# 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, 2024**

**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)** |

**Registrant's telephone number, including area code 858-345-1494**

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

| Title of each class | Trading symbol | 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 $4.6 million, based on the closing price of the registrant's common stock on the Nasdaq Capital Market of $6.348 per share.

The number of outstanding shares of the registrant's common stock, par value $0.0001 per share, as of March 3, 2025 was 1,492,858.

**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 2025 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, 2024.

**EVOKE PHARMA, INC.**
**FORM 10-K — ANNUAL REPORT**
**For the Fiscal Year Ended December 31, 2024**

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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 (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (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 ("Gimoti"), 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 United States 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 retrospective, real-world study of over 500 diabetic gastroparesis patients 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 Neurogastroenterology and 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.

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 manage glucose control through several mechanisms, including enhancement of glucose-dependent insulin secretion, slowed gastric emptying, and reduction of postprandial glucagon release and food intake. GLP-1 induced slowed gastric emptying may reveal underlying gastroparesis in diabetic patients and/or cause patients to experience symptoms suggestive of gastroparesis. Although there is no definitive evidence that GLP-1 agonists cause gastroparesis, the results of a 2023 study published in the Journal of the American Medical Association (JAMA) showed 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.

The growing market penetration of GLP-1 agonists for both diabetes and obesity management further underscores this concern. By 2030, an estimated 54.9 million people in the U.S. are projected to have diabetes, with 80% of adults with type 2 diabetes meeting the criteria for GLP-1 receptor agonists or SGLT2 inhibitors, yet historically, only 10% have utilized such treatments. In addition, GLP-1 agonists are expected to reach approximately 15 million adults in the U.S. for obesity treatment alone, further expanding their impact on gastric motility.

Recent reports have linked GLP-1 agonists to severe gastrointestinal complications, including gastroparesis. For example, a CNN Health article from July 2023 highlighted cases of patients experiencing gastric paralysis after taking GLP-1 medications, and another report from October 2023 referenced concerns about serious digestive issues affecting thousands of individuals worldwide. Although definitive causal evidence is still under investigation, the association between GLP-1 use and gastroparesis risk remains a growing area of clinical and regulatory interest.

In a 2024 study, a retrospective cross-sectional analysis of real-world data from 10,328 adults with diabetes/obesity in the National Institutes of Health, All of Us cohort reported 5.1% of patients taking a GLP-1 agonist experienced signs and symptoms consistent with gastroparesis. Gastrointestinal adverse effects from the use of GLP-1 agonists are fairly common and we believe it could have an impact on the gastroparesis market given the widespread use and the large population expected to be exposed to these agents.

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 of a well-characterized drug product like metoclopramide 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 whether or not a patient's stomach is emptying on a given day; (2) during episodes of vomiting, Gimoti may provide predictable systemic drug levels because absorption is 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 $5.0 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, 2024, there were approximately $75.4 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 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 pharmacokinetic ("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 *Gastroenterology* estimated that in 2021 a GI diagnosis or symptom led to 14.5 million emergency department visits and 2.9 million hospital admissions in the United States. The annual cost of these GI disorders in 2021 was estimated to be $111.8 billion.

The GI pharmaceutical market in the U.S. has expanded significantly, with 2024 prescription drug spending estimated to be between $22–$28 billion. Growth is driven by biologics for IBD, widespread PPI use, and increased awareness of gastroparesis and motility disorders. Despite affecting millions, upper GI motility disorders have seen limited innovation, leaving a significant unmet need. Gastroparesis, in particular, remains underserved, creating a strong market opportunity. Gimoti is positioned to address this treatment gap, offering an alternative for patients with impaired gastric emptying. With rising demand for GI treatments, we believe our focus on gastroparesis therapy innovation positions us as a key player in this growing market.

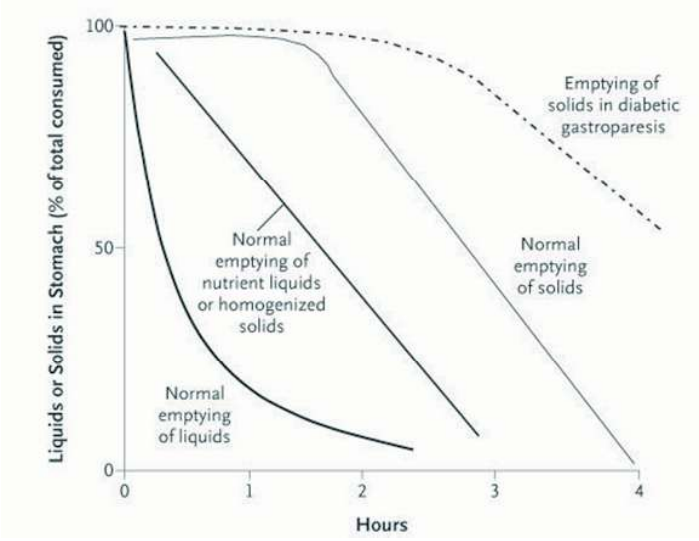
***GI Motility Disorders***

Motility disorders are some of the most common GI disorders. Motility disorders affect the orderly contractions and 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 ("IFFGD") 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 fecal 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 *World Journal of Gastroenterology* in 2017. Additionally, the study reported, from 1997 to 2013, total hospitalizations with a primary diagnosis of gastroparesis increased by a factor of six. The mean hospital charges increased by 159% from $13,350 (after inflation) in 1997 to $34,585 per patient in 2013.

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, infection, and may 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 Neurogastroenterology and Motility Society Task Force on Gastroparesis, up to 4% of the United States ("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 ("CDC") 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 2023 study published in *Neurogastroenterology & Motility* states that approximately 36% of gastroparesis patients suffer from idiopathic gastroparesis, which means the cause is unknown. 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 for gastroparesis include erythromycin and Botox® injected via endoscopic procedure directly into the lower gastric sphincter. Previously-approved drugs, such as cisapride and tegaserod, that had been used off-label for gastroparesis symptoms, 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.

**Our Solution: Gimoti (Metoclopramide) Nasal Spray**

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 diabetic gastroparesis patients. With Gimoti being approved for the treatment of diabetic gastroparesis, patients and physicians now have access to an outpatient therapy that can be administered and absorbed even when patients are experiencing delayed gastric emptying or nausea and vomiting.

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 into 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 to 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 the 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 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 utilizes its internal sales organization, along with other commercial functions, for market access, marketing, distribution and other related patient support services. We record sales for Gimoti and retain more than 80% of net product profits once the parties' costs are reimbursed. As of December 31, 2024, there were approximately $75.4 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 receives 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 (the "Eversana Amendment"). The Eversana 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.

Upon expiration or termination of the agreement, we will retain all profits from product sales and assume all corresponding commercialization responsibilities. 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 Eversana Agreement; if we discontinue the development or production of Gimoti; if the net profit is negative for any two consecutive calendar quarters (the "Net Profit Quarterly Termination Right") beginning with the measurement date of June 30, 2023; 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, 2024, either party had the right to exercise the Net Profit Quarterly Termination Right ("NPQTR"), which either party could do until March 1, 2025, which is the end of the 60-day period following the end of the quarter. The NPQTR expired unexercised on March 1, 2025.

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 NPQTR, we have agreed to reimburse Eversana for its unreimbursed commercialization costs for the prior twelve-month period and other certain 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 $5.0 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 bears 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 $2.0 million and in December 2020 we borrowed the remaining $3.0 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 and cash equivalents. 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 transitioned 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 were transitioned to ASPN Pharmacy ("ASPN"). The purpose of this transition was to improve the approval of out-of-network prescription volume that was increasing across the platform. Although the transition initially created some slowing in managing patients and filling prescriptions, ASPN is now processing inbound prescriptions at a pace that is 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, 2024, Eversana had 27 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 Awareness, Trial, and Usage ("ATU") 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 92% of gastroenterologist-affiliated 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 prucalopride).

- 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

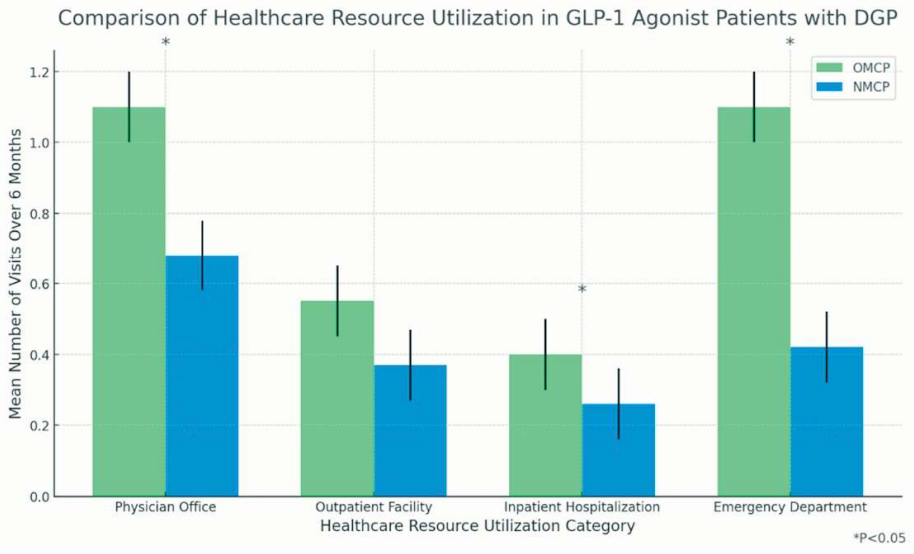
Gimoti scored better in treating nausea and abdominal pain than all other comparators (oral metoclopramide, liquid metoclopramide, domperidone and prucalopride). Gimoti was the only product for which all respondents reported symptom improvement. In contrast, approximately 23% to 32% of respondents reported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

In October 2024, we announced the presentation of data studying diabetic gastroparesis patients using GLP-1 receptor agonists and also using Gimoti (metoclopramide nasal spray) at the American College of Gastroenterology 2024 Annual Meeting. The real-world retrospective study evaluated the impact of Gimoti in patients with DGP who were concurrently using GLP-1 receptor agonists. The study compared healthcare resource utilization (“HRU”) between patients using Gimoti (metoclopramide nasal spray (“NMCP”)) and those using oral metoclopramide (“OMCP”), specifically focusing on individuals with a prior GLP-1 prescription. Adult patients with a DGP diagnosis and at least 6 months of data pre- and post-index (treatment initiation), continuous data were included. Significant reductions in both all-cause and gastroparesis-related office and emergency room visits were observed in patients currently taking GLP-1 medications who were treated with Gimoti versus oral metoclopramide.

Key Study Findings Presented at American College of Gastroenterology 2024 included-

- Patients with prior GLP-1 history had numerically reduced HRU after taking NMCP.
    - In NMCP patients, all-cause emergency department (ED) visits decreased by 55% (mean [SD]: 0.25 [1.13] post-index vs. 0.55 [1.30] pre-index; P=0.063); and
    - DGP- related ED visits decreased by 28% (mean [SD]: 0.18 [0.99] post-index vs 0.25 [1.28] pre-index; P=0.203)
- In patients taking GLP-1, those that took NMCP had fewer healthcare visits compared to those taking OMCP.
    - All-cause and DGP-related ED visits were 91% lower (cIRR: 0.09, 95% CI: 0.01, 0.42; P=0.001) and 89% lower (cIRR: 0.11, 95% CI: 0, 0.93; P=0.046) for NMCP vs. OMCP; and

- All-cause and DGP-related office visits were 41% lower (cIRR: 0.59, 95% CI: 0.37, 0.94; P=0.027) and 66% lower (cIRR: 0.34, 95% CI: 0.017, 0.65; P=0.001) for NMCP vs.OMCP.
- All-cause clinic, outpatient, and inpatient visits showed similar outcomes favoring NMCP vs. OMCP.
- In DGP patients with a prior claim for GLP-1, NMCP use was associated with numerically reduced all-cause and DGP-related HRU compared to pre-treatment utilization and OMCP treated controls.




