UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 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, 2022

☐ Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the period from _____ to _____

Commission file number 0-25466

CYCLO THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Nevada	59-3029743
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)
6714 NW 16 th Street, Suite B , Gainesville , Florida	32653
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (386) 418-8060

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $.0001 per share	CYTH	The Nasdaq Stock Market LLC
Warrants to purchase Common Stock	CYTHW	The Nasdaq Stock Market LLC

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 Section 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 twelve months (or for such shorter period that the registrant was required to submit and post 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 ☒

As of June 30, 2022, the aggregate market value of the registrant's Common Stock held by non-affiliates was $ 14,693,080 based on the closing price of the Common Stock on The Nasdaq Capital Market on such date.

As of March 15, 2023, there were 10,554,900 shares of registrant's Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for the registrant's 2023 Annual Meeting of Stockholders which will be filed with the Commission no later than 120 days after the registrant's fiscal year ended December 31, 2022, are incorporated by reference into Part III of this report.

CYCLO THERAPEUTICS, INC.
ANNUAL REPORT ON FORM 10-K
For the Year Ended December 31, 2022

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PART I

Item 1. Business.

Overview

Cyclo Therapeutics, Inc. ("we," "our," "us," or the "Company") was organized as a Florida corporation on August 9, 1990, with operations beginning in July 1992. In conjunction with a restructuring in 2000, we changed our name from Cyclodextrin Technologies Development, Inc. to CTD Holdings, Inc. We changed our name to Cyclo Therapeutics, Inc. in September 2019 to better reflect our current business, and on November 6, 2020, we reincorporated from the State of Florida to the State of Nevada.

We are a clinical stage biotechnology company that develops cyclodextrin-based products for the treatment of neurodegenerative diseases. We filed a Type II Drug Master File with the U.S. Food and Drug Administration ("FDA") in 2014 for our lead drug candidate, Trappsol® Cyclo™ (hydroxypropyl beta cyclodextrin) as a treatment for Niemann-Pick Type C disease ("NPC"). NPC is a rare and fatal autosomal recessive genetic disease resulting in disrupted cholesterol metabolism that impacts the brain, lungs, liver, spleen, and other organs. In 2015, we launched an International Clinical Program for Trappsol® Cyclo™ as a treatment for NPC. In 2016, we filed an Investigational New Drug application ("IND") with the FDA, which described our Phase I clinical plans for a randomized, double blind, parallel group study at a single clinical site in the U.S. The Phase I study evaluated the safety and pharmacokinetics of Trappsol® Cyclo™ along with markers of cholesterol metabolism and markers of NPC during a 12-week treatment period of intravenous administration of Trappsol® Cyclo™ every two weeks to participants 18 years of age and older. The IND was approved by the FDA in September 2016, and in January 2017 the FDA granted Fast Track designation to Trappsol® Cyclo™ for the treatment of NPC. Initial patient enrollment in the U.S. Phase I study commenced in September 2017, and in May 2020 we announced Top Line data showing a favorable safety and tolerability profile for Trappsol® Cyclo™ in this study.

We have also completed a Phase I/II clinical study approved by European regulatory bodies with clinical trial centers in the United Kingdom, Sweden, and in Israel. The Phase I/II study evaluated the safety, tolerability and efficacy of Trappsol® Cyclo™ through a range of clinical outcomes, including neurologic, respiratory, and measurements of cholesterol metabolism and markers of NPC. Consistent with the 12-week phase 1 study (single US site), the European/Israel study administered Trappsol® Cyclo™ intravenously to NPC patients every two weeks in a double-blind, randomized trial, but differs in that the study period was for 48 weeks (24 doses). In March of 2021 we announced that 100% of patients who completed the trial (9 out of 12) improved or remained stable, and 89% met the efficacy outcome measure of improvement in at least two domains of the 17-domain NPC severity scale.

Additionally, in February 2020 we had a face-to-face "Type C" meeting with the FDA with respect to the initiation of our pivotal Phase III clinical trial of Trappsol® Cyclo™ based on the clinical data obtained to date. At that meeting, we also discussed with the FDA submitting a New Drug Application (NDA) under Section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for the treatment of NPC in pediatric and adult patients with Trappsol® Cyclo™. A similar request was submitted to the European Medicines Agency ("EMA") in February 2020, seeking scientific advice and protocol assistance from the EMA for proceeding with a Phase III clinical trial in Europe. In October 2020 we received a "Study May Proceed" notification from the FDA with respect to the proposed Phase III clinical trial, and in June of 2021 we commenced enrollment in TransportNPC, a pivotal Phase III study of Trappsol® Cyclo™ for the treatment of NPC.

Preliminary data from our completed clinical studies suggest that Trappsol® Cyclo™ clears toxic deposits of cholesterol and other lipids from cells, has a consistent pharmacokinetic profile peripherally, and crosses the blood-brain-barrier in individuals suffering from NPC, and results in neurological and neurocognitive benefits and other clinical improvements in NPC patients. The full significance of these findings will be determined as part of the final analysis of data derived from our clinical trials (both completed and ongoing).

On May 17, 2010, the FDA designated Trappsol® Cyclo™ as an orphan drug for the treatment of NPC, which would provide us with the exclusive right to sell Trappsol® Cyclo™ for the treatment of NPC for seven years following FDA drug approval. In April 2015, we also obtained Orphan Drug Designation for Trappsol® Cyclo™ in Europe, which will provide us with 10 years of market exclusivity following regulatory approval, which period will be extended to 12 years upon acceptance by the EMA's Pediatric Committee of our pediatric investigation plan (PIP) demonstrating that Trappsol® Cyclo™ addresses the pediatric population. On January 12, 2017, we received Fast Track Designation from the FDA, and on December 1, 2017, the FDA designated NPC a Rare Pediatric Disease.

We are also exploring the use of cyclodextrins in the treatment of Alzheimer's disease. In January 2018, the FDA authorized a single patient IND expanded access program using Trappsol® Cyclo™ for the treatment of Alzheimer's disease. After 18 months of treatment in this geriatric patient with late-onset disease, the disease was stabilized and the drug was well tolerated. The patient also exhibited signs of improvement with less volatility and shorter latency in word-finding. We prepared a synopsis for an early stage protocol using Trappsol® Cyclo™ intravenously to treat Alzheimer's disease that was presented to the FDA in January of 2021. We received feedback from the FDA on this synopsis in April 2021 and incorporated the feedback into an IND for a Phase II study for the treatment of Alzheimer's disease with of Trappsol® Cyclo™ that we submitted to the FDA in November 2021. In December of 2021, we received IND clearance from the FDA, allowing us to proceed with our Phase II study of Trappsol® Cyclo™ for the treatment of Alzheimer's disease. U.S. sites for the study were activated during the second half of 2022, with patient dosing beginning in the first quarter of 2023.

We filed an international patent application in October 2019 under the Patent Cooperation Treaty directed to the treatment of Alzheimer's disease with cyclodextrins, and we are pursuing national and regional stage applications based on this international application. The terms of any patents resulting from these national or regional stage applications would be expected to expire in 2039 if all the requisite maintenance fees are paid.

We also continue to operate our legacy fine chemical business, consisting of the sale of cyclodextrins and related products to the pharmaceutical, nutritional, and other industries, primarily for use in diagnostics and specialty drugs. However, our core business has transitioned to a biotechnology company primarily focused on the development of cyclodextrin-based biopharmaceuticals for the treatment of disease from a business that had been primarily reselling basic cyclodextrin products.

Niemann-Pick Type C Disease

NPC is an ultra-rare, genetic and progressive disease that impairs the ability of the body to recycle cholesterol and other types of lipids, resulting in damage to the body's tissues, including the brain. The symptoms upon onset of NPC vary from premature death during the first months after birth, mainly due to end stage liver disease, to a progressive disorder not diagnosed until adulthood. The disease affects the brain as well as various internal organs. Symptoms of NPC usually occur during early to late childhood, including difficulties in swallowing, loss of speech and cognition, motor coordination and ambulation. During this period, affected individuals may also develop impairment of intellectual ability, psychiatric disturbances and progressive loss of memory. Symptoms include enlargement of the liver and/or spleen and lung diseases, epileptic seizures and dystonia. Systemic symptoms of NPC are more common in infancy or childhood and the rate of progression is usually much slower in individuals with onset of symptoms during adulthood. Age of onset of neurologic symptoms is one predictor of severity of disease. Approximately half of NPC patients are adults with a less aggressive form of the disease that progresses more slowly, and is frequently initially misdiagnosed, as these patients are more likely to present with dementia, psychiatric symptoms and other symptoms. In the US, patients are increasingly diagnosed in their 50's and 60's.

NPC is caused by mutations in one of two genes, NPC1 (in 95% of patients) or NPC2, which prevent cells from properly processing cholesterol and other lipids and lead to an accumulation of lipids in the lysosomes, resulting in cell toxicity, inflammation, loss of cell function or cell death. In the central nervous system, it results in progressive motor and brain impairment. Genetic diseases are determined by the combination of the pair of genes for a particular trait received from the father and the mother. NPC is an autosomal recessive disorder, *i.e.* two copies of an abnormal gene must be present in order for the disease or trait to develop. Although uncertainty exists about the exact function of the NPC1 and NPC2 protein products, they are known to be involved in the trafficking (transportation) of cholesterol within a compartment of the cell called the lysosome. Hence, a mutated gene may lead to faulty NPC protein production and, as a consequence, an abnormal accumulation of cholesterol and other lipids in the organs most commonly affected, such as the liver, spleen and brain. In addition, as with other neurodegenerative diseases such as Alzheimer's disease and Parkinson's disease, NPC patients exhibit elevated levels of the proteins amyloid and tau in their cerebrospinal fluid.

Addressable Market

We estimate the incidence of NPC to be one in 100,000 live births and that there are currently 3,000 existing NPC patients worldwide, with approximately 1,370 new NPC cases each year. Based on an average annual price of approximately $404,750 for an intravenously administered drug to treat an orphan disease, we estimate the total addressable annual market for treating NPC with Trappsol® Cyclo™ to be approximately $550 million.

Treatment Options for NPC

The majority of current treatment options are directed towards the specific symptoms apparent in each individual. These include, for example, referral to a therapist to optimize the swallowing function, prescription of anti-seizure medications to prevent seizures and prescription of melatonin to treat insomnia and other sleep problems caused by the disease. Symptomatic treatment may require the coordinated efforts of a team of specialists.

Zavesca (miglustat), which was originally developed by Actelion Pharmaceuticals and is now owned by Johnson & Johnson and is also now available as a generic product in several countries, is currently the only approved treatment for NPC. It is approved only in Europe, Canada, Australia, New Zealand and several countries in Asia and in South America as Zavesca and in Japan as Brazaves. In Europe, miglustat is indicated for the treatment of progressive neurological manifestations in adult patients and pediatric patients with NPC disease. The FDA declined to approve miglustat for NPC in 2010 and requested more data be provided. A range of side effects are known to be associated with miglustat, including weight loss, decreased appetite, diarrhea, nausea and thrombocytopenia. While miglustat has not been approved by the FDA for the treatment of NPC, it has been approved by the FDA for the treatment of Gaucher Type I disease. In addition, studies are currently being performed to test the safety and efficacy of other treatment options, which are discussed in more detail below under "—Competition."

