prescribing data available from customers. The Company's analysis also contemplated application of the constraint in accordance with the guidance, under which it determined a significant reversal of revenue would not occur in a future period. If actual results in the future vary from estimates, the Company will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known. Liabilities for co-pay assistance of approximately $66,000 at each of December 31, 2023 and December 31, 2022, are classified as accounts payable and accrued expenses in the balance sheets.

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, except awards with a performance condition. Awards with a performance condition commence vesting when the satisfaction of the performance condition is probable. 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. Expected volatility was calculated based on historical volatility of the Company's common stock. The assumed dividend yield was based on the Company never paying cash dividends and having no expectation of paying cash dividends in the foreseeable future. The Company accounts for forfeitures as the forfeitures occur.

Research and Development Expenses

Research and development costs are expensed as incurred and primarily include compensation and related benefits, stock-based compensation expense, costs paid to third-party contractors for product development activities and drug product materials, and technology acquisition milestones. The Company will expense the clinical, regulatory and manufacturing costs related to the post-marketing commitment to conduct a single dose PK clinical trial of Gimoti to characterize dose proportionality of a lower dose strength of Gimoti, as well as other costs that may occur for any additional clinical trials the Company may pursue to expand the indication of Gimoti.

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. Diluted net loss per share is calculated by dividing the net loss by the weighted-average number of common stock and common stock equivalents outstanding for the period

determined using the treasury-stock method. Dilutive common stock equivalents are comprised of warrants to purchase common stock and options to purchase common stock under the Company's equity incentive plan.

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 for the years ended December 31, 2023 and 2022:

	Year Ended December 31,	
	2023	2022
Common stock options	624,232	491,851
Total excluded securities	624,232	491,851

Recently Adopted Accounting Pronouncements

In June 2016, the Financial Accounting Standards Board, ("FASB") issued ASU 2016-13, *Financial Instruments – Credit Losses: Measurement of Credit Losses on Financial Instruments*, which amended the impairment model by requiring entities to use a forward-looking approach based on expected losses to estimate credit losses on certain types of financial instruments, including trade receivables and available-for-sale debt securities. This update was effective for annual periods beginning after December 15, 2022. The adoption of this new standard did not have a material impact on the Company's financial statements.

Recently Issued Accounting Pronouncements — Not Yet Adopted

In November 2023, the FASB issued ASU 2023-07, Segment Reporting (Topic 280) Improvements to Reportable Segment Disclosures ("Topic 280"), which modifies the disclosure and presentation requirements of reportable segments. The amendments in the update require the disclosure of significant segment expenses that are regularly provided to the CODM and included within each reported measure of segment profit and loss. The amendments also require disclosure of all other segment items by reportable segment and a description of its composition. Additionally, the amendments require disclosure of the title and position of the CODM and an explanation of how the CODM uses the reported measure(s) of segment profit or loss in assessing segment performance and deciding how to allocate resources. Lastly, the amendment requires that a public entity that has a single reportable segment provide all the disclosures required by ASU 2023-07 and all existing segment disclosures in Topic 280. This update is effective for annual periods beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. Early adoption is permitted. The Company is currently evaluating the impact that this guidance will have on the presentation of its financial statements and accompanying notes.

In December 2023, the FASB issued ASU No. 2023-09 ("ASU 2023-09"), "Improvements to Income Tax Disclosures." ASU 2023-09 requires disaggregated information about a reporting entity's effective tax rate reconciliation as well as information on income taxes paid. ASU 2023-09 is effective for public entities with annual periods beginning after December 15, 2024 and for private businesses for annual periods beginning after December 15, 2025, with early adoption permitted. The Company is currently evaluating the impact of this guidance on its financial statement disclosures.

3. Commitments and Contingencies

Leases

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, December 2019, December 2020, February 2022, and August 2022 and expired on October 31, 2023. 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. The Company noted that the implicit rate in the lease was not determinable and calculated its incremental borrowing rate of 10% upon execution of the lease. In October 2023, the Company entered into a 12-month lease agreement for office space in Solana Beach, effective November 1, 2023, that expires on October 31, 2024.

Leases with an initial term of 12 months or less are not recorded on the balance sheet and operating lease expense for these leases are recognized on a straight-line basis over the lease term as general and administrative expense within the accompanying financial statements. The operating lease expense of $154,000 and $150,000 is included in the general and administrative expense for the years ended December 31, 2023 and 2022, respectively. The cash paid for the operating leases was $146,000 and $39,000 for the years ended December 31, 2023 and 2022, respectively.

As of December 31, 2023, the Company has future minimum lease payments under its existing facility lease of approximately $63,000 payable in 2024. The remaining lease term was 0.83 years as of December 31, 2023 and December 31, 2022, respectively.

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. At the time of the Gimoti NDA approval, the Company recorded the $5 million payable owed to Mallinckrodt, along with a $5 million research and development expense. The $5 million milestone payment was paid in July 2021.

The remaining $47 million in milestone payments depended on Gimoti's commercial success. The Company was required to pay Mallinckrodt a low single digit royalty percentage on net sales of Gimoti. As of December 31, 2023, the Company has paid Mallinckrodt approximately $134,000 in royalties on net sales of Gimoti. The Company's obligation to pay such royalties and milestones terminated due to the expiration of the last patent right covering Gimoti transferred under the asset purchase agreement.

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, 2023 or 2022.

Common Stock

As of December 31, 2023, there were 3,343,070 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.

At the Market Equity Offering Program

In December 2020, the Company filed a shelf registration statement with the SEC on Form S-3 (the "shelf registration statement") which was declared effective by the SEC on January 6, 2021. In December 2020, the Company also entered into an At Market Issuance Sales Agreement (the "ATM Sales Agreement"), with B. Riley FBR, Inc. ("FBR") and H.C. Wainwright & Co. (together with FBR, the "Sales Agents"), pursuant to which the Company was able to sell from time to time, at its option, up to an aggregate of $30 million worth of shares of the Company's common stock through the Sales Agents. No shares were sold during the year ended December 31, 2023. During the year ended December 31, 2022, the Company sold 621,697 shares of common stock at a weighted-average price per share of $11.97 pursuant to the ATM Sales Agreement and received proceeds of approximately $7.3 million, net of commissions and fees.

The shelf registration statement, including the prospectus related to the ATM Sales Agreement, expired on January 6, 2024.

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.

During 2023, there were no outstanding warrants to purchase shares of common stock. During 2022, no warrants were exercised and warrants to purchase 139,972 shares of common stock expired.

Equity Incentive Award Plans

In August 2013, the Company adopted the 2013 Equity Incentive Award Plan (the "2013 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. Since its adoption, the Company's stockholders have amended and restated the 2013 Plan. As of May 2023, the Company's stockholders increased the number of shares of common stock authorized for issuance under the 2013 Plan to an aggregate of 1,194,717 shares and extended the term of the 2013 Plan to March 2033. In addition, the number of shares available for issuance is annually increased on the first day of each fiscal year by that number of shares equal to the least of (a) six 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 50,000,000 shares.

As a result of the annual increases since the 2013 Plan originated, and the increase of stock options reserved under the restatements of the 2013 Plan approved by the Company's stockholders through May 2023, the Company has increased the number shares reserved for issuance under the 2013 Plan by 1,352,800 shares. As of December 31, 2023, 547,838 options remain available for future grant under the 2013 Plan. On January 1, 2024, the Company further increased the number of shares reserved for issuance under the 2013 Plan by 200,584 shares, making 748,422 options available for future grant under the 2013 Plan.

Options granted under the 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 153,750 and 78,247 shares of common stock in 2023 and 2022, respectively. The exercise price of all options granted during the years ended December 31, 2023 and 2022 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 2013 Plan is as follows:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2022	491,851	$ 19.11	7.22	
Granted	153,750	$ 3.07	9.23	
Expired	(21,369)	$ 45.78	-	
Outstanding at December 31, 2023	624,232	$ 14.25	7.05	-
Vested and expected to vest at December 31, 2023	624,232	$ 14.25	7.05	-
Exercisable at December 31, 2023	418,591	$ 14.64	6.23	-

The aggregate intrinsic values of outstanding options are calculated as the difference between the exercise price of the underlying options and the closing price of our common stock of $1.05 at December 31, 2023.

The weighted average grant date fair value per share of employee stock options granted during the years ended December 31, 2023 and 2022, was $2.42 and $4.86, respectively.

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 2,500 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) 2,500 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 8,333 shares (to an aggregate of 20,833 shares), to increase the annual evergreen provision from 2,500 shares to 8,333 shares, and to extend the term of the ESPP into 2027. In May 2023, 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 170,833 shares), and to increase the annual evergreen provision by the lesser of (a) one percent of the outstanding shares of common stock on the last day of the immediately preceding calendar year, or (b) such other amount determined by the Company's board of directors, and to extend the term of the ESPP into 2033. The Company has increased the number shares reserved for issuance under the ESPP by 168,333 shares since the inception of the ESPP. As of December 31, 2023, 145,381 shares remain available for future issuance under the ESPP. On January 1, 2024, the Company further increased the number of shares reserved for future issuance under the ESPP by 33,430 shares, making 178,811 shares available for future issuance under the ESPP after that increase.

No shares of common stock were issued through the ESPP during 2023 and 2022.

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 assumptions for option grants during the years ended December 31, 2023 and 2022:

	Year Ended December 31,	
	2023	**2022**
Risk free interest rate	1.34%-3.39%	1.67%-3.55%
Expected option term	5.5- 6.0 years	5.5- 6.0 years
Expected volatility of common stock	99.34%- 103.64%	97.04%- 113.23%
Expected dividend yield	0.0%	0.0%

The Company recognized 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, 2023 and 2022 as follows:

	Year Ended December 31,	
	2023	**2022**
Research and development	$ 2,840	$ 11,278
Selling, general and administrative	1,125,269	1,447,431
Total stock-based compensation expense	$ 1,128,109	$ 1,458,709

As of December 31, 2023, there was approximately $1.1 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 0.75 years.

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance consists of the following:

	December 31,	
	2023	**2022**
Stock options issued and outstanding	624,232	491,851
Authorized for future option grants	547,838	146,497
Authorized for employee stock purchase plan	145,381	37,048
Total common stock reserved for future issuance	1,317,451	675,396

6. 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, 2023 and 2022, the Company adopted Safe Harbor 401(k) provisions. A contribution of $3,000 was required to be made to the accounts of employees for the year ended December 31, 2023 in order to maintain the Plan's compliance with Internal Revenue Service regulations. No contributions were made during 2022.

7. Commercial Services and Loan Agreements with Eversana

On January 21, 2020, the Company entered into a commercial services agreement (as amended, the "Eversana Agreement") with Eversana for the commercialization of Gimoti. Pursuant to the Eversana Agreement, Eversana commercializes and distributes Gimoti in the United States. Eversana also manages the marketing of Gimoti to targeted health care providers, as well as the sales and distribution of Gimoti in 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 both parties' costs are reimbursed. For the years ended December 31, 2023 and 2022, approximately $4.4 million and $2.0 million of Eversana profit sharing costs were included as selling, general and administrative costs, respectively. As of December 31, 2023, unreimbursed commercialization costs to Eversana were approximately $63.5 million. Such costs will generally be payable only as net product profits are recognized. 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. On February 1, 2022, the Eversana Agreement was amended to extend the term from June 19, 2025 (five years from the date the Food & Drug Administration approved the Gimoti new drug application) to December 31, 2026, unless terminated earlier pursuant to its terms. This amendment also increased the percentage of net product profit retained by the Company and increased the proportion of costs that are reimbursed to Eversana to the extent Eversana has accumulated unreimbursed costs.

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; if the Company discontinues the development or production of Gimoti; if the net profit is negative for any two consecutive calendar quarters beginning with the first full calendar quarter 24 months following commercial launch; if the cumulative net product profits fail to reach certain thresholds in the first three years following 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.

As of December 31, 2023, either party has the right to exercise the Net Profit Quarterly Termination Right, which it may do for a 60-day period following the end of the quarter. Each party will continue to have the option to exercise this termination right for the 60-day period following the end of future quarters so long as the net profit under the agreement remains negative for consecutive quarters.

In the event that the Company initiates such termination, the Company shall pay to Eversana a one-time payment equal to all of Eversana's unreimbursed cost plus a portion of Eversana's commercialization costs incurred in the 12 months prior to termination. 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. If Eversana terminates the agreement due to an uncured material breach by the Company, or if the Company terminates the Eversana Agreement in certain circumstances, including pursuant to the Net Profit Quarterly Termination Right, the Company has agreed to reimburse Eversana for its unreimbursed commercialization costs for the prior

twelve-month period and certain other costs. In addition, Eversana may terminate the Eversana Agreement if the Company withdraws Gimoti from the market for more than 90 days.

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 million to the Company upon FDA approval of the Gimoti NDA under certain customary conditions. The Eversana Credit Facility terminates on December 31, 2026, unless terminated earlier pursuant to its terms. 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%, with such interest due at the end of the loan term. In 2020 the Company borrowed $5 million under the Eversana Credit Facility.

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 November 3, 2022, the Company and Eversana entered into Amendment No. 2 (the "Amendment") to the Eversana Agreement. The Amendment provides that the preexisting rights of both parties to terminate the commercial services agreement within 30 days of the first three annual anniversaries of commercial launch, if net sales of Gimoti did not meet certain annual thresholds, would be modified solely for 2022 such that either party can terminate by written notice to the other party by November 30, 2022. Neither party terminated the Agreement under this Amendment.

8. 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, 2023. The Company has an uncertain tax position ("UTP") of approximately $2.0 million related to California net operating losses at December 31, 2023. 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, 2023 and 2022:

	December 31,	
	2023 (%)	2022 (%)
Federal statutory rate	21	21
Change in valuation allowance	(3)	-
State income taxes, net of federal benefit	1	2
Removal of net operating losses and other credits	(16)	(24)
Impact of state tax rate change	(1)	1
Stock compensation and other permanent items	(2)	-
Effective income tax rate	-	-

Pursuant to Internal Revenue Code of 1986 ("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 excluded the deferred tax assets for net operating losses of approximately $25.8 million and a research and development credit of approximately $3.6 million generated through December 31, 2023 from its deferred tax asset. 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 are as follows:

	December 31,	
	2023	2022
Deferred tax assets:		
Stock compensation expense	$ 1,839,000	$ 1,825,000
Capitalized R&D	161,000	125,000
Lease liability	-	29,000
Accruals and other	294,000	136,000
Total deferred tax assets	2,294,000	2,115,000
Deferred tax liabilities:		
Right of use asset	-	(29,000)
Total deferred tax liabilities	-	(29,000)
Less valuation allowance	(2,294,000)	(2,086,000)
Net deferred tax assets (liabilities)	$ -	$ -

The deferred tax assets and valuation allowance as of December 31, 2023 increased by $208,000. The Company carries a full valuation allowance against these deferred tax assets, therefore, the adjustments had no effect on the balance sheets, statements of operations and cash flows for the periods presented.

At December 31, 2023, the Company has federal and state net operating loss carryforwards of approximately $105.8 million and $53.6 million, respectively. The federal and state 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 $43.9 million do not expire and will carry forward indefinitely. At December 31, 2023, the Company also has federal and California research tax credit carryforwards of approximately $2.4 million and $1.5 million, respectively. The federal research credit carryforwards will begin expiring in 2027 unless previously utilized. The California research credit will carry forward indefinitely. Pursuant to U.S. tax legislation enacted in December 2017, 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 2023 and 2022. As such, the balance of unrecognized tax benefits (excluding interest and penalties) was approximately $2.0 million at December 31, 2023 and 2022. The Company will recognize interest and penalties related to unrecognized tax benefits as income tax expense when incurred. To date, since no benefit has been taken related to the UTP, there has been no interest and penalties recognized.

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.

9. Subsequent Events

On February 13, 2024, the Company sold 5,134,731 common stock units (the "Common Stock Units"), at a public offering price of $0.68 per Common Stock Unit and, to certain investors, 5,894,680 pre-funded warrant units (the "PFW Units"), at a public offering price of $0.6799 per PFW Unit. Each Common Stock Unit consists of (i) one share of common stock, (ii) a Series A Warrant to purchase one share of common stock (the "Series A Warrant"), (iii) a Series B Warrant to purchase one share of common stock (the "Series B Warrant"), and (iv) a Series C Warrant to purchase one share of common stock (the "Series C Warrant"). Each PFW Unit consists of (i) a pre-funded warrant to purchase one share of common stock, (ii) a Series A Warrant, (iii) a Series B Warrant, and (iv) a Series C Warrant. After deducting underwriting discounts and

commissions and offering expenses paid by the Company, the net proceeds to the Company from this offering are estimated to be approximately $6.1 million.

The Pre-Funded Warrants have an exercise price of $0.0001 per share. The Series A Warrants, Series B Warrants and the Series C Warrants have an exercise price of $0.68 per share. The Pre-Funded Warrants, Series A Warrants and Series B Warrants are exercisable immediately. The Series C Warrants are subject to a vesting schedule and may only be exercised to the extent and in proportion to a holder of the Series C Warrants exercising its corresponding Series B Warrants. The Series A Warrants will expire on February 13, 2029, which is five years from the date of issuance. The Series B Warrants will expire on November 13, 2024, which is nine months from the date of issuance. The Series C Warrants will also expire on November 13, 2024, provided that to the extent and in proportion to a holder of the Series C Warrants exercising its corresponding Series B Warrants included in the applicable unit, such Series C Warrant will expire on February 13, 2029.