The study's specific cohort consisted of 92 total patients between the nasal metoclopramide (NMCP, N=51) and oral metoclopramide (OMCP, N=41) groups. The NMCP group had a slightly older average age (55.1 years) compared to the OMCP group (53.1 years). A notable portion of the NMCP group (31.4%) had experienced hospitalizations or emergency department visits prior to treatment, compared to 19.5% in the OMCP group.

A separate post-hoc analysis reviewed safety data from a female subgroup enrolled in a previous Phase 3 study, which subgroup included 36 women using GLP-1 drugs during the 28-day study. These patients had an average age of 51.4 years, with 67% identifying as Caucasian and 33% as Black. Among these, 13 were treated with Gimoti and 23 with placebo. The majority (94%) of the participants completed the study, with no serious adverse events reported in either group.

**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, who 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. ("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 | Complete Response |
| Deudomperidone (CIN-102) | Dopamine 2/3 antagonist | Oral | CinRx | Phase 2 |
| PCS12852 | 5-HT4 receptor agonist | Oral | Processa | Phase 2 |
| Naronapride | 5-HT4 receptor agonist | Oral | Renexxion | 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. In September 2024, Vanda reported that it received a Complete Response Letter from the FDA denying approval of the application but would continue to pursue approval of tradipitant.

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 Phase 2 trial (N=60) was initiated with an estimated completion date of March 2021. As of March 13, 2025, 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, Phase 2 study in 400 patients with diabetic gastroparesis.

PCS12852 is a 5-HT4 reception agonist. A Phase 2a (N=25) 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.

Naronapride is a 5-HT4 receptor agonist. In June 2024, Renexxion announced the opening of enrollment for a Phase 2 U.S.trial enrolling 320 patients. Primary results are scheduled to be delivered in mid-2025.

**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, 2024:

- 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, once 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; ; US continuation applications 17/366,818 and 17/366,839, once granted, will also be Orange Book listable.
- 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 one European patent and two 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 PCT patent applications have been filed and which are 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 registered trademarks for EVOKE PHARMA and for Gimoti in the United States.

***Confidential Information and Inventions Assignment Agreements***

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

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

**Government Regulation**

***FDA Regulations***

In the United States, pharmaceutical products are subject to extensive regulation by FDA. The Federal Food, Drug, and Cosmetic Act ("FFDCA"), and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, record keeping, 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 ("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 ("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 ("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 ("cGMP") regulations, including, for devices and device components, those currently set forth in the FDA's Quality System Regulation ("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 ("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 ("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 ("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, record keeping, 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 ("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 ("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 90$^{th}$ 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 ("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 ("CMS"), the federal agency that administers the MDRP and Medicare programs. For the MDRP, these data include the average manufacturer price ("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 ("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 ("VA"), Federal Supply Schedule ("FSS") pricing program. Under the VA/FSS program, we must report the Non-Federal Average Manufacturer Price ("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 ("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 contained a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement adjustments and fraud and abuse changes. Additionally, the ACA increased 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; and increased the number of entities eligible for discounts under the 340B program. 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 (which began 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. The Centers for Medicare & Medicaid Services ("CMS") has published the negotiated prices for the initial ten drugs, which will first be effective in 2026, and the list of the subsequent 15 drugs that will be subject to negotiation, 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, drug price increase disclosure, and other transparency measures, and, in some cases, measures designed to encourage importation from other countries and bulk purchasing. Some states have enacted legislation creating so-called prescription drug affordability boards, which ultimately may attempt to impose price limits on certain drugs in these states. 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 (the "CCPA"), the California Privacy Rights Act (the "CPRA"), and the European Union General Data Protection Regulation (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, 2024, we had three 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 7. Segments* to our financial statements included in this Annual Report on Form 10-K for information regarding our development and commercialization of pharmaceutical products segment. 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 ("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 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. As of December 31, 2024, we and Eversana each have the right to exercise the NPQTR 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 the NPQTR 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. We currently have no intent to terminate the Eversana Agreement. If Eversana exercises the NPQTR, the outstanding principal and interest under the Eversana Credit Facility would be due within 90 days after the effective date of such termination. In addition, we would need to establish a commercial infrastructure in order to continue distributing Gimoti. The timing and costs associated with this are not clear, but we believe they would be substantial. If Eversana were to exercise the NPQTR in the near term, we believe, based on our current operating plans, that our cash and cash equivalents as of December 31, 2024 of approximately $13.6 million, plus cash flows from net sales of Gimoti, would be sufficient to fund our operations into the first quarter of 2026. 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. 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 $7.1 million as of December 31, 2024, to be payable if we or Eversana exercise the NPQTR, or upon other certain termination events;
- the repayment of unreimbursed commercialization costs to Eversana, approximately $75.4 million as of December 31, 2024, to be payable only as net product profits are recognized, or upon certain termination events that are in our control;
- 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 100,000,000 shares of common stock. As of December 31, 2024, we had 1,486,009 shares of common stock outstanding and have reserved an aggregate of 464,508 shares of common stock for issuance under our equity incentive award plan and employee stock purchase plan.

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-contamination 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 have 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, in recent 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. If a prolonged government shutdown occurs, or if renewed 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 boxed 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 record keeping 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, 2024, we had three 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. 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: Matthew J. D'Onofrio, our Chief Executive Officer, Mark Kowieski, our Chief Financial 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 ("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 ("CMS"), the federal agency that administers the MDRP and Medicare programs. For the MDRP, these data include the average manufacturer price ("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 ("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 ("VA"), Federal Supply Schedule ("FSS"), pricing program. Under the VA/FSS program, we must report the Non-Federal Average Manufacturer Price ("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, and increased the number of entities eligible for discounts under the 340B program.

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 (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 (which began 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. CMS has published the negotiated prices for the initial ten drugs, which will first be effective in 2026, and the list of the subsequent 15 drugs that will be subject to negotiation, 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, drug price increase disclosure and other transparency measures, and, in some cases, measures designed to encourage importation from other countries and bulk purchasing. Some states have enacted legislation creating so-called prescription drug affordability boards, which ultimately may attempt to impose price limits on certain drugs in these states. 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. 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 Gimoti and uses thereof 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 ("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 its active ingredient: metoclopramide hydrochloride. 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. 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. (“Teva”), indicating that it has submitted to the FDA an abbreviated new drug application (“ANDA”), seeking approval to manufacture and sell a generic version of Gimoti (metoclopramide hydrochloride) nasal spray equivalent 15 mg base/spray prior to the expiration of two of our 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, reexamination, post grant review, or inter parties review 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, reexamination, post grant review, inter parties review, 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 may 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. As of December 31, 2024, we and Eversana each have the right to exercise the NPQTR 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. We currently have no intent to terminate the Eversana Agreement. If Eversana exercises the NPQTR, the outstanding principal and interest under the Eversana Credit Facility would be due within 90 days after the effective date of such termination. If Eversana were to exercise the Net Profit Quarterly Termination Right in the near term, we believe, based on our current operating plans, that our cash and cash equivalents as of December 31, 2024 of approximately $13.6 million, plus cash flows from net sales of Gimoti, would be sufficient to fund our operations into the first quarter of 2026. The Company would need to establish a commercial infrastructure in order to continue distributing Gimoti, and the timing and costs associated with this are not clear, but the Company believes they would be substantial, so this period could be shortened.

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, 2024 was approximately $5.4 million. As of December 31, 2024, we had an accumulated deficit of approximately $128.8 million. Losses have resulted principally from costs incurred in our clinical trials, research and development programs and from our general and administrative expenses, especially since we became a public company in September 2013. In the future, we intend to continue 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 entered into an underwriting agreement (the "Underwriting Agreement") with Craig-Hallum Capital Group LLC and Laidlaw & Company (UK) Ltd. (collectively, the "Underwriters"), relating to the issuance and sale of 427,886 common stock units (the "Common Stock Units") at a public offering price of $8.16 per Common Stock Unit and, to certain investors, 491,221 pre-funded warrant units (the "PFW Units") at a public offering price of $8.1588 per PFW Unit (the "February 2024 Offering"). Each Common Stock Unit consisted 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 consisted 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. The Company also issued warrants to the Underwriters to purchase up to 45,955 shares of common stock, equal to 5% of the securities sold in the February 2024 Offering (the "Representatives' Warrants"). The Series A Warrants are fully exercisable and recognized as a freestanding instrument. In accordance with the terms and provisions of the Series C Warrants, the Series C Warrants are not exercisable, in part or in whole, at any time unless the Series B Warrants have been exercised. If Series B Warrants were not exercised before November 13, 2024, the corresponding Series C Warrants were no longer deemed outstanding and cannot be exercised. Net cash proceeds from the February 2024 Offering was $6.2 million after deducting underwriter and offering expenses.

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, 2024, we had federal and state net operating loss carryforwards of approximately $110.8 million and $55.8 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**

***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 Common Warrants.***

Each Common 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.

***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, following a hearing before the Nasdaq Hearings Panel (the "Panel"), and several quarters in which we demonstrated continued compliance with the Minimum Stockholders' Equity Requirements, we were notified on June 4, 2024, that the Panel determined that we had regained compliance with the Minimum Stockholders' Equity Requirement. Pursuant to Nasdaq Listing Rule 5815(d)(4)(A), we will be subject to a discretionary panel monitor through June 4, 2025. If, within that one-year monitoring period, we fail to maintain compliance with any Nasdaq continued listing requirement, the Listing Qualifications Staff (the "Staff") of Nasdaq will issue a Delist Determination Letter, and we will have an opportunity to request a new hearing with the initial Panel or a newly convened Hearings Panel if the initial Panel is unavailable. Notwithstanding Nasdaq Listing Rule 5810(c)(2), we will not be permitted to provide the Staff with a plan of compliance with respect to any deficiency that arises during the one-year monitoring period, and the Staff will not be permitted to grant additional time for us to regain compliance with respect to any deficiency.

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) (the "Minimum Bid Price Requirement").

In May 2024, our stockholders granted our board of directors the authority to effect a reverse stock split of our outstanding common stock. In order to regain compliance with the Minimum Bid Price Requirement by August 19, 2024, on July 31, 2024, we filed an amendment (the "Amendment") to our amended and restated certificate of incorporation to effectuate a reverse stock split of our common stock. Pursuant to the Amendment, at the effective time of 12:01 a.m. Eastern Time on August 1, 2024, each twelve (12) shares of our common stock issued and outstanding was combined into one (1) validly

issued, fully paid and non-assessable share of common stock (the "Reverse Stock Split"). The par value and the authorized shares of our 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, options to purchase common stock, per-share data and related information have been retroactively adjusted to reflect the Reverse Stock Split for all periods presented.

On August 15, 2024, we received a letter from Nasdaq stating we had regained compliance with the Minimum Bid Price Requirement and the minimum bid price matter was closed.

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.

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

Not applicable.

**Item 1C. Cybersecurity.**

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 of directors ("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 of the Board (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 Chief Executive Officer and Chief Financial 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 2024. 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 28, 2025, there were nine 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 $5.0 million revolving credit facility, or the Eversana Credit Facility, that became available upon FDA approval of the Gimoti NDA. In 2020, we borrowed $5.0 million under the Eversana Credit Facility, which expires on December 31, 2026, unless terminated earlier pursuant to its terms. As of December 31, 2024, there were approximately $75.4 million in cumulative unreimbursed commercialization costs under the Eversana Agreement, to be payable 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, warrants, and pre-funded warrants in public offerings. 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, 2024, we had cash and cash equivalents of approximately $13.6 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. If Eversana were to exercise the NPQTR in the near term, we believe, based on our current operating plan, that our cash and cash equivalents as of December 31, 2024 of approximately $13.6 million, plus cash flows from net sales of Gimoti, would be sufficient to fund our operations into the first quarter of 2026. 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. 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.