Due to the limited availability, efficacy and side effects of existing treatment options, we believe that a significant unmet need for treatment of NPC continues to exist, and that we may be the only company with a drug candidate that treats both the systemic and neurological manifestations of NPC.

Cyclodextrins

Cyclodextrins are donut shaped rings of glucose (sugar) molecules. Cyclodextrins are formed naturally by the action of bacterial enzymes on starch. They were first noticed and isolated in 1891. The bacterial enzyme naturally creates a mixture of at least three different cyclodextrins depending on how many glucose units are included in the molecular circle; six glucose units yield alpha cyclodextrin; seven units, beta cyclodextrin; eight units, gamma cyclodextrin. The more glucose units in the molecular ring, the larger the cavity in the center of the ring. The inside of this ring provides an excellent resting place for "oily" molecules while the outside of the ring is compatible with water, allowing clear, stable solutions of cyclodextrins to exist in aqueous environments even when an "oily" molecule is carried within the ring. The net result is a molecular carrier that comes in small, medium, and large sizes with the ability to transport and deliver "oily" materials using plain water as the solvent. It is the ability of molecular encapsulation of compounds that makes cyclodextrins so useful chemically and pharmaceutically.

Use of Cyclodextrins to Treat NPC

Natural cyclodextrins have been confirmed to be generally recognized as safe (GRAS) in most of the world, including the U.S. Moreover, approvals of products containing cyclodextrins by the FDA since 2001 suggest that regulatory approval for new products may be easier to obtain in the future. In 2001, Janssen Pharmaceutica, now a subsidiary of Johnson & Johnson, received FDA approval to market Sporanox®, an antifungal which contained hydroxypropyl beta cyclodextrin as an excipient. In 2009, one of our products was used in an FDA approved compassionate use investigational new drug protocol for the treatment of NPC. Under the Orphan Drug Act, companies that develop a drug for a disorder affecting fewer than 200,000 people in the United States may seek designation as an orphan drug. If such designation is approved, a company will have the ability to sell the drug exclusively for seven years following FDA drug approval, and the company may receive clinical trial tax incentives.

Trappsol® Cyclo™ is the first use of a cyclodextrin as an active pharmaceutical and not just as an inactive formulation excipient. On May 17, 2010, the FDA designated Trappsol® Cyclo™ as an orphan drug for the treatment of NPC. We have also obtained Orphan Drug Designation for Trappsol® Cyclo™ in Europe. Trappsol® Cyclo™ has been administered to more than 20 NPC patients in compassionate use programs around the world, including in the U.S., Brazil and Spain. Patients participating in these compassionate use programs demonstrated one or more of the following benefits: a reduction in liver size; restoration of language skills; resolution of interstitial lung disease; improvement in fine and gross motor skills, improvement in behavioral aspects of the disease, and improvement in quality of life. The doctors and patients participating in these programs, including patients that have been administered Trappsol® Cyclo™ intravenously for more than five years, have made their data available to us, which we used to design our clinical studies in the U.S. and abroad, and which we published in a peer-reviewed journal with treating physicians as co-authors.

Our Clinical Studies

As set forth in greater detail below, to date, our clinical studies have preliminarily demonstrated that Trappsol® Cyclo™ is safe and efficacious in the treatment of NPC over a range of dose groups. When measuring efficacy in NPC patients, we utilize the NPC Clinical Severity Scale developed by the National Institutes of Health (NIH) which measures clinical signs and symptoms across “major domains” and “minor domains” as follows:

Nine major domains: ambulation, cognition, eye movement, fine motor, hearing, memory, seizures, speech, and swallowing.

Eight minor domains: auditory brainstem response, behavior, gelastic cataplexy, hyperreflexia, incontinence, narcolepsy, psychiatric, and respiratory problems.

Major domains are scored on a scale of zero to five, with zero showing no disability, and minor domains add up to two points for severity of condition per domain.

Global Phase III Clinical Study (TransportNPC)

Our ongoing Phase III clinical trial (CTD-TCNPC-301), TransportNPC, is a prospective, randomized, double-blind, placebo controlled therapeutic study for up to 93 patients age three and older with confirmed diagnosis of NPC1. The objective of this study is to evaluate the safety, tolerability and efficacy of 2000 mg/kg doses of Trappsol® Cyclo™ (hydroxypropyl betacyclodextrin) administered intravenously by slow infusion every two weeks as compared to placebo. Patients will be randomized to receive Trappsol® Cyclo™ or placebo at a 2:1 ratio. The study duration is 96 weeks, with an unblinded interim analysis at 48 weeks. An open-label extension of up to 96 weeks follows the interventional study. Patients whose disease progression worsens by two levels in the Clinical Global Impression of Severity scale over 12 weeks, starting at week 36, may be moved to open label treatment. Efficacy will be measured at week 48 and week 96 by a composite score of major disease features. A sub-study is ongoing and being conducted outside of the U.S. for up to 12 patients age 0 - 3 years who may be asymptomatic. Outcomes for the sub-study are safety, clinical and caregiver impression of disease.

European and Israeli Phase I/II Clinical Study

We completed our Phase I/II clinical study in Europe, the United Kingdom and Sweden. This study evaluated the safety, tolerability and efficacy of Trappsol® Cyclo™ through a range of clinical outcomes, including neurologic, and respiratory, in addition to measurements of cholesterol metabolism and markers of NPC, in three dose groups (1500 mg/kg, 2000 mg/kg and 2500 mg/kg). The first patient was dosed in this study in July 2017, and in February 2020, we announced completion of enrollment of 12 patients in this study. The efficacy outcome measures and results from this study are as follows:

Efficacy Outcome Measure 1: At least a one-point reduction (or improvement) in two or more of the 17 domains measured under the NPC Clinical Severity Scale.

Results:

- Six of seven patients met this endpoint (86% of those who completed).
- Improvements seen in swallow, ambulation, ability to manage seizures, saccadic eye movements, fine motor skills, and cognition. (Individual patient profiles differed, i.e. patients improved differently.)
- Patients not receiving any intervention beyond standard of care would be expected to worsen in total score by 1.5 points over one year.

Efficacy Outcome Measure 2: Change from baseline in “Global Impression of Disease” at 48 weeks.

Results:

- Using the Clinician’s Global Impression of Improvement scale, five of seven patients who completed the trial improved, and the other 2 patients stabilized**.**
- five of seven improved in at least one of these features: walking, speaking, swallowing, fine motor and cognition. These five features are determined by NPC patients and their caregivers to be the most important for quality of life. A composite in improvement in these five features will be the primary outcome measure for our pivotal Phase III trial.

Additional Data:

- As a group, the first seven patients to complete the clinical trial meet both efficacy outcome measures for the study.
- Individual patients showed improvements in all dose groups.
- Trappsol® Cyclo™ demonstrated a highly favorable safety profile.
- Trappsol® Cyclo™ was shown to cross the blood brain barrier.
- Successive administration of Trappsol® Cyclo™ decreased tau levels, suggesting neuroprotective benefit.
- Trappsol® Cyclo™ improves neurological features of NPC, including ataxia, and quality of life for patients.
- Based on data provided, we have selected the 2000 mg/kg dose for our pivotal Phase III trial.

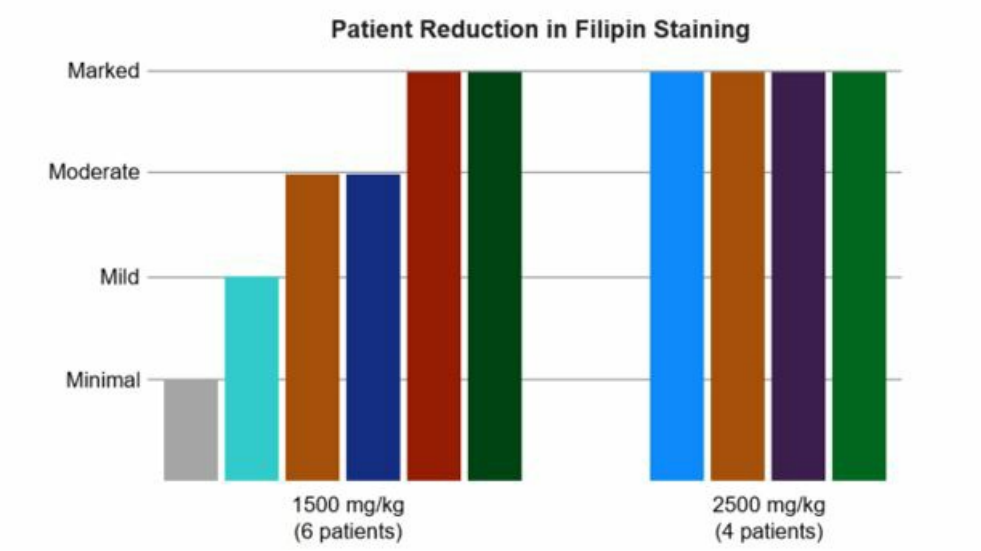
US Phase I Clinical Study

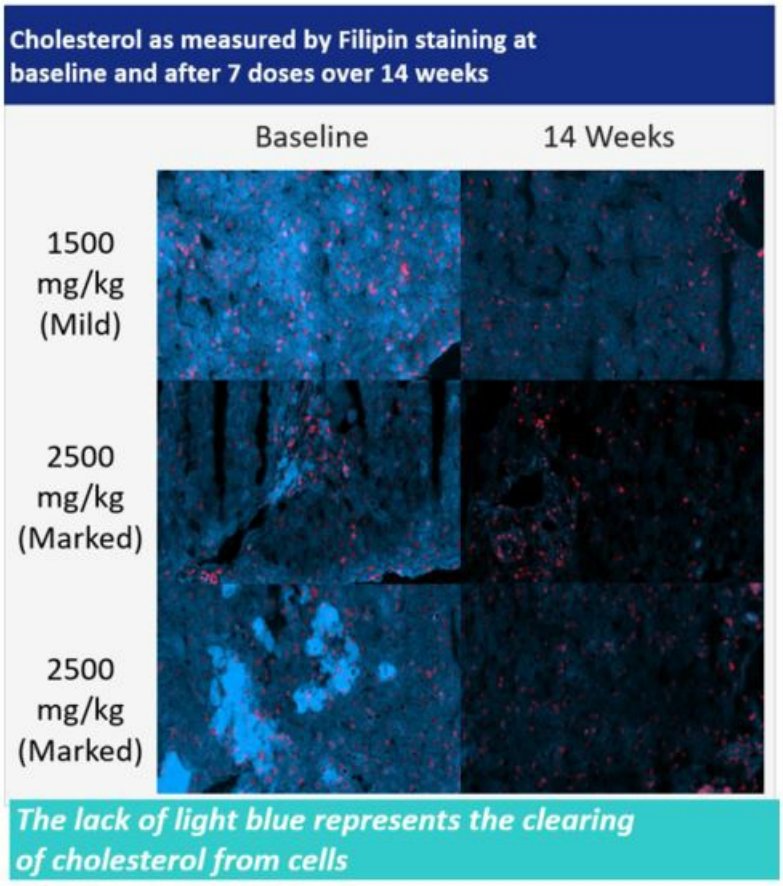
In September 2016, the FDA approved our Phase I clinical plans for a randomized, double blind, parallel group study in the U.S. The Phase I study evaluated the safety of Trappsol® Cyclo™ along with markers of cholesterol metabolism and markers of NPC during a 14-week treatment period of intravenous administration of Trappsol® Cyclo™ every two weeks to participants 18 years of age and older in two dose groups (1500 mg/kg and 2500 mg/kg). Enrollment in this study was completed in October 2019, and in May 2020 we announced Top Line data showing a favorable safety and tolerability profile for Trappsol® Cyclo™ in this study. Additional date from this study includes the following data:

- Liver biopsies and biochemical data on cholesterol homeostasis demonstrated that Trappsol® Cyclo™ removes trapped cholesterol from liver cells and impacts cholesterol homeostasis.
- Tau decreased after seven doses in a majority of patients, suggesting that IV administration of Trappsol® Cyclo™ is preventing neurodegeneration in NPC patients.
- Efficacy signals from Trappsol® Cyclo™ include neurological improvements, higher energy, and greater focus exhibited by the patient.
- All eligible patients requested continuation of Trappsol® Cyclo™ administration in the extension protocol via home infusion.
- In January we reported positive efficacy data on all eight patients participating in the protocol.

Trappsol® Cyclo™ Removes Cholesterol from Liver Cells

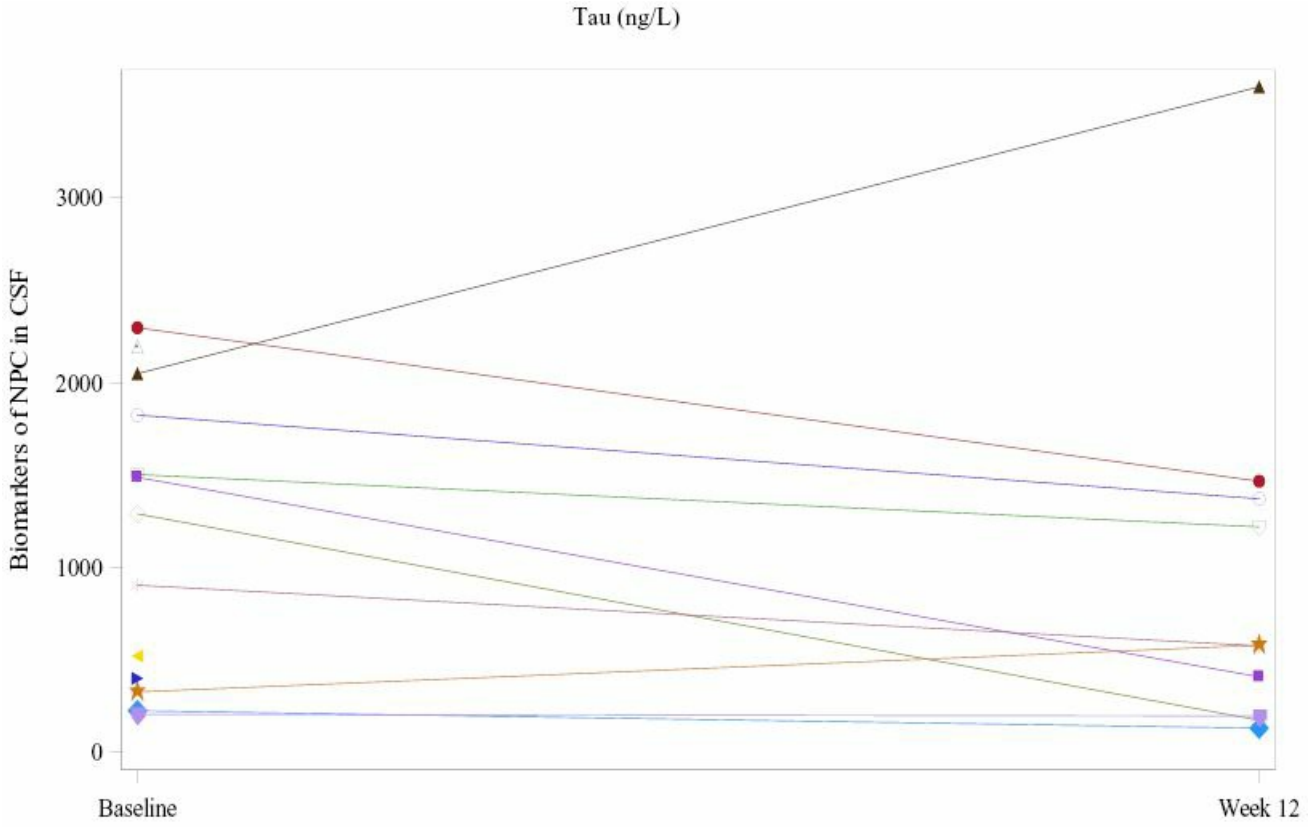
Cholesterol accumulates abnormally in the cells of NPC patients. Based on our clinical studies we believe that Trappsol® Cyclo™ can function like the NPC1 protein, allowing cholesterol and other lipids to be moved normally through cells. The administration of both 1500 mg/kg and 2500 mg/kg dosages in our clinical trials demonstrated that Trappsol® Cyclo™ clears cholesterol from peripheral organs. Management believes this is evidence of a pathway to treat the systemic and neurologic manifestations of the disease. The reduction in cholesterol can be visualized directly in liver cells through biopsies and fillipin staining, as shown below.





Trappsol® Cyclo™ Reduces Tau

Tau is a protein found in elevated levels in the cerebrospinal fluid (CSF) of NPC patients, as well as patients with other neurodegenerative diseases such as Alzheimer's disease and Parkinson's disease. Data from our clinical studies demonstrate that Trappsol® Cyclo™ reduces tau levels. The chart below shows tau levels measured in the CSF of 10 NPC patients who had lumbar punctures prior to treatment with Trappsol® Cyclo™ and after seven doses over a 14-week period in our Phase I study, with six of 10 patients showing a reduction in tau levels, two remained stable, and two with increased levels of tau. Data from three patients in our Phase I/II study showed a similar pattern of tau reduction in all three patients at 24 weeks and 48 weeks.



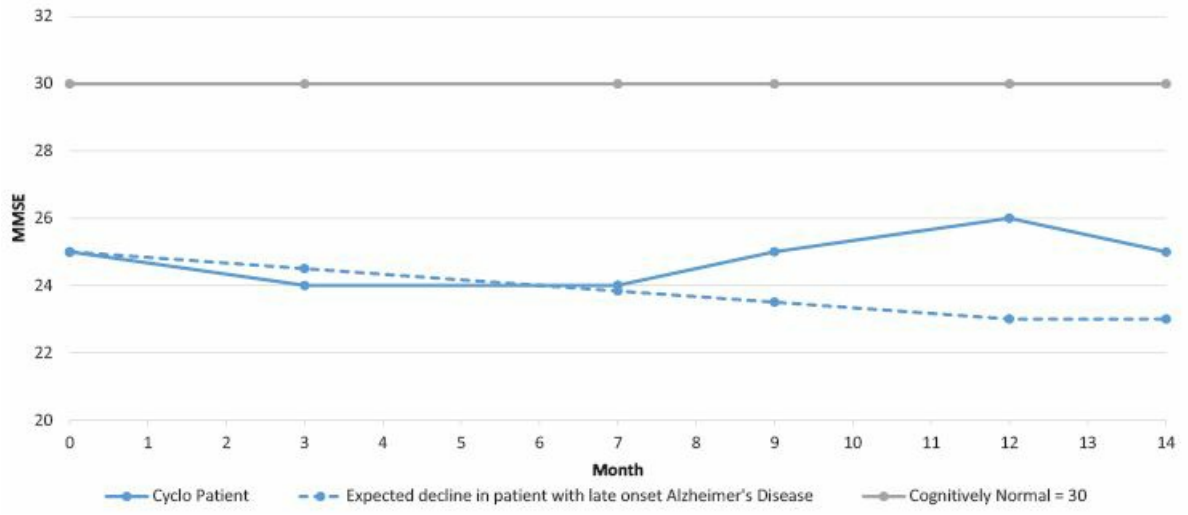
Use of Cyclodextrins to Treat Alzheimer's Disease

Because NPC and Alzheimer's disease share many features, we have been exploring the treatment of Alzheimer's disease with Trappsol® Cyclo™. In particular, both NPC and Alzheimer's patients exhibit cognitive decline, increased levels of tau in CSF, and amyloid beta plaques in the brain, neurofibrillary tangles in the brain, and lysosomal enlargement in neurons in the brain.

Cell and animal studies using hydroxypropyl beta cyclodextrin ("HPBCD") to treat Alzheimer's disease have shown:

- HPBCD added to cells that over-express the precursor protein of amyloid beta, APP, lowers amyloid beta plaques; and
- HPBCD given subcutaneously to a mouse that over-expresses APP:
    - Reduces amyloid beta plaques by reducing cleavage of APP;
    - Improves memory as shown in a standard water maze test;
    - Reduces microgliosis (a marker of inflammation); and
    - Up-regulates proteins (e.g. NPC1) involved in cholesterol transport and amyloid beta clearance.

In January 2018, the FDA authorized a single patient IND expanded access program using Trappsol® Cyclo™ for the treatment of Alzheimer's disease. After 18 months of monthly intravenous infusions, the patient's disease did not progress as measured with standard clinical cognitive tools applied in patients with Alzheimer's disease. The patient withdrew from this treatment for reasons unrelated to the safety of Trappsol® Cyclo™. The table below measures the patient's Mini Mental State Evaluation (a measurement used to assess patients with Alzheimer's disease) during the treatment period.



Intellectual Property and Regulatory Exclusivities

We filed an international patent application in October 2019 under the Patent Cooperation Treaty directed to the treatment of Alzheimer's disease with cyclodextrins, and we are pursuing national and regional stage applications based on this international application. The terms of any patents resulting from these national or regional stage applications would be expected to expire in 2039 if all the requisite maintenance fees are paid. In addition, the designation of Trappsol® Cyclo™ as an orphan drug for the treatment of NPC by the FDA and European regulators would provide us with seven years, and 10 to 12 years, of market exclusivity, respectively, following regulatory approval. We also believe that our formulation and manufacturing process for Trappsol® Cyclo™ is protected by trade secrets. We have also protected our Trappsol® and Aquaplex® trademarks by registering them with the U.S. Patent and Trademark Office.