Exhibit Index

Exhibit Number	Description of Exhibit	Incorporated by Reference				Filed Herewith
		Form	File Number	Date of Filing	Exhibit Number	
3.1	Amended and Restated Certificate of Incorporation of the Company	8-K	001-36075	9/30/2013	3.1	
3.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation of the Company	8-K	001-36075	5/20/2022	3.1	
3.3	Amended and Restated Bylaws of the Company	8-K	001-36075	9/30/2013	3.2	
4.1	Form of the Company's Common Stock Certificate	S-1	333-188838	8/16/2013	4.1	
4.2	Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934	10-Q	001-36075	05/10/2022	4.9	
4.3	Form of Pre-Funded Warrant	S-1/A	333-275443	12/15/2023	4.2	
4.4	Form of Series A Warrant	S-1/A	333-275443	01/11/2024	4.3	
4.5	Form of Series B Warrant	S-1/A	333-275443	01/11/2024	4.4	
4.6	Form of Series C Warrant	S-1/A	333-275443	01/11/2024	4.5	
4.7	Form of Representative Warrant	8-K	001-36075	02/14/2024	4.1	
10.1#	Form of Indemnity Agreement for Directors and Officers	S-1	333-188838	05/24/2013	10.1	
10.2#	Amended and Restated Employment Agreement, effective as of June 7, 2013, between the Company and David A. Gonyer	S-1	333-188838	06/14/2013	10.2	
10.3#	Amended and Restated 2013 Equity Incentive Award Plan and form of option agreement thereunder	8-K	001-36075	05/11/2023	10.1	
10.4#	2013 Amended and Restated Employee Stock Purchase Plan	8-K	001-36075	05/11/2023	10.2	
10.5#	Amended and Restated Retention Letter, dated May 22, 2013, between the Company and David A. Gonyer	S-1	333-188838	06/14/2013	10.7	
10.6#	Amended and Restated Retention Letter, dated May 22, 2013, between the Company and Matthew D'Onofrio	S-1	333-188838	06/14/2013	10.8	
10.7†	Asset Purchase Agreement, dated as of June 1, 2007, between the Company and Questcor Pharmaceuticals, Inc.	S-1	333-188838	5/24/2013	10.10	
10.8#	Employment Agreement, effective as of December 1, 2013, between the Company and Marilyn R. Carlson	8-K	001-36075	12/02/2013	10.1	
10.9#	Amendment to Amended and Restated Employment Agreement, effective as of January 25, 2017 between the Company and Matthew D'Onofrio	10-K	001-36075	3/15/2017	10.25	

Exhibit Number	Description of Exhibit	Incorporated by Reference				Filed Herewith
		Form	File Number	Date of Filing	Exhibit Number	
10.10#	Amendment to Employment Agreement, effective as of January 25, 2017, between the Company and Marilyn R. Carlson	10-K	001-36075	3/15/2017	10.26	
10.11†	Manufacturing Services Agreement dated November 7, 2017, between the Company and Patheon UK Limited					X
10.12†	Master Supply Agreement dated as of May 11, 2016 by and between the Company and Cosma S.p.A.	10-Q	001-36075	8/15/2016	10.3	
10.13	Amendment to Asset Purchase Agreement entered into by and between the Company and Mallinckrodt ARD Inc. dated March 21, 2018	10-Q	001-36075	5/14/2018	10.1	
10.14†	Commercial Services Agreement, dated as of January 21, 2020, between the Company and Eversana Life Science Services, LLC	10-Q	001-36075	5/12/2020	10.1	
10.15†	Loan Agreement, dated as of January 21, 2020, between the Company and Eversana Life Science Services, LLC	10-Q	001-36075	5/12/2020	10.2	
10.16†	3PL Agreement between the Company and Eversana Life Science Services, LLC dated August 27, 2020	10-Q	001-36075	11/10/2020	10.1	
10.17#	Non-Employee Director Compensation Policy	10-Q	001-36075	8/10/2023	10.1	
10.18†	Amendment No. 1 to the Commercial Services Agreement, dated as of February 1, 2022, between the Company and Eversana Life Sciences Services, LLC	10-Q	001-36075	5/10/2022	10.1	
10.19†	Amendment No. 2 to the Commercial Services Agreement, dated as of November 3, 2022, between the Company and Eversana Life Sciences Services, LLC	10-Q	001-36075	11/09/2022	10.1	
10.20	Sixth Amendment to Standard Office Lease dated October 9, 2023, between the Company and SB Corporate Center III-IV, LLC.	10-Q	001-36075	11/09/2023	10.1	
23.1	Consent of BDO USA, P.C., Independent Registered Public Accounting Firm					X
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934					X
31.2	Certification of Chief Financial Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934					X

Exhibit Number	Description of Exhibit	Incorporated by Reference				Filed Herewith
		Form	File Number	Date of Filing	Exhibit Number	
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					X
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					X
97	Policy for Recovery of Erroneously Awarded Compensation					X
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the inline XBRL document					
101.SCH	Inline XBRL Taxonomy Extension Schema Document					
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document					
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document					
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					
104.PRE	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)					

† Portions of this exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.
# 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 14, 2024

By: /s/ David A. Gonyer, R.Ph.
David A. Gonyer, R.Ph.
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, R.Ph David A. Gonyer, R.Ph.	Chief Executive Officer and Director (principal executive officer)	March 14, 2024
/s/ Matthew J. D'Onofrio Matthew J. D'Onofrio	President, Chief Operating Officer, Treasurer and Secretary (principal financial and accounting officer)	March 14, 2024
/s/ Cam L. Garner Cam L. Garner	Chairman of the Board of Directors	March 14, 2024
/s/ Todd C. Brady, M.D., Ph.D. Todd C. Brady, M.D., Ph.D.	Director	March 14, 2024
/s/ Malcolm R. Hill, Pharm. D. Malcolm R. Hill, Pharm. D.	Director	March 14, 2024
/s/ Vickie W. Reed Vickie W. Reed	Director	March 14, 2024
/s/ Kenneth J. Widder, M.D. Kenneth J. Widder, M.D.	Director	March 14, 2024

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE EVOKE PHARMA, INC. HAS DETERMINED THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO EVOKE PHARMA, INC. IF PUBLICLY DISCLOSED.

Manufacturing Services Agreement

7 November 2017

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MANUFACTURING SERVICES AGREEMENT

THIS MANUFACTURING SERVICES AGREEMENT (the "Agreement") is made as of October 31, 2017 (the "**Effective Date**")

B E T W E E N:

PATHEON UK LIMITED of Kingfisher Drive, Covingham, Swindon Wiltshire, SN23 5BZ, UK
a corporation existing under the laws of England

("**Patheon**"),

- and -

EVOKE PHARMA, INC. of 420 Stevens Ave, Suite 370, Solana Beach, California 92075, USA
a corporation existing under the laws of California

("**Client**").

THIS AGREEMENT WITNESSES THAT in consideration of the rights conferred and the obligations assumed herein, and for other good and valuable consideration (the receipt and sufficiency of which are acknowledged by each party), and intending to be legally bound the parties agree as follows:

ARTICLE 1

STRUCTURE OF AGREEMENT AND INTERPRETATION

1.1 Definitions.

The following terms will, unless the context otherwise requires, have the respective meanings set out below and grammatical variations of these terms will have corresponding meanings:

"**Active Materials**", **"Active Pharmaceutical Ingredients" or "API"** means the materials listed in Schedule D;

"**Active Materials Credit Value**" means the value of the Active Materials for certain purposes of this Agreement, as set forth in Schedule D;

"**Actual Annual Yield**" or "**AAY**" has the meaning specified in Section 2.2(a);

"**Actual Yearly Volume**" or "**AYV**" has the meaning specified in Section 4.2.1;

"**Affiliate**" means:

(a) a business entity which owns, directly or indirectly, a controlling interest in a party to this Agreement, by stock ownership or otherwise; or

(b) a business entity which is controlled by a party to this Agreement, either directly or indirectly, by stock ownership or otherwise; or

(c) a business entity, the controlling interest of which is directly or indirectly common to the majority ownership of a party to this Agreement;

For this definition, "control" means the ownership of shares carrying at least a majority of the votes for the election of the directors of a corporation;

“Annual Product Review Report” means the annual product review report prepared by Patheon or an Affiliate of Patheon as described in Title 21 of the United States Code of Federal Regulations, Section 211.180(e);

"**Annual Report"** means the annual report to the FDA prepared by Client regarding the Product as described in Title 21 of the United States Code of Federal Regulations, Section 314.81(b)(2);

"**Annual Volume**" means the minimum volume of Product to be manufactured in any Year of this Agreement as set forth in Schedule B;

"**Applicable Laws**" means (i) for Patheon, the Laws of the jurisdiction where the Manufacturing Site is located; and (ii) for Client and the Products, the Laws of all jurisdictions where the Products are manufactured, distributed, and marketed as these are agreed and understood by the parties in this Agreement;

"**Authority**" means any governmental or regulatory authority, department, body or agency or any court, tribunal, bureau, commission or other similar body, whether federal, state, provincial, county or municipal;

“Bill Back Items” means the expenses for all third party supplier fees for the purchase or use of columns, standards, tooling, non-standard pallets, PAPR or PPE suits (where applicable) and other project-specific items necessary for Patheon to perform the Manufacturing Services, and which are not included as Components;

"**Business Day**" means a day other than a Saturday, Sunday or a day that is a statutory holiday in the United Kingdom or the jurisdiction where the Manufacturing Site is located, namely France, and the USA;

“**Capital Equipment Agreement**” means a separate agreement that the parties may enter into that will address responsibility for the purchase of capital equipment and facility modifications that may be required to perform the Manufacturing Services;

"**cGMPs**" means, as applicable, current good manufacturing practices as described in:

(a) Parts 210 and 211 of Title 21 of the United States' Code of Federal Regulations;

(b) EC Directive 2003/94/EC; and

(c) Division 2 of Part C of the *Food and Drug Regulations* (Canada);

together with the latest Health Canada, FDA and EMA guidance documents pertaining to manufacturing and quality control practice, all as updated, amended and revised from time to time;

"Client Intellectual Property" means Intellectual Property generated or derived by Client before entering into this Agreement, or by Patheon while performing any Manufacturing Services or otherwise generated or derived by Patheon in its business which Intellectual Property is specific to the development, manufacture, use, and/or sale of Client's Product or Active Materials that are the subject of the Manufacturing Services (including, but not limited to, any new use, new formulation or any change in the method of producing, testing or storing Product in each case that are specific to the Product), including but not limited to (i) any regulatory filings made by Client, formulations, chemical compositions, or Specifications of the Product, and (ii) any and all Confidential Information of Client, including any chemical structures, composition of matter rights, process technology and other Inventions owned or controlled by Client at the Effective Date;

"**Client Property**" has the meaning specified in Section 8.3(v);

"**Client-Supplied Components**" means those Components to be supplied by Client or that have been supplied by Client;

"**CMC**" has the meaning specified in Section 7.8(c);

"**Commencement Date**" means the date on which any Regulatory Authority first approves Client's Product for commercial manufacture as notified by Client to Patheon;

"**Components**" means, collectively, all packaging components, raw materials, ingredients, excipients, containers, and other materials (including labels, product inserts and other labelling for the Products) required to manufacture the Products in accordance with the Specifications, other than the Active Materials;

"**Confidential Information**" has the meaning specified in Section 11.1;

"**Conversion Fee**" means the Price for performing the Manufacturing Services excluding the cost of Components;

"C-TPAT" has the meaning specified in Section 2.1(f);

"**Deficiencies**" have the meaning specified in Section 7.8(d);

"**Deficiency Notice**" has the meaning specified in Section 6.1(a);

"Delivery Date" means the date scheduled for shipment of Product under a Firm Order as set forth in Section 5.1(d);

"Disclosing Party" has the meaning specified in Section 11.1;

"**EMA**" means the European Medicines Agency;

"**FDA**" means the United States Food and Drug Administration;

"**Firm Orders**" have the meaning specified in Section 5.1(c);

"**Force Majeure Event**" has the meaning specified in Section 13.7;

"**GST**" has the meaning specified in Section 13.16(a)(iii);

"**Health Canada**" means the section of the Canadian Government known as Health Canada and includes, among other departments, the Therapeutic Products Directorate and the Health Products and Food Branch Inspectorate;

"**Importer of Record**" has the meaning specified in Section 3.2(a);

"**Initial Term**" has the meaning specified in Section 8.1;

"**Intellectual Property**" includes, without limitation, rights in patents, patent applications, formulae, trademarks, trademark applications, trade-names, Inventions, copyrights, industrial designs, trade secrets, and know how;

"**Invention**" means information about any innovation, improvement, development, discovery, computer program, device, trade secret, method, know-how, process, technique or the like, whether or not written or otherwise fixed in any form or medium, regardless of the media on which it is contained and whether or not patentable or copyrightable;

"**Inventory**" means all inventories of Components and work-in-process produced or held by Patheon for the manufacture of the Products but, for greater certainty, does not include the Active Materials;

"**Laws**" means all laws, statutes, ordinances, regulations, rules, by-laws, judgments, decrees or orders of any Authority;

"Long Term Forecast" has the meaning specified in Section 5.1(a);

"**Manufacturing Services**" means the manufacturing, quality control, quality assurance, stability testing, packaging, and related services, as set forth in this Agreement, required to manufacture Product or Products using the Active Materials, Components, and Bill Back Items;

"**Manufacturing Site**" means the applicable facility where the Manufacturing Services are performed that is owned and operated by Patheon France S.A.S that is located at located at 40, boulevard de Champaret - BP 448 38317 Bourgoin-Jallieu Cedex (France);

"Materials" means all Components and Bill Back Items required to manufacture the Products in accordance with the Specifications, other than the Active Materials;

"**Maximum Credit Value**" means the maximum value of Active Materials that may be credited by Patheon under this Agreement, as set forth on Schedule D;

"**Minimum Order Quantity**" means the minimum number of batches of the Product to be produced during the same cycle of manufacturing as set forth on Schedule B;

"**Obsolete Stock**" has the meaning specified in Section 5.2(b);

"**Patheon Competitor**" means a business that derives greater than [***] of its revenues from performing contract pharmaceutical development or commercial manufacturing services for third parties;

"Patheon Intellectual Property" means Intellectual Property generated or derived by Patheon before performing any Manufacturing Services, or Intellectual Property that is otherwise generated

or derived by Patheon in its business which Intellectual Property is not specific to, or dependent upon, Client's Active Material or Product including, without limitation, Inventions and Intellectual Property which may apply to manufacturing processes or the formulation or development of drug products, drug product dosage forms or drug delivery systems unrelated to the specific requirements of the Product(s); provided that Patheon Intellectual Property shall not include Product Inventions;

"Price" means the price measured in EUROS to be charged by Patheon for performing the Manufacturing Services, and includes the cost of Components (other than Client-Supplied Components), certain cost items as set forth on Schedule B, and annual stability testing costs as set forth on Schedule C (as defined in Section 13.1);

"**Product(s)**" means the product(s) listed on Schedule A;

"**Product Claims**" have the meaning specified in Section 6.3(c);

"**Quality Agreement**" means the separate and binding agreement between Client and Patheon France S.A.S setting out the quality assurance standards for the Manufacturing Services to be performed by Patheon for Client for this Agreement;

"**Recall**" has the meaning specified in Section 6.2(a);

"**Recipient**" has the meaning specified in Section 11.1;

"**Regulatory Authority**" means the FDA, EMA, and Health Canada and any other foreign regulatory agencies competent to grant marketing approvals for pharmaceutical products including the Products in the Territory;

"**Regulatory Approval**" has the meaning specified in Section 7.8(a);

"**Representatives**" means a party's directors, officers, employees, advisers, agents, consultants, subcontractors, service partners, professional advisors, or representatives;

"Resident Jurisdiction" has the meaning specified in Section 13.16(a)(i);

"**Shortfall**" has the meaning specified in Section 2.2(b);

"**Specifications**" means the file for the Product, which is given by Client to Patheon in accordance with the procedures listed on Schedule A and which contains documents relating to the Product, including, without limitation:

(a) specifications for Active Materials and Components;

(b) manufacturing specifications, directions, and processes;

(c) storage requirements;

(d) all environmental, health and safety information for the Product including material safety data sheets; and

(e) the finished Product specifications, packaging specifications and shipping requirements for the Product;

all as updated, amended and revised from time to time by Client in accordance with the terms of this Agreement;

"Surplus" has the meaning specified in Section 2.2(c);

"**Target Yield**" has the meaning specified in Section 2.2(a);

"**Target Yield Determination Batches**" has the meaning specified in Section 2.2(a);

"**Tax**" or "**Taxes**" have the meaning specified in Section 13.16(a);

"**Technical Dispute**" has the meaning specified in Section 12.2;

"**Territory**" means world-wide;

"**Third Party Rights**" means the Intellectual Property of any third party;

"**VAT**" has the meaning specified in Section 13.16(d);

"**Year**" means in the first year of this Agreement, the period from the Effective Date up to and including December 31 of the same calendar year, and thereafter will mean a calendar year.

"**Yearly Forecast Volume**" or "**YFV**" has the meaning specified in Section 4.2.1; and

"**Zero Forecast Period**" has the meaning specified in Section 5.1(f).

1.2 Currency.

Unless otherwise agreed in writing, all monetary amounts expressed in this Agreement are in EUROS.

1.3 Sections and Headings.

The division of this Agreement into Articles, Sections, Subsections, and Schedules and the insertion of headings are for convenience of reference only and will not affect the interpretation of this Agreement. Unless otherwise indicated, any reference in this Agreement to a Section or Schedule refers to the specified Section, or Schedule to this Agreement. In this Agreement, the terms "**this Agreement**", "**hereof**", "**herein**", "**hereunder**" and similar expressions refer to this Agreement as a whole and not to any particular part, Section, or Schedule of this Agreement.

1.4 Singular Terms.

Except as otherwise expressly stated or unless the context otherwise requires, all references to the singular will include the plural and vice versa.