**Nasdaq Listing and Reverse Stock Split**

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, following a hearing before the Nasdaq Hearings Panel (the "Panel"), and several quarters in which we demonstrated continued compliance with the Minimum Stockholders' Equity Requirements, we were notified on June 4, 2024, that the Panel determined that we had regained compliance with the Minimum Stockholders' Equity Requirement. Pursuant to Nasdaq Listing Rule 5815(d)(4)(A), we will be subject to a discretionary panel monitor through June 4, 2025. If, within that one-year monitoring period, we fail to maintain compliance with any Nasdaq continued listing requirement, the Listing Qualifications Staff (the "Staff") of Nasdaq will issue a Delist Determination Letter, and we will have an opportunity to request a new hearing with the initial Panel or a newly convened Hearings Panel if the initial Panel is unavailable. Notwithstanding Nasdaq Listing Rule 5810(c)(2), we will not be permitted to provide the Staff with a plan of compliance with respect to any deficiency that arises during the one-year monitoring period, and the Staff will not be permitted to grant additional time for us to regain compliance with respect to any deficiency.

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) (the "Minimum Bid Price Requirement").

In May 2024, our stockholders granted our board of directors the authority to effect a reverse stock split of our outstanding common stock. In order to regain compliance with the Minimum Bid Price Requirement by August 19, 2024, on July 31, 2024, we filed an amendment (the "Amendment") to our amended and restated certificate of incorporation to effectuate a reverse stock split of our common stock. Pursuant to the Amendment, at the effective time of 12:01 a.m. Eastern Time on August 1, 2024, each twelve (12) shares of our common stock issued and outstanding was combined into one (1) validly issued, fully paid and non-assessable share of common stock (the "Reverse Stock Split"). The par value and the authorized shares of our 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, options to purchase common stock, per-share data and related information have been retroactively adjusted to reflect the Reverse Stock Split for all periods presented.

On August 15, 2024, we received a letter from Nasdaq stating we had regained compliance with the Minimum Bid Price Requirement and the minimum bid price matter was closed.

**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 (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. 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-pay assistance to commercially insured patients meeting certain eligibility requirements, as well as to uninsured patients. Co-pay 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 revenue metrics continue to increase. Net product sales during the year ended December 31, 2024 were approximately $10.2 million compared to net product sales of approximately $5.2 million during the year ended December 31, 2023, an increase of approximately 97.8%. In November 2023, we transitioned our Gimoti pharmacy services to ASPN Pharmacy (ASPN). The purpose of this transition was to improve the approval of the out-of-network prescriptions that were increasing across our prior platform. Although the transition initially created some slowing in managing patients and filling prescriptions, 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. In addition to the ASPN transition, we added several new pharmacies to our pharmacy platform during the year ended December 31, 2024, which has allowed for better insurance coverages due to geographic restrictions for filling prescriptions. Adding pharmacies has also added redundancy and capacity to fill prescriptions and reduced reliance on having a single pharmacy partner. ASPN is now processing inbound prescriptions at a pace that is showing improved patient capture and conversion to reimbursed fills by insurers, and reduced reliance on savings programs.

There were approximately 6,478 new inbound prescriptions into our reimbursement centers during the year ended December 31, 2024, a 22% increase compared to the prior year, which has also led to a 72% increase in fills. 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 67% of the time. We believe some patients choose not to refill their prescriptions due to remission of symptoms. Cumulatively, we grew the prescribers base by 46% during the year ended December 31, 2024.

The ASPN team accesses the Medicare and Medicaid systems and other commercial insurer platforms to facilitate product reimbursement submissions for patients seeking treatment. For the year ended December 31, 2024, these government programs made up approximately 32.9% of the filled prescriptions for Gimoti. From the commercial launch of Gimoti through December 31, 2024, 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. We believe the sales force continues to establish itself as a strong GI motility commercial organization in the U.S. with growing influence and connections to the GI community. We continue to make headway with GI groups as we establish our sales process and prescription assistance processes at offices on our target call list. We believe this is ultimately leading to more prescriptions once the offices are familiar with the specialty pharmacy systems and ASPN. Furthermore, from our experience, it appears that, within larger gastroenterology teams, once the first physician adopts the use of Gimoti, it has led other physicians within the same practice to begin prescribing Gimoti as well.

Key Opinion Leaders (“KOLs”) are actively presenting data regarding the safety profile for Gimoti. Data presented at the May 2024 Digestive Disease Week indicated a far lower incidence of tardive dyskinesia (“TD”) than previously published. This retrospective data was generated from a US based database with over 270 million patient lives. The outcome showed a 0.1% incidence of TD for gastroparesis patients taking any form of metoclopramide for any diagnosis.

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. Compared to patients in the oral metoclopramide cohort, patients taking Gimoti experienced fewer visits to a physician's office and 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. In October 2024 during the American College of Gastroenterology (ACG) meeting, additional data related to the comparative study between Gimoti and oral metoclopramide showed a similar benefit for persons also taking GLP-1 treatments. This continues to be an area of interest for gastroenterologists who are more frequently seeing patients with delayed gastric emptying accompanying GLP-1 therapy. These data have recently been provided, or are being prepared for 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. We are in discussion with the 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 product 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 ("U.S. GAAP"). The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. We evaluate these estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Our actual results may differ materially from these estimates under different assumptions or conditions.

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

***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 ASC 606, 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-pay assistance to commercially insured patients meeting certain eligibility requirements, as well as to uninsured patients. Co-pay 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.

**Results of Operations**

***Comparison of Years Ended December 31, 2024 and 2023***

The following table summarizes the results of our operations for the fiscal years ended December 31, 2024 and 2023:

| | Year Ended December 31, | | | |
|---|---|---|---|---|
| | 2024 | 2023 | $ Change | % Change |
| Net product sales | $ 10,249,415 | $ 5,180,630 | $ 5,068,785 | 98% |
| Cost of goods sold | $ 356,531 | $ 201,879 | $ 154,652 | 77% |
| Research and development expenses | $ 16,322 | $ 181,907 | $ (165,585) | -91% |
| Selling, general and administrative expenses | $ 15,080,699 | $ 12,227,735 | $ 2,852,964 | 23% |

*Net Product Sales.* Net product sales for the year ended December 31, 2024 compared to the year ended December 31, 2023 increased by approximately $5.1 million. The increase in product sales during 2024 is due to increased conversion rate due to the expanded pharmacy network, a greater number of physicians within larger gastroenterology teams prescribing Gimoti after first-physician adoption, and patients re-filling at a higher rate than the prior year.

*Cost of Goods Sold.* Cost of goods sold for the year ended December 31, 2024 compared to the year ended December 31, 2023 increased by approximately $0.2 million. The increase in cost of goods sold during 2024 is primarily due to an increase in stability costs due to additional commercial product batches completing stability testing, along with an overall increase in sales.

*Research and Development Expenses.* Research and development expenses for the year ended December 31, 2024 compared to the year ended December 31, 2023 decreased by approximately $0.2 million primarily due to stability testing costs incurred in 2023 on a pre-commercial product batch with no such costs incurred in 2024.

*Selling, General and Administrative Expenses.* Selling, general and administrative expenses for the year ended December 31, 2024 compared to the year ended December 31, 2023 increased by approximately $2.9 million, primarily due to an increase of $4.4 million in marketing and Eversana profit sharing amount as a direct result of an increase in net product sales. These increases were partially offset by decreases of $1.1 million in wages, taxes, and employee insurance, including a $0.4 million decrease in stock-based compensation expense, and $0.5 million for legal, accounting, directors and officers liability insurance and other costs associated with being a public company.

**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 $5.0 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 $5.0 million from the Eversana Credit Facility.

As of December 31, 2024, we had approximately $13.6 million in cash and cash equivalents. We anticipate that we will continue to incur losses from operations due to commercialization activities, including manufacturing Gimoti, conducting the post-marketing commitment single-dose 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 our operations. Both we and Eversana may terminate the commercial services agreement (as described in *Note 5 – Commercial Services and Loan Agreements with Eversana*), pursuant to the NPQTR (as defined in *Note 5*); however, we have no intent to terminate the Eversana Agreement. There can be no assurance that Eversana will not exercise its right pursuant to the NPQTR. Should Eversana exercise its right under the NPQTR, the Loan Agreement (as described in *Note 5*) would also be terminated and we would be responsible for repaying the principal and accrued interest on the loan, which was $7.1 million as of December 31, 2024, within 90 days of the effective date of the termination. In addition, we would need to establish a commercial infrastructure in order to continue distributing Gimoti. The timing and costs associated with this are not clear, but we believe they would be substantial. As a result, management 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. 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.

In February 2024, we sold 427,886 common stock units (the “Common Stock Units”), at a public offering price of $8.16 per Common Stock Unit and, to certain investors, 491,221 pre-funded warrant units (the “PFW Units”), at a public offering price

of $8.1588 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 $6.2 million.

As discussed in *Note 4 – Stockholders' Equity*, during March, June and September 2024, we amended certain warrant agreements with our Series B and Series C warrant holders (the "Warrant Amendments"). Pursuant to the Warrant Amendments to the extend a warrant holder exercised their Series B warrants prior to their respective exercise deadlines, as defined in the amendment documents (the "Amendment Exercise Deadline"), the holders corresponding Series C Warrants vested and became exercisable for the lesser of (i) three times the number of Series B Warrants exercised by the holder and (ii) the total number of Series C Warrants outstanding to the holder. Following each Amendment Exercise Deadline, if such holder exercised any remaining Series B Warrants, the remaining Series C Warrants, if any, vested and became exercisable on a one-for-one basis as to the same number of Series B Warrants exercised. The Warrant Amendments allowed a holder to elect to receive Pre-Funded Warrants upon exercise of Series B Warrants and Series C Warrants in lieu of shares of the our common stock, at a purchase price of $8.1588 per warrant exercised and an exercise price of $0.0012 per Pre-Funded Warrant. Net cash proceeds from the March, June and September 2024 Warrant Amendment were $1.2 million, $0.3 million and $0.4 million, respectively, after deducting underwriter commissions and offering expenses. The Series B Warrants expired on November 13, 2024, which was nine months from the date of issuance. The Series C Warrants also expired 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.

In September 2024, we entered into an amendment with certain holders of our Series A Warrants, Series B Warrants and Series C Warrants (the "September 2024 Exercise Price Warrant Amendment"), pursuant to which such holders agreed to pay $3.99 per Series A Warrant or Series C Warrant to reduce the exercise price of the Series A Warrants and Series C Warrants from $8.16 to $0.01. To the extent the holder did not elect to modify all outstanding Series A Warrants and Series C Warrants, the remaining Series A Warrants and Series C Warrants held by each holder retained an exercise price of $8.16 per Series A Warrant or Series C Warrant. Net proceeds from the September 2024 Exercise Price Warrant Amendment were approximately $2.5 million.

*Capital Resource Requirements*

On October 16, 2024, we entered into the Seventh Amendment to our existing office lease agreement. The Seventh Amendment extends the term of the lease from October 31, 2024 to March 31, 2027. The Seventh Amendment provides for an initial monthly base rent of approximately $6,500, with stated escalation clauses each November first through the lease term. We are also responsible for common area maintenance costs associated with the leased space.

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; and
- costs associated with any other product candidates that we may develop, in-license or acquire.

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, 2024 and 2023:

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2024 | 2023 | $ Change |
| Net cash used in operating activities | $ (5,458,742) | $ (4,984,977) | $ (473,765) |
| Net cash provided by (used in) financing activities | $ 14,315,916 | $ (119,296) | $ 14,435,212 |
| Net increase (decrease) in cash and cash equivalents | $ 8,857,174 | $ (5,104,273) | $ 13,961,447 |

*Operating Activities.* The primary use of our cash has been to fund our commercial sales and manufacturing of Gimoti and other general operations. The cash used in operating activities during the years ended December 31, 2024 and 2023 was primarily related to commercialization activities for Gimoti and other general operational activities. We expect that cash used in operating activities during the remainder of 2025 will be in-line with cash used during similar periods in 2024 because growing sales are expected to offset 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, 2024, cash provided by financing activities was $14.3 million primarily due to the sale of Common Stock and Pre-Funded Warrants, and the exercise of Series A Warrants, Series B Warrants, and Series C Warrants that were initially issued in the February 2024 offering.

**Off-Balance Sheet Arrangements**

Through December 31, 2024, 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 October 2023, we entered into an operating lease for a new office space in Solana Beach, California. In October 2024, the lease was amended, to extend the expiration date to March 31, 2027. The amended lease commenced on November 1, 2024. As of December 31, 2024, future minimum lease payments for our operating lease are approximately $0.2 million. We also pay pass through costs and utility costs, which are expensed as incurred.