Competition

There is currently no known cure for NPC. Although we face competition in the commercialization of a drug product to treat NPC, we believe that we may be the only company with a drug candidate that treats both the systemic and neurological manifestations of NPC. Actelion, a subsidiary of Johnson & Johnson, has a drug, Miglustat, not approved in the US, which treats some of the neurologic symptoms of the disease in some patients. Orphazyme, a public company based in Denmark, has a drug candidate, Arimoclomal, in development and has initiated a rolling NDA submission with the FDA based on limited neurological benefit in sub-groups of the NPC population. In addition, IntraBio is developing a drug candidate for the treatment of NPC with preliminary reports of benefit to a sub-set of neurologic features, primarily ataxia. IntraBio has not yet reached its pivotal trial stage. We believe our clinical progress, our close connections with patient advocacy groups in the U.S. and Europe, and the fact that we have a finished product currently in use in human patients all give us a competitive advantage over potential competitors.

We have also noted increased competition for the distribution of small quantities of cyclodextrins. Those we have examined are small operations or small offerings of a larger distributor that lack the focus and depth of expertise offered by us. They are also most often not price competitive with our products. We believe there is a perceived barrier to entry into the cyclodextrin industry because of the lack of general experience with cyclodextrins. We have established business relationships with many of the producers and consumers of cyclodextrins worldwide and, over more than 30 years, we have developed an unmatched experience database. We believe these relationships and market knowledge provide significant business advantages.

Research and Development

We are currently pursuing clinical programs in the U.S., Europe, North Africa, Australia and Israel in an effort to gain market authorization of our bio-pharmaceutical product for the treatment of NPC. We have made a substantial investment in the research and development of our Trappsol® Cyclo™ product as we seek approval for marketing the product for the treatment of NPC. We are also exploring the use of cyclodextrins in the treatment of Alzheimer's disease. We will continue to expend substantial funds in support of these efforts with the progression of our clinical trials, which we commenced in 2017. Research and development expenses remained consistent at approximately $9,000,000 in 2022, compared to $9,154,000 in 2021.

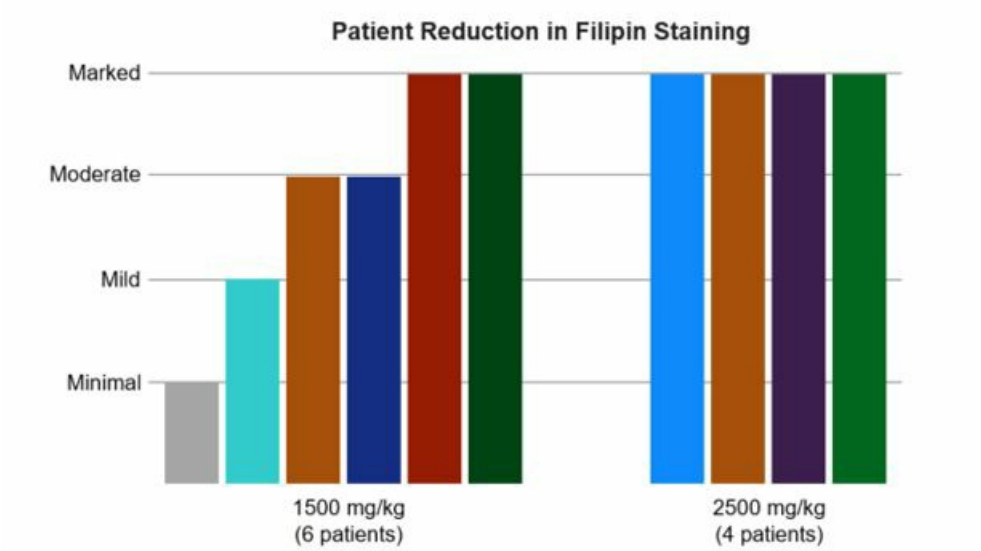
Government Regulation

The development, production and marketing of biopharmaceutical products, which include the proposed uses of Trappsol® Cyclo™ to treat disease, including NPC, are subject to regulation by governmental authorities in the United States, at the federal, state and local levels, and in other countries. These regulations govern, among other things, the research, development, testing, manufacture, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, and import and export of biopharmaceutical products. The processes for obtaining regulatory approvals in the United States and other countries, along with subsequent compliance with applicable statutes and regulations, require the expenditure of substantial time and financial resources.

United States Government Regulation

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations and guidance. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and non-U.S. statutes, regulations and guidance requires the expenditure of substantial time and financial resources. Failure to comply with the applicable United States requirements at any time during the drug development process, including preclinical and clinical testing, the approval process or post-approval process, may subject an applicant to delays in conducting the preclinical study or clinical trial, regulatory review, approval, a variety of administrative or judicial sanctions, such as the FDA's refusal to approve a pending NDA, other applications, license suspension or revocation, withdrawal of an approval, imposition of a clinical hold, issuance of warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, civil or criminal investigations brought by the FDA, the DOJ and other government entities, including state agencies and associated civil or criminal penalties.

The process required by the FDA before a drug may be marketed in the United States generally involves:



- completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's good laboratory practice regulations;

- completion of the manufacture, under cGMP conditions, of the drug substance and drug product that the sponsor intends to use in clinical trials along with required analytical and stability testing;
- submission to the FDA of an investigational new drug, or IND, application for clinical trials, which must become effective before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, at each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled clinical trials, in accordance with good clinical practice, or GCP, requirements to establish the safety, potency, purity and efficacy of the proposed drug for each proposed indication;
- payment of user fees;
- preparation and submission to the FDA of an NDA requesting marketing for one or more proposed indications, including submission of detailed information on the manufacture and composition of the product in clinical development and proposed labelling;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities, including those of third parties at which the product, or components thereof, are produced to assess compliance with cGMP requirements, and to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- satisfactory completion of an FDA inspection of selected clinical sites to assure compliance with GCPs and the integrity of the clinical data;
- FDA review and approval of the NDA; and
- compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy, or REMS, and any post-approval studies or other post-marketing commitments required by the FDA.

Preclinical Studies

Preclinical studies include laboratory evaluation of product chemistry, toxicity and formulation, as well as animal studies to assess potential safety and efficacy. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data and any available clinical data or literature, among other things, to the FDA as part of an IND. Some preclinical testing may continue even after the IND is submitted. An IND is an exemption from the FDCA that allows an unapproved product candidate to be shipped in interstate commerce for use in an investigational clinical trial and a request for FDA authorization to administer such investigational product to humans. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin.

As a result, submission of an IND may not result in the FDA allowing clinical trials to commence. If the FDA raises concerns or questions either during this initial 30-day period, or at any time during the IND process, it may choose to impose a partial or complete clinical hold. Clinical holds are imposed by the FDA whenever there is concern for patient safety and may be a result of new data, findings, or developments in clinical, preclinical, and/ or chemistry, manufacturing, and controls. This order issued by the FDA would delay either a proposed clinical trial or cause suspension of an ongoing trial, until all outstanding concerns have been adequately addressed and the FDA has notified the company that investigations may proceed. This could cause significant delays or difficulties in completing our planned clinical trial or future clinical trials in a timely manner.

Expanded Access to an Investigational Drug for Treatment Use

Expanded access, sometimes called "compassionate use," is the use of investigational products outside of clinical trials to treat patients with serious or immediately life-threatening diseases or conditions when there are no comparable or satisfactory alternative treatment options. The rules and regulations related to expanded access are intended to improve access to investigational products for patients who may benefit from investigational therapies. FDA regulations allow access to investigational products under an IND by the company or the treating physician for treatment purposes on a case-by-case basis for: individual patients (single-patient IND applications for treatment in emergency settings and non-emergency settings); intermediate-size patient populations; and larger populations for use of the investigational product under a treatment protocol or treatment IND application.

When considering an IND application for expanded access to an investigational product with the purpose of treating a patient or a group of patients, the sponsor and treating physicians or investigators will determine suitability when all of the following criteria apply: patient(s) have a serious or immediately life threatening disease or condition, and there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition; the potential patient benefit justifies the potential risks of the treatment and the potential risks are not unreasonable in the context or condition to be treated; and the expanded use of the investigational drug for the requested treatment will not interfere initiation, conduct, or completion of clinical investigations that could support marketing approval of the product or otherwise compromise the potential development of the product.

There is no obligation for a sponsor to make its drug products available for expanded access; however, as required by the 21st Century Cures Act passed in 2016, if a sponsor has a policy regarding how it responds to expanded access requests, it must make that policy publicly available. Although these requirements were rolled out over time, they have now come into full effect. This provision requires drug companies to make publicly available their policies for expanded access for individual patient access to products intended for serious diseases. Sponsors are required to make such policies publicly available upon the earlier of initiation of a Phase II or Phase III clinical trial; or 15 days after the investigational drug receives designation as a breakthrough therapy, fast track product, or regenerative medicine advanced therapy.

In addition, on May 30, 2018, the Right to Try Act was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational products that have completed a Phase I clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment with an investigational product without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a manufacturer to make its investigational products available to eligible patients as a result of the Right to Try Act.

Clinical Trials

Clinical trials involve the administration of the investigational new drug to human subjects, including healthy volunteers or patients with the disease or condition to be treated, under the supervision of qualified investigators in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, inclusion and exclusion criteria, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND.

A sponsor who wishes to conduct a clinical trial outside the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. When a foreign clinical trial is conducted under an IND, all FDA IND requirements must be met unless waived. When a foreign clinical trial is not conducted under an IND, the sponsor must ensure that the trial complies with certain regulatory requirements of the FDA in order to use the clinical trial as support for an IND or application for marketing approval. Specifically, the FDA requires that such clinical trials be conducted in accordance with GCP, including review and approval by an independent ethics committee and informed consent from participants. The GCP requirements encompass both ethical and data integrity standards for clinical trials. The FDA's regulations are intended to help ensure the protection of human subjects enrolled in non-IND foreign clinical trials, as well as the quality and integrity of the resulting data. They further help ensure that non-IND foreign trials are conducted in a manner comparable to that required for clinical trials in the United States.

In addition, an IRB at each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must continue to oversee the clinical trial while it is being conducted. The IRB will consider, among other things, clinical trial design, patient informed consent, ethical factors, and the safety of human subjects. An IRB overseeing a clinical trial of an investigational product must operate in compliance with FDA regulations. The FDA, the IRB, or the clinical trial sponsor may suspend or discontinue a clinical trial at any time for various reasons, including a finding that the clinical trial is not being conducted in accordance with FDA requirements or that the participants are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive GCP rules and the requirements for informed consent. Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health for public dissemination on their ClinicalTrials.gov website.

Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined. Additional studies may be required after approval.

- Phase I: The drug is initially introduced into a limited number of healthy human subjects or patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an initial indication of its effectiveness.
- Phase II: The drug typically 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 diseases and to determine dosage tolerance and optimal dosage. Multiple Phase II clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more costly Phase II clinical trials. Once Phase II clinical trials demonstrate that a dose range of the product candidate is potentially effective and has an acceptable safety profile, it proceeds to Phase III clinical trials.
- Phase III: The drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the safety and efficacy of the product for approval, to establish the overall risk-benefit profile of the product and to provide adequate information for the labeling of the product. A well-controlled, statistically robust Phase III trial may be designed to deliver the data that regulatory authorities will use to decide whether or not to approve, and, if approved, how to appropriately label a drug; such Phase III studies are referred to as “pivotal.”