1.5 Schedules.

The following Schedules are attached to, incorporated in, and form part of this Agreement:

Schedule A	-	Product List and Specifications
Schedule B	-	Minimum Order Quantity, Annual Volume, and Price
Schedule C	-	Annual Stability Testing [and Validation Activities (if applicable)]
Schedule D	-	Active Materials, Active Materials Credit Value, and Maximum Credit Value
Schedule E	-	Technical Dispute Resolution
Schedule F	-	Quarterly Active Materials Inventory Report
Schedule G	-	Report of Annual Active Materials Inventory Reconciliation and Calculation of Actual Annual Yield

ARTICLE 2

PATHEON'S MANUFACTURING SERVICES

2.1 Manufacturing Services.

2.1.1 **Appointment**. Subject to the terms of this Agreement, Client hereby appoints Patheon to perform the Manufacturing Services for the "**Territory**" and to supply "**Product**" to Client for its commercial purposes, and Patheon hereby agrees to perform the Manufacturing Services and supply the Product to Client for its commercial purposes in accordance with the Specifications, cGMPs and all Applicable Laws for the Product Price set forth in Schedule B. Except as otherwise set forth in this Section 2.1, Client will have the right to purchase Product from Patheon during the term of this Agreement by placing Firm Orders for its Product requirements in accordance with Section 5.1. Notwithstanding the foregoing, during the Initial Term, Client agrees to purchase from Patheon [***] of its Product requirements based on total number of bottles ordered (the "**Exclusivity Obligation**"). Any Product produced with respect to qualifying such alternative Product manufacturers shall not count towards Client's Exclusivity Obligation hereunder. Patheon will be obligated to manufacture and supply all such Product ordered pursuant to Section 5. But the Exclusivity Obligation will cease to be binding on Client and will be permanently converted into a non-exclusive right to purchase Product from Patheon for the remaining portion of the Initial Term (i) in the event of a material breach by Patheon of any of the terms of this Agreement, which breach is not cured within the period set forth in Section 8.2(a), or (ii) under the circumstances set forth in Section 2.2(f). In the event that Client's requirements for Product exceed those identified in Schedule B and such required increase in production by Patheon needs additional capital investment, then the parties shall discuss in good faith the allocation of cost and timelines associated therewith. In the absence of any good faith agreement, Client shall be entitled to obtain the additional product above Patheon's existing capacity from a third party without any obligation to Patheon. In the event that Patheon enters into any other agreements, including licensing or manufacturing agreements, with any third parties in relation to the manufacture of any product(s) for intranasal administration of metoclopramide, Client's Exclusivity Obligation under this Section 2.1.1 shall immediately terminate.

Client will be entitled to take such steps as are necessary to qualify one or more alternative Product manufacturers at any time during the term of this Agreement. Patheon agrees to cooperate with Client and provide all assistance, at Client's expense, as may reasonably be requested by Client to qualify

an alternate manufacturer. Patheon will not have to give an alternative manufacturer access to the Manufacturing Site.

2.1.2 **Performance of Manufacturing Services**. In performing the Manufacturing Services, Patheon and Client agree that:

(a) Conversion of Active Materials and Components. Patheon will convert Active Materials and Components into Products.

(b) Quality Control and Quality Assurance. Patheon will perform the quality control and quality assurance testing specified in the Quality Agreement. Batch review and release to Client will be the responsibility of Patheon's quality assurance group. Patheon will perform its batch review and release responsibilities in accordance with Patheon's standard operating procedures. Each time Patheon ships Products to Client, it will give Client a certificate of analysis and certificate of compliance including a statement that the batch has been manufactured and tested in accordance with Specifications and cGMPs. Client will have sole responsibility for the release of Products to the market. The form and style of batch documents, including, but not limited to, batch production records, lot packaging records, equipment set up control, operating parameters, and data printouts, raw material data, and laboratory notebooks are the exclusive property of Patheon. Specific Product related information contained in those batch documents is Client property.

(c) Components. Patheon will purchase all Components (with the exception of Client-Supplied Components) and test all Components (including Client-Supplied Components if required by the specifications) at Patheon's expense as required by the Specifications.

(d) Stability Testing. Patheon will conduct stability testing on the Products in accordance with the protocols set out in the Specifications for the separate fees and during the time periods set out in Schedule C. Patheon will not make any changes to these testing protocols without prior written approval from Client. If a confirmed stability test failure occurs, Patheon will notify Client within [***], after which Patheon and Client will jointly determine the proceedings and methods to be undertaken to investigate the cause of the failure, including which party will bear the cost of the investigation. Patheon will not be liable for these costs unless it has failed to perform the Manufacturing Services in accordance with the Specifications and cGMPs. Patheon will give Client all stability test data and results at Client's request.

(e) Packaging and Artwork. Patheon will package the Products in accordance with the Specifications. Client will be responsible for the cost of artwork development. Patheon with consent of Client, will determine and imprint the batch numbers and expiration dates for each Product shipped. The batch numbers, the serialization numbers and expiration dates will be affixed on the Products and on the shipping carton of each Product as outlined in the Specifications and as required by cGMPs. Client may, in its sole discretion, make changes to labels, product inserts, and other packaging for the Products. Those changes will be submitted by Client to all applicable Regulatory Authorities and other third parties responsible for the approval of the Products. Client will be responsible for the cost of labelling obsolescence when changes occur, as contemplated in Section 4.4. Patheon's name will not appear on the label or anywhere else on the Products unless: (i) required by any Laws; or (ii) Patheon consents in writing to the use of its name. At least [***] prior to the Delivery Date of Product for which new or modified artwork is required,

Client will provide at no cost to Patheon, final camera ready artwork for all packaging Components to be used in the manufacture of the Product that meet the Specifications. For the avoidance of doubt, the parties acknowledge and agree that Client will be responsible for complying with any and all regulatory requirements for the labeling of the Product.

(f) Active Materials and Client-Supplied Components. As soon as possible and at least [***] before the scheduled production date, Client will deliver the Active Materials and any Client-Supplied Components to the Manufacturing Site DDP (Incoterms 2010), at no cost to Patheon, with any VAT paid by Client, in sufficient quantity to enable Patheon to manufacture the desired quantities of Product and to ship Product on the Delivery Date. If the Active Materials and/or Client-Supplied Components are not received [***] before the scheduled production date, Patheon may delay the shipment of Product by the same number of days as the delay in receipt of the Active Materials and/or Client-Supplied Components. But if Patheon is unable to manufacture Product to meet this new shipment date due to prior third party production commitments, Patheon may delay the shipment until a later date as agreed to by the parties. All shipments of Active Material will be accompanied by certificate(s) of analysis from the Active Material manufacturer and the Client, confirming the identity and purity of the Active Materials and its compliance with the Active Material specifications. For Active Materials or Client-Supplied Components which may be subject to import or export, Client agrees that its vendors and carriers will comply with applicable requirements of the U.S. Customs and Border Protection Service and the Customs Trade Partnership Against Terrorism ("**C-TPAT**").

(g) Bill Back Items. Bill Back Items will be charged to Client, with prior written approval, at Patheon's cost plus an [***] handling fee, with a maximum handling fee of [***] per item acquired. Patheon will use commercially reasonable efforts to obtain the best available pricing for all Bill Back Items, and will provide Client with an estimate for the actual costs of Bill Back.

(h) Validation Activities (if applicable). At the Client's request, Patheon will (i) assist in the development and approval of the validation protocols for analytical methods and manufacturing procedures (including packaging procedures) for the Products and (ii) validate all applicable processes, methods, equipment, utilities, facilities and computers used in the manufacture, packaging, storage, testing and release of Products in conformance with all Applicable Laws, including, but not limited to, cGMPs. Upon request, Patheon will provide to Client a copy of the results of Product specific validation when such results are available. The fees for this service are not included in the Price and will be mutually agreed from time to time.

(i) Product Rejection for Finished Product Specification Failure. If a batch or a portion of a batch is rejected (outside of typical batch yield variations) and the deviation does not determine that Patheon has failed to provide the Manufacturing Services in accordance with the Specifications, cGMPs, or Applicable Laws ("**Rejected Properly Manufactured Product"**), Client will pay Patheon the applicable fee per unit for the Rejected Properly Manufactured Product. For greater certainty, Client will pay Patheon the applicable fee per unit for the Rejected Properly Manufactured Product under the circumstances described in Section 6.3(c). The API in the Rejected Properly Manufactured Product will be included in the "Quantity Converted" for purposes of calculating the "Actual Annual Yield" under Section 2.2(a).

(j) Storage. Until finished Products have been issued a Certificate of Analysis and Compliance or unless otherwise directly requested by Client, Patheon shall store all such Products in preparation for shipment to Client's destination of choice identifiably distinct from any other raw material and finished or filled product stocks and shall comply with all storage requirements set forth in the Specifications and all Applicable Laws, including, but not limited to, cGMPs. Patheon shall assume responsibility for any loss or damage to such finished Product while stored by Patheon.

(k) Additional Services. If Client requests services other than those expressly set forth herein (such as qualification of a new packaging configuration or shipping studies, or validation of alternative batch sizes), Patheon will provide a good faith and reasonable written quote of the fee for the additional services and Client will advise Patheon whether it wishes to have the additional services performed by Patheon. The scope of work and fees will be set forth in a separate agreement signed by the parties. The terms and conditions of this Agreement will apply to these services.

2.2 Active Material Yield.

(a) Reporting. Patheon will give Client a quarterly inventory report of the Active Materials held by Patheon using the inventory report form set out in Schedule F, which will contain the following information for the quarter:

Quantity Received: The total quantity of Active Materials that complies with the Specifications and is received at the Manufacturing Site during the applicable period.

Quantity Dispensed: The total quantity of Active Materials dispensed at the Manufacturing Site during the applicable period. The Quantity Dispensed is calculated by adding the Quantity Received to the inventory of Active Materials that complies with the Specifications held at the beginning of the applicable period, less the inventory of Active Materials that complies with the Specifications held at the end of the period. The Quantity Dispensed will only include Active Materials received and dispensed in commercial manufacturing of Products and, for certainty, will not include any (i) Active Materials that must be retained by Patheon as samples, (ii) Active Materials contained in Product that must be retained as samples, (iii) Active Materials used in testing (if applicable), and (iv) Active Materials received or dispensed in technical transfer activities or development activities during the applicable period, including without limitation, any regulatory, stability, validation or test batches manufactured during the applicable period.

(b) **Quantity Converted:** The total amount of Active Materials contained in the Products manufactured with the Quantity Dispensed (including any additional Products produced in accordance with Section 6.3(a) or 6.3(b)), delivered by Patheon, and not rejected, recalled or returned in accordance with Section 6.1 or 6.2 because of Patheon's failure to perform the Manufacturing Services in accordance with Specifications, cGMPs, and Applicable Laws.

(c) Within [***] after the end of each Year, Patheon will prepare an annual reconciliation of Active Materials on the reconciliation report form set forth in Schedule G including the calculation of the "**Actual Annual Yield**" or "**AAY**" for the Product at the Manufacturing

Site during the Year. AAY is the percentage of the Quantity Dispensed that was converted to Products and is calculated as follows:

$$\frac{\text{Quantity Converted during the Year}}{\text{Quantity Dispensed during the Year}} \times [***]$$

After Patheon has produced a minimum of 25 successful commercial production batches of Product (for clarity, including batches for marketing product, prescription product or a combination thereof) and has produced commercial production batches for at least [***] at the Manufacturing Site (collectively, the "**Target Yield Determination Batches**"), the parties will agree on the target yield for the Product at the Manufacturing Site (each, a "**Target Yield**"). The Target Yield will be revised annually to reflect the actual manufacturing experience as agreed to by the parties.

(b) Shortfall Credit Calculation. Patheon will use commercially reasonable efforts to maintain AAY levels for the Product above the applicable Target Yield. If the Actual Annual Yield falls more than [***] for less than [***] batch [***] for [***] batches, or [***] for greater than [***] batches below the respective Target Yield in a Year, then the shortfall for the Year (the "**Shortfall**") will be calculated as follows:

Shortfall = [***]

(c) Surplus Calculation. If the Actual Annual Yield is more than the respective Target Yield in a Year, then the surplus for that Year (the "**Surplus**") will be determined based on the following calculation:

Surplus = [***]

(c) Credit for Shortfall. If there is a Shortfall for the Product in a Year, then Patheon will credit Client's account for the amount of the Shortfall not later than [***] after the end of the Year. If there is a Surplus for a Product in a Year, then Patheon will be entitled to apply the amount of the Surplus as a credit against any Shortfall for that Product which may occur in the next Year. If there is no Shortfall in the next Year the Surplus credit will expire. Each credit under this Section 2.2(c) will be summarized on the reconciliation report form set forth in Schedule G. Upon expiration or termination of this Agreement, any remaining credit owing under this Section will be paid to Client. The Annual Shortfall, if any, will be disclosed by Patheon on the reconciliation report form.

(d) Casualty Losses. Patheon shall notify Client in writing in the event that an amount of API with a value greater than or equal to [***] of API is damaged, lost or otherwise rendered unusable at any one time as soon as practicable following such incident. In addition, and notwithstanding any provision in this Section 2.2 to the contrary, [***] involving Patheon's Manufacturing Site (a "**Casualty Loss**") within [***] after Patheon receives the proceeds of insurance from its insurance provider in cleared funds and an appropriate invoice from Client. Patheon's liability for a Casualty Loss will not exceed the lesser of [***] USD or [***]. Patheon shall only insure Active Materials up to the values recommended and provided to Patheon by Client. If any such losses are unrecoverable due to the under-estimation of such values, then Patheon shall not be liable for such unrecoverable losses. Said insurance shall be on an "all risks of physical damage" form, subject to the policy's terms and conditions with exclusions such as: Delay, Deterioration, Inherent Vice, Nuclear Hazards, Loss of Market, Wear and Tear, Error or Deficiency in Design, Mechanical or

Electrical Malfunction, Infidelity of the Assured or its Employees, Radioactive Contamination, Losses caused by Process, Mysterious Disappearance, Taking of Inventory, Biological, Biochemical or Electromagnetic Contamination. For purposes of calculating the AAY above, all Active Materials reimbursed to Client as a Casualty Loss shall be removed from the Quantity Received and Quantity Dispensed totals.

(e) Maximum Credit. Excluding liability for Casualty Losses, Patheon's liability for Active Material calculated in accordance with this Section 2.2 the Product in a Year will not exceed, in the aggregate, the Maximum Credit Value set forth in Schedule D.

(f) No Material Breach. It will not be a material breach of this Agreement by Patheon under Section 8.2(a) if the Actual Annual Yield is less than the Target Yield. But Client will be released from the Exclusivity Obligation set forth in Section 2.1.1 if the Actual Annual Yield falls more than [***] below the Target Yield in any Year.

ARTICLE 3

CLIENT'S OBLIGATIONS

3.1 Payment.

Upon receipt of a properly rendered invoice in accordance with Section 5.5, Client will pay Patheon for performing the Manufacturing Services according to the Prices specified in Schedules B and C. These Prices may be subject to adjustment under other parts of this Agreement. Client will also pay Patheon for any Bill Back Items.

3.2 Active Materials and Qualification of Additional Sources of Supply.

(a) Client will at its sole cost and expense deliver the Active Materials to Patheon in accordance with Section 2.1(f). If applicable, Patheon and the Client will reasonably cooperate to permit the import of the Active Materials to the Manufacturing Site. Client's obligation will include obtaining the proper release of the Active Materials from the applicable Customs Agency and Regulatory Authority. Client or Client's designated broker will be the "**Importer of Record**" for Active Materials imported to the Manufacturing Site. The Active Materials will be held by Patheon on behalf of Client as set forth in this Agreement. Title to the Active Materials will at all times remain the property of Client. Any Active Materials received by Patheon will only be used by Patheon to perform the Manufacturing Services. Client will be responsible for paying for all rejected Product that arises from defects in the Active Materials which could not be reasonably discoverable by Patheon using the test methods set forth in the Specifications. Client's failure to supply Patheon with Active Materials in accordance with the timeframes set forth in Section 2.1(f) will not be deemed a breach of this Agreement.

(b) If Client asks Patheon to qualify an additional source for the Active Material or any Component, Patheon may agree to evaluate the Active Material or Component to be supplied by the additional source to determine if it is suitable for use in the Product. The parties will agree on the scope of work to be performed by Patheon at Client's cost. For an Active Material, this work at a minimum will include: (i) laboratory testing to confirm the Active Material meets existing specifications; (ii) manufacture of an experimental batch of Product that will be placed on [***] accelerated stability; and (iii) manufacture of [***]

validation batches that will be placed on concurrent stability (one batch may be the registration batch if manufactured at full scale).

(d) Patheon will promptly advise Client if it encounters supply problems, including delays and/or delivery of non-conforming Active Material or Components from a Client designated additional source; and Patheon and Client will cooperate to reduce or eliminate any supply problems from these additional sources of supply. Client will be obligated to certify all Client designated sources of supply on an annual basis at its expense and will provide Patheon with copies of these annual certifications as specified in the Quality Agreement. If Patheon agrees to certify a Client designated additional sources of supply on behalf of Client, it will do so at Client's expense.

ARTICLE 4

CONVERSION FEES AND COMPONENT COSTS

4.1 First Year Pricing.

The Price for the first Year will be listed in Schedules B and C and will be subject to the adjustments set forth in Sections 4.2 and 4.3. The Price may also be [***] by Patheon at any time upon written notice to Client if there are changes to the underlying manufacturing, packaging or testing assumptions set forth in Schedule B that result in an increase or decrease in the cost of performing the Manufacturing Services.