**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 Financial 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, 2024 we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial 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 Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2024.

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

Internal control over financial reporting refers to the process designed by, or under the supervision of, our Chief Executive Officer and Chief Financial 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 Financial 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, 2024, the end of our most recent fiscal year.

**Remediation of Material Weakness**

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company’s annual or interim financial statements will not be prevented or detected on a timely basis.

As disclosed in "Part II Item 9A Controls and Procedures" in our Annual Report on Form 10-K/A for the year ended December 31, 2023, we identified a material weakness in internal control related to ineffectively designed controls over review of the Eversana Credit Facility, ongoing compliance monitoring and the proper application of GAAP for such agreement.

During the year ended December 31, 2024, we completed an assessment regarding the appropriate GAAP in relation to the Eversana Credit Facility’s debt covenants, and we changed the design of our quarterly debt compliance control to address the proper GAAP. During the fourth quarter of 2024, we completed our testing of the operating effectiveness of the implemented control and found it to be effective. As a result, we have concluded the material weakness has been remediated as of December 31, 2024.

**Changes in Internal Control Over Financial Reporting**

Except as described above, 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, 2024 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, 2024, none of our officers or directors adopted, modified or terminated any contract, instruction or written plan for the purchase or sale of our securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) or any non Rule 10b5-1 trading arrangement.

**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 (the "Definitive Proxy Statement"), which is expected to be filed not later than 120 days after the end of our fiscal year ended December 31, 2024,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.

We have adopted an insider trading policy and procedures governing the purchase, sale, and/or other dispositions of our securities by our directors, officers, employees and other covered persons that are designed to promote compliance with insider trading laws, rules and regulations, and the Nasdaq Stock Market LLC listing rules, as applicable. A copy of our Insider Trading Compliance Program is filed as Exhibit 19.1 to this annual report on Form 10-K. It is our policy to comply with U.S. insider trading laws and regulations, including with respect to transactions in our own securities.

### Item 11. Executive Compensation.

Information required by this item will be contained in our Definitive Proxy Statement 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 and is incorporated herein by reference.

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

Information required by this item will be contained in our Definitive Proxy Statement 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 and is incorporated herein by reference.

## PART IV

**Item 15. Exhibits and Financial Statement Schedules.**

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

1. *Financial Statements.* The financial statements of Evoke Pharma, Inc., together with the report thereon of BDO USA, P.C., an independent registered public accounting firm, are filed as part of this Annual Report on Form 10-K beginning on page F-1.

2. *Financial Statement Schedules.*

None.

3. *Exhibits*

The following is a list of exhibits filed as part of this Annual Report on Form 10-K (including those incorporated herein by reference):

| | | Incorporated by Reference | | | | |
|---|---|---|---|---|---|---|
| Exhibit Number | Description of Exhibit | Form | File Number | Date of Filing | Exhibit Number | Filed or Furnished Herewith |
| 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 | Certificate of Amendment of Amended and Restated Certificate of Incorporation of the Company | 8-K | 001-36075 | 5/28/2024 | 3.1 | |
| 3.4 | Certificate of Amendment of Amended and Restated Certificate of Incorporation of the Company | 8-K | 001-36075 | 8/1/2024 | 3.1 | |
| 3.5 | 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 | 1/11/2024 | 4.3 | |
| 4.5 | Form of Series B Warrant | S-1/A | 333-275443 | 1/11/2024 | 4.4 | |
| 4.6 | Form of Series C Warrant | S-1/A | 333-275443 | 1/11/2024 | 4.5 | |
| 4.7 | Form of Representative Warrant | 8-K | 001-36075 | 2/14/2024 | 4.1 | |
| 4.8 | Form of March 2024 Warrant Amendment | 8-K | 001-36075 | 3/25/2024 | 4.1 | |
| 4.9 | Form of June 2024 Warrant Amendment | 8-K | 001-36075 | 6/20/2024 | 4.1 | |
| 4.10 | Form of Exercise Price Warrant Amendment | 8-K | 001-36075 | 9/27/2024 | 4.1 | |

| Exhibit Number | Description of Exhibit | Incorporated by Reference | | | | Filed or Furnished Herewith |
|---|---|---|---|---|---|---|
| | | Form | File Number | Date of Filing | Exhibit Number | |
| 4.11 | Form of Series C Vesting Warrant Amendment | 8-K | 001-36075 | 9/27/2024 | 4.2 | |
| 10.1# | Form of Indemnity Agreement for Directors and Officers | S-1 | 333-188838 | 5/24/2013 | 10.1 | |
| 10.2# | Amended and Restated 2013 Equity Incentive Award Plan | 8-K | 001-36075 | 5/11/2024 | 10.1 | |
| 10.3# | Amended and Restated 2013 Employee Stock Purchase Plan | 8-K | 001-36075 | 5/11/2023 | 10.2 | |
| 10.4# | Amended and Restated Retention Letter, dated May 22, 2013, between the Company and Matthew D'Onofrio | S-1 | 333-188838 | 6/14/2013 | 10.8 | |
| 10.5† | 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 | |
| 10.6# | Employment Agreement, effective as of December 1, 2013, between the Company and Marilyn R. Carlson | 8-K | 001-36075 | 12/2/2013 | 10.1 | |
| 10.7# | 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 | |
| 10.8# | 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 | |
| 10.9# | Second Amended and Restated Employment Agreement, effective as of August 8, 2024 by and between the Company and Matthew D'Onofrio | 10-Q | 001-36075 | 11/7/2024 | 10.1 | |
| 10.10# | Amended and Restated Employment Agreement, effective as of August 8, 2024 by and between the Company and Mark Kowieski | 10-Q | 001-36075 | 11/7/2024 | 10.2 | |
| 10.11# | Amended and Restated Employment Agreement, effective as of August 8, 2024 by and between the Company and Marilyn R. Carlson | 10-Q | 001-36075 | 11/7/2024 | 10.3 | |
| 10.12† | Manufacturing Services Agreement dated November 7, 2017, between the Company and Patheon UK Limited | 10-K | 001-36075 | 3/14/2024 | 10.11 | |
| 10.13† | 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 | |
| 10.14 | 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 | |
| 10.15† | 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 | |
| 10.16† | 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 | |

| Exhibit Number | Description of Exhibit | Incorporated by Reference | | | | Filed or Furnished Herewith |
|---|---|---|---|---|---|---|
| | | Form | File Number | Date of Filing | Exhibit Number | |
| 10.17† | 3PL Agreement between the Company and Eversana Life Science Services, LLC dated August 27, 2020 | 10-Q | 001-36075 | 11/10/2020 | 10.1 | |
| 10.18# | Non-Employee Director Compensation Policy | 10-Q | 001-36075 | 8/10/2023 | 10.1 | |
| 10.19† | 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 | |
| 10.20† | 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 | 11/9/2022 | 10.1 | |
| 10.21 | Sixth Amendment to Standard Office Lease dated October 9, 2023, between the Company and SB Corporate Center III-IV, LLC. | 10-Q | 001-36075 | 11/9/2023 | 10.1 | |
| 10.22 | Seventh Amendment to Standard Office Lease dated October 16, 2024 between the Company and SB Corporate Center III-IV, LLC. | 10-Q | 001-36075 | 11/7/2024 | 10.4 | |
| 10.23 | Letter Agreement, dated September 27, 2024, by and between the Company and certain affiliates of Nantahala Capital Management, LLC | 8-K | 001-36075 | 9/27/2024 | 10.1 | |
| 19.1 | Insider Trading Compliance Program | | | | | |
| 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 |
| 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 | 10-K | 001-36075 | 3/14/2024 | 97 | |
| 101.SCH | Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document. | | | | | |
| 104 | Cover Page Interactive Data File – the cover page interactive data file does not appear in | | | | | |

| Exhibit Number | Description of Exhibit | Incorporated by Reference | | | | Filed or Furnished Herewith |
|---|---|---|---|---|---|---|
| | | Form | File Number | Date of Filing | Exhibit Number | |
| | the Interactive Data File because its XBRL tags are embedded within the XBRL document. | | | | | |

† 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.

**Item 16. Form 10-K Summary.**

None.

## 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 13, 2025

By: /s/ Matthew J. D'Onofrio
Matthew J. D'Onofrio
Chief Executive Officer
(Principal Executive Officer)

**Evoke Pharma, Inc.**

Date: March 13, 2025

By: /s/ Mark Kowieski
Mark Kowieski
Chief Financial Officer
(Principal Financial and Accounting 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/ Matthew J. D'Onofrio<br>Matthew J. D'Onofrio | Chief Executive Officer (Principal Executive Officer) | March 13, 2025 |
| /s/ Mark Kowieski<br>Mark Kowieski | Chief Financial Officer (Principal Financial and Accounting Officer) | March 13, 2025 |
| /s/ Cam L. Garner<br>Cam L. Garner | Chairman of the Board of Directors | March 13, 2025 |
| /s/ Todd C. Brady, M.D., Ph.D.<br>Todd C. Brady, M.D., Ph.D. | Director | March 13, 2025 |
| /s/ Malcolm R. Hill, Pharm. D.<br>Malcolm R. Hill, Pharm. D. | Director | March 13, 2025 |
| /s/ Vickie W. Reed<br>Vickie W. Reed | Director | March 13, 2025 |
| /s/ Benjamin Smeal<br>Benjamin Smeal | Director | March 13, 2025 |
| /s/ Kenneth J. Widder, M.D.<br>Kenneth J. Widder, M.D. | Director | March 13, 2025 |
| _____<br>Greg Pyszcymuka | Director | March 13, 2025 |

**Evoke Pharma, Inc.**
**Index to Financial Statements**

## Report of Independent Registered Public Accounting Firm

Stockholders 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, 2024 and 2023, 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, 2024 and 2023, and the results of its operations and its cash flows for 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 and Note 5 to the financial statements, the Company has suffered recurring losses and negative cash flows from operations since inception, expects to continue to incur losses in the foreseeable future, and Eversana Life Science Services, LLC ("Eversana") has the right to terminate the commercial services agreement (as amended, the "Eversana Agreement") for the commercialization of Gimoti. 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 Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters 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 matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

***Revenue under the Eversana Agreement***

As described in Notes 2 and 5 to the financial statements, the Company's product Gimoti is commercialized through the Company's commercial partner Eversana pursuant to the Eversana Agreement. 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 existence and accuracy of revenue under the Eversana Agreement as a critical audit matter. The principal consideration that led to our determination was that performing procedures and evaluating the audit evidence related to the existence and accuracy of revenue transactions involved a high degree of auditor effort due to the significance of net product sales and volume of transactions.

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

- Testing revenue transactions, on a sample basis, by obtaining and inspecting prescription purchase orders, shipping documents, and cash receipts from Eversana.
- Confirming the sales quantity of prescriptions processed with certain service providers that fulfill orders and comparing that to information provided by Eversana.

***Classification of Warrants***

As described in Note 4 to the financial statements, in February 2024, the Company sold common stock units and pre-funded warrant units, and issued common stock warrants to the underwriters ("Common Stock Warrants") (collectively, the "February 2024 Offering"). Each common stock unit consisted 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 pre-funded warrant unit consisted 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. The Company determined the Series A, Series B, Series C, Pre-Funded, and Common Stock Warrants issued in 2024 were equity classified and recorded them as a component of additional paid-in capital.

During 2024, the Company entered into amendments with certain Series A, Series B, and Series C Warrant holders (the "Warrant Amendments"). The Company determined that the incremental changes in fair value resulting from the Warrant Amendments were equity issuance costs and recorded them as a component of additional paid-in capital.

We identified the evaluation of the financial statement classification for (i) the issuance of the Series A, Series B, Series C, Pre-Funded, and Common Stock Warrants in the February 2024 Offering; and (ii) the Warrant Amendments as a critical audit matter. Our principal considerations included the existence of accounting complexities related to certain provisions of the warrant agreements, including legally detachable and separately exercisable, settlement provisions and derivative elements. Auditing these elements involved especially complex auditor judgment due to the terms of the applicable agreements, including the extent of expertise needed.