- Phase IV: In some cases, the FDA may conditionally approve an NDA for a product candidate on the sponsor’s agreement to conduct additional clinical trials after NDA approval. In other cases, a sponsor may voluntarily conduct additional clinical trials post-approval to gain more information about the drug. Such post-approval trials are typically referred to as Phase IV clinical trials.

Progress reports detailing the results of the clinical trials must be submitted, at least annually, to the FDA, and more frequently if serious adverse events, or SAEs, occur. Phase I, Phase II and Phase III clinical trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB’s requirements, or if the drug has been associated with unexpected serious harm to patients.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

Compliance with cGMP Requirements

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in full compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The Public Health Service Act emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. Manufacturers and others involved in the manufacture and distribution of products must also register their establishments with the FDA and certain state agencies. Both domestic and foreign manufacturing establishments must register and provide additional information to the FDA upon their initial participation in the manufacturing process. Any product manufactured by or imported from a facility that has not registered, whether foreign or domestic, is deemed misbranded under the FDCA. Establishments may be subject to periodic unannounced inspections by government authorities to ensure compliance with cGMPs and other laws. Inspections must follow a “risk-based schedule” that may result in certain establishments being inspected more frequently. Manufacturers may also have to provide, on request, electronic or physical records regarding their establishments. Delaying, denying, limiting, or refusing inspection by the FDA may lead to a product being deemed to be adulterated.

Marketing Approval

Assuming successful completion of the required clinical testing, the results of the preclinical studies and clinical trials, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the product for one or more indications. In most cases, the submission of an NDA is subject to a substantial application user fee. Under the PDUFA guidelines that are currently in effect, the FDA has a goal of ten months to review and act on a standard NDA and six months to review and act on a priority NDA, measured from the date of "filing" of a standard NDA for an NME. This review typically takes eight months from the date the NDA is submitted to the FDA because the FDA has approximately two months to make a "filing" decision, although timing is not certain, particularly with the FDA's current focus on COVID-19.

In addition, under the Pediatric Research Equity Act of 2003, as amended and reauthorized, certain NDAs or supplements to an NDA must contain data that are adequate to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. Sponsors must also submit pediatric study plans prior to the assessment data. Those plans must contain an outline of the proposed pediatric study or studies the applicant plans to conduct, including study objectives and design, any deferral or waiver requests, and other information required by regulation. The applicant, the FDA, and the FDA's internal review committee must then review the information submitted, consult with each other, and agree upon a final plan. The FDA or the applicant may request an amendment to the plan at any time.

For products intended to treat a serious or life-threatening disease or condition, the FDA must, upon the request of an applicant, meet to discuss preparation of the initial pediatric study plan or to discuss deferral or waiver of pediatric assessments. In addition, FDA will meet early in the development process to discuss pediatric study plans with sponsors and FDA must meet with sponsors by no later than the end-of-the Phase I meeting for serious or life-threatening diseases and by no later than 90 days after FDA's receipt of the study plan.

The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. Additional requirements and procedures relating to deferral requests and requests for extension of deferrals are contained in the Food and Drug Administration Safety and Innovation Act. Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan designation.

The FDA also may require submission of a REMS plan to ensure that the benefits of the drug outweigh its risks. The REMS plan could include medication guides, physician communication plans, assessment plans, and/or elements to assure safe use, such as restricted distribution methods, patient registries or other risk minimization tools.

The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA reviews an NDA to determine, among other things, whether the drug is safe and effective and whether the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, quality and purity.

The FDA may refer an application for a novel drug to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

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

The FDA generally accepts data from foreign clinical trials in support of an NDA if the trials were conducted under an IND. If a foreign clinical trial is not conducted under an IND, the FDA nevertheless may accept the data in support of an NDA if the study was conducted in accordance with GCP requirements and the FDA is able to validate the data through an on-site inspection, if deemed necessary. Although the FDA generally requests that marketing applications be supported by some data from domestic clinical studies, the FDA may accept foreign data as the sole basis for marketing approval if the foreign data are applicable to the U.S.

The testing and approval process for an NDA requires substantial time, effort and financial resources, and takes several years to complete. Data obtained from preclinical and clinical testing are not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. The FDA may not grant approval of an NDA on a timely basis, or at all.

After evaluating the NDA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a complete response letter. A complete response letter generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA and may require additional clinical or preclinical testing, manufacturing or formulation modifications or other changes in order for the FDA to reconsider the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

Even if the FDA approves a product, it may limit the approved indications for use of the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase IV clinical trials, be conducted to further assess a drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution and use restrictions or other risk management mechanisms under a REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Orphan Drug Designation

Trappsol® Cyclo™ has been granted orphan drug status by the FDA. It has been used by a limited number of customers for the treatment of NPC under the supervision of a physician following an Investigational New Drug (IND) protocol approved by the FDA. Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States, or if it affects more than 200,000, there is no reasonable expectation that sales of the drug in the United States will be sufficient to offset the costs of developing and making the drug available in the United States. Orphan drug designation must be requested before submitting an NDA. A product becomes an orphan when it receives orphan drug designation from the Office of Orphan Products Development at the FDA based on acceptable confidential requests made under the regulatory provisions. The product must then go through the review and approval process like any other product. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

A sponsor may request orphan drug designation of a previously unapproved product or new orphan indication for an already marketed product. If the FDA approves a sponsor's marketing application for a designated orphan drug for use in the rare disease or condition for which it was designated, the sponsor is eligible for tax credits and a seven-year period of marketing exclusivity, during which the FDA may not approve another sponsor's marketing application for a drug with the same active moiety and intended for the same use or indication as the approved orphan drug, except in limited circumstances, such as if a subsequent sponsor demonstrates its product is clinically superior. During a sponsor's orphan drug exclusivity period, competitors, however, may receive approval for drugs with different active moieties for the same indication as the approved orphan drug, or for drugs with the same active moiety as the approved orphan drug, but for different indications. Orphan drug exclusivity could block the approval of one of our products for seven years if a competitor obtains approval for a drug with the same active moiety intended for the same indication before we do, unless we are able to demonstrate that grounds for withdrawal of the orphan drug exclusivity exist, or that our product is clinically superior. Further, if a designated orphan drug receives marketing approval for an indication broader than the rare disease or condition for which it received orphan drug designation, it may not be entitled to exclusivity.

The period of exclusivity begins on the date that the marketing application is approved by the FDA and applies only to the indication for which the product has been designated. The FDA may approve a second application for the same product for a different use or a second application for a clinically superior version of the product for the same use. The FDA cannot, however, approve the same product made by another manufacturer for the same indication during the market exclusivity period unless it has the consent of the sponsor or the sponsor is unable to provide sufficient quantities.

Special FDA Expedited Review and Approval Programs; Priority Review Voucher

The FDA has various programs, including fast track designation, accelerated approval, priority review, and breakthrough therapy designation, which are intended to expedite or simplify the process for the development and FDA review of drugs that are intended for the treatment of serious or life threatening diseases or conditions and demonstrate the potential to address unmet medical needs. The purpose of these programs is to provide important new drugs to patients earlier than under standard FDA review procedures. In January 2017 the FDA granted Fast Track designation to Trappsol® Cyclo™ for the treatment of NPC.

To be eligible for a fast track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need. The FDA will determine that a product will fill an unmet medical need if it will provide a therapy where none exists or provide a therapy that may be potentially superior to existing therapy based on efficacy or safety factors. The FDA may review sections of the NDA for a fast track product on a rolling basis before the complete application is submitted. If the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

The FDA may give a priority review designation to drugs that are designed to treat serious conditions, and if approved, would provide a significant improvement in treatment, or provide a treatment where no adequate therapy exists. A priority review means that the goal for the FDA to review an application is six months, rather than the standard review of ten months under current PDUFA guidelines. Under the current PDUFA agreement, these six and ten month review periods are measured from the “filing” date rather than the receipt date for NDAs for new molecular entities, which typically adds approximately two months to the timeline for review and decision from the date of submission. Most products that are eligible for fast track designation may be considered appropriate to receive a priority review.

In addition, products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may be eligible for accelerated approval and may be approved on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require a sponsor of a drug receiving accelerated approval to perform post-marketing studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical endpoint, and the drug may be subject to accelerated withdrawal procedures.

Breakthrough therapy designation is for a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA must take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a breakthrough therapy.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. We may explore some of these opportunities for our product candidate as appropriate.

On December 1, 2017, the FDA designated NPC a Rare Pediatric Disease. Rare Pediatric Disease designation by FDA enables priority review voucher eligibility upon U.S. market approval of a designated drug for rare pediatric diseases. The rare pediatric disease-priority review voucher program is intended to encourage development of therapies to prevent and treat rare pediatric diseases. The voucher, which is awarded upon NDA approval to the sponsor of a designated rare pediatric disease can be sold or transferred to another entity and used by the holder to receive priority review for a future NDA submission, which reduces the FDA review time of such future submission from ten to six months.

Coverage and Reimbursement

The future commercial success of any approved product candidate will depend in part on the extent to which governmental payor programs at the federal and state levels, including Medicare and Medicaid, private health insurers and other third-party payors provide coverage for and establish adequate reimbursement levels for our product candidate. Government health administration authorities, private health insurers and other organizations generally decide which drugs they will pay for and establish reimbursement levels for healthcare. In particular, in the United States, private health insurers and other third-party payors often provide reimbursement for products and services based on the level at which the government, through the Medicare or Medicaid programs, provides reimbursement for such treatments. In the United States, the European Union, or EU, and other potentially significant markets for our product candidate, government authorities and third-party payors are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which often has resulted in average selling prices lower than they would otherwise be. Further, the increased emphasis on managed healthcare in the United States and on country and regional pricing and reimbursement controls in the European Union will put additional pressure on product pricing, reimbursement and usage, which may adversely affect our future product sales and results of operations. These pressures can arise from rules and practices of managed care groups, judicial decisions and laws and regulations related to Medicare, Medicaid and healthcare reform, pharmaceutical coverage and reimbursement policies and pricing in general.

Impact of Healthcare Reform on our Business

The United States and some foreign jurisdictions are considering enacting or have enacted a number of additional legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our product candidate profitably, if approved. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts, which include major legislative initiatives to reduce the cost of care through changes in the healthcare system, including limits on the pricing, coverage, and reimbursement of pharmaceutical and biopharmaceutical products, especially under government-funded health care programs, and increased governmental control of drug pricing.

There have been several U.S. government initiatives over the past few years to fund and incentivize certain comparative effectiveness research, including creation of the Patient-Centered Outcomes Research Institute under the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA. It is also possible that comparative effectiveness research demonstrating benefits in a competitor's product could adversely affect the sales of our product candidate. If third-party payors do not consider our product candidate to be cost-effective compared to other available therapies, they may not cover our product candidate, once approved, as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our product on a profitable basis.