4.2 Price Adjustments – Subsequent Years' Pricing.

After the first Year, Patheon may adjust the Price effective January 1st of each Year as follows:

(a) Manufacturing and Stability Testing Costs. Patheon may adjust the conversion component of the Price and the annual stability testing costs for inflation, based upon the preliminary number for any increase in the "Indices de salaires mensuels de base des salaries de l'industrie pharmaceutique", published by Les Entreprises du médicament (LEEM) during the prior Contractual Year (For illustration: http://www.leem.org/article/les-indices-des-salaires-de-lindustrie-pharmaceutique) in August of the preceding Year compared to the final number for the same month of the Year prior to that, unless the parties otherwise agree in writing. On or about [***] of each Year, Patheon will give Client a statement setting forth the calculation for the inflation adjustment to be applied in calculating the Price for the next Year.

(b) Component Costs. If Patheon incurs an increase in Component costs during the Year (for clarity, this excludes Client-Supplied Components), it may increase the Price for the next Year to pass through the additional Component costs at Patheon's cost; provided, however, that in the event any proposed increase in the cost of a Component exceeds [***] of the cost for that Component upon which the most recent fee quote was based, and that a change of supplier is mutually agreed between Patheon and Client pursuant to Section 4.2(e), Patheon and Client will use commercially reasonable efforts to locate an equivalent alternative lower cost supplier for the applicable Component. If as a result of both parties' efforts pursuant to Section 4.2(e) (but not if Patheon is acting alone) Patheon incurs a net decrease (including any rebates or discounts) in Component costs during the Year, the net cost savings will be [***] in accordance with Section 4.2(e) and it will

decrease the Price for the next Year to pass through the additional Component cost savings allocated to Client (but not those allocated to Patheon). On or about [***] of each Year, Patheon will give Client information about the increase or decrease in Component costs which will be applied to the calculation of the Price for the next Year to reasonably demonstrate that any Price increase or decrease is in compliance with this Section 4.2(b). But Patheon will not be required to give information to Client that is subject to obligations of confidentiality between Patheon and its suppliers.

(c) Pricing Basis. Client acknowledges that the Price in any Year is quoted based upon the Minimum Order Quantity and the Annual Volume specified in Schedule B. The Price is subject to change if the specified Minimum Order Quantity changes or if the Annual Volume is not ordered in a Year. For greater certainty, if Patheon and Client agree that the Minimum Order Quantity will be reduced or the Annual Volume in the lowest tier will not be ordered in a Year whether as a result of a decrease in estimated Annual Volume or otherwise and, as a result of the reduction, Patheon demonstrates to Client that its costs to perform the Manufacturing Services or to acquire the Components for the Product will increase on a per unit basis (including the amount of the increase), then Patheon may increase the Price by an amount sufficient to absorb the documented increased costs. On or before November 30 of each Year, Patheon will give Client a statement setting forth the information to be applied in calculating those cost increases for the next Year. But Patheon will not be required to give information to Client that is subject to obligations of confidentiality between Patheon and its suppliers.

(d) Tier Pricing (if applicable). The pricing in Schedule B is set forth in Annual Volume tiers based upon the Client's volume forecasts under Section 5.1. The Client will be invoiced during the Year for the unit price set forth in the Annual Volume tier based on the [***] forecast provided in September of the previous Year. Within [***] after the end of each Year or of the termination of the Agreement, Patheon will send Client a reconciliation of the actual volume of Product ordered by the Client during the Year with the pricing tiers. If Client has overpaid during the Year, Patheon will issue a credit to the Client for the amount of the overpayment within [***] after the end of the Year or will issue payment to the Client for the overpayment within [***] after the termination of the Agreement. If Client has underpaid during the Year, Patheon will issue an invoice to the Client under Section 5.5 for the amount of the underpayment within [***] after the end of the Year or termination of the Agreement. If Client disagrees with the reconciliation, the parties will work in good faith to resolve the disagreement amicably. If the parties are unable to resolve the disagreement within [***], the matter will be handled under Section 12.1.

(e) Cost Improvement Program. Patheon and Client agree to work together to develop cost reduction initiatives as part of an overall cost improvement program, provided such program does not involve additional capital or extraordinary costs unless otherwise agreed to by parties in writing. All net cost savings (net of implementation costs) realized from the cost improvement program [***], unless otherwise agreed to by the parties in writing. A "Cost Reduction Initiative" for the purpose of this Agreement will be an initiative that reduces the internal or out-of-pocket costs incurred by a party in connection with the performance of its obligations under this Agreement. It is further agreed by the parties that on-going method improvements developed or adopted by either Client or Patheon independently of the other party(ies), will not be a cost reduction initiative under this section, and there will be no obligation on such party to share the net cost savings realized from such improvement with the other party(ies) to this Agreement.

(f) For all Price adjustments under this Section 4.2, Patheon will deliver to Client on or before [***] of each Year a revised Schedule B to be effective for Product delivered on or after the first day of the next Year. If in any Year Patheon would have been entitled to increase the Price based on any of the provisions of this Section 4.2 but Patheon did not exercise its right to do so, then at the expiry of any subsequent Year, Patheon will be entitled to make cumulative adjustments as set out in Section 4.2 based on changes during all of the preceding Years since Patheon last adjusted the Price.

4.3 Price Adjustments – Current Year Pricing.

During any Year, the Prices set out in Schedule B will be adjusted as follows:

Extraordinary Increases in Component Costs. If, at any time, market conditions result in Patheon's cost of Components being materially greater than normal forecasted increases, then Patheon will be entitled to adjust the Price for any affected Product to compensate it for the increased Component costs. Changes materially greater than normal forecasted increases will have occurred if: (i) the cost of a Component increases by [***] of the cost for that Component upon which the most recent Price or fee quote was based; or (ii) the aggregate cost for all Components required to manufacture the Product increases by [***] of the total Component costs for the Product upon which the most recent fee quote was based. If Component costs have been previously adjusted to reflect an increase in the cost of one or more Components, the adjustments set out in (i) and (ii) above will operate based on the last cost adjustment for the Components.

For a Price adjustment under this Section 4.3, Patheon will deliver to Client a revised Schedule B and budgetary pricing information, adjusted Component costs, and other documents reasonably sufficient to demonstrate that a Price adjustment is justified. Upon request of Client, Patheon will share the standard prices to be paid by Patheon to its supplier for the Components as stipulated in Patheon's SAP system, it being understood and agreed that Patheon will have no obligation to deliver any supporting documents that are subject to obligations of confidentiality between Patheon and its suppliers, but Patheon shall use commercially reasonable efforts to minimize the restrictions imposed by such confidentiality obligations on disclosure of supporting documents to Client. The revised Price will be effective for any Product delivered on or after the first day of the month following Client's receipt of the revised Schedule B.

4.4 Adjustments Due to Technical Changes or Regulatory Authority Requirements.

Amendments to the Specifications or the Quality Agreement requested by Client will be implemented only following a technical and cost review that Patheon will perform at Client's cost and are subject to Client and Patheon reaching agreement on Price changes required because of the amendment. Amendments to the Specifications, the Quality Agreement, or the Manufacturing Site requested by Patheon will only be implemented following the written approval of Client, the approval not to be unreasonably withheld, conditioned or delayed. If Client accepts a proposed Price change, the proposed change in the Specifications or the Quality Agreement and the associated scope of work will be implemented at Client's cost, and the Price change will become effective, only for those orders of Product that are manufactured under the revised Specifications. In addition, Client agrees to purchase, at the price paid by Patheon (including all costs incurred by Patheon for the purchase, handling and transport of the Inventory), all Inventory held under the "old" Specifications and purchased or maintained by Patheon in order to fill Firm Orders or under Section 5.2, if the Inventory can no longer be used under the revised Specifications. Patheon will use commercially reasonable efforts to cancel any open purchase orders for Components no

longer required under any revised Specifications that were placed by Patheon with suppliers in order to fill Firm Orders or under Section 5.2 and if the orders may not be cancelled without penalty, will be assigned to and paid for by Client. Additional payments or price increases may also be required to compensate Patheon for fees and other expenses incurred by Patheon to comply with additional Regulatory Authority requirements which apply to the Manufacturing Services.

4.5 Multi-Country Packaging Requirements.

If Client decides to have Patheon perform Manufacturing Services for the Product for more than one country inside the Territory, then Client will inform Patheon of the packaging requirements for each such country and Patheon will prepare a quotation for consideration by Client of any additional costs for Components (other than Client-Supplied Components) and the changeover fees for the Product destined for each new country. The agreed additional packaging requirements and related packaging costs and change over fees will be set out in a written amendment to this Agreement.

ARTICLE 5

ORDERS, SHIPMENT, INVOICING, PAYMENT

5.1 Orders and Forecasts.

(a) Long Term Forecast. As soon as reasonably practicable following the Effective Date, Client will give Patheon a non-binding [***] forecast of Client's volume requirements for the Product for each Year during the term of the Agreement (the "**Long Term Forecast**"). The Long Term Forecast will thereafter be updated [***] during the Initial Term. If Patheon is unable to accommodate any portion of the Long Term Forecast, it will notify Client and the parties will agree on any revisions to the forecast.

(b) Rolling [***] Forecast. As soon as reasonably practicable following the Effective Date, Client will give Patheon a non-binding [***] forecast of the volume of Product that Client expects to order in the first [***] of commercial manufacture of the Product. This forecast will then be updated by Client on or before the tenth day of each month on a rolling forward basis. Client will update the forecast forthwith if it determines that the volumes estimated in the most recent forecast have changed by more than [***]. The most recent [***] forecast will prevail.

(c) Firm Orders. On a rolling basis during the term of this Agreement, Client will issue an updated [***] forecast on or before the [***] of each month. This forecast will start on the first day of the next month. The first [***] of this updated forecast will be considered binding firm orders. Concurrent with the [***] forecast, Client will issue a new firm written order in the form of a purchase order or otherwise ("**Firm Order**") by Client to purchase and, when accepted by Patheon, for Patheon to manufacture and deliver the agreed quantity of the Products. The Delivery Date will not be less than [***] following the date that the Firm Order is submitted. Firm Orders submitted to Patheon will specify Client's purchase order number, quantities by Product type, monthly delivery schedule, and any other elements necessary to ensure the timely manufacture and shipment of the Products. The quantities of Products ordered in those written orders will be firm and binding on Client and may not be reduced by Client. Expedited Firm Orders will be subject to additional fees.

(d) Acceptance of Firm Order. Patheon will accept Firm Orders by sending an acknowledgement to Client within [***] of its receipt of the Firm Order. The

acknowledgement will include, subject to confirmation from the Client, the Delivery Date for the Product ordered. The Delivery Date may be amended by agreement of the parties or as set forth in Section 2.1(f). If Patheon fails to acknowledge receipt of a Firm Order within the [***] period, the Firm Order will be deemed to have been accepted by Patheon.

(e) Cancellation of a Firm Order. If Client cancels a Firm Order, Client will pay Patheon [***] of the Conversion Fee for the Firm Order.

5.2 Zero Volume Forecast.

If Client forecasts zero volume for [***] period during the term of this Agreement (the "**Zero Forecast Period**"), then Patheon will have the option, at its sole discretion, to provide a [***] notice to Client of Patheon's intention to terminate this Agreement on a stated day within the Zero Forecast Period. Client thereafter will have [***] to either (i) withdraw the zero forecast and re-submit a reasonable volume forecast, or (ii) negotiate other terms and conditions on which this Agreement will remain in effect. Otherwise, Patheon will have the right to terminate this Agreement at the end of the [***] notice period.

5.3 Reliance by Patheon.

(a) Client understands and acknowledges that Patheon will rely on the Firm Orders and rolling forecasts submitted under Section 5.1(b) in ordering the Components (other than Client-Supplied Components) required to meet the Firm Orders. In addition, Client understands that to ensure an orderly supply of the Components**,** Patheon may want to purchase the Components in sufficient volumes to meet the production requirements for Products during part or all of the forecasted periods referred to in Section 5.1(b) or to meet the production requirements of any longer period agreed to by Patheon and Client. Accordingly, Client authorizes Patheon to purchase Components to satisfy the Manufacturing Services requirements for Products for the first [***] contemplated in the most recent forecast given by Client under Section 5.1(b). Patheon may make other purchases of Components to meet Manufacturing Services requirements for longer periods if agreed to in writing by the parties. Client will give Patheon written authorization to order Components for any launch quantities of Product requested by Client which will be considered a Firm Order when accepted by Patheon.

(b) Client will reimburse Patheon for the cost of Components ordered by Patheon under Firm Orders or under Section 5.2(a) that are not included in finished Products manufactured for Client within six months after the forecasted month for which the purchases have been made (or for a longer period as the parties may agree) or if the Components have expired or are rendered obsolete due to changes in artwork or applicable regulations during the period (collectively, "**Obsolete Stock**"). This reimbursement will include Patheon's cost to purchase (plus a [***] handling fee up to [***] per line item) and destroy the Obsolete Stock; provided, however, that the client will have the option but not the obligation to take title to and possession of all or any portion of such Components by written notice to Patheon, in which case Patheon will cooperate with the Client in the surrender, delivery and transfer of such Components as promptly as is commercially reasonable, with any shipping and related expenses to be borne by the Client. If any non-expired Components are used in Products subsequently manufactured for Client or in third party products manufactured by Patheon, Client will receive credit for any costs of those Components previously paid to Patheon by Client.

(c) If Client fails to take possession or arrange for the destruction of non-expired Components within [***] of purchase or, in the case of the delivery of conforming finished Product not accepted by Client within [***] of manufacture, Client will pay Patheon [***] per pallet per month thereafter for storing the Components or finished Product. Storage fees for Components or Product which contain controlled substances or require refrigeration will be charged at [***] per pallet per month. Storage fees are subject

to a one pallet minimum charge per month. Patheon may ship finished Product held by it longer than one month to the Client at Client's expense on [***] written notice to the Client.

5.4 Minimum Orders.

Client may order Manufacturing Services for batches of Products only in multiples of the Minimum Order Quantities as set out in Schedule B.

5.5 Delivery and Shipping.

The Product will be delivered to Client only after it has been manufactured and packaged in accordance with the Specifications. Unless agreed in advance by the Parties in writing, Patheon shall not deliver any Products prior to approval by Patheon's Quality Assurance department in accordance with the applicable Quality Agreement and Applicable Law. Shipments of Products will be made EXW (INCOTERMS 2010) Patheon's shipping point unless otherwise mutually agreed. Risk of loss or of damage to Products will remain with Patheon until Patheon loads the Products onto the carrier's vehicle for shipment at the shipping point at which time risk of loss or damage will transfer to Client. Patheon will, in accordance with Client's instructions and as agent for Client, at Client's risk (i) arrange for shipping, including preparing and executing a packing list, so that the Product will be delivered to the delivery address on the delivery date set forth in the applicable Firm Order, with such shipping to be paid by Client and (ii) at Client's risk and expense, obtain any export license or other official authorization necessary to export the Products. For clarity, the export of a drug product to non-EU countries which do not have a marketing authorization in France is subject to an export declaration to the French Health Authorities (ANSM). The export declaration can be handled by Patheon, this activity is charged [***] per export declaration that is actually shipped (as requested by Client). Client will arrange for insurance (including transit insurance) for the Product at all times from delivery and will select the freight carrier used by Patheon to ship Products and may monitor Patheon's shipping and freight practices as they pertain to this Agreement. Shipment charges will either be paid by Client directly to the shipping company or by Patheon to the shipping company on Client's behalf, in which case Client will pay Patheon the cost of shipment together with a handling fee of [***] up to [***] per shipment. Client will be responsible for complying with all applicable export laws and regulations and will pay any applicable export fees or taxes. Products will be packed and transported in accordance with the Specifications. Patheon will use commercially reasonable efforts to ensure that the date that Product is QP batch certified by Patheon will not be more than three months after the date of manufacture (excluding any Product that is the subject of a deviation or any event not solely within Patheon's control).

5.6 Invoices and Payment.

Invoices will be sent by email to the email address given by Client to Patheon in writing. Invoices will be issued when the Product is manufactured and released by Patheon to the Client. Patheon will also submit to Client, with each shipment of Products, a duplicate copy of the invoice covering the shipment. Patheon will also give Client an invoice covering any Inventory, Bill Back Items or Components which are to be purchased by Client under Section 5.2 of this Agreement. Each invoice will, to the extent applicable, identify Client's Manufacturing Services purchase order number, Product numbers, names and quantities, unit price, freight charges, and the total amount to be paid by Client. Client will pay all invoices within [***] of the date of confirmed delivery email transmission of the invoice, i.e. confirmed by delivery receipt of the email transmission. If any portion of an invoice is disputed, the Client will pay Patheon for the undisputed amount and the parties will use good faith efforts to reconcile the disputed amount as soon as practicable. Interest on undisputed past due accounts will accrue at [***] per month which is equal to an annual rate of [***].

5.7 Delays.

Claims for late delivery of Products will be dealt with by reasonable agreement of the parties, it being understood and agreed that Patheon, upon Client's request, will in any case use all reasonable efforts to remedy any late delivery of Products to be delivered under this Agreement. It is understood and agreed that if the Firm Order is more than [***] late Client may cancel any Firm Order for Products that are not delivered by Patheon in accordance with the agreed timelines, without any payment for such Firm Order being due by Client to Patheon provided that a Firm Order may not be cancelled (i) if any delay is caused by a late or incomplete delivery of Active Material or any related documentation or (ii) if Patheon has commenced performance of the Manufacturing Services relating to the Firm Order. Patheon shall be entitled to invoice any part of a Firm Order that has been delivered in accordance with Section 5.5. Any claim for a late delivery by Patheon will be deemed waived if it has not been presented within [***] of the date of receipt of invoice by Client. Any Firm Orders for Products cancelled pursuant to this Section 5.7 shall count towards Client's Exclusivity Obligation.