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

- Evaluating the appropriateness of management's conclusions through the review of: (i) the relevant terms of the warrant agreements and amendments, (ii) the completeness and accuracy of the Company's technical accounting analysis, and (iii) the appropriateness of application of the relevant accounting literature.
- Utilizing personnel with expertise in relevant technical accounting to assist in: (i) evaluating relevant terms of the warrant agreements and amendments in relation to the appropriate accounting literature, and (ii) assessing the appropriateness of conclusions reached by the Company.

/s/ BDO USA, P.C.

We have served as the Company's auditor since 2014.
San Diego, California
March 13, 2025

**Evoke Pharma, Inc.**
**Balance Sheets**

| | December 31, | |
|---|---|---|
| | 2024 | 2023 |
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 13,596,600 | $ 4,739,426 |
| Accounts receivable, net of allowance for credit losses of $0 | 2,420,373 | 673,071 |
| Prepaid expenses | 731,945 | 885,040 |
| Inventories | 445,081 | 481,840 |
| Other current assets | 43,898 | 47,532 |
| Total current assets | 17,237,897 | 6,826,909 |
| Operating lease right-of-use asset | 154,184 | — |
| Deferred offering costs | 120,614 | 241,637 |
| Other long-term assets | 6,312 | — |
| Total assets | $ 17,519,007 | $ 7,068,546 |
| **Liabilities and stockholders' equity (deficit)** | | |
| Current liabilities: | | |
| Accounts payable and accrued expenses | $ 2,341,191 | $ 1,711,778 |
| Accrued compensation | 865,650 | 1,324,010 |
| Operating lease liability | 59,533 | — |
| Note payable | 5,000,000 | 5,000,000 |
| Accrued interest payable | 2,113,665 | 1,612,295 |
| Total current liabilities | 10,380,039 | 9,648,083 |
| Operating lease liability, net of current portion | 100,958 | — |
| Total liabilities | 10,480,997 | 9,648,083 |
| Commitments and contingencies | | |
| Stockholders' equity (deficit): | | |
| Preferred stock, $0.0001 par value; authorized shares — 5,000,000 as of December 31, 2024 and December 31, 2023; issued and outstanding shares — zero as of December 31, 2024 and December 31, 2023 | — | — |
| Common stock, $0.0001 par value; authorized shares — 100,000,000 and 50,000,000 as of December 31, 2024 and December 31, 2023, respectively; issued and outstanding shares — 1,486,009 and 278,558 as of December 31, 2024 and December 31, 2023, respectively | 149 | 28 |
| Additional paid-in capital | 135,829,493 | 120,859,873 |
| Accumulated deficit | (128,791,632) | (123,439,438) |
| Total stockholders' equity (deficit) | 7,038,010 | (2,579,537) |
| Total liabilities and stockholders' equity (deficit) | $ 17,519,007 | $ 7,068,546 |

*See accompanying notes to these financial statements.*

**Evoke Pharma, Inc.**
**Statements of Operations**

| | Year Ended December 31, | |
|---|---|---|
| | 2024 | 2023 |
| Net product sales | $ 10,249,415 | $ 5,180,630 |
| Operating expenses: | | |
| Cost of goods sold | 356,531 | 201,879 |
| Research and development | 16,322 | 181,907 |
| Selling, general and administrative | 15,080,699 | 12,227,735 |
| Total operating expenses | 15,453,552 | 12,611,521 |
| Loss from operations | (5,204,137) | (7,430,891) |
| Other income (expense): | | |
| Interest income | 353,313 | 138,596 |
| Interest expense | (501,370) | (500,000) |
| Total other expense | (148,057) | (361,404) |
| Net loss | $ (5,352,194) | $ (7,792,295) |
| Net loss per share of common stock, basic and diluted | $ (2.81) | $ (27.97) |
| Weighted-average shares used to compute basic and diluted net loss per share | 1,905,072 | 278,558 |

*See accompanying notes to these financial statements.*

**Evoke Pharma, Inc.**
**Statements of Stockholders' Equity (Deficit)**

| | Common Stock | | Additional Paid-In Capital | Accumulated Deficit | Total Stockholders' Equity (Deficit) |
|---|---|---|---|---|---|
| | Shares | Amount | | | |
| Balance as of December 31, 2022 | 278,558 | $ 28 | $ 119,731,764 | $ (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 as of December 31, 2023 | 278,558 | 28 | 120,859,873 | (123,439,438) | (2,579,537) |
| Stock-based compensation expense | — | — | 773,121 | — | 773,121 |
| Issuance of common stock, Pre-Funded Warrants, Series A Warrants, Series B Warrants, and Series C Warrants, net of issuance costs | 427,886 | 43 | 6,172,580 | — | 6,172,623 |
| Amendment and issuance of common stock from the March 2024 Amendment of Series B Warrants and Series C Warrants, net of issuance costs | 9,967 | 1 | 1,229,873 | — | 1,229,874 |
| Amendment and issuance of Pre-Funded Warrants from the June 2024 Amendment of Series B Warrants and Series C Warrants, net of issuance costs | — | — | 308,429 | — | 308,429 |
| Amendment and issuance of common stock from the September 2024 Exercise Price Warrant Amendment of Series A Warrants and Series C Warrants, net of issuance costs | 24,509 | 3 | 2,532,446 | — | 2,532,449 |
| Amendment and issuance of common stock from the September 2024 Amendment of Series B Warrants and Series C Warrants, net of issuance costs | 51,062 | 5 | 370,617 | — | 370,622 |
| Issuance of common stock from the exercise of Pre-Funded Warrants, Series A Warrants, Series B Warrants, and Series C Warrants, net of issuance costs | 583,657 | 58 | 3,582,756 | — | 3,582,814 |
| Issuance of common stock from cashless exercise of Pre-Funded Warrants and Modified Series A Warrants | 110,370 | 11 | (11) | — | — |
| Redemption of fractional shares due to reverse stock split | — | — | (191) | — | (191) |
| Net loss | — | — | — | (5,352,194) | (5,352,194) |
| Balance as of December 31, 2024 | 1,486,009 | $ 149 | $ 135,829,493 | $ (128,791,632) | $ 7,038,010 |

*See accompanying notes to these financial statements.*

**Evoke Pharma, Inc.**
**Statements of Cash Flows**

| | Year Ended December 31, | |
|---|---|---|
| | 2024 | 2023 |
| **Operating activities** | | |
| Net loss | $ (5,352,194) | $ (7,792,295) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Stock-based compensation expense | 773,121 | 1,128,109 |
| Non-cash interest expense | 501,370 | 500,000 |
| Obsolete inventory adjustment | 3,920 | — |
| Non-cash operating lease expense | 12,764 | 129,704 |
| Change in operating assets and liabilities: | | |
| Accounts receivable | (1,747,302) | (48,239) |
| Prepaid expenses and other assets | 29,803 | 31,932 |
| Inventories | 32,839 | (192,462) |
| Accounts payable and accrued expenses | 751,754 | 655,126 |
| Accrued compensation | (458,360) | 732,852 |
| Operating lease liabilities | (6,457) | (129,704) |
| Net cash used in operating activities | (5,458,742) | (4,984,977) |
| **Financing activities** | | |
| Proceeds from February 2024 Offering | 6,718,211 | — |
| Payment of February 2024 Offering costs | (426,292) | (119,296) |
| Proceeds from March 2024 Warrant Amendment | 1,229,874 | — |
| Proceeds from June 2024 Warrant Amendment, net of issuance costs | 308,429 | — |
| Proceeds from September 2024 Exercise Price Warrant Amendment, net of issuance costs | 2,532,449 | — |
| Proceeds from September 2024 Warrant Amendment, net of issuance costs | 370,622 | — |
| Proceeds from exercise of Pre-Funded Warrants, Series A Warrants, Series B Warrants and Series C Warrants | 3,582,814 | — |
| Redemption of fractional shares due to reverse stock split | (191) | — |
| Net cash provided by (used in) financing activities | 14,315,916 | (119,296) |
| Net increase (decrease) in cash and cash equivalents | 8,857,174 | (5,104,273) |
| Cash and cash equivalents at beginning of period | 4,739,426 | 9,843,699 |
| Cash and cash equivalents at end of period | $ 13,596,600 | $ 4,739,426 |
| | | |
| **Supplemental disclosure of non-cash investing and financing activities** | | |
| February 2024 Offering costs in accounts payable and accrued expenses | $ — | $ 122,340 |
| Operating lease right-of-use asset obtained in exchange for lease liability | $ 164,253 | $ — |

*See accompanying notes to these financial statements.*

**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 and commercialization 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. As of December 31, 2024, the Company had approximately $13.6 million in cash and cash equivalents. 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. Both the Company and Eversana may terminate the commercial services and loan agreement (as described in *Note 5 – Commercial Services and Loan Agreements with Eversana*), pursuant to the Net Profit Quarterly Termination Right (NPQTR) (as defined in *Note 5*); however, the Company has no intent to terminate the Eversana Agreement. There can be no assurance that Eversana will not exercise its right pursuant to the NPQTR. Should Eversana exercise its right under the NPQTR, the Loan Agreement, as described in *Note 5*, would also be terminated and the Company would be responsible for repaying the principal and accrued interest on the loan, which was $7.1 million as of December 31, 2024, within 90 days of the effective date of the termination. In addition, the Company would need to establish a commercial infrastructure in order to continue distributing Gimoti. The timing and costs associated with this are not clear, but the Company believes they would be substantial. As a result, management believes that there is substantial doubt about the Company's 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. 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.

### Reverse Stock Split

On May 22, 2024, 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 July 31, 2024, the Company filed an amendment (the "Amendment") to its amended and restated certificate of incorporation to effectuate a reverse stock split of the Company's common stock. Pursuant to the Amendment, at the effective time of 12:01 a.m. Eastern Time on August 1, 2024, each twelve (12) shares of the

Company's common stock issued and outstanding was combined into one (1) validly issued, fully paid and non-assessable share of common stock (the "Reverse Stock Split"). The par value and the authorized shares of the Company's common stock were not adjusted as a result of the Reverse Stock Split. All the Company's issued and outstanding common stock, warrants to purchase common stock, options to purchase common stock, per-share data and related information have been retroactively adjusted to reflect the Reverse Stock Split for all periods presented.

**2. Summary of Significant Accounting Policies**

**Use of Estimates**

The preparation of financial statements in conformity with accounting principles generally accepted in the United States ("GAAP") requires management to make estimates and assumptions that affect the 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. On an ongoing basis, the Company evaluates its estimates, including those related to the valuation of share-based awards, the fair value of warrants and the assessment of its ability to fund operations for at least the next 12 months from the date of issuance of these financial statements. Estimates are based on historical experience and other market-specific or other relevant assumptions that management believes to be reasonable under the circumstances. Estimates are assessed each reporting period and updated to reflect current information. As future events and their effects cannot be determined with precision, actual results may materially differ from those estimates or assumptions.

**Cash and Cash Equivalents**

The Company deposits its cash with reputable financial institutions that are insured by the Federal Deposit Insurance Corporation ("FDIC"). This cash is held in checking, cash sweep, and money market accounts. At times, deposits held may exceed the amount of insurance provided by the FDIC. The Company maintains an insured cash sweep account in which cash from its main operating checking account is invested overnight in highly liquid, short-term investments. The Company considers all highly liquid investments with a maturity date of 90 days or less at the date of purchase to be cash equivalents. The Company has not experienced any losses in its cash and cash equivalents and management believes the Company is not exposed to significant credit risk with respect to such accounts. The Company's cash and 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, 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 the note payable approximates fair value since the debt is due on demand as of December 31, 2024 and the carrying value is the settlement value, 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.

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 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, if any. The Company evaluates its estimate of expected credit losses based on a combination of factors, including historical experience, assessment of specific customer-related risks, review of outstanding invoices, forecasts about the future, and various other assumptions and estimates. As of January 1, 2023,

accounts receivable totaled $0.6 million. The allowance for credit losses was zero at December 31, 2024 and 2023, and no bad debt expense was recorded for the years ended December 31, 2024 and 2023.