The ACA became law in March 2010 and substantially changed the way healthcare is financed by both governmental and private insurers. Among other measures that may have an impact on our business, the ACA established an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents; a new Medicare Part D coverage gap discount program; and a new formula that increases the rebates a manufacturer must pay under the Medicaid Drug Rebate Program. Additionally, the ACA extended manufacturers' Medicaid rebate liability, expanded eligibility criteria for Medicaid programs, and expanded entities eligible for discounts under the Public Health Service pharmaceutical pricing program. There have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the current presidential administration to repeal or replace certain aspects of the ACA, and we expect such challenges and amendments to continue. Since January 2017, President Trump has signed Executive Orders designed to delay the implementation of any certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. One Executive Order directed federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. The second Executive Order terminated the cost-sharing subsidies that reimburse insurers under the ACA. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. In addition, CMS has recently proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. In December 2018, CMS published a new final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of the federal court litigation regarding the method CMS uses to determine this risk adjustment. On April 27, 2020, the U.S. Supreme Court reversed the Federal Circuit decision that previously upheld Congress' denial of $12 billion in ACA risk corridor payments to certain ACA qualified health plans and health insurance issuers. The full effects of this gap in reimbursement on third-party payors, the viability of the ACA marketplace, providers, and potentially our business, are not yet known. In addition, in December 2019, a three-judge panel of the Fifth Circuit Court of Appeals partially affirmed a district court decision that had declared the entire ACA invalid. The ACA's future continues to be uncertain as the law's constitutionality has been challenged and will be considered by the U.S. Supreme Court in *California v. Texas* . This ongoing litigation challenges the ACA's minimum essential coverage provision (known as the individual mandate) and raises questions about the entire law's survival. The ACA remains in effect while the litigation is pending. However, if all or most of the law ultimately is struck down, it may have complex and far-reaching consequences for the nation's health care system.

At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what biopharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing.

There have been, and likely will continue to be, additional legislative and regulatory proposals at the foreign, federal, and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. Such reforms could have an adverse effect on anticipated revenues from product candidates that we may successfully develop and for which we may obtain marketing approval and may affect our overall financial condition and ability to develop product candidates.

Other Healthcare Laws

Outside the United States, our ability to market a product is contingent upon obtaining marketing authorization from the appropriate regulatory authorities. The requirements governing market authorization, pricing and reimbursement vary widely from country to country. In order to market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of our product candidate. Whether or not we obtain marketing approval for a drug in the United States, we would need to obtain the necessary approvals by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the drug in those countries. The approval process varies from country to country and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from and be longer than that required to obtain approval in the United States. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others.

Our Legacy Fine Chemical Business

Substantially all of our revenues are currently derived from our legacy fine chemical business, consisting of the sale of cyclodextrins, including cyclodextrin complexes, the resale of cyclodextrins manufactured by others for our clients to their specifications, and our own licensed cyclodextrin products. We have trademarked certain products under our Trappsol® and Aquaplex® product lines. The Trappsol® product line includes basic cyclodextrins, and cyclodextrins with different chemical adducts resulting in more than 261 different cyclodextrins products available for sale from us. The Aquaplex® product line includes various cyclodextrins combined with more than 80 different active ingredients that, only as a complex, then become water soluble; we currently list for sale more than 116 different Aquaplex® products. Historically, substantially all of our sales of Aquaplex® products were to one chemical supply house, Sigma-Aldrich Fine Chemical. Sales of Trappsol® and Aquaplex® comprise approximately 99% and 1%, respectively, of our 2022 product sales. The Trappsol® and Aquaplex® products can be used in many industries, the largest being the food and pharmaceutical industries.

Natural and chemically modified cyclodextrins are available from at least four major commercial manufacturers around the world, including Wacker Biosolutions, a division of Wacker Chemie AG (Germany), with a production facility located in Adrian, Michigan; Mitsubishi Chemical Corporation (Japan); Roquettes Freres (France); and Hangzhou Pharma and Chem Co. (China). Prior to 2008, we purchased all of our Aquaplex® cyclodextrin complex products from Cyclodextrin Research & Development Laboratory, which is located in Budapest, Hungary; there are few, if any, other sources in the world for commercial quantities of current Good Manufacturing Practice (c-GMP) cyclodextrin complexes. While we continue to purchase many of our cyclodextrin materials from Cyclodextrin Research & Development Laboratory, we also produce our own Aquaplex® materials. Additionally, we use third party manufacturers, such as Equinox Chemical in Albany, Georgia, to develop cyclodextrin complexes. We historically have not had difficulties obtaining natural and chemically modified cyclodextrins from our suppliers and we do not expect to experience any difficulties obtaining adequate cyclodextrins for our current and expected expanded future needs.

Cyclodextrin Product Background

Cyclodextrins are molecules that bring together oil and water, making the oily materials soluble in water, and have potential applications anywhere oil and water must be used together. Cyclodextrins can improve the solubility and stability of a wide range of drugs. Many promising drug compounds are unusable or have serious side effects because they are either unstable or poorly soluble in water. Strategies for administering currently approved compounds involve injection of formulations requiring pH adjustment and/or the use of organic solvents. The result is frequently painful, irritating, or damaging to the patient. These side effects can be ameliorated by cyclodextrins. Cyclodextrins also have many potential uses in drug delivery for topical applications to the eyes and skin.

Successful applications of cyclodextrins have been established in biotechnology, pharmaceuticals, agrochemicals, analytical chemistry, cosmetics, diagnostics, electronics, foodstuffs, and toxic waste treatment. Stabilization of food flavors and fragrances is the largest current worldwide market for cyclodextrin applications. We and others have developed cyclodextrin-based applications in stabilization of flavors for food products; elimination of undesirable tastes and odors; preparation of antifungal complexes for foods and pharmaceuticals; stabilization of fragrances and dyes; reduction of foaming in foods, cosmetics and toiletries; and the improvement of quality, stability and storability of foods.

Cyclodextrins are manufactured commercially in large quantities by mixing purified enzymes with starch solutions. A mixture of alpha, beta, and gamma cyclodextrins can be manufactured by this enzymatic modification of starch with purified natural enzymes and therefore are considered to be natural products. Additional processing is required to isolate and separate the individual cyclodextrins. The purified alpha, beta and gamma cyclodextrins are referred to collectively as natural or native cyclodextrins.

The hydroxyl chemical groups on each glucose unit in a cyclodextrin molecule provide chemists with ways to modify the properties of the cyclodextrins, i.e. to make them more water soluble or less water soluble, thereby making them better carriers for a specific chemical. The cyclodextrins that result from chemical modifications are no longer considered natural and are referred to as chemically modified cyclodextrins. Since the property modifications achieved are often advantageous to a specific application, the Company does not believe the loss of the natural product categorization will prevent its ultimate pharmaceutical use. It does, however, create a greater regulatory burden.

Other Cyclodextrin Uses

Applications of cyclodextrins in personal products and for industrial uses have appeared in many patents and patent applications. Cyclodextrins are used in numerous brand-name household goods, including fabric softeners and air fresheners. With increased manufacturing capacity and supply, the prices of the natural cyclodextrins have decreased to the point that use of these materials is considered in even the most price sensitive goods.

In Japan, at least twelve pharmaceutical preparations are now marketed which contain cyclodextrins; there are also multiple products in Europe and the United States. Cyclodextrins permit the use of all routes of administration. Ease of delivery and improved bioavailability of such well-known drugs as nitroglycerin, dexamethasone, PGE(1&2), and cephalosporin permit these “old” drugs to command new market share and sometimes new patent lives. Because of the value added, it is management’s opinion that the dollar value of the worldwide market for products containing cyclodextrins and for complexes of cyclodextrins can be substantially greater than that of the market sales of the cyclodextrin itself.

Customers

We currently sell our legacy fine chemical products directly to customers in the pharmaceutical, diagnostics, and industrial chemical industries, and to chemical supply distributors. For the year ended December 31, 2022, our revenues consisted of 99% basic natural and chemically modified cyclodextrins and 1% cyclodextrin complexes.

Our cyclodextrin sales historically involve small quantities (i.e., less than 1.0 kg). We sell directly to our customers, package the orders at our facility and ship using common carriers.

The majority of our revenues are from five to ten customers who have historically been repeat purchasers. For the years ended December 31, 2022 and 2021, three and four customers accounted for 68% and 73% of our sales, respectively. Sigma-Aldrich Fine Chemical, Inc. accounted for approximately 85% and 99% of our 2022 and 2021 annual sales, respectively, of Aquaplex®. In a given year, we typically sell to fewer than 200 individual customers. Our industrial customers buy products from us as needed primarily for product research and development purposes. Therefore, it is difficult to predict future sales from these customers, as it is dependent on the current cyclodextrin related research and development activities of others, which we have monitored in the past by following the issuance and applications of patents in the US and elsewhere.

We intend to continue promoting the use of Trappsol® and Aquaplex® products in the research and product development activities of existing and new customers and clients.

Employees

We currently employ nine people on a full-time basis. None of our employees belong to a union. We believe relations with our employees are good.

Item 1A. Risk Factors.

Risks Related to our Financial Position and Capital Needs

We have suffered recent losses and our future profitability is uncertain.

We have incurred net losses of approximately $15.5 million and $14.3 million for the years ended December 31, 2022 and December 31, 2021, respectively. Our recent losses have predominantly resulted from research and development expenses for our Trappsol® Cyclo™ product and other general operating expenses, including personnel costs. We believe our expenses will continue to increase as we conduct clinical trials and continue to seek regulatory approval for the use of Trappsol® Cyclo™ in the treatment of NPC and Alzheimer's disease. As a result, we expect our operating losses to continue until such time, if ever, that product sales, licensing fees, royalties and other sources generate sufficient revenue to fund our operations. We cannot predict when, if ever, we might achieve profitability and cannot be certain that we will be able to sustain profitability, if achieved.

Even with the proceeds from our recent securities offerings, we will need additional capital to fund our operations as planned.

For the year ended December 31, 2022, our operations used approximately $15.1 million in cash. At December 31, 2022, the Company had a cash balance of approximately $1.5 million and current liabilities of approximately $3.5 million. Although we raised approximately $3.7 million in the registered direct offering and concurrent private placement we completed in January 2023, we will need additional capital to maintain our operations, continue our research and development programs, conduct clinical trials, seek regulatory approvals and manufacture and market our products. We will seek such additional funds through public or private equity or debt financings and other sources. We cannot be certain that adequate additional funding will be available to us on acceptable terms, if at all. If we cannot raise the additional funds required for our anticipated operations, we may be required to reduce the scope of or eliminate our research and development programs, delay our clinical trials and the ability to seek regulatory approvals, downsize our general and administrative infrastructure, or seek alternative measures to avoid insolvency. If we raise additional funds through future offerings of shares of our Common Stock or other securities, such offerings would cause dilution of current stockholders' percentage ownership in the Company, which could be substantial. Future offerings also could have a material and adverse effect on the price of our Common Stock.