ARTICLE 6

PRODUCT CLAIMS AND RECALLS

6.1 Product Claims.

(a) Product Claims. Client has the right to reject and return, at Patheon's expense for any Products for which Patheon has responsibility under Section 6.3 (and otherwise at Client's expense), any portion of any shipment of Products that deviate from the Specifications, cGMPs, or Applicable Laws, without invalidating any remainder of the shipment. Client will visually inspect the Products manufactured by Patheon upon receipt thereof and will give Patheon written notice (a "**Deficiency Notice**") of all claims for Products that deviate from the Specifications, cGMPs, or Applicable Laws, within [***] after Client's receipt thereof (or, in the case of any defects not reasonably susceptible to discovery upon receipt of the Product, within [***] after discovery by Client, but not after the expiration date of the Product). Should Client fail to give Patheon the Deficiency Notice within the applicable [***] period, then the delivery will be deemed to have been accepted by Client on the [***] after delivery or discovery, as applicable.

(b) Determination of Deficiency. Upon receipt of a Deficiency Notice, Patheon will have [***] to advise Client by notice in writing that it disagrees with the contents of the Deficiency Notice, if applicable. If Client and Patheon fail to agree within [***] after Patheon's notice to Client as to whether any Products identified in the Deficiency Notice deviate from the Specifications, cGMPs, or Applicable Laws, then the parties will mutually select an independent laboratory to evaluate if the Products deviate from the Specifications, cGMPs, or Applicable Laws. The parties will cause the independent laboratory to conduct its evaluation as promptly as reasonably practicable. This evaluation will be binding on the parties. If the evaluation certifies that any Products deviate from the Specifications, cGMPs, or Applicable Laws, Client may reject those Products in the manner contemplated in this Section 6.1 and Patheon will be responsible for the cost of the evaluation. If the evaluation does not so certify for any of the Products, then Client will be deemed to have accepted delivery of the Products which are deemed to be conforming on the date the evaluation is delivered by the independent laboratory to the parties and Client will be responsible for the cost of the evaluation. With respect to any Products which Patheon agrees are deficient in accordance with the Deficiency Notice, or which are otherwise found to be deficient by the independent laboratory, Client will be entitled to the remedies set forth in Section 6.3(a).

(c) Shortages. Claims for shortages in the amount of Products shipped by Patheon will be dealt with by reasonable agreement of the parties.

6.2 Product Recalls and Returns.

(a) Records and Notice. Patheon and Client will each maintain records necessary to permit a Recall of any Products delivered to Client or customers of Client. Each party will promptly notify the other by telephone (to be confirmed in writing) of any information which might affect the marketability, safety or effectiveness of the Products or which might result in the Recall or seizure of the Products. Upon receiving this notice or upon this discovery, each party will stop making any further shipments of any Products in its possession or control until a decision has been made whether a Recall or some other corrective action is necessary. The decision to initiate a Recall or to take some other corrective action, if any, will be made and implemented by Client. "**Recall**" will mean any action (i) by Client to recover title to or possession of quantities of the Products sold or shipped to third parties (including, without limitation, the voluntary withdrawal of Products from the market); or (ii) by any regulatory authorities to detain or destroy any of the Products. Recall will also include any action by either party to refrain from selling or shipping quantities of the Products to third parties which would be subject to a Recall if sold or shipped.

(b) Recalls. If (i) any Regulatory Authority issues a directive, order or, following the issuance of a safety warning or alert about the Product, a written request that any Product be Recalled, (ii) a court of competent jurisdiction orders a Recall, or (iii) Client determines that any Product should be Recalled or that a "Dear Doctor" letter is required relating the restrictions on the use of any Product, Patheon will co-operate as reasonably required by Client, having regard to all applicable laws and regulations.

(c) Product Returns. Client will have the responsibility for handling customer returns of the Products. Patheon will give Client any assistance that Client may reasonably require to handle the returns.

6.3 Patheon's Responsibility for Defective and Recalled Products.

(a) Defective Product. If Client rejects Products under Section 6.1 and the deviation is determined to have arisen from Patheon's failure to provide the Manufacturing Services in accordance with the Specifications, cGMPs, or Applicable Laws, Patheon will credit Client's account for Patheon's invoice price for the defective Products. If Client previously paid for the defective Products, Patheon will promptly, at Client's election, either: (i) refund the invoice price for the defective Products; (ii) offset the amount paid against other amounts due to Patheon hereunder; or (iii) replace the Products with conforming Products, (provided that Patheon is able to manufacture replacement Product at the same Manufacturing Site as that of the rejected Products),without Client being liable for payment therefor under Section 3.1, contingent upon the receipt from Client of all Active Materials and Client-Supplied Components required for the manufacture of the replacement Products. Patheon's responsibility for any loss of Active Materials in defective Product will be captured and calculated in the Active Materials Yield under Section 2.2.

(b) Recalled Product. If a Recall or return results from, or arises out of, a failure by Patheon to perform the Manufacturing Services in accordance with the Specifications, cGMPs, or Applicable Laws, Patheon will be responsible for the documented out-of-pocket expenses of the Recall or return and will promptly, at Client's election, either: (i) refund the invoice price for such Recalled or returned Products; (ii) offset such Recalled Product Credit Amount against other amounts due to Patheon hereunder; or (iii) use its commercially reasonable efforts to replace such Recalled or returned Products with conforming Products using the next available manufacturing slot without the Client being liable for payment therefore, contingent upon the receipt from Client of all Active Materials and Client-Supplied Components required for the manufacture of the replacement Products. In all other circumstances, Recalls, returns, or other corrective actions will be made at Client's direction, cost and expense. Patheon's responsibility for any loss of Active Materials in Recalled Product will be captured and calculated in the Active Materials Yield under Section 2.2.

(c) Except as set forth in Sections 6.3(a) and (b) above and for breaches of its representations and warranties set forth in Section 9.3 below, Patheon will not be liable to Client nor have any responsibility to Client for any deficiencies in, or other liabilities associated with, any Product manufactured by it, (collectively, "**Product Claims**"). For greater certainty, Patheon will have no obligation for any Product Claims to the extent the Product Claim (i) is caused by deficiencies in the Specifications, the safety, efficacy, or marketability of the Products or any distribution thereof, (ii) results from a defect in a Component that is not reasonably discoverable by Patheon using the test methods set forth in the Specifications, (iii) results from a defect in the Active Materials, Client-Supplied Components or Components supplied by a Client designated additional source that is not reasonably discoverable by Patheon using the test methods set forth in the Specifications, (iv) is caused by actions of Client or third parties occurring after the Product is shipped by Patheon under Section 5.5, (v) is due to packaging design or labelling defects or omissions for which Patheon has no responsibility, (vi) is due to any unascertainable reason despite Patheon having performed the Manufacturing Services in accordance with the Specifications, cGMP's, and Applicable Laws, or (vii) is due to any other breach by Client of its obligations under this Agreement.

6.4 Disposition of Defective or Recalled Products.

Client will not dispose of any damaged, defective, returned, or Recalled Products for which it intends to assert a claim against Patheon without Patheon's prior written authorization to do so. Alternatively, Patheon may instruct Client to return the Products to Patheon. Patheon will bear the cost of disposition for any damaged, defective, returned or Recalled Products for which it bears responsibility under Section 6.3, and will promptly reimburse Client for any such costs which may be incurred by Client. In all other circumstances, Client will bear the cost of disposition, including all applicable fees for Manufacturing Services, for any damaged, defective, returned, or Recalled Products. Notwithstanding the foregoing, the Client will have the right at all times to retain a reasonable sample of such Products for its own archival purposes.

6.5 Healthcare Provider or Patient Questions and Complaints.

Client will have the sole responsibility for responding to questions and complaints from its customers. Questions or complaints received by Patheon from Client's customers, healthcare providers or patients will be promptly referred to Client. Patheon will co-operate as reasonably required to allow Client to determine the cause of and resolve any questions and complaints. This assistance will include follow-up investigations, including testing. In addition, Patheon will give Client all agreed upon information that will enable Client to respond properly to questions or complaints about the Products as set forth in the Quality Agreement. Patheon will notify Client promptly and in any event not later than specified in the Quality Agreement after it becomes aware of any adverse event associated with the use of the Products, whether or not determined to be attributable to the Products, and whether or not deemed to be serious or non-serious. Such information will be sent to the Client as set forth in the Quality Agreement. If it is determined that the cause of the complaint or adverse event resulted from a failure by Patheon to perform the Manufacturing Services in accordance with the Specifications, cGMPs, and Applicable Laws, Patheon will bear all costs incurred under this Section 6.5. In all other circumstances, such costs will be borne by Client.

6.6 Sole Remedy.

Except for the indemnity set forth in Section 10.3 and subject to the limitations set forth in Sections 10.1 and 10.2, the remedies described in this Article 6 will be Client's sole remedy for any failure by Patheon to provide the Manufacturing Services in accordance with the Specifications, cGMPs, and Applicable Laws or for any breach by Patheon of its representations and warranties set forth in Section 9.3.

ARTICLE 7

CO-OPERATION

7.1 Quarterly Review.

Each party will forthwith upon execution of this Agreement appoint one of its employees to be a relationship manager responsible for liaison between the parties. The relationship managers will meet not less than quarterly to review the current status of the business relationship and manage any issues that have arisen.

7.2 Governmental Agencies.

Subject to Section 7.8, each party may communicate with any governmental agency, including but not limited to governmental agencies responsible for granting Regulatory Approval for the Products, regarding the Products if, in the opinion of that party's counsel, the communication is necessary to comply with the terms of this Agreement or the requirements of any law, governmental order or regulation. Unless, in the reasonable opinion of its counsel, there is a legal prohibition against doing so, a party will permit the other party to accompany and take part in any communications with the agency, and to receive copies of all communications from the agency.

7.3 Records and Accounting by Patheon.

Patheon will keep records of the manufacture, testing, and shipping of the Products, Active Materials, and Components and retain samples of the Products, Active Materials, and Components as are necessary to comply with all Applicable Laws, including manufacturing regulatory requirements applicable to Patheon, the Manufacturing Site, the Products, the Active Materials and/or Components (provided that the requirements applicable to the Products, Active Materials and Components are notified and agreed with Patheon in advance), as well as to assist with resolving Product complaints and other similar investigations. Copies of the records and samples will be retained for one year following the date of Product expiry, or longer if required by law or regulation, following which time Client will be contacted concerning the delivery and destruction of the documents and/or samples of Products. Patheon reserves the right to destroy or return to Client, at Client's sole expense, any document or samples for which the retention period has expired if Client fails to arrange for destruction or return within [***] of receipt of notice from Patheon. Client is responsible for retaining samples of the Products necessary to comply with the legal/regulatory requirements applicable to Client.

7.4 Inspection.

Client may inspect Patheon reports and records relating to this Agreement during normal business hours and with reasonable advance notice, but a Patheon representative must be present during the inspection.

7.5 Access.

Patheon will give Client reasonable access at agreed times to the areas of the Manufacturing Site in which the Products are manufactured, stored, handled, or shipped to permit Client to verify that the Manufacturing Services are being performed in accordance with the Specifications, cGMPs, and Applicable Laws. But, with the exception of "for-cause" audits, Client will be limited each Year to one cGMP-type audit, lasting no more than [***] days, and involving no more than two auditors. Client may request additional cGMP-type audits, additional audit days, or the participation of additional auditors subject

to payment to Patheon of a fee of [***] for each additional audit day and [***] per audit day for each additional auditor. The right of access set forth in Sections 7.4 and 7.5 will not include a right to access or inspect Patheon's financial records. Patheon will support the Pre-Approval Inspection of the FDA ("PAI") and equivalent regulatory inspection for other jurisdictions (where applicable) and provide a copy of the resulting report. The first PAI is at no cost to Client. Additional PAI or equivalent support will be subject to additional fees.

7.6 Regulatory Inspections.

Patheon will make its internal practices, books and records relating to the manufacture of the Products available and allow access to all facilities used for manufacturing the Products to any Authority having jurisdiction over the manufacture of the Products for the purposes of determining Patheon's compliance with Applicable Laws, including, but not limited to, cGMPs. Patheon will notify Client by telephone and e-mail within [***] of any proposed or announced inspections, and as soon as possible (but in any case within [***]) after any unannounced inspection, by any Authority relating to the Products. Patheon will provide the Client with a reasonable description in writing of each such inspection promptly (but in no event later than specified in the Quality Agreement) thereafter, and with copies of any Authority-issued inspection observation reports (including, without limitation, form 483s and equivalent forms from other regulatory bodies) and Authority correspondence, purged only of confidential information that is unrelated to the Products. Patheon will also notify Client of receipt of any other form 483's or warning letters or any other significant regulatory action which Patheon's quality assurance group determines could impact the regulatory status of the Products. Patheon and Client will cooperate in resolving any concerns with any Authority, and the Client may review Patheon's responses to any such reports and communications, and Patheon will in its reasonable discretion incorporate into such responses any comments received from the Client. Patheon will also inform the Client of any action taken by any Authority against Patheon or any of its officers or employees which may be reasonably expected to adversely affect the Products or Patheon's ability to supply the Products hereunder within a time period specified in the Quality Agreement.

7.7 Reports.

Patheon will supply on an annual basis all Product data in its control, including release test results, complaint test results, and all investigations (in manufacturing, testing, and storage), that Client reasonably requires in order to complete any filing under any applicable regulatory regime, including any Annual Report that Client is required to file with the FDA. At the Client's request, Patheon will provide a copy of the Patheon standard Annual Product Review Report to the Client at no additional cost unless otherwise specified in Schedule B. Any additional data or report requested by Client beyond the scope of cGMPs and customary FDA requirements, including Continuous Process Verification data, will be subject to an additional fee to be agreed upon between Patheon and the Client.

7.8 Regulatory Filings.

(a) Regulatory Authority. Client will have the sole responsibility at Client's expense for filing all documents with all Regulatory Authorities and taking any other actions that may be required for the receipt and/or maintenance of Regulatory Authority approval for the commercial manufacture, distribution and sale of the Products ("**Regulatory Approval**") and will provide copies thereof to Patheon on request. Patheon will assist Client, to the extent consistent with Patheon's obligations under this Agreement, to obtain Regulatory Authority approval for the commercial manufacture, distribution and sale of the Products as quickly as reasonably possible.

(b) Verification of Data. At least [***] prior to filing any documents with any Regulatory Authority that incorporate data generated by Patheon, Client will give Patheon a copy of the documents incorporating this data to give Patheon the opportunity to verify the accuracy and regulatory validity of those documents as they relate to Patheon generated data; provided, however, that the parties may agree to a shorter time for the review as needed.

(c) Verification of CMC. At least [***] prior to filing with any Regulatory Authority any documentation which is, or is equivalent to, the FDA's Chemistry and Manufacturing Controls ("**CMC**") related to any Marketing Authorization, such as a US New Drug Application, US Abbreviated New Drug Application, US Biologics Licence Application, or EU Marketing Authorisation Application, Client will give Patheon a copy of the CMC as well as all supporting documents which have been relied upon to prepare the CMC. This disclosure will permit Patheon to verify that the CMC accurately describes the validation or scale-up work that Patheon has performed and the manufacturing processes that Patheon will perform under this Agreement. Client will give Patheon copies of all regulatory filings at the time of submission which contain CMC information regarding the Product. Notwithstanding the foregoing, Client may omit from the materials provided to Patheon any CMC documentation and supporting documents which have been previously provided to Patheon by Client and which have not been modified or edited by Client.

(d) Deficiencies. If, in Patheon's sole discretion, acting reasonably, Patheon determines that any of the information given by Client under clauses (b) and (c) above is inaccurate or deficient in any manner whatsoever (the "**Deficiencies**"), Patheon will notify Client in writing of the Deficiencies. The parties will work together to have the Deficiencies resolved prior to the date of filing of the relevant application and in any event before any pre-approval inspection or before the Product is placed on the market if a pre-approval inspection is not performed, provided that to the extent of any disagreement concerning the form or content any information or submissions covered by subsections (b) and (c) above, Client will have the final decision-making authority.

(e) Client Responsibility. For clarity, the parties agree that in reviewing the documents referred to in subsections (b) and (c) above, Patheon's role will be limited to verifying the accuracy of the description of the work undertaken or to be undertaken by Patheon. Subject to the foregoing, Patheon will not assume any responsibility for the accuracy of any application for receipt of an approval by a Regulatory Authority. The Client is solely responsible for the preparation and filing of the application for approval by the Regulatory Authority and any relevant costs will be borne by the Client, excepts as otherwise provided in this Section 7.8.

(f) Inspection by Regulatory Authorities. If Client does not give Patheon the documents requested under subsection (b) and (c) above within the time specified and if Patheon reasonably believes that Patheon's standing with a Regulatory Authority may be jeopardized, Patheon may, in its sole discretion, delay or postpone any inspection by the Regulatory Authority until Patheon has reviewed the requested documents and is satisfied with their contents.

(g) Pharmacovigilance. Client will be responsible, at its expense, for all pharmacovigilance obligations for the Products pursuant to Applicable Laws. Patheon will promptly provide to Client any information or data which it compiles pursuant to pharmacovigilance obligations or activities as specified in the Quality Agreement.

(h) No Patheon Responsibility. Patheon will not assume any responsibility for the accuracy or cost of any application for Regulatory Approval. If a Regulatory Authority, or other governmental body, requires Patheon to incur fees, costs or activities in relation to the Products which Patheon considers unexpected and extraordinary, then Patheon will notify Client in writing and the parties will discuss in good faith appropriate mutually acceptable actions, including fee/cost sharing, or termination of all or any part of

this Agreement. Patheon will not be obliged to undertake these activities or to pay for the fees or costs if, in Patheon's sole discretion, doing so is commercially inadvisable for Patheon.