**Inventories**

The Company's inventories consisted of the following:

| | December 31, | |
|---|---|---|
| | 2024 | 2023 |
| Raw materials | $ 257,467 | $ 361,219 |
| Finished goods | 187,614 | 120,621 |
| Total inventories | $ 445,081 | $ 481,840 |

Inventories are stated at the lower of cost (first-in first-out basis) or net realizable value. The Company's raw materials inventories and work-in-process are held at its third-party suppliers and its finished goods inventories are held by Eversana. The Company records such inventories as consigned inventories.

**Deferred Offering Costs**

Deferred offering costs represent legal, accounting, and other direct costs related to future equity financings and are recognized as a non-current asset on the balance sheets. After consummation of the equity financing, the offering costs are recognized as a reduction of proceeds and reclassified to additional paid-in capital on the balance sheet. Should a planned equity financing be abandoned, terminated, or significantly delayed, the deferred offering costs are immediately written off as an administrative expense. As of December 31, 2024, the Company had deferred offering costs of $0.1 million related to the filing of a shelf registration statement in August 2024. As of December 31, 2023, the Company had deferred offering costs of $0.2 million related to the public offering completed in February 2024. Upon completion of the public offering these costs were reclassified to additional paid-in capital.

***Leases***

The Company recognizes leases under Accounting Standards Codification ("ASC") 842, *Leases*. Under ASC 842, leases include all agreements in which the Company obtains control of an identified asset. A lease liability is recognized at commencement date based on the present value of the lease payments over the lease term. The interest rate used to determine the present value of the future lease payments is the Company's incremental borrowing rate, because the interest rate implicit in most of the Company's leases is not readily determinable. The incremental borrowing rate is estimated to approximate the interest rate on a collateralized basis with similar terms and payments, and in similar economic environments.

The Company elected to apply the practical expedients permitted under the guidance exempting the recognition of qualified short-term leases, meaning the Company recognizes expense on a straight-line basis and will not recognize a right-of-use asset or lease liability for these leases. The Company also elected to combine lease and non-lease components for all classes of underlying assets. Variable costs associated with the lease, such as maintenance and utilities, are not included in the measurement of right-of-use assets and lease liabilities but rather are expensed when the events determining the amount of variable consideration to be paid have occurred.

If a lease includes options to extend the lease term, the Company only includes the periods it is reasonably certain to exercise as of the lease commencement date and monitors its plans to renew its leases each reporting period. The Company's lease portfolio consists of its headquarters.

**Warrants**

The Company accounts for warrants as equity-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance in ASC 480, *Distinguishing Liabilities from Equity* and ASC 815, *Derivatives and Hedging*. The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to the Company's own common stock and whether the warrant holders could potentially require "net cash settlement" in a circumstance outside of the Company's control, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent quarterly period end date while the warrants are outstanding.

For warrants that meet all criteria for equity classification, the warrants are required to be recorded as additional paid-in capital in the balance sheets at the time of issuance. Equity-classified warrants are measured at their estimated fair value on the issuance date using either the Black-Scholes option pricing model or a Monte-Carlo simulation model based on the applicable assumptions, which include the exercise price of the warrants, the Company's stock price and volatility, the expected warrant term, the risk-free interest rate, the expected dividends, and if applicable, the vesting behavior.

**Revenue Recognition**

At the inception of a collaboration arrangement, the Company first assesses whether the contractual arrangement is within the scope of ASC 808, *Collaborative Arrangements* ("ASC 808") to determine whether the arrangement involves a joint operating activity and involves two (or more) parties that are both active participants in the activity and exposed to significant risks and rewards dependent on the commercial success of such activity. Then the Company determines whether the collaboration arrangement in its entirety represents a contract with a customer as defined by ASC 606, *Revenue from Contracts with Customers* ("ASC 606"). If only a portion of the collaboration arrangement is potentially with a customer, the Company applies the distinct good or service unit-of-account guidance in ASC 606 to determine whether there is a unit of account that should be accounted for under ASC 606.

The Company has entered into a collaborative arrangement with Eversana for the commercialization and distribution of Gimoti in the United States. Under this arrangement, Eversana is responsible for market access, marketing, distribution, and patient support services, while the Company retains ownership of Gimoti and all legal, regulatory, and manufacturing responsibilities. The Company records sales for Gimoti. The Company reimburses Eversana for its commercialization costs pursuant to an agreed upon budget and a percentage of product profits, if any, which are recorded within selling, general and administrative expenses in the statement of operations. The Company has determined that the underlying patient is the customer and the Company is the principal in its relationship with Eversana based on the indicators of control occurring prior to product transfer to the customer, including risks related to inventory and responsibility for product fulfillment. Payment terms are net 30.

In accordance with ASC 606, 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 allocated to the respective performance obligation when the customer obtains control of the product.

Product sales are recognized net of any applicable variable consideration. The Company uses judgment to estimate variable consideration including (i) Medicaid and Medicare program rebates ("MMPR"), (ii) sales-related adjustments, wherever applicable, including patient support programs, rebates, and other sales related discounts and (iii) co-pay assistance. The MMPR for these programs are determined based on statutory provisions and are estimated based on the expected number of claims and related cost associated with the customer transaction. Medicaid and Medicare rebates of $0.2 million and $46,000 were recorded as accounts payable and accrued expenses on the balance sheets as of December 31, 2024 and 2023, respectively.

Co-pay 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 assistance liabilities are estimated using prescribing data available from customers. The Company's analysis also contemplates application of the constraint in accordance with the guidance, under which it determines 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 could affect net product revenue and earnings in the period such variances become known. Liabilities for co-pay assistance of approximately $0.1 million each as of December 31, 2024 and 2023, respectively, are classified as accounts payable and accrued expenses in the balance sheets.

The Company does not allow for product returns. The Company may replace damaged product upon shipment, but such amounts are immaterial. Cash receipts from sales come directly from the Company's commercial partner, Eversana, and are typically received in 30 to 60 days after month-end.

**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 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 is 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 is calculated using the simplified method as prescribed by accounting guidance for stock-based compensation. Volatility is calculated based on the historical volatility of the Company's common stock. The assumed dividend yield is 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. 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.

**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. Pre-Funded Warrants issued and sold by the Company to purchase shares of its common stock are included in the calculation of basic net loss per common share if the exercise price of the pre-funded warrants represents *de minimis* consideration and is non-substantive in relation to the price paid for the warrant, and if the warrants are immediately exercisable with no further vesting conditions or contingencies associated with them. The 1,060,316 shares of the Company's common stock underlying the Pre-Funded Warrants, Modified Series A Warrants and Modified Series C Warrants described in *Note 4 – Stockholders' Equity*, are included in the weighted-average outstanding common stock in the calculation of basic and diluted net loss per share due to their nominal exercise price. The Company considers Series A Warrants, Series B Warrants, Series C Warrants, and Representatives' Warrants to be participating securities, because holders of such instruments participate in the event a dividend is paid on common stock. The holders of the Series A Warrants, Series B Warrants, Series C Warrants, and Representatives' Warrants do not have a contractual obligation to share in the Company's losses. As such, losses are attributed entirely to common stockholders and for periods in which the Company has reported a net loss, diluted loss per common share is the same as basic loss per common share. 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.

The following table sets forth the outstanding potentially dilutive securities that have been excluded from the calculation of diluted net loss per share for the years ended December 31, 2024 and 2023 because to do so would be anti-dilutive:

| | December 31, | |
|---|---|---|
| | 2024 | 2023 |
| Warrants to purchase common stock | 792,731 | — |
| Common stock options | 126,015 | 51,983 |
| Total excluded securities | 918,746 | 51,983 |

**Recently Adopted Accounting Pronouncements**

In November 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2023-07, *Segment Reporting (Topic 280) Improvements to Reportable Segment Disclosures*, which modifies the disclosure and presentation requirements of reportable segments ("ASU 2023-07"). The amendments in the update require the disclosure of significant segment expenses that are regularly provided to the chief operating decision maker (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. The adoption of ASU 2023-07 resulted in enhanced disclosures as included in *Note. 7 Segment Information,* but did not impact to our results of operations, cash flows and financial condition.

**Recently Issued Accounting Pronouncements — Not Yet Adopted**

From time to time, new accounting pronouncements are issued by the FASB or other standards setting bodies that are adopted as of the specified effective date. The Company believes the impact of recently issued standards, other than those noted below, and any issued but not yet effective standards will not have a material impact on our financial statements upon adoption.

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.

In November 2024, the FASB issued ASU No. 2024-03, *Income Statement-Reporting Comprehensive Income-Expense Disaggregation Disclosures (Subtopic 220-40)* (ASU 2024-03). The amendments in this update require disclosure, in the notes to the financial statements, of specific expense categories present within expense captions presented on the face of the income statement within continuing operations of public business entities. The amendments in this update are effective for annual periods beginning after December 15, 2026 and interim periods beginning after December 15, 2027. Early adoption is permitted. The amendments should be applied either prospectively to financial statements issued for reporting periods after the effective date of this ASU or retrospectively to any and all prior periods presented in the financial statements. The impact of adoption this ASU on the Company's disclosures is currently being evaluated.

In January 2025, the FASB issued ASU No. 2025-01**,** *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Clarifying the Effective Date***.** The amendment in this update clarifies the effective date of ASU 2024-03, which is that public business entities are required to adopt the guidance in annual reporting periods beginning after December 15, 2026, and interim periods within annual reporting periods beginning after December 15, 2027. The impact of adoption of this ASU on the Company's disclosures is currently being evaluated.

**3. Commitments and Contingencies**

**Leases**

In December 2016, the Company entered into an operating lease for office space in Solana Beach, California (the "Initial Lease"). The Initial Lease commenced on January 1, 2017, and as amended, expired on October 31, 2023.

Upon expiration of the Initial Lease, the Company entered into an operating lease for a new office space in Solana Beach, California commencing on November 1, 2023 and expiring on October 31, 2024 (the "Short-Term Lease"). The Short-Term Lease qualified as a short-term lease under ASC 842 and was not recorded on the balance sheet. Operating lease expense for the Short-Term Lease was recognized on a straight-line basis over the lease term as general administrative expense within the statement of operations.

Upon expiration of the Short-Term Lease, the Company entered into an amendment for the same office space in Solana Beach commencing on November 1, 2024 and expiring on March 31, 2027 (the "Current Lease"). As the Current Lease agreement did not include an implicit rate, the Company estimated the incremental borrowing rate of 10% utilized to discount future minimum lease payments based on information available at lease commencement. Operating lease expense for the Current Lease is recognized on a straight-line basis over the lease term. The Company recognized an ROU asset obtained in exchange for new lease obligations of $0.2 million upon commencement of the Current Lease. The new lease liability obligation is recorded in operating lease liability and operating lease liability, net of current portion in the balance sheets. As of December 31, 2024, the remaining lease term was 2.3 years.

The following table summarizes supplemental lease information for the years ended December 31, 2024 and 2023:

| | Year Ended December 31, | |
|---|---|---|
| | 2024 | 2023 |
| Lease costs[1] | $ 75,883 | $ 154,027 |
| Cash paid for leases | $ 69,575 | $ 146,329 |

(1) Lease costs and cash paid for leases includes $63,119 and $12,624 of short-term lease expense for the years ended December 31, 2024 and 2023. Variable lease costs included in general and administrative expense for the years ended December 31, 2024 and 2023 were immaterial.

Future lease payments as of December 31, 2024 were as follows:

| Years Ending December 31, | |
|---|---|
| 2025 | $ 77,871 |
| 2026 | 80,207 |
| 2027 | 20,551 |
| Total future lease payments | 178,629 |
| Less: imputed interest | (18,138) |
| Total lease liability | $ 160,491 |

## 4. 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, 2024 and 2023.

### Common Stock

As of December 31, 2024, there were 1,486,009 shares of common stock outstanding. Each share of common stock is entitled to one vote. The holders of the common stock, on an as converted basis, are 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.