The report of our independent registered public accounting firm expresses substantial doubt about our ability to continue as a going concern.

Our auditors, WithumSmith+Brown, PC., have indicated in their report on our consolidated financial statements for the fiscal year ended December 31, 2022, that conditions exist that raise substantial doubt about our ability to continue as a going concern due to our recurring losses from operations and significant accumulated deficit. In addition, we continue to experience negative cash flows from operations. A "going concern" opinion could impair our ability to finance our operations through the sale of equity. Our ability to continue as a going concern will depend upon the availability of equity financing which represents the primary source of cash flows that will permit us to meet our financial obligations as they come due and continue our research and development efforts.

We have not received approval for any drug candidate for commercial sale and, as a result, we have never generated any revenue from the sale of biopharmaceutical products, and expect to continue to incur significant financial losses in the future, which makes it difficult to assess our future viability.

While we sell cyclodextrins for use and research in numerous industries, we have not yet received the necessary regulatory approvals to commercially sell any biopharmaceutical products. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk, including risks related to the regulatory approval process. Because the focus of our business has transitioned to the development of cyclodextrin-based products for the treatment of disease, we anticipate that our expenses will increase substantially as we:

- continue our ongoing and planned development of Trappsol® Cyclo™ for multiple indications;
- initiate, conduct and complete ongoing, anticipated or future preclinical studies and clinical trials for our current and future product candidates;

- seek marketing approvals for product candidates that successfully complete clinical trials; and

- establish a sales, marketing and distribution infrastructure to commercialize products for which we may obtain marketing approval.

We will continue to incur significant losses until such time, if ever, as we are able to commercialize our drug candidates. If we are not able to do so we may not sustain a viable business.

Risks Related to Product Development, Regulatory Approval and Commercialization

We are largely dependent upon the success of our Trappsol® Cyclo™ product, which may never receive regulatory approval.

Our lead drug candidate, Trappsol® Cyclo™ is the focus of much of our management team's development efforts. The product is currently designated as an orphan drug for the treatment of NPC in the United States and Europe. We plan to continue to make substantial investment in continued research and development of our Trappsol® Cyclo™ product in connection with obtaining approval for marketing the product for the treatment of NPC, as well as Alzheimer's disease. The potential population of NPC patients is small, and our ability to market the drug for use other than research is severely constrained by regulatory restrictions. In the course of its development, our Trappsol® Cyclo™ drug product will be subject to extensive and rigorous government regulation through the European Medicines Agency in the E.U. and through the Food and Drug Administration (FDA) in the United States. Regulatory approval in any jurisdiction cannot be guaranteed. There can be no guarantees that our product will be effective and safe in the treatment of NPC, Alzheimer's disease or any other disease nor is there any guarantee that it will be deemed by the regulatory agencies of any jurisdiction to be effective and safe. Despite the time and expense involved in developing a drug candidate, failure of a drug candidate can occur at any stage of development and for many reasons, including without limitation negative or inconclusive results from pre-clinical data or clinical trials. Failure to comply with applicable regulatory requirements in any jurisdiction, either before or after product approval, may subject us to administrative or judicially imposed sanctions.

Even if Trappsol® Cyclo™ receives regulatory approval, we may not be successful in our commercialization efforts and Trappsol ® Cyclo™ may fail to achieve the degree of market acceptance by physicians, patients, healthcare payors and others in the medical community necessary for commercial success.

Even if Trappsol® Cyclo™ receives regulatory approval, we may not be successful in our commercialization efforts and market acceptance by physicians, patients, third-party payors and others in the medical community may be less than estimated. Market acceptance will require us to build and maintain strong relationships with healthcare professionals involved in the treatment of NPC. The number of healthcare professionals associated with treatment centers that address NPC is limited. A failure to build or maintain these important relationships with these healthcare professionals and treatment centers could result in lower market acceptance. Our efforts to educate physicians, patients, third-party payors and others in the medical community on the benefits of Trappsol® Cyclo™ may require significant resources and may never be successful. The degree of market acceptance of Trappsol® Cyclo™, if approved for commercial sale, will depend on a number of factors, including:

- its efficacy;

- limitations or warnings or any restrictions on the use of Trappsol® Cyclo™, together with other medications, and the prevalence and severity of any side effects;

- the availability and efficacy of alternative treatments;
- the effectiveness of sales and marketing efforts and the strength of marketing and distribution support;
- the cost-effectiveness of Trappsol® Cyclo™ compared to alternative therapies and the ability to offer such drug for sale at competitive prices; and
- availability and amount of coverage and reimbursement from government payors, managed care plans and other third-party payors.

The results of our clinical trials may not support our product claims or may result in the discovery of adverse side effects.

Even if our clinical trials are completed as planned, we cannot be certain that their results will support our product claims or that any regulatory authority whose approval we will require in order to market and sell our products in any territory will agree with our conclusions regarding them. Success in pre-clinical studies and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that clinical trials will replicate the results of prior trials and pre-clinical studies. The clinical trial process may fail to demonstrate that our product candidates are safe and effective for the proposed indicated uses, which could cause us to abandon a product and may delay development of others. Any delay or termination of our clinical trials will delay the filing of our regulatory submissions and, ultimately, our ability to commercialize our product candidates and generate revenues. It is also possible that patients enrolled in clinical trials will experience adverse side effects that are not currently part of the product candidate's profile.

Clinical trials involve a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

We have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including FDA approval. Clinical trials are expensive and complex, can take many years and have uncertain outcomes. We cannot predict whether we will encounter problems with any of our completed, ongoing or planned clinical trials that will cause us or regulatory authorities to delay or suspend clinical trials, or delay the analysis of data from completed or ongoing clinical trials. We estimate that clinical trials of Trappsol® Cyclo™ for the treatment of NPC will continue for several years, but they may take significantly longer to complete. Failure can occur at any stage of the testing and we may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent commercialization of our current or future therapeutic candidates, including but not limited to:

- delays in securing clinical investigators or trial sites for the clinical trials;
- delays in obtaining institutional review board and other regulatory approvals to commence a clinical trial;
- slower than anticipated patient recruitment and enrollment;
- negative or inconclusive results from clinical trials;
- unforeseen safety issues;
- uncertain dosing issues;
- an inability to monitor patients adequately during or after treatment; and
- problems with investigator or patient compliance with the trial protocols.

A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials, even after seeing promising results in earlier clinical trials. Despite the results reported in earlier clinical trials for Trappsol® Cyclo™, we do not know whether any Phase III or other clinical trials we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market Trappsol® Cyclo™. If later-stage clinical trials do not produce favorable results, our ability to obtain regulatory approval for Trappsol® Cyclo™ may be adversely impacted.

Later discovery of previously unknown problems could limit our ability to market or sell Trappsol ® Cyclo™, even if it is initially approved, and can expose us to product liability claims.

Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with any third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- refusals or delays in the approval of applications or supplements to approved applications;
- refusal of a regulatory authority to review pending market approval applications or supplements to approved applications;
- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market or voluntary or mandatory product recalls or seizures;
- fines, warning letters, or holds on clinical trials;
- import or export restrictions;
- injunctions or the imposition of civil or criminal penalties;
- restrictions on product administration, requirements for additional clinical trials, or changes to product labeling requirements; or
- recommendations by regulatory authorities against entering into governmental contracts with us.

Discovery of previously unknown problems or risks relating to our product could also subject us to potential liabilities through product liability claims.

If we do not obtain required approvals in other countries in which we aim to market our products, we will be limited in our ability to export or sell the products in those markets.

Our lack of experience in conducting clinical trials in any jurisdiction may negatively impact the approval process in those jurisdictions where we intend to seek approval of Trappsol® Cyclo™. If we are unable to obtain and maintain required approval from one or more foreign jurisdictions where we would like to sell Trappsol® Cyclo™, we will be unable to market products as intended, our international market opportunity will be limited and our results of operations will be harmed.

We rely in part on third parties for research and clinical trials for products using Trappsol ® Cyclo™.

We rely on contract research organizations (“CROs”), academic institutions, corporate partners, and other third parties to assist us in managing, monitoring, and otherwise carrying out clinical trials and research activities. We rely or will rely heavily on these parties for the execution of our clinical studies and control only certain aspects of their activities. Accordingly, we may have less control over the timing and other aspects of these clinical trials than if we conducted them entirely on our own. Although we rely on these third parties to manage the data from clinical trials, we will be responsible for confirming that each of our clinical trials is conducted in accordance with its general investigational plan and protocol. Our failure, or the failure of third parties on which we rely, to comply with the strict requirements relating to conducting, recording, and reporting the results of clinical trials, or to follow good clinical practices, may delay the regulatory approval process or cause us to fail to obtain regulatory approval for Trappsol® Cyclo™.

We currently have no marketing and sales organization for our pharmaceutical candidates and may have to invest significant resources to develop these capabilities. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be able to generate product revenue.

We have no internal sales, marketing or distribution capabilities for the sale of biopharmaceutical products. If any of our drug candidates ultimately receives regulatory approval, we may not be able to effectively market and distribute it. We may have to seek collaborators, especially for marketing and sales outside of the United States, or invest significant amounts of financial and management resources to develop internal sales, distribution and marketing capabilities. We may not be able to enter into collaborations or hire consultants or external service providers to assist us in sales, marketing and distribution functions on acceptable financial terms, or at all. In addition, our product revenues and our profitability, if any, may be lower if we rely on third parties for these functions than if we were to market, sell and distribute products that we develop ourselves. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. Even if we determine to perform sales, marketing and distribution functions ourselves, we could face a number of additional related risks, including:

- we may not be able 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 revenue generated by our product candidates that we may develop, in-license or acquire; and
- our direct sales and marketing efforts may not be successful.

We rely upon third parties for the manufacture of Trappsol® Cyclo™ and are dependent on their quality and effectiveness.

Trappsol® Cyclo™ requires precise, high-quality manufacturing. The failure to achieve and maintain high manufacturing standards, including the failure to conform to c-GMP (current Good Manufacturing Practice), or to detect or control anticipated or unanticipated manufacturing errors or the frequent occurrence of such errors, could result in discontinuance or delay of ongoing or planned clinical trials, delays or failures in product testing or delivery, cost overruns, product recalls or withdrawals, patient injury or death, and other problems that could seriously hurt our business. Contract drug manufacturers often encounter difficulties involving production yields, quality control and quality assurance and shortages of qualified personnel. These manufacturers are subject to stringent regulatory requirements, including the FDA's c-GMP regulations and similar foreign laws and standards. If our contract manufacturers fail to maintain ongoing compliance at any time, the production of our product candidates could be interrupted, resulting in delays or discontinuance of our clinical trials, additional costs and loss of potential revenues.

We face competition from well-funded companies to treat NPC.

We face competition from other entities, including pharmaceutical and biotechnology companies and governmental institutions that are working on supporting orphan drug designations and clinical trials for the neurological manifestations of NPC. Some of these entities are well-funded, with more financial, technical and personnel resources than we have, and have more experience than we do in designing and implementing clinical trials. If we are unable to compete effectively against our current or future competitors, sales of our Trappsol® Cyclo™ product may not grow and our financial condition may suffer.