ARTICLE 8

TERM AND TERMINATION

8.1 Initial Term.

This Agreement will become effective as of the Effective Date and will continue until December 31 of the Year that is five full Years after the Commencement Date (the "**Initial Term**"), unless terminated earlier by one of the parties in accordance herewith. This Agreement will automatically renew after the Initial Term for successive terms of one Year each (each a "**Renewal Term**"), unless either party gives written notice to the other party of its intention to terminate this Agreement at least 18 months prior to the end of the Initial Term or 18 months prior to the end of any Renewal Term.

8.2 Termination for Cause.

(a) Either party at its sole option may terminate this Agreement upon written notice where the other party has failed to remedy a material breach of any of its representations, warranties, or other obligations under this Agreement within [***] following receipt of a written notice of the breach from the aggrieved party that expressly states that it is a notice under this Section 8.2(a).

(b) Either party at its sole option may immediately terminate this Agreement upon written notice, but without prior advance notice, to the other party if: (i) the other party 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 by the other party; or (iii) this Agreement is assigned by the other party for the benefit of creditors.

(c) Client may terminate this Agreement upon [***] prior written notice if any Authority takes any action, or raises any objection, that prevents Client from importing, exporting, purchasing, or selling the Product. But if this occurs, Patheon and Client must still fulfill all of its obligations under Section 8.3 and 8.4 below and under any Capital Equipment Agreement regarding the Product.

(d) Patheon or Client may terminate this Agreement upon [***] prior written notice if Client or Patheon assigns under Section 13.6 any of its rights under this Agreement to an assignee that is: (i) in the opinion of the non-assigning Party acting reasonably, not a credit worthy substitute for the assigning Party; or (ii) a Patheon or Client Competitor.

8.3 Obligations on Termination.

(a) If this Agreement is completed, expires, or is terminated in whole or in part for any reason, then:

(i) Patheon will cease the manufacture of Products and will terminate any unfilled orders with third parties that Patheon may have previously submitted with respect to Components, to the extent such orders may be terminated or revoked;

(ii) Client will take delivery of and pay for all undelivered Products that are manufactured and/or packaged under a Firm Order, at the Price in effect at the time the Firm Order was placed;

(iii) Client will purchase, at Patheon's out-of-pocket cost (including all costs incurred by Patheon for the purchase and handling of the Inventory), the Inventory applicable to the Products which was purchased, produced or maintained by Patheon in contemplation of filling Firm Orders or in accordance with Section 5.3 prior to expiration or notice of termination being given;

(iv) Client will satisfy the purchase price payable under Patheon's non-cancellable orders with suppliers of Components, if the orders were made by Patheon in reliance on Firm Orders or in accordance with Section 5.3 and prior to expiration or notice of termination being given; and

(v) Client acknowledges that no Patheon Competitor will be permitted access to the Manufacturing Site; and Client will make commercially reasonable efforts, at its own expense, to remove from Patheon site(s), within [***], all unused Active Material and Client-Supplied Components, all applicable Inventory and Materials (whether current or obsolete), supplies, undelivered Product, chattels, equipment or other moveable property owned by Client, related to the Agreement and located at a Patheon site or that is otherwise under Patheon's care and control ("**Client Property**"). If Client fails to remove the Client Property within [***] following the completion, termination, or expiration of the Agreement, Client will pay Patheon [***] per pallet, per month, one pallet minimum (except that Client will pay [***] per pallet, per month, one pallet minimum, for any of the Client Property that contains controlled substances, requires refrigeration or other special storage requirements) thereafter for storing the Client Property and will assume any third party storage charges invoiced to Patheon regarding the Client Property. Patheon will invoice Client for the storage charges as set forth in Section 5.6 of this Agreement.

(b) Any completion, termination or expiration of this Agreement will not affect any outstanding obligations or payments due prior to the completion, termination or expiration, nor will it prejudice any other remedies that the parties may have under this Agreement or any related Capital Equipment Agreement. For greater certainty, completion, termination or expiration of this Agreement for any reason will not affect the obligations and responsibilities of the parties under Articles 10 and 11 and Sections 5.5, 5.6, 8.3, 13.1, 13.2, 13.3 and 13.16, all of which survive any completion, termination or expiration.

8.4 Technology Transfer.

Following termination of this Agreement for any reason, or at Client's request during a period beginning at least [***] before the end of the term of this Agreement following the Parties' reasonable conclusion that this Agreement will not be extended after the term of this Agreement, Patheon shall provide assistance to transfer part or all of the Client's manufacturing process, know-how and analytical testing methodology for the Product to Client or Client's designee ("**Technology Transfer**") to assist Client or its designee to manufacture the Product. Patheon shall also disclose to Client or its designee any Patheon Intellectual Property that has been used by Patheon to perform the Manufacturing Services. For the purposes of such assistance, Patheon shall, upon request of Client

prepare a written proposal to implement the Technology Transfer, including fees therefore. Client shall pay the agreed fees for any of such Technology Transfer provided by Patheon. No Patheon Competitor will be permitted access to the Manufacturing Site pursuant to this Section.

ARTICLE 9

REPRESENTATIONS, WARRANTIES AND COVENANTS

9.1 Authority.

Each party covenants, represents, and warrants that:

(a) it has the full right and authority to enter into this Agreement and that it is not aware of any impediment that would inhibit its ability to perform its obligations hereunder;

(b) this Agreement has been duly executed and delivered by, and is a legal and valid obligation binding upon such party, subject to the effects of bankruptcy, insolvency, or other laws of general application affecting the enforcement of creditor rights and judicial principles affecting the availability of specific performance and general principles of equity, whether enforceability is considered a proceeding at law or equity; and

(c) the entry into, the execution and delivery of, and the carrying out and other performance of its obligations under this Agreement by such party (i) does not conflict with, or contravene or constitute any default under, any agreement, instrument or understanding, oral or written, to which it is a party, including, but not limited to, its certificate of incorporation or by-laws, and (ii) does not violate Applicable Laws or any judgment, injunction, order or decree of any Authority having jurisdiction over it.

9.2 Client Warranties.

Client covenants, represents, and warrants that:

(a) Non-Infringement.

(i) the Specifications for each of the Products are its or its Affiliate's property and that Client may lawfully disclose the Specifications to Patheon;

(ii) any Client Intellectual Property, used by Patheon in performing the Manufacturing Services according to the Specifications (A) is owned or controlled by Client or its Affiliate, (B) may be lawfully used as directed by Client, and (C) to its knowledge does not infringe and will not infringe any Third Party Rights;

(iii) to the knowledge of Client, the performance of the Manufacturing Services by Patheon for the Product under this Agreement or the use or other disposition of the Product by Patheon as may be required to perform its obligations under this Agreement does not and will not infringe any Third Party Rights;

(iv) to the knowledge of Client, there are no actions or other legal proceedings involving the Client that concerns the infringement of Third Party Rights related to any of the Specifications, or any of the Active Materials and the Components, or

the sale, use, or other disposition of any Product made in accordance with the Specifications;

(b) Quality and Compliance.

(i) the Specifications for the Product conforms to all applicable cGMPs and Applicable Laws;

(ii) the Products, if labelled and manufactured in accordance with the Specifications and in compliance with applicable cGMPs and Applicable Laws (i) may be lawfully sold and distributed in every jurisdiction in which Client markets the Products, (ii) will be fit for the purpose intended, and (iii) will be safe for human consumption;

(iii) on the date of shipment, the API will conform to the specifications for the API that Client has given to Patheon and that the API will be adequately contained, packaged, and labelled and will conform to the affirmations of fact on the container.

9.3 Patheon Warranties.

Patheon covenants, represents, and warrants that:

(a) it will perform the Manufacturing Services in accordance with the Specifications, cGMPs, and Applicable Laws;

(b) any Patheon Intellectual Property used by Patheon to perform the Manufacturing Services (i) is Patheon's or its Affiliate's unencumbered property, (ii) may be lawfully used by Patheon, and (iii) does not infringe and will not infringe any Third Party Rights;

(c) it will not in the performance of its obligations under this Agreement use the services of any person it knows is debarred or suspended under 21 U.S.C. §335(a) or (b);

(d) it does not currently have, and it will not hire, as an officer or an employee any person whom it knows has been convicted of a felony under the laws of the United States for conduct relating to the regulation of any drug product under the United States *Federal Food, Drug, and Cosmetic Act*;

(e) it has and will maintain throughout the term of this Agreement, the expertise, with respect to personnel and equipment, to fulfill the obligations established hereunder, and has obtained all requisite material licenses, authorizations and approvals required by all Authorities to manufacture the Products (excluding the Regulatory Approval);

(f) the Manufacturing Site, all other facilities, all equipment and all personnel to be employed by Patheon in rendering the Manufacturing Services are currently, and will be at the time each batch of Products is produced, qualified in accordance with all Applicable Laws, including, but not limited to, cGMPs;

(g) there are no pending or uncorrected citations or adverse conditions noted in any inspection of the Manufacturing Site or any other facilities to be employed by Patheon in rendering the Manufacturing Services which would cause the Products to be misbranded or adulterated within the meaning of the Act, including, but not limited to, all cGMPs;

(h) to the knowledge of Patheon, the Patheon Intellectual Property used by Patheon to manufacture the finished Product in accordance with this Agreement does not and will not infringe any Third Party Rights, except to the extent caused or contributed to by any breach of Client's warranties under Section 9.2(a);

(i) to the knowledge of Patheon, there are no claims against Patheon asserting that any Patheon Intellectual Property to be used for the Manufacturing Services infringes, misappropriates, or violates any Third Party Rights;

(j) all employees, consultants, subcontractors and agents performing services for Patheon hereunder have assigned, or will assign, in writing to Patheon all of their right, title and interest in, to and under any and all Inventions directly relating to the Product; and

(k) all Product manufactured and supplied to the Client under this Agreement will not be, as a result of any failure by Patheon to provide the Manufacturing Services in accordance with the Specifications, cGMPs, or Applicable Laws, adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act or other Applicable Laws as of the time that the finished Product is transferred to the carrier at Patheon's shipping point.

9.4 Permits.

(a) Client will be solely responsible for obtaining or maintaining, on a timely basis, any permits or other regulatory approvals for the Products or the Specifications, including, without limitation, all marketing and post-marketing approvals.

(b) Patheon will maintain at all relevant times all governmental permits, licenses, approval, and authorities required to enable it to lawfully and properly perform the Manufacturing Services.

9.5 No Warranty.

EXCEPT AS SET FORTH IN THIS SECTION 9, NEITHER PARTY MAKES ANY WARRANTY OF ANY KIND, EITHER EXPRESSED OR IMPLIED, BY FACT OR LAW, OTHER THAN THOSE EXPRESSLY SET FORTH IN THIS AGREEMENT. PATHEON MAKES NO WARRANTY OR CONDITION OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY WARRANTY OR CONDITION OF MERCHANTABILITY FOR THE PRODUCTS.

ARTICLE 10

REMEDIES AND INDEMNITIES

10.1 Consequential and Other Damages.

Under no circumstances whatsoever will either party be liable to the other in contract, tort, negligence, breach of statutory duty, or otherwise for (i) any (direct or indirect) loss of profits, of production, of anticipated savings, of business, or goodwill or (ii) for any other liability, damage, costs, or expense of any kind incurred by the other party of an indirect or consequential nature, regardless of any notice of the possibility of these damages.

10.2 Limitation of Liability.

(a) Active Materials. Except as expressly set forth in Section 2.2 and Article 6, under no circumstances will Patheon be responsible for any loss or damage to the Active Materials. Patheon's maximum responsibility for loss or damage to the Active Materials will not exceed the Maximum Credit Value set forth in Schedule D.

(b) Maximum Liability. Except for any liability arising (i) [***], or (ii) under [***], or (iii) in connection with Section 10.2(c), and subject to Section 10.2(d), Patheon's maximum aggregate liability to Client in any Year under this Agreement, including, without limitation, any liability arising under Section 6.3(b) relating to the expenses of a Recall or Product return, Sections 2.2 or 10.3 (except as stated above) hereof or resulting from any and all breaches of its representations, warranties, or any other obligations under this Agreement will not exceed [***] of revenues (being payments of the Price) received from Client and its Affiliates or properly invoiced under this Agreement by Patheon during the 12-month period prior to the event giving rise to the applicable claim or set of related claim(s) arising out of the same facts or circumstances.

(c) Defective or Recalled Product. Patheon's maximum aggregate liability to Client for any obligation to (i) refund, offset or replace any defective Product under Section 6.3(a) or (ii) replace any recalled Product under Section 6.3(b), will not exceed [***] of the Price for the defective or recalled Product as applicable. This Section 10.2(c) will not be subject to Section 10.2(b).

(d) Death, Personal Injury and Fraudulent Misrepresentation. Nothing contained in this Agreement shall act to exclude or limit either party's liability for (i) personal injury or death caused by the negligence of either party; (ii) fraudulent misrepresentation; or (iii) any acts or omissions for which the governing law prohibits the exclusion or limitation of liability.

10.3 Patheon Indemnity.

Patheon agrees to defend and indemnify Client, its officers, employees, and agents against all losses, damages, costs, claims, demands, judgments and liability to, from and in favour of third parties (other than Affiliates) resulting from, or relating to any claim of personal injury or property damage to the extent that the injury or damage is the result of (i) a failure by Patheon to perform the Manufacturing Services in accordance with the Specifications, cGMPs, and Applicable Laws, or (ii) any other breach of the Agreement by Patheon, including, without limitation, any representation, warranty or covenant contained herein, except to the extent that the losses, damages, costs, claims, demands, judgments, and liability are due to the negligence or wrongful act(s) of Client, its officers, employees, agents, or Affiliates.

10.4 Client Indemnity.

Client agrees to defend and indemnify Patheon, its officers, employees, and agents against all losses, damages, costs, claims, demands, judgments and liability to, from and in favour of third parties (other than Affiliates) resulting from, or relating to any claim of infringement or alleged infringement of any Third Party Rights in the Products, or any portion thereof, or any claim of personal injury or property damage to the extent that the injury or damage is arises other than from (i) a failure by Patheon to perform the Manufacturing Services in accordance with the Specifications, cGMPs, and Applicable Laws, or (ii) any other breach of this Agreement by Patheon, including, without limitation, any representation, warranty or covenant contained herein, except to the extent that the losses, damages, costs, claims, demands, judgments, and liability are due to the negligence or wrongful act(s) of Patheon, its officers, employees, agents, or Affiliates.

10.5 Indemnification Procedure

If a claim occurs for which a party has an indemnification obligation under Section 10.3 or 10.4, the indemnified party (the "**Indemnitee**") will: (a) promptly notify the indemnifying party (the "**Indemnitor**") in writing of the claim; (b) use commercially reasonable efforts to mitigate the effects of the claim; (c) reasonably cooperate with the Indemnitor in the defense of the claim; and (d) permit the Indemnitor to control the defense and settlement of the claim, with counsel reasonably satisfactory to the Indemnitee, all at the Indemnitor 's cost and expense. If the Indemnitor assumes the defense of the claim, the Indemnitee may participate in such defense with the Indemnitee's own counsel who will be retained, at the Indemnitee's sole cost and expense; provided, however, that neither the Indemnitor nor the Indemnitee will consent to the entry of any judgment or enter into any settlement with respect to the claim without the prior written consent of the other party, which consent will not be unreasonably withheld or delayed. If the Indemnitee withholds consent in respect of a judgment or settlement involving only the payment of money by the Indemnitor and which would not involve any stipulation or admission of liability or result in the Indemnitee becoming subject to injunctive relief or other relief, the Indemnitor will have the right, upon written notice to the Indemnitee within five days after receipt of the Indemnitee's written denial of consent, to pay to the Indemnitee, or to a trust for its or the applicable third party's benefit, such amount established by such judgment or settlement in addition to all interest, costs or other charges relating thereto, together with all attorneys' fees and expenses incurred to such date for which the Indemnitor is obligated under this Agreement, if any, at which time the Indemnitor's rights and obligations with respect to such claim will cease. The Indemnitor will not be liable for any settlement or other disposition of a claim by the Indemnitee which is reached without the written consent of the Indemnitor.

10.6 Reasonable Allocation of Risk.

This Agreement (including, without limitation, this Article 10) is reasonable and creates a reasonable allocation of risk for the relative profits the parties each expect to derive from the Products. Patheon assumes only a limited degree of risk arising from the manufacture, distribution, and use of the Products because Client has developed and holds the marketing approval for the Products, Client requires Patheon to manufacture and label the Products strictly in accordance with the Specifications, cGMPs and Applicable Law, and Client, not Patheon, is best positioned to inform and advise potential users about the circumstances and manner of use of the Products.

ARTICLE 11

CONFIDENTIALITY

11.1 Confidential Information.

"**Confidential Information**" means any information disclosed by the Disclosing Party to the Recipient (whether disclosed in oral, written, electronic or visual form) that is non-public, confidential or proprietary including, without limitation, information relating to the Disclosing Party's patent and trademark applications, process designs, process models, drawings, plans, designs, data, databases and extracts therefrom, formulae, methods, know-how and other intellectual property, its clients or client confidential information, finances, marketing, products and processes and all price quotations, manufacturing or professional services proposals, information relating to composition, proprietary technology, and all other information relating to manufacturing capabilities and operations. In addition, all analyses, compilations, studies, reports or other documents prepared by any party's Representatives containing the Confidential Information will be considered Confidential Information. Samples or materials provided hereunder as well as any and all information derived from the approved analysis of the samples or materials will also constitute Confidential Information. For the purposes of this ARTICLE 11, a party or its Representative receiving

Confidential Information under this Agreement is a "**Recipient**," and a party or its Representative disclosing Confidential Information under this Agreement is the "**Disclosing Party**."