### Equity Transactions

*February 2024 Offering*

In February 2024, the Company entered into an underwriting agreement (the "Underwriting Agreement") with Craig-Hallum Capital Group LLC and Laidlaw & Company (UK) Ltd. (collectively, the "Underwriters"), relating to the issuance and sale of 427,886 common stock units (the "Common Stock Units") at a public offering price of $8.16 per Common Stock Unit and, to certain investors, 491,221 pre-funded warrant units (the "PFW Units") at a public offering price of $8.1588 per PFW Unit (the "February 2024 Offering"). Each Common Stock Unit consisted 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 consisted 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. The Company also issued warrants to the Underwriters to purchase up to 45,955 shares of common stock, equal to 5% of the securities sold in the February 2024 Offering (the "Representatives' Warrants"). The Series A Warrants are fully exercisable and are recognized as a freestanding financial instruments. In accordance with the terms and provisions of the Series C Warrants, the Series C Warrants were not exercisable, in part or in whole, at any time unless the Series B Warrants had been exercised. If Series B Warrants were not exercised before November 13, 2024, the corresponding Series C Warrants were no longer deemed outstanding and could not be exercised. Furthermore, the Series B Warrants and Series C Warrants could not be transferred by the holder without the consent of the Company, and, therefore the Series B Warrants and Series C Warrants were accounted for as a single unit of account.

Net cash proceeds from the February 2024 Offering was $6.2 million after deducting underwriter and offering expenses. The Pre-Funded Warrants, Series A Warrants, Series B Warrants, and Series C Warrants are equity classified and were recognized as additional paid-in capital in the balance sheets. The Representatives' Warrants were accounted for under ASC 718, *Compensation — Stock Compensation*, and were recognized as an equity issuance cost at their grant date fair value within additional paid-in capital in the balance sheets.

*August 2024 Shelf Registration Statement*

On August 29, 2024, the Company filed a universal shelf registration statement on Form S-3 (the "Shelf Registration Statement"), covering the offering of up to $50.0 million of common stock, preferred stock, debt securities, warrants, and/or units, subject to the "Baby Shelf Limitation" which limits the amount that the Company can offer to up to one-third of its public float during any 12-month period so long as our public float remains below $75.0 million. The Shelf Registration Statement was declared effective by the SEC on September 6, 2024.

As of December 31, 2024, there have been no shares of common stock, preferred stock, debt securities, warrants, and/or units issued under the Shelf Registration Statement.

*At The Market Equity Offering*

The Company had previously entered into a Sales Agreement (the "Sales Agreement") with H.C. Wainwright & Co., LLC ("Wainwright"), under which the Company may, from time to time, sell shares of its common stock having an aggregate offering price of up to approximately $1.9 million through Wainwright (the "ATM Offering"). The Shelf Registration Statement included a prospectus covering the offering, issuance and sale of up to approximately $1.9 million of the Company's common stock from time to time through the ATM Offering (the "ATM Prospectus"). In November 2024, the Company filed a prospectus supplement to amend and supplement the ATM Prospectus to update the amount of shares it is eligible to sell under the "Baby Shelf Limitation" to $3.1 million under the Sales Agreement.

The Company did not issue any shares of common stock pursuant to the ATM Offering during the years ended December 31, 2024.

**Warrant Amendments**

In each of March, June and September 2024, the Company entered into substantially similar amendments with certain holders of its Series B Warrants and Series C Warrants (individually, the "March 2024 Warrant Amendment," "June 2024 Warrant Amendment," and the "September 2024 Warrant Amendment," respectively and collectively, the "Warrant Amendments"). Pursuant to the Warrant Amendments, to the extent a holder exercised its Series B Warrants prior to their respective exercise deadlines, as defined in the amendment documents (the "Amendment Exercise Deadline"), the holder's corresponding Series C Warrants vested and became exercisable for the lesser of (i) three times the number of Series B Warrants exercised by the Holder and (ii) the total number of Series C Warrants outstanding to the holder. Following each Amendment Exercise Deadline, if the holder exercised any remaining Series B Warrants, the remaining Series C Warrants, if any, vested and became exercisable on a one-for-one basis as to the same number of Series B Warrants exercised.

The Warrant Amendments allowed a holder to elect to receive Pre-Funded Warrants upon exercise of Series B Warrants and Series C Warrants in lieu of shares of the Company's common stock, at a purchase price of $8.1588 per warrant exercised and an exercise price of $0.0012 per Pre-Funded Warrant.

Net cash proceeds from the March, June and September 2024 Warrant Amendment were $1.2 million, $0.3 million and $0.4 million, respectively, after deducting underwriter commissions and offering expenses. The Warrant Amendments were entered into to encourage the exercise of Series B Warrants in order to obtain capital to meet the Minimum Stockholders' Equity

Requirement as more fully discussed in *Note 1. Organization and Basis of Presentation*. The Warrant Amendments neither changed the number of shares of common stock underlying each series of warrants nor its equity classification. The incremental change in fair value from the Warrant Amendments was accounted for as equity issuance costs and recognized within additional paid-in capital in the balance sheets.

*September 2024 Exercise Price Warrant Amendment*

In September 2024, the Company also entered into an amendment with certain holders of its Series A Warrants, Series B Warrants and Series C Warrants (the "September 2024 Exercise Price Warrant Amendment"). Pursuant to the September 2024 Exercise Price Warrant Amendment, such holders who agreed to pay a non-refundable up-front payment of $3.99 per Series A Warrant or Series C Warrant prior to September 30, 2024 deadline (as defined in the September 2024 Exercise Price Amendment) had the exercise price reduced for each of the Series A Warrants and Series C Warrants from $8.16 to $0.01 (such Series A Warrants and Series C Warrants modified to have a reduced exercise price referred to as the "Modified Series A Warrants" and "Modified Series C Warrants"). To the extent such holder did not elect to modify all outstanding Series A Warrants and Series C Warrants, the remaining Series A Warrants and Series C Warrants held by each holder retained an exercise price of $8.16 per Series A Warrant or Series C Warrant.

Net cash proceeds from the September 2024 Exercise Price Warrant Amendment were $2.5 million after deducting underwriter and offering expenses. The September 2024 Exercise Price Warrant Amendment was entered to encourage the modification of Series A Warrants and Series C Warrants in order to obtain capital to meet the Minimum Stockholders' Equity Requirement. The September 2024 Exercise Price Warrant Amendment neither changed the number of shares of Common Stock underlying each series of warrants nor its equity classification. The incremental change in fair value from the September 2024 Exercise Price Warrant Amendment was an equity issuance cost and was recognized within additional paid-in capital in the balance sheets.

In connection with the September 2024 Exercise Price Warrant Amendment, the Company entered into a letter agreement, dated September 27, 2024 (the "Letter Agreement"), with certain affiliates of Nantahala Capital Management, LLC (collectively, "Nantahala"), pursuant to which, subject to certain limitations, the Company provided Nantahala the right to appoint (or cause to be nominated) (i) one member of the Company's board of directors (the "Board") and one member of each Board committee so long as Nantahala, together with its affiliates, beneficially owns at least 5.0% of the Company's outstanding shares of common stock and (ii) two members of the Board so long as Nantahala, together with its affiliates, beneficially owns at least 15.0% of the Company's outstanding shares of common stock, subject to certain exceptions.

**Warrants**

Each of the outstanding warrants is convertible on a one-for-one basis into the Company's common stock and are fully exercisable as of December 31, 2024. The following table is a summary of the Company's warrants outstanding as of December 31, 2024:

| | Number of Warrants Outstanding | Exercise Price | Initial Exercise Date | Expiration Date |
|---|---|---|---|---|
| Pre-Funded Warrants | 528,609 | $ 0.0012 | February 13, 2024 | Until Exercised in Full |
| Series A Warrants | 354,022 | $ 8.16 | February 13, 2024 | February 13, 2029 |
| Modified Series A Warrants[1] | 281,080 | $ 0.01 | February 13, 2024 | February 13, 2029 |
| Series C Warrants | 392,754 | $ 8.16 | February 13, 2024 | February 13, 2029 |
| Modified Series C Warrants[1] | 250,627 | $ 0.01 | February 13, 2024 | February 13, 2029 |
| Representatives' Warrants | 45,955 | $ 13.47 | August 13, 2024 | February 13, 2029 |
| Total warrants | 1,853,047 | | | |

(1) The Modified Series A Warrants and Modified Series C Warrants represent Series A Warrants and Series C Warrants, respectively, modified under the September 2024 Exercise Price Warrant Amendment.

In August 2024, the Company issued 84,436 shares of common stock for *de minimis* proceeds, through the exercise of Pre-Funded warrants with an exercise price per share of $0.0012.

In October 2024, the Company issued 499,221 shares of common stock for net proceeds of $3.6 million, through the exercise of 191,911 Series A Warrants, 163,398 Series B Warrants, 91,911 Series C Warrants and 52,001 Pre-Funded Warrants at a

weighted-average exercise price of $7.31 per share. Pursuant to the terms and provisions of the Series B and Series C Warrants issued in the February 2024 Offering, 502,428 Series B Warrants and 159,308 Series C Warrants expired on November 13, 2024. No other warrants expired during the year ended December 31, 2024.

There were no warrants outstanding as of December 31, 2023. During the year ended December 31, 2023, no warrants were exercised or expired.

**Stock-Based Compensation**

*Equity Incentive Plan*

In August 2013, the Company's board of directors adopted the 2013 Equity Incentive Award Plan (the "2013 Plan"), which allows the Company to 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. The 2013 Plan was most recently amended by the Company's stockholders in May 2024 (the "Restated 2013 Plan") to increase the number of shares of common stock authorized for future issuance to an aggregate of 449,608 shares and extends the term of the Restated 2013 Plan to March 2034. The Restated 2013 Plan maintains its evergreen provision, which increases the number of shares available for issuance annually on the first day of each fiscal year by the 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 2013 Plan may not exceed an aggregate of 20,833,333 shares.

As of December 31, 2024, 449,608 shares of common stock remain reserved for future issuance under the Restated 2013 Plan. On January 1, 2025, the Company further increased the number of shares reserved for issuance under the 2013 Plan by 89,161 shares, to a total of 538,769 shares available for future grant under the Restated 2013 Plan.

*Stock Options*

Stock options granted under the 2013 Plan have ten-year terms from the date of grant and generally vest over a one year or four year period.

The following table summarizes the Company's stock option activity under the Restated 2013 Plan during the year ended December 31, 2024:

| | Shares | Weighted-Average Exercise Price | Weighted-Average Remaining Contractual Term (in years) | Aggregate Intrinsic Value |
|---|---|---|---|---|
| Outstanding at December 31, 2023 | 51,983 | $ 170.90 | 7.1 | |
| Granted | 126,015 | 5.29 | | |
| Expired | (248) | 1,036.80 | | |
| Forfeited or cancelled | (51,735) | 166.75 | | |
| Outstanding at December 31, 2024 | 126,015 | $ 5.29 | 7.2 | $ — |
| Vested and expected to vest at December 31, 2024 | 126,015 | $ 5.29 | 7.2 | $ — |
| Exercisable at December 31, 2024 | 5,442 | $ 5.27 | 7.5 | $ — |

The weighted-average grant date fair value per share of employee stock options granted during the years ended December 31, 2024 and 2023, was $4.35 and $29.04, respectively. During the years ended December 31, 2024 and 2023, no options were exercised.

In November 2024, the Board approved the cancelation of all out-of-the money options with an exercise price greater than or equal to $25.00 per share. Since a re-grant did not accompany the cancelation nor did the option holders receive other consideration, the Company accounted for the cancelation as a repurchase of the options for no consideration and accordingly

recognized all previously unrecognized expense, of $0.1 million, as of the cancelation date. On November 30, 2024, the Company cancelled 34,617 options held by eight grantees with a weighted-average exercise price of $164.47.