11.2 Use of Confidential Information.

The Recipient will use the Confidential Information solely for the purpose of meeting its obligations under this Agreement. The Recipient will keep the Confidential Information strictly confidential and will not disclose the Confidential Information in any manner whatsoever, in whole or in part, other than to those of its Representatives who (i) have a need to know the Confidential Information for the purpose of this Agreement; (ii) have been advised of the confidential nature of the Confidential Information and (iii) have obligations of confidentiality and non-use to the Recipient no less restrictive than those of this Agreement. Recipient will protect the Confidential Information disclosed to it by using all reasonable precautions to prevent the unauthorized disclosure, dissemination or use of the Confidential Information, which precautions will in no event be less than those exercised by Recipient with respect to its own confidential or proprietary Confidential Information of a similar nature.

11.3 Exclusions.

The obligations of confidentiality will not apply to the extent that the information:

(a) is or becomes publicly known through no breach of this Agreement or fault of the Recipient or its Representatives;

(b) is in the Recipient's possession at the time of disclosure by the Disclosing Party other than as a result of the Recipient's breach of any legal obligation;

(c) is or becomes known to the Recipient on a non-confidential basis through disclosure by sources, other than the Disclosing Party, having the legal right to disclose the Confidential Information, provided that the other source is not known by the Recipient to be bound by any obligations (contractual, legal, fiduciary, or otherwise) of confidentiality to the Disclosing Party with respect to the Confidential Information;

(d) is independently developed by the Recipient without use of or reference to the Disclosing Party's Confidential Information as evidenced by Recipient's written records; or

(e) is expressly authorized for release by the written authorization of the Disclosing Party.

Any combination of information which comprises part of the Confidential Information are not exempt from the obligations of confidentiality merely because individual parts of that Confidential Information were publicly known, in the Recipient's possession, or received by the Recipient, unless the combination itself was publicly known, in the Recipient's possession, or received by the Recipient.

11.4 Photographs and Recordings.

Neither party will take any photographs or videos of the other party's facilities, equipment or processes, nor use any other audio or visual recording equipment (such as camera phones) while at the other party's facilities, without that party's express written consent.

11.5 Permitted Disclosure.

Notwithstanding any other provision of this Agreement, the Recipient may disclose Confidential Information of the Disclosing Party to the extent required, as advised by counsel, in response to a valid order of a court or other governmental body or as required by law, regulation or stock exchange rule. But the Recipient will advise the Disclosing Party in advance of the disclosure to the extent practicable and permissible by the order, law, regulation or stock exchange rule and any other applicable law, will reasonably cooperate with the Disclosing Party, if required, in seeking an appropriate protective order or other remedy, and will otherwise continue to perform its obligations of confidentiality set out herein. If any public disclosure is required by law, the parties will consult concerning the form of announcement prior to the public disclosure being made.

11.6 Marking.

The Disclosing Party agrees to use reasonable efforts to summarize in writing the content of any oral disclosure or other non-tangible disclosure of Confidential Information to the Recipient within [***] of the disclosure, but failure to provide this summary will not affect the nature of the Confidential Information disclosed to the Recipient if the Confidential Information was identified as confidential or proprietary when disclosed orally or in any other non-tangible form.

11.7 Return of Confidential Information.

Upon the written request of the Disclosing Party, the Recipient will promptly return the Confidential Information to the Disclosing Party or, if the Disclosing Party directs, destroy all Confidential Information disclosed in or reduced to tangible form including any copies thereof and any summaries, compilations, analyses or other notes derived from the Confidential Information except for one copy which may be maintained by the Recipient for its records. The retained copy will remain subject to all confidentiality provisions contained in this Agreement.

11.8 Remedies.

The parties acknowledge that monetary damages may not be sufficient to remedy a breach by either party of this Agreement and agree that the non-breaching party will be entitled to seek specific performance, injunctive and/or other equitable relief to prevent breaches of this Agreement and to specifically enforce the provisions hereof in addition to any other remedies available at law or in equity. These remedies will not be the exclusive remedies for breach of this Agreement but will be in addition to any and all other remedies available at law or in equity.

ARTICLE 12

DISPUTE RESOLUTION

12.1 Commercial Disputes.

If any dispute arises out of this Agreement (other than a dispute under Section 6.1(b) or a Technical Dispute, as defined herein), the parties will first try to resolve it amicably. In that regard, any party may send a notice of dispute to the other, and each party will appoint, within [***] from receipt of the notice of dispute, a single representative having full power and authority to resolve the dispute. The representatives will meet as necessary in order to resolve the dispute. If the representatives fail to resolve the matter within [***] from their appointment, or if a party fails to appoint a representative within the [***] period set forth above, the dispute will immediately be referred to the Chief Operating Officer (or another

officer as he/she may designate) of each party who will meet and discuss as necessary to try to resolve the dispute amicably. Should the parties fail to reach a resolution under this Section 12.1, the dispute will be referred to a court of competent jurisdiction in accordance with Section 13.17.

12.2 Technical Dispute Resolution.

If a dispute arises (other than disputes under Sections 6.1(b) or 12.1) between the parties that is exclusively related to technical aspects of the manufacturing, packaging, labelling, quality control testing, handling, storage, or other activities under this Agreement (a "**Technical Dispute**"), the parties will make all reasonable efforts to resolve the dispute by amicable negotiations. In that regard, senior representatives of each party will, as soon as possible and in any event no later than [***] after a written request from either party to the other, meet in good faith to resolve any Technical Dispute. If, despite this meeting, the parties are unable to resolve a Technical Dispute within a reasonable time, and in any event within [***] of the written request, the Technical Dispute will, at the request of either party, be referred for determination to an expert in accordance with Schedule E If the parties cannot agree that a dispute is a Technical Dispute, Section 12.1 will prevail. For greater certainty, the parties agree that the release of the Products for sale or distribution under the applicable marketing approval for the Products will not by itself indicate compliance by Patheon with its obligations for the Manufacturing Services and further that nothing in this Agreement (including Schedule E) will remove or limit the authority of the relevant qualified person (as specified by the Quality Agreement) to determine whether the Products are to be released for sale or distribution.

ARTICLE 13

MISCELLANEOUS

13.1 Inventions.

(a) All Inventions and Intellectual Property generated or derived by Patheon while performing the Manufacturing Services, to the extent it is specific to the development, manufacture, use, and sale of Client's Product or Active Materials that are the subject of the Manufacturing Services, including, but not limited to, any new use, new formulation or any change in the method of producing, testing or storing the Product in each case that are specific to the Product ("**Product Inventions**"), will be the exclusive Intellectual Property of Client. Patheon shall and hereby does assign to Client all right title and interest in and to the Product Inventions. Patheon will execute such instruments as will be required to evidence or effectuate the Client's ownership of Product Inventions, and will cooperate upon reasonable request in the prosecution of patents and other Intellectual Property rights related thereto at Client's cost.

(b) Inventorship of all Inventions and Intellectual Property generated or derived by either party pursuant to this agreement shall be determined in accordance with United States patent law, regardless of where the applicable activities occurred.

(c) Either party will give the other party written notice, as promptly as practicable, of all Inventions which can reasonably be deemed to constitute improvements or other modifications of the Products or processes or technology generated, derived, owned or otherwise controlled by the party during the term of this Agreement.

13.2 Intellectual Property.

(a) For the term of this Agreement, Client hereby grants to Patheon a non-exclusive, paid-up, royalty-free, non-transferable license of Client's Intellectual Property which Patheon must use in order to perform the Manufacturing Services.

(b) Patheon hereby grants to Client a perpetual, irrevocable, non-exclusive, paid-up, royalty-free, transferable license (with the right to sublicense) to use the Patheon Intellectual Property used by Patheon to perform the Manufacturing Services to enable Client to manufacture or have manufactured the Product(s).

(c) Subject to Section 13.1, all Client Intellectual Property, including Product Inventions, will be the exclusive property of Client, and all Patheon Intellectual Property will be the exclusive property of Patheon.

(d) Neither party has, nor will it acquire, any interest in any of the other party's Intellectual Property unless otherwise expressly agreed to in writing. Neither party will use any Intellectual Property of the other party, except as specifically authorized by the other party or as required for the performance of its obligations under this Agreement.

(e) Each party hereby acknowledges that it does not have, and will not acquire any interest in any of the other party's trademarks or trade names unless otherwise expressly agreed. Each party agrees not to use any trademarks or trade names of the other party, except as specifically authorized by the other party in writing both as to the names or marks which may be used and as to the manner and prominence of use. All goodwill in any trademarks will inure to the benefit of the trademark owner. Client, in its sole discretion, will determine the trademarks and trade names owned or licensed by Client to be used in connection with the Products, including without limitation, the trademarks and trade names which will appear on the labels, packaging, and any promotional or other materials related to the Products. Patheon will use those trademarks and trade names notified by Client to Patheon for use in the labelling and packaging of the Products, and Patheon will use only such notified trademarks and trade names for such purpose. Upon expiration or termination of this Agreement, Patheon will immediately cease using all of Client's trademarks and trade names.

(f) Each party will be solely responsible for the costs of filing, prosecution, and maintenance of its own Intellectual Property, including trademarks and trademark applications and patents and patent applications.

13.3 Insurance.

Each party will maintain commercial general liability insurance, including blanket contractual liability insurance covering the obligations of that party under this Agreement through the term of this Agreement and for a period of [***] thereafter. This insurance will have policy limits of not less than (i) [***] for each occurrence for personal injury or property damage liability; and (ii) [***] in the aggregate per annum for product and completed operations liability. If requested each party will give the other a certificate of insurance evidencing the above and showing the name of the issuing company, the policy number, the effective date, the expiration date, and the limits of liability. The insurance certificate will further provide for a minimum of 30 days' written notice to the insured of a cancellation of, or material change in, the insurance. If a party is unable to maintain the insurance policies required under this Agreement through no fault of its own, then the party will forthwith notify the other party in writing and the parties will in good faith negotiate appropriate amendments to the insurance provision of this Agreement in order to provide adequate assurances.

13.4 Independent Contractors.

The parties are independent contractors and this Agreement will not be construed to create between Patheon and Client any other relationship such as, by way of example only, that of employer-employee, principal agent, joint-venturer, co-partners, or any similar relationship, the existence of which is expressly denied by the parties.

13.5 No Waiver.

Either party's failure to require the other party to comply with any provision of this Agreement will not be deemed a waiver of the provision or any other provision of this Agreement, with the exception of Sections 6.1 and 8.2 of this Agreement.

13.6 Assignment.

(a) Patheon may not assign this Agreement or any of its associated rights or obligations without the written consent of Client, this consent not to be unreasonably withheld. But Patheon may arrange for subcontractors to perform specific testing services arising under this Agreement without the consent of Client; provided, however, the Patheon will provide advance notice of the name and function of any such subcontractor. Further it is specifically agreed that Patheon may subcontract any part of the Manufacturing Services under this Agreement to any of its Affiliates. Patheon will remain solely liable to Client for its obligations under this Agreement, and for the obligations of the applicable Affiliate of Patheon under the Quality Agreement, if the Manufacturing Services are subcontracted.

(b) Subject to Section 8.2(d), Client may assign this Agreement or any of its associated rights or obligations without approval from Patheon. But Client will give Patheon prior written notice of any assignment (where and to the extent possible), any assignee will covenant in writing with Patheon to be bound by the terms of this Agreement, and Client will remain liable hereunder. Any partial assignment will be subject to Patheon's cost review of the assigned Products and Patheon may terminate this Agreement or any assigned part thereof, on [***] prior written notice to Client and the assignee if good faith discussions do not lead to agreement on amended Manufacturing Service fees within a reasonable time.

(c) Despite the foregoing provisions of this Section 13.6, either party may assign this Agreement to any of its Affiliates or to a successor to or purchaser of all or substantially all of its business, but the assignee must execute an agreement with the non-assigning party whereby it agrees to be bound hereunder.

13.7 Force Majeure.

Neither party will be liable for the failure to perform its obligations under this Agreement if the failure is caused by an event beyond that party's reasonable control, including, but not limited to, strikes or other labor disturbances, lockouts, riots, quarantines, communicable disease outbreaks, wars, acts of terrorism, fires, floods, storms, interruption of or delay in transportation, defective equipment, lack of or inability to obtain fuel, power or components, or compliance with any order or regulation of any government entity acting within colour of right (a "**Force Majeure Event**"). A party claiming a right to excused performance under this Section 13.7 will immediately notify the other party in writing of the extent of its inability to perform, which notice will specify the event beyond its reasonable control that prevents the performance. Neither party will be entitled to rely on a Force Majeure Event to relieve it from an obligation

to pay money (including any interest for delayed payment) which would otherwise be due and payable under this Agreement.

13.8 Additional Product.

Additional products may be added to this Agreement and the additional products will be governed by the general conditions hereof with any special terms (including, without limitation, price) governed by executed amendments to Schedules A, B, C, and D as applicable.

13.9 Notices.

Any notice, approval, instruction or other written communication required or permitted hereunder will be sufficient if made or given to the other party by personal delivery, by telecopy, facsimile communication, or confirmed receipt email or by sending the same by first class mail, postage prepaid to the respective addresses, telecopy or facsimile numbers or electronic mail addresses set forth below:

If to Client:

Evoke Pharma, Inc.
420 Stevens Ave, Suite 370
Solana Beach, California 92075 USA

Attention: Matt D'Onofrio

Email address:MDOnofrio@EvokePharma.com

If to Patheon:

Patheon UK Limited
Kingfisher Drive
Covingham
Swindon Wiltshire SN3 5BZ
England

Attention: Legal Director
Facsimile No: [***]
Email address: [***]

or to any other addresses, telecopy or facsimile numbers or electronic mail addresses given to the other party in accordance with the terms of this Section 13.9. Notices or written communications made or given by personal delivery, telecopy, facsimile, or electronic mail will be deemed to have been sufficiently made or given when sent (receipt acknowledged), or if mailed, five days after being deposited in the United States, Canada, or European Union mail, postage prepaid or upon receipt, whichever is sooner.

13.10 Severability.

If any provision of this Agreement is determined by a court of competent jurisdiction to be invalid, illegal, or unenforceable in any respect, that determination will not impair or affect the validity,

legality, or enforceability of the remaining provisions, because each provision is separate, severable, and distinct.

13.11 Entire Agreement.

This Agreement, together with the Quality Agreement, constitutes the full, complete, final and integrated agreement between the parties relating to the subject matter hereof and supersedes all previous written or oral negotiations, commitments, agreements, transactions, or understandings concerning the subject matter hereof. Any modification, amendment, or supplement to this Agreement must be in writing and signed by authorized representatives of both parties. In case of conflict, the prevailing order of documents will be this Agreement and the Quality Agreement.

13.12 Other Terms.

No terms, provisions or conditions of any purchase order or other business form or written authorization used by Client or Patheon will have any effect on the rights, duties, or obligations of the parties under or otherwise modify this Agreement, regardless of any failure of Client or Patheon to object to the terms, provisions, or conditions unless the document specifically refers to this Agreement and is signed by both parties.

13.13 No Third Party Benefit or Right.

For greater certainty, nothing in this Agreement will confer or be construed as conferring on any third party any benefit or the right to enforce any express or implied term of this Agreement.

13.14 Execution in Counterparts.

This Agreement may be executed in two or more counterparts, by original, facsimile or “pdf” signature, each of which will be deemed an original, but all of which together will constitute one and the same instrument.

13.15 Use of Client Name.

Patheon will not make any use of Client’s name, trademarks or logo or any variations thereof, alone or with any other word or words, without the prior written consent of Client, which consent will not be unreasonably withheld. Despite this, Client agrees that Patheon may include Client’s name and logo in customer lists or related marketing and promotional material for the purpose of identifying users of Patheon’s Manufacturing Services. Client will have right to disclose name of Patheon as manufacturing partner to regulatory, financial and public investors.

13.16 Taxes.

(a) The Client will bear all taxes, duties, levies and similar charges (and any related interest and penalties) ("**Tax**" or "**Taxes**"), however designated, imposed as a result of the provision by the Patheon of Services under this Agreement, except:

(i) any Tax based on net income or gross income that is imposed on Patheon by its jurisdiction of formation or incorporation ("**Resident Jurisdiction**");

(ii) any Tax based on net income or gross income that is imposed on Patheon by jurisdictions other than its Resident Jurisdiction if this tax is based on a permanent establishment of Patheon; and

(iii) any Tax that is recoverable by Patheon in the ordinary course of business for purchases made by Patheon in the course of providing its Services, such as Value Added Tax (as more fully defined in subparagraph (d) below), Goods & Services Tax ("**GST**") and similar taxes.

(b) If the Client is required to bear a tax, duty, levy or similar charge under this Agreement by any state, federal, provincial or foreign government, including, but not limited to, Value Added Tax, the Client will pay the tax, duty, levy or similar charge and any additional amounts to the appropriate taxing authority as are necessary to ensure that the net amounts received by Patheon hereunder after all such payments or withholdings equal the amounts to which Patheon is otherwise entitled under this Agreement as if the tax, duty, levy or similar charge did not exist.

(c) Patheon will not collect an otherwise applicable tax if the Client's purchase is exempt from Patheon's collection of the tax and a valid tax exemption certificate is furnished by the Client to Patheon.

(d) If Section 13.16 (a)(iii) does not apply, any payment due under this Agreement for the provision of Services to the Client by Patheon is exclusive of value added taxes, turnover taxes, sales taxes or similar taxes, including any related interest and penalties (hereinafter all referred to as "**VAT**"). If any VAT is payable on a Service supplied by Patheon to the Client under this Agreement, this VAT will be added to the invoice amount and will be for the account of (and reimbursable to Patheon by) the Client. If VAT on the supplies of Patheon is payable by the Client under a reverse charge procedure (i.e., shifting of liability, accounting or payment requirement to recipient of supplies), the Client will ensure that Patheon will not effectively be held liable for this VAT by the relevant taxing authorities or other parties. Where applicable, Patheon will use its reasonable commercial efforts to ensure that its invoices to the Client are issued in such a way that these invoices meet the requirements for deduction of input VAT by the Client, if the Client is permitted by law to do so.