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:

| | Year Ended December 31, | |
|---|---|---|
| | 2024 | 2023 |
| Risk free interest rate | 3.8% – 4.5% | 1.34% – 3.39% |
| Expected option term (in years) | 5.5 – 6.0 | 5.5 – 6.0 |
| Volatility of common stock | 105.8% – 107.1% | 99.3% – 103.6% |
| Expected dividend yield | 0.0% | 0.0% |

*Employee Stock Purchase Plan*

In June 2013, the Company's board of directors adopted the 2013 Equity Employee Share Purchase Plan (the "2013 ESPP"), which allows eligible employees to purchase shares of the Company's common stock through payroll deductions at a price equal to 85% of the lesser of the fair market value of the Company's common stock on the first trading day of the offering period or on the applicable purchase date. The offering period is determined by the compensation committee and may be up to 27 months long. Current offering periods commence on each of September 1 and March 1 during the term. Purchase dates will be set for the last trading day in each six-month period and will occur on each of August 31 and February 28 (unless such days are not trading days). The 2013 ESPP was most recently amended by the Company's stockholders in May 2023 (the "Restated 2013 ESPP") to increase the number of shares of common stock authorized for future issuance to an aggregate of 104,166 shares and extends the term of the Restated 2013 ESPP until terminated by the board of directors. The Restated 2013 ESPP also amended its evergreen provision, which increases the number of shares available for issuance annually on the first day of each fiscal year, such that the number of shares equal to the least of (a) one 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 awards under the Restated 2013 ESPP may not exceed an aggregate of 833,333 shares.

During the years ended December 31, 2024 and 2023, there were no shares of common stock issued under the Restated 2013 ESPP. As of December 31, 2024, 14,900 shares of common stock remain reserved for future issuance under the Restated 2013 ESPP. On January 1, 2025, the Company further increased the number of shares reserved for issuance under the Restated 2013 ESPP by 14,860 shares, making 29,760 options available for future grant under the Restated 2013 ESPP.

The estimated fair value of each ESPP award granted was determined on the date of purchase date using the Black-Scholes option-pricing valuation model with the following assumptions:

| | Year Ended December 31, |
|---|---|
| | 2024 |
| Risk free interest rate | 4.9% |
| Expected option term (in years) | 0.5 |
| Volatility of common stock | 91.5% |
| Expected dividend yield | 0.0% |

There were no ESPP awards granted during the year ended December 31, 2023.

**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 Company recognized stock-based compensation expense as follows:

| | Year Ended December 31, | |
|---|---|---|
| | 2024 | 2023 |
| Research and development | $ 4,231 | $ 2,840 |
| Selling, general and administrative | 768,890 | 1,125,269 |
| Total stock-based compensation expense | $ 773,121 | $ 1,128,109 |

| | Year Ended December 31, | |
|---|---|---|
| | 2024 | 2023 |
| Stock options | $ 766,908 | $ 1,128,109 |
| ESPP | 6,213 | — |
| Total stock-based compensation expense | $ 773,121 | $ 1,128,109 |

As of December 31, 2024, there was approximately $0.5 million of unrecognized compensation costs related to outstanding options, which are expected to be recognized over a weighted-average period of 2.6 years.

As of December 31, 2024, there was approximately $3,000 of unrecognized compensation costs related to the ESPP, which are expected to be recognized over a weighted-average period of 0.2 years.

**Common Stock Reserved for Future Issuance**

Common stock reserved for future issuance as of December 31, 2024 is as follows:

| | |
|---|---|
| Stock options issued and outstanding | 126,015 |
| Warrants issued and outstanding | 1,853,047 |
| Authorized for future option grants | 449,608 |
| Authorized for employee stock purchase plan | 14,900 |
| Total common stock reserved for future issuance | 2,443,570 |

**5. 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 utilizes its internal sales organization, along with other commercial functions, for market access, marketing, distribution and other related patient support services. The Company records sales for Gimoti and retain more than 80% of net product profits once both parties' costs are reimbursed. For the years ended December 31, 2024 and 2023, approximately $8.7 million and $4.4 million of Eversana profit sharing costs were included as selling, general and administrative costs, respectively. As of December 31, 2024, unreimbursed commercialization costs to Eversana were approximately $75.4 million. Such costs will generally be payable only as net product profits are recognized or upon certain termination events. Eversana receives 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 (the "Eversana Amendment"). The Eversana 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 Eversana Agreement; if the Company discontinues the development or production of Gimoti; if the net profit is negative for any two consecutive calendar quarters (the "Net Profit Quarterly Termination Right") beginning with the measurement date of June 30, 2023; 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.

The Company's net profits were negative for the two preceding calendar quarters as of December 31, 2024, and therefore, Eversana or the Company could have exercised the Net Profit Quarterly Termination Right ("NPQTR") during the 60-day period after quarter-end. Since the note payable and accrued interest payable could be accelerated by Eversana by terminating the Eversana Agreement as of December 31, 2024, those payments were recorded as current liabilities as of December 31, 2024. Each party continues to have the option to exercise the NPQTR for the 60-day period following the end of future quarters so long as the net profit under the Eversana Agreement remains negative for consecutive quarters.

In the event 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 NPQTR, 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 $5.0 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 $5.0 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.

**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 discretionary contributions have been made by the Company to date. For the years ended December 31, 2024 and 2023, the Company adopted Safe Harbor 401(k) provisions.

**7. Segment Information**

Operating segments are defined as components of an enterprise for which separate financial information is regularly evaluated by the chief operating decision maker (CODM), which is the Company's Chief Executive Officer, in deciding how to allocate

resources and assess performance. The Company's CODM evaluates the Company's financial information including budget-versus-actual results and cash projections on an aggregate basis when assessing performance for allocating financial and personnel resources. The Company is not organized by market and is managed and operated as one business.

The Company identifies its operating segments based on its business activities. The Company operates within a single operating segment being the development and commercialization of pharmaceutical products. The development and commercialization of pharmaceutical products segment generates revenues in the United States. The Company's administrative functions including finance, business development and procurement, support the development and commercialization of pharmaceutical products segment. The Company operates primarily in one geographic area, being the United States. The CODM allocates resources (inclusive of both capital and personnel) based upon the Company's net loss, which is utilized to monitor budget-to-actual variances on a monthly basis.

The accounting policies of the development and commercialization of pharmaceutical products segment are the same as those described in *Note 2. Summary of Significant Accounting Policies*. All Company assets are in the United States. The measure of segment assets is reported on the balance sheets as total assets. The Company does not have intra-entity sales or transfers.

The Company has no transactions denominated in foreign currencies nor any tangible or intangible property for which is recognizes depreciation or amortization and depreciating assets are not part of the CODMs evaluation or decision-making process.

The following table summarizes the Company's financial data for its development and commercialization of pharmaceutical products segment:

| | Year Ended December 31, | |
|---|---|---|
| | 2024 | 2023 |
| Net product sales | $ 10,249,415 | $ 5,180,630 |
| | | |
| Less: | | |
| Cost of goods sold | (356,531) | (201,879) |
| Eversana profit sharing | (8,733,347) | (4,401,590) |
| Employee expenses | (2,481,056) | (3,188,601) |
| Professional fees | (2,059,591) | (2,553,662) |
| Stock-based compensation | (773,121) | (1,128,109) |
| Sales and marketing expenses | (750,272) | (659,535) |
| Other operating expenses[1] | (299,634) | (478,145) |
| Interest income | 353,313 | 138,596 |
| Interest expense (non-cash) | (501,370) | (500,000) |
| Total segment costs loss and net loss | $ (5,352,194) | $ (7,792,295) |

(1) Includes ongoing product development costs, occupancy costs (including rent and utilities), administrative costs, travel and business taxes.

**8. Income Taxes**

A reconciliation of the federal statutory income tax rate and the effective income tax rate is as follows:

| | December 31, | |
|---|---|---|
| | 2024 | 2023 |
| Federal statutory rate | 21% | 21% |
| Change in valuation allowance | 13% | -19% |
| State income taxes, net of federal benefit | 2% | 1% |
| Stock option cancellation impact | -38% | —% |
| Impact of state tax rate change | 3% | —% |
| Stock compensation and other permanent items | -1% | -1% |
| Other | —% | -2% |
| Effective income tax rate | —% | —% |

Significant components of the Company's deferred tax assets are as follows:

| | December 31, | |
|---|---|---|
| | 2024 | 2023 |
| Deferred tax assets | | |
| Net operating loss carryforwards | $ 25,012,000 | $ 23,803,000 |
| Research and development tax credits | 2,842,000 | 2,842,000 |
| Stock-based compensation | 11,000 | 1,839,000 |
| Capitalized research and development | 168,000 | 161,000 |
| Lease liability | 37,000 | — |
| Accruals and others | 196,000 | 294,000 |
| Total deferred tax assets | 28,266,000 | 28,939,000 |
| Less: Valuation allowance | (28,230,000) | (28,939,000) |
| Deferred tax assets, net of valuation allowance | 36,000 | — |
| Deferred tax liabilities | | |
| Right-of-use assets | (36,000) | — |
| Total deferred tax liabilities | (36,000) | — |
| Net deferred tax assets (liabilities) | $ — | $ — |

The Company revised its prior year deferred tax assets and rate reconciliation tables to include deferred tax assets from net operating losses and research and development tax credits with a corresponding valuation allowance that were previously excluded. The Company also revised its uncertain tax position in the prior year for a portion of the research and development credits not deemed to be more likely than not. 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. The deferred tax assets and valuation allowance as of December 31, 2024 decreased by approximately $0.7 million.

As of December 31, 2024, the Company has federal and state net operating loss carryforwards of approximately $110.8 million and $55.8 million, respectively. The federal NOL carry forwards (generated prior to 2018) of $61.9 million begin expiring in 2027. The federal NOL carryforwards (generated after 2018) of $48.9 million will never 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. The California NOL begin expiring in 2028 and other state NOL carryforwards begin expiring in various years, starting in 2037.

As of December 31, 2024, the Company had research and development credit carryforwards of $2.4 million for federal income tax purposes and $1.5 million for California state income tax purposes available to reduce future taxable income, if any. The federal research and development credit carryforwards expire beginning 2028 and California credits can be carried forward indefinitely.

The Company's ability to utilize its net operating loss and research and development credit carryforwards may be limited pursuant to Internal Revenue Code of 1986 ("IRC") Sections 382 and 383 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, and does not expect this analysis to be completed within the next twelve months.

On June 27, 2024, California Senate Bill 167 ("SB 167") was enacted into law, which provides for a three-year suspension of net operating losses ("NOLs") under the California Personal Income Tax and Corporation Tax, a three-year cap on the use of business incentive tax credits to offset no more than $5.0 million of tax per year, and retroactive application of the Franchise Tax Board's Legal Ruling 2006-1 issued on April 28, 2006, with respect to the treatment of apportionment factors attributable to income exempt from California Corporation Tax Law. The Company has a taxable loss for the year ending December 31, 2024, and therefore is not affected by the limitation.

On June 29, 2024, California Senate Bill 175 ("SB 175") was also enacted into law, which is a companion bill to SB 167. SB 175 allows corporate income taxpayers to get refunds for a range of tax credits, including the research and development and orphan drug credits. It allows for a taxpayer to make an irrevocable election to receive an annual refundable credit amount for qualified credits. For taxable years beginning on or after January 1, 2024, and before January 1, 2027, taxpayers may receive a refundable credit equal to 20% of the qualified credits that would have otherwise been available but for the $5.0 million business tax credit limitation enacted in SB 167. The Company has a taxable loss for the year ending December 31, 2024, and therefore is not affected by the SB 175 limitation.

The following table, summarizes the activity related to our uncertain tax positions:

| | Years Ended December 31, | |
|---|---|---|
| | 2024 | 2023 |
| **Balance at the beginning of the year** | $ 3,273,000 | $ 3,273,000 |
| Increase (decrease) related to prior year tax positions | — | — |
| Increase (decrease) related to current year tax positions | — | — |
| Increase (decrease) related to settlements with taxing authorities | — | — |
| Increase (decrease) related to lapse in statute of limitations | — | — |
| **Balance at the end of the year** | $ 3,273,000 | $ 3,273,000 |

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. It is not anticipated that there will be significant change in the unrecognized tax benefits over the next 12 months. 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 uncertain tax positions, there has been no interest and penalties recognized.

The Company is subject to taxation in the U.S. federal jurisdiction and various state jurisdictions. The Company is subject to examination of its income tax returns since inception by U.S. federal and state tax authorities due to its NOLs and R&D credits. The Company is not currently under audit with the Internal Revenue Service, state or local jurisdictions, nor has it been notified of any other potential future income tax audit.