(e) Any Tax that Client pays, or is required to pay, but which Client believes should properly be paid by Patheon pursuant hereto may not be offset against sums due by Client to Patheon whether due pursuant to this Agreement or otherwise.

13.17 Governing Law.

This Agreement will be construed and enforced in accordance with the laws of the State of New York, New York, U.S.A. without regard to the application of principles of conflicts of law. In relation to such matters, both Parties shall submit to the exclusive jurisdiction of the state and federal courts located in the State of New York, New York. THE PARTIES EXPRESSLY WAIVE THEIR RESPECTIVE RIGHTS TO A JURY TRIAL IN RESPECT OF ANY MATTER RELATING TO THIS AGREEMENT OR ITS FORMATION. Notwithstanding the foregoing, Patheon and Client agree that either party will be entitled to seek interim relief (injunctive or otherwise) from any court of competent jurisdiction if there is a breach of this Agreement. The UN Convention on Contracts for the International Sale of Goods will not apply to this Agreement.

[Signature page to follow]

IN WITNESS WHEREOF, the duly authorized representatives of the parties have executed this Agreement as of the Effective Date.

PATHEON UK LIMITED

By: _____

Name: _____

Title: _____

EVOKE PHARMA, INC.

By: _____

Name: David A. Gonyer

Title: President and CEO

SCHEDULE A

PRODUCT AND SPECIFICATIONS

Product

[***]

Specifications

[***]

SCHEDULE B

ANNUAL VOLUME

[***]

MINIMUM ORDER QUANTITY AND PRICE

[***]

The following cost items are included in the Price for the Products:

[***]

The following cost items are not included in the Price for the Products:

[***]

Manufacturing Parameters

[***]

Packaging Parameters

[***]

Testing Conditions

[***]

SCHEDULE C

ANNUAL STABILITY TESTING [and VALIDATION ACTIVITIES (if applicable)]

[***]

SCHEDULE D

ACTIVE MATERIALS

Active Materials	Supplier
[***]	[***]

ACTIVE MATERIALS CREDIT VALUE

The Active Materials Credit Value will be as follows:

PRODUCT	ACTIVE MATERIALS	ACTIVE MATERIALS CREDIT VALUE
[***]	[***]	[***]

MAXIMUM CREDIT VALUE

Patheon's liability for Active Materials calculated in accordance with Section 2.2 of the Agreement in a Year will not exceed, in the aggregate, the maximum credit value set forth below:

PRODUCT	MAXIMUM CREDIT VALUE
[***]	[***]

SCHEDULE E

TECHNICAL DISPUTE RESOLUTION

Technical Disputes which cannot be resolved by negotiation as provided in Section 12.2 of the Agreement will be resolved in the following manner:

1. **Appointment of Expert**. Within [***] after a party requests under Section 12.2 of the Agreement that an expert be appointed to resolve a Technical Dispute, the parties will jointly appoint a mutually acceptable expert with experience and expertise in the subject matter of the dispute. If the parties are unable to so agree within the [***] period, or if there is a disclosure of a conflict by an expert under Paragraph 2 hereof which results in the parties not confirming the appointment of the expert, then an expert (willing to act in that capacity hereunder) will be appointed by an experienced arbitrator on the roster of the American Arbitration Association.

2. **Conflicts of Interest**. Any person appointed as an expert will be entitled to act and continue to act as an expert even if at the time of his appointment or at any time before he gives his determination, he has or may have some interest or duty which conflicts or may conflict with his appointment if before accepting the appointment (or as soon as practicable after he becomes aware of the conflict or potential conflict) he fully discloses the interest or duty and the parties will, after the disclosure, have confirmed his appointment.

3. **Not Arbitrator**. No expert will be deemed to be an arbitrator and the provisions of the American Arbitration Act or of any other applicable statute (foreign or domestic) and the law relating to arbitration will not apply to the expert or the expert's determination or the procedure by which the expert reaches his determination under this Schedule E.

4. **Procedure**. Where an expert is appointed:

(a) Timing. The expert will be so appointed on condition that (i) he promptly fixes a reasonable time and place for receiving representations, submissions or information from the parties and that he issues the authorizations to the parties and any relevant third party for the proper conduct of his determination and any hearing and (ii) he renders his decision (with full reasons) within [***] (or another other date as the parties and the expert may agree) after receipt of all information requested by him under Paragraph 4(b) hereof.

(b) Disclosure of Evidence. The parties undertake one to the other to give to any expert all the evidence and information within their respective possession or control as the expert may reasonably consider necessary for determining the matter before him which they will disclose promptly and in any event within [***] of a written request from the relevant expert to do so.

(c) Advisors. Each party may appoint any counsel, consultants and advisors as it feels appropriate to assist the expert in his determination and so as to present their respective cases so that at all times the parties will co-operate and seek to narrow and limit the issues to be determined.

(d) Appointment of New Expert. If within the time specified in Paragraph 4(a) above the expert will not have rendered a decision in accordance with his appointment, a new expert may (at the request of either party) be appointed and the appointment of the existing expert will

thereupon cease for the purposes of determining the matter at issue between the parties except if the existing expert renders his decision with full reasons prior to the appointment of the new expert, then this decision will have effect and the proposed appointment of the new expert will be withdrawn.

(e) Final and Binding. The determination of the expert will, except for fraud or manifest error, be final and binding upon the parties.

(f) Costs. Each party will bear its own costs for any matter referred to an expert hereunder and, in the absence of express provision in the Agreement to the contrary, the costs and expenses of the expert will be shared equally by the parties.

For greater certainty, the release of the Products for sale or distribution under the applicable marketing approval for the Products will not by itself indicate compliance by Patheon with its obligations for the Manufacturing Services and further that nothing in this Agreement (including this Schedule E) will remove or limit the authority of the relevant qualified person (as specified by the Quality Agreement) to determine whether the Products are to be released for sale or distribution.

SCHEDULE F

QUARTERLY ACTIVE MATERIALS INVENTORY REPORT

TO: EVOKE PHARMA, INC.

FROM: PATHEON UK LIMITED [or applicable Patheon Affiliate]

RE: Active Materials quarterly inventory report under Section 2.2(a) of the Manufacturing Services Agreement dated • (the "**Agreement**")

Reporting quarter: _____

Active Materials on hand
at beginning of quarter: _____ kg (A)

Active Materials on hand
at end of quarter: _____ kg (B)

Quantity Received during quarter: _____ kg (C)

Quantity Dispensed during quarter: _____ kg
[***]

Quantity Converted during quarter: _____ kg
(total Active Materials in Products produced
and not rejected, recalled or returned)

Capitalized terms used in this report have the meanings given to the terms in the Agreement.

PATHEON UK LIMITED
[or applicable Patheon Affiliate] DATE:_____

Per: _____
Name:
Title:

SCHEDULE G

REPORT OF ANNUAL ACTIVE MATERIALS INVENTORY RECONCILIATION

AND CALCULATION OF ACTUAL ANNUAL YIELD

TO: EVOKE PHARMA, INC.

FROM: PATHEON UK LIMITED [or applicable Patheon Affiliate]

RE: Active Materials annual inventory reconciliation report and calculation of Actual Annual Yield under Section 2.2(a) of the Manufacturing Services Agreement dated 31 October, 2017 (the "**Agreement**")

Reporting Year ending: _____

Active Materials on hand
at beginning of Year: _____ kg (A)

Active Materials on hand
at end of Year: _____ kg (B)

Quantity Received during Year: _____ kg (C)

Quantity Dispensed during Year: _____ kg (D)
[***]

Quantity Converted during Year: _____ kg (E)
(total Active Materials in Products produced
and not rejected, recalled or returned)

Active Materials Credit Value: EUR_____ / kg (F)

Target Yield: _____ % (G)

Actual Annual Yield: _____ % (H)
[***]

Shortfall: EUR_____ (I)
[***] (if a negative number, insert zero)

Based on the foregoing reimbursement calculation Patheon will reimburse Client the amount of EUR_____.

Surplus Credit: EUR_____ (J)
[***]

Based on the foregoing reimbursement calculation Patheon may carry forward one Year a Surplus Credit in the amount of EUR .

Capitalized terms used in this report have the meanings given to the terms in the Agreement.

DATE: _____

PATHEON UK LIMITED
[or applicable Patheon Affiliate]

Per: _____
Name:
Title:

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 the Registration Statements on Form S-3 (No. 333-251614) and Form S-8 (No. 333-273912, 333-224897, 333-219960, 333-211302, and 333-191518) of Evoke Pharma, Inc. (the "Company") of our report dated March 14, 2024, relating to the financial statements which appears in this Annual Report on Form 10-K. Our report contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

/s/ BDO USA, P.C.

San Diego, California
March 14, 2024

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 14, 2024

/s/ David A. Gonyer
David A. Gonyer
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 14, 2024

/s/ Matthew J. D'Onofrio
Matthew J. D'Onofrio
President, Chief Operating 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, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, David A. Gonyer, 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 14, 2024

/s/ David A. Gonyer
David A. Gonyer
Chief Executive Officer
(Principal 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, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Matthew J. D'Onofrio, President, Chief Operating 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 14, 2024

/s/ Matthew J. D'Onofrio
Matthew J. D'Onofrio
President, Chief Operating Officer,
Treasurer and Secretary
(Principal Financial 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.

EVOKE PHARMA, INC.
POLICY FOR RECOVERY OF ERRONEOUSLY AWARDED COMPENSATION

Evoke Pharma, Inc. (the "***Company***") has adopted this Policy for Recovery of Erroneously Awarded Compensation (the "***Policy***"), effective as of October 2, 2023 (the "***Effective Date***"). Capitalized terms used in this Policy but not otherwise defined herein are defined in Section 11.

1. Persons Subject to Policy

This Policy shall apply to current and former Officers of the Company.

2. Compensation Subject to Policy

This Policy shall apply to Incentive-Based Compensation received on or after the Effective Date. For purposes of this Policy, the date on which Incentive-Based Compensation is "received" shall be determined under the Applicable Rules, which generally provide that Incentive-Based Compensation is "received" in the Company's fiscal period during which the relevant Financial Reporting Measure is attained or satisfied, without regard to whether the grant, vesting or payment of the Incentive-Based Compensation occurs after the end of that period.

3. Recovery of Compensation

In the event that the Company is required to prepare a Restatement, the Company shall recover, reasonably promptly, the portion of any Incentive-Based Compensation that is Erroneously Awarded Compensation, unless the Committee has determined that recovery would be Impracticable. Recovery shall be required in accordance with the preceding sentence regardless of whether the applicable Officer engaged in misconduct or otherwise caused or contributed to the requirement for the Restatement and regardless of whether or when restated financial statements are filed by the Company. For clarity, the recovery of Erroneously Awarded Compensation under this Policy will not give rise to any person's right to voluntarily terminate employment for "good reason," or due to a "constructive termination" (or any similar term of like effect) under any plan, program or policy of or agreement with the Company or any of its affiliates.

4. Manner of Recovery; Limitation on Duplicative Recovery

The Committee shall, in its sole discretion, determine the manner of recovery of any Erroneously Awarded Compensation, which may include, without limitation, reduction or cancellation by the Company or an affiliate of the Company of Incentive-Based Compensation or Erroneously Awarded Compensation, reimbursement or repayment by any person subject to this Policy of the Erroneously Awarded Compensation, and, to the extent permitted by law, an offset of the Erroneously Awarded Compensation against other compensation payable by the Company or an affiliate of the Company to such person. Notwithstanding the foregoing, unless otherwise prohibited by the Applicable Rules, to the extent this Policy provides for recovery of Erroneously Awarded Compensation already recovered by the Company pursuant to Section 304 of the Sarbanes-Oxley Act of 2002 or Other Recovery Arrangements, the amount of Erroneously Awarded Compensation already recovered by the Company from the recipient of such Erroneously

Awarded Compensation may be credited to the amount of Erroneously Awarded Compensation required to be recovered pursuant to this Policy from such person.

5. Administration

This Policy shall be administered, interpreted and construed by the Committee, which is authorized to make all determinations necessary, appropriate or advisable for such purpose. The Board of Directors of the Company (the "***Board***") may re-vest in itself the authority to administer, interpret and construe this Policy in accordance with applicable law, and in such event references herein to the "Committee" shall be deemed to be references to the Board. Subject to any permitted review by the applicable national securities exchange or association pursuant to the Applicable Rules, all determinations and decisions made by the Committee pursuant to the provisions of this Policy shall be final, conclusive and binding on all persons, including the Company and its affiliates, equityholders and employees. The Committee may delegate administrative duties with respect to this Policy to one or more directors or employees of the Company, as permitted under applicable law, including any Applicable Rules.

6. Interpretation

This Policy will be interpreted and applied in a manner that is consistent with the requirements of the Applicable Rules, and to the extent this Policy is inconsistent with such Applicable Rules, it shall be deemed amended to the minimum extent necessary to ensure compliance therewith.

7. No Indemnification; No Liability

The Company shall not indemnify or insure any person against the loss of any Erroneously Awarded Compensation pursuant to this Policy, nor shall the Company directly or indirectly pay or reimburse any person for any premiums for third-party insurance policies that such person may elect to purchase to fund such person's potential obligations under this Policy. None of the Company, an affiliate of the Company or any member of the Committee or the Board shall have any liability to any person as a result of actions taken under this Policy.

8. Application; Enforceability

Except as otherwise determined by the Committee or the Board, the adoption of this Policy does not limit, and is intended to apply in addition to, any other clawback, recoupment, forfeiture or similar policies or provisions of the Company or its affiliates, including any such policies or provisions of such effect contained in any employment agreement, bonus plan, incentive plan, equity-based plan or award agreement thereunder or similar plan, program or agreement of the Company or an affiliate or required under applicable law (the "***Other Recovery Arrangements***"). The remedy specified in this Policy shall not be exclusive and shall be in addition to every other right or remedy at law or in equity that may be available to the Company or an affiliate of the Company.

9. Severability

The provisions in this Policy are intended to be applied to the fullest extent of the law; provided, however, to the extent that any provision of this Policy is found to be unenforceable or invalid under any applicable law, such provision will be applied to the maximum extent permitted, and shall automatically be deemed amended in a manner consistent with its objectives to the extent necessary to conform to any limitations required under applicable law.

10. Amendment and Termination

The Board or the Committee may amend, modify or terminate this Policy in whole or in part at any time and from time to time in its sole discretion. This Policy will terminate automatically when the Company does not have a class of securities listed on a national securities exchange or association.

11. Definitions

"***Applicable Rules***" means Section 10D of the Exchange Act, Rule 10D-1 promulgated thereunder, the listing rules of the national securities exchange or association on which the Company's securities are listed, and any applicable rules, standards or other guidance adopted by the Securities and Exchange Commission or any national securities exchange or association on which the Company's securities are listed.

"***Committee***" means the committee of the Board responsible for executive compensation decisions comprised solely of independent directors (as determined under the Applicable Rules), or in the absence of such a committee, a majority of the independent directors serving on the Board.

"***Erroneously Awarded Compensation***" means the amount of Incentive-Based Compensation received by a current or former Officer that exceeds the amount of Incentive-Based Compensation that would have been received by such current or former Officer based on a restated Financial Reporting Measure, as determined on a pre-tax basis in accordance with the Applicable Rules.

"***Exchange Act***" means the Securities Exchange Act of 1934, as amended.

"***Financial Reporting Measure***" means any measure determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measures derived wholly or in part from such measures, including GAAP, IFRS and non-GAAP/IFRS financial measures, as well as stock or share price and total equityholder return.

"***GAAP***" means United States generally accepted accounting principles.

"***IFRS***" means international financial reporting standards as adopted by the International Accounting Standards Board.

"***Impracticable***" means (a) the direct costs paid to third parties to assist in enforcing recovery would exceed the Erroneously Awarded Compensation; provided that the Company (i) has made reasonable attempts to recover the Erroneously Awarded Compensation, (ii) documented

such attempt(s), and (iii) provided such documentation to the relevant listing exchange or association, (b) to the extent permitted by the Applicable Rules, the recovery would violate the Company's home country laws pursuant to an opinion of home country counsel; provided that the Company has (i) obtained an opinion of home country counsel, acceptable to the relevant listing exchange or association, that recovery would result in such violation, and (ii) provided such opinion to the relevant listing exchange or association, or (c) recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the requirements of 26 U.S.C. 401(a)(13) or 26 U.S.C. 411(a) and the regulations thereunder.

"***Incentive-Based Compensation***" means, with respect to a Restatement, any compensation that is granted, earned, or vested based wholly or in part upon the attainment of one or more Financial Reporting Measures and received by a person: (a) after beginning service as an Officer; (b) who served as an Officer at any time during the performance period for that compensation; (c) while the issuer has a class of its securities listed on a national securities exchange or association; and (d) during the applicable Three-Year Period.

"***Officer***" means each person who serves as an executive officer of the Company, as defined in Rule 10D-1(d) under the Exchange Act.

"***Restatement***" means an accounting restatement to correct the Company's material noncompliance with any financial reporting requirement under securities laws, including restatements that correct an error in previously issued financial statements (a) that is material to the previously issued financial statements or (b) that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

"***Three-Year Period***" means, with respect to a Restatement, the three completed fiscal years immediately preceding the date that the Board, a committee of the Board, or the officer or officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare such Restatement, or, if earlier, the date on which a court, regulator or other legally authorized body directs the Company to prepare such Restatement. The "Three-Year Period" also includes any transition period (that results from a change in the Company's fiscal year) within or immediately following the three completed fiscal years identified in the preceding sentence. However, a transition period between the last day of the Company's previous fiscal year end and the first day of its new fiscal year that comprises a period of nine to 12 months shall be deemed a completed fiscal year.