Our business and operations would suffer in the event of computer system failures or security breaches.

In the ordinary course of our business, we collect, store and transmit confidential information, including intellectual property, proprietary business information and personal information. Despite the implementation of security measures, our internal computer systems, and those of our contract research organizations, or CROs, and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, cyberattacks, natural disasters, fire, terrorism, war and telecommunication and electrical failures. Cyberattacks are increasing in their frequency, sophistication and intensity. Cyberattacks could include the deployment of harmful malware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. Significant disruptions of our information technology systems or security breaches could adversely affect our business operations and/or result in the loss, misappropriation, and/or unauthorized access, use or disclosure of, or the prevention of access to, confidential information (including trade secrets or other intellectual property, proprietary business information and personal information), and could result in financial, legal, business and reputational harm to us. If such disruptions were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs. For example, the loss of clinical trial data from completed, ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Further, the COVID-19 pandemic has resulted in a significant number of our employees and partners working remotely, which increases the risk of a data breach or issues with data and cybersecurity. To the extent that any disruption or security breach results in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our future product candidates could be delayed.

Risks Related to Our Intellectual Property

The rights we rely upon to protect our unpatented trade secrets may be inadequate.

To manufacture and produce Trappsol® Cyclo™, we rely primarily on unpatented trade secrets, know-how and technology which are difficult to protect, especially in the pharmaceutical industry, where much of the information about a product must be made public during the regulatory approval process. We seek to protect trade secrets, in part, by entering into confidentiality agreements with third-party manufacturers, employees, consultants and others. These parties may breach or terminate these agreements or may refuse to enter into such agreements with us, and we may not have adequate remedies for such breaches. Furthermore, these agreements may not provide meaningful protection for our trade secrets or other proprietary information and may not provide an adequate remedy in the event of unauthorized use or disclosure of confidential information or other breaches of the agreements. Despite our efforts to protect our trade secrets, we or others may unintentionally or willfully disclose our proprietary information to competitors.

If we fail to maintain trade secret protection, our competitive position may be adversely affected. Competitors may also independently discover our trade secrets. Enforcement of claims that a third party has illegally obtained and is using trade secrets is expensive, time consuming and uncertain. If our competitors independently develop equivalent knowledge, methods and know-how, we would not be able to assert our trade secrets against them and our business could be harmed.

We cannot ensure that patent rights relating to inventions described and claimed in our pending patent applications will issue or that patents based on our patent applications will not be challenged and rendered invalid and/or unenforceable.

We have patent applications pending with respect to the treatment of Alzheimer's disease with Trappsol® Cyclo™. However, we cannot predict:

- if and when patents may issue based on our patent applications;
- the scope of protection of any patent issuing based on our patent applications;
- whether the claims of any patent issuing based on our patent applications will provide protection against competitors;
- whether or not third parties will find ways to invalidate or circumvent our patent rights, or claim co-ownership rights in our patent rights, which may impact our ability to enforce our patent rights against third parties;
- whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications; or
- whether we will need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose.

We cannot be certain that the claims in our pending patent applications will be considered patentable by the U.S. Patent and Trademark Office or by patent offices in foreign countries. Even if the patents do issue based on our patent applications, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, our patents may not adequately exclude third parties from practicing relevant technology or prevent others from designing around our claims. If the breadth or strength of our intellectual property position with respect to our product candidates is threatened, it could dissuade companies from collaborating with us and threaten our ability to commercialize our product candidates. It is possible that third parties with whom we have collaborated may contend that they co-own patent rights we have filed, which, if correct and in the absence of an agreement to the contrary, could prevent us from asserting the patent rights against our competitors. Furthermore, in the event of litigation or administrative proceedings, we cannot be certain that the claims in any of our issued patents will be considered valid by courts in the United States or foreign countries.

We are susceptible to intellectual property suits that could cause us to incur substantial costs or pay substantial damages or prohibit us from selling our product candidates.

There is a substantial amount of litigation over patent and other intellectual property rights in the biotechnology industry. Whether or not a product infringes a patent involves complex legal and factual considerations, the determination of which is often uncertain. Searches typically performed to identify potentially infringed patents of third parties are often not conclusive and, because patent applications can take many years to issue, there may be applications now pending, which may later result in issued patents which our current or future products may infringe or be alleged to infringe. In addition, our competitors or other parties may assert that our product candidates and the methods employed may be covered by patents held by them. If any of our products infringes a valid patent, we could be prevented from manufacturing or selling such product unless we are able to obtain a license or able to redesign the product in such a manner as to avoid infringement. A license may not always be available or may require us to pay substantial royalties. We also may not be successful in any attempt to redesign our product to avoid infringement, nor does a later redesign protect the Company from prior infringement. We are aware of third party U.S. patents and patent applications, which may be relevant to our lead product candidate Trappsol® Cyclo™ for treating Niemann-Pick Type C disease. Although we believe that we would not infringe a valid claim of those patents or pending patent applications, if issued, the owner of the patent rights may disagree with our assessment and bring an infringement action against us. There is no assurance that a court would find in our favor on questions of infringement or validity. Infringement and other intellectual property claims, with or without merit, can be expensive and time-consuming to litigate and can divert our management's attention from operating our business.

We may need to initiate lawsuits to protect or enforce our intellectual property rights, which could be expensive and, if we lose, could cause us to lose some of our intellectual property rights, which would harm our ability to compete in the market.

In order to protect or enforce our intellectual property rights, we may initiate patent, trademark and related litigation against third parties, such as infringement suits or requests for injunctive relief. Our ability to establish and maintain a competitive position may be achieved in part by prosecuting claims against others who we believe to be infringing its rights. Any lawsuits that we initiate could be expensive, take significant time and divert our management's attention from other business concerns and the outcome of litigation to enforce our intellectual property rights in patents, trade secrets or trademarks is highly unpredictable. Litigation also puts our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, or adversely affect our ability to distribute any products that are subject to such litigation. In addition, we may 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, including attorney fees, if any, may not be commercially valuable.

Risks Related to Legal and Regulatory Compliance Matters

The pharmaceutical business is subject to increasing government regulation and reform, including with respect to price controls, reimbursement and access to drugs, which could adversely affect our future revenues and profitability.

To the extent our products are developed, commercialized, and successfully introduced to market, they may not be considered cost-effective, and third-party or government reimbursement might not be available or sufficient. Globally, governmental and other third-party payors are becoming increasingly aggressive in attempting to contain health care costs by strictly controlling, directly or indirectly, pricing and reimbursement and, in some cases, limiting or denying coverage altogether on the basis of a variety of justifications, and we expect pressures on pricing and reimbursement from both governments and private payors inside and outside the U.S. to continue.

If we obtain the required regulatory approval to sell our drug candidates, we will be subject to substantial pricing, reimbursement, and access pressures from state Medicaid programs, private insurance programs and pharmacy benefit managers, and the implementation of U.S. health care reform legislation that is increasing these pricing pressures. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, instituted comprehensive health care reform, and includes provisions that, among other things, reduce and/or limit Medicare reimbursement, and impose new and/or increased taxes. The future of the Affordable Care Act and its constituent parts are uncertain at this time.

In almost all markets, pricing and choice of prescription pharmaceuticals are subject to governmental control. Therefore, the price of our products and their reimbursement in Europe and in other countries is and will be determined by national regulatory authorities. Reimbursement decisions from one or more of the European markets may impact reimbursement decisions in other European markets. A variety of factors are considered in making reimbursement decisions, including whether there is sufficient evidence to show that treatment with the product is more effective than current treatments, that the product represents good value for money for the health service it provides, and that treatment with the product works at least as well as currently available treatments.

The continuing efforts of government and insurance companies, health maintenance organizations, and other payors of health care costs to contain or reduce costs of health care may affect our future revenues and profitability or those of our potential customers, suppliers, and collaborative partners, as well as the availability of capital.

United States federal and state privacy laws, and equivalent laws of other nations, may increase our costs of operation and expose us to civil and criminal sanctions.

Regulation of data processing is evolving, as federal, state, and foreign governments continue to adopt new, or modify existing, laws and regulations addressing data privacy and security, and the collection, processing, storage, transfer, and use of data. These new or proposed laws and regulations are subject to differing interpretations and may be inconsistent among jurisdictions, and guidance on implementation and compliance practices are often updated or otherwise revised, which adds to the complexity of processing personal data. These and other requirements could require us or our collaborators to incur additional costs to achieve compliance, limit our competitiveness, necessitate the acceptance of more onerous obligations in our contracts, restrict our ability to use, store, transfer, and process data, impact our or our collaborators' ability to process or use data in order to support the provision of our products, affect our or our collaborators' ability to offer our products in certain locations, or cause regulators to reject, limit or disrupt our clinical trial activities.

We and our collaborators may be subject to federal, state and foreign data protection laws and regulations (i.e., laws and regulations that address privacy and data security). In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state personal information laws, state data breach notification laws, state health information privacy laws and federal and state consumer protection laws and regulations 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. In addition, 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 the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH. Depending on the facts and circumstances, we could be subject to civil or criminal penalties if we knowingly use or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

Risks Related to Employee Matters

We are dependent on our executive officers, and we may not be able to pursue our current business strategy effectively if we lose them.

Our success to date has largely depended on the efforts and abilities of our executive officers, namely N. Scott Fine, our Chief Executive Officer, Jeffrey L. Tate, Ph.D., our Chief Operating Officer, and Lise Kjems, MD, PhD, our Chief Medical Officer. Our ability to manage our operations and meet our business objectives could be adversely affected if, for any reason, such officers do not remain with us.

Our employees, clinical trial investigators, CROs, consultants, vendors and any potential commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards.

We are exposed to the risk of fraud or other misconduct by our employees, clinical trial investigators, CROs, consultants, vendors and any potential commercial partners. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates: (i) U.S. laws and regulations or those of foreign jurisdictions, including those laws that require the reporting of true, complete and accurate information, (ii) manufacturing standards, (iii) federal and state health and data privacy, security, fraud and abuse, government price reporting, transparency reporting requirements, and other healthcare laws and regulations in the United States and abroad or (iv) laws that require the true, complete and accurate reporting of financial information or data. Such misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of conduct applicable to all of our employees, as well as a disclosure program and other applicable policies and procedures, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from government funded healthcare programs, such as Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional integrity reporting and oversight obligations, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

If we fail to comply with the U.S. federal Anti-Kickback Statute and similar state and foreign country laws, we could be subject to criminal and civil penalties and exclusion from federally funded healthcare programs including the Medicare and Medicaid programs and equivalent third country programs, which would have a material adverse effect on our business and results of operations.

A provision of the Social Security Act, commonly referred to as the federal Anti-Kickback Statute, prohibits the knowing and willful offer, payment, solicitation or receipt of any form of remuneration, directly or indirectly, in cash or in kind, to induce or reward the referring, ordering, leasing, purchasing or arranging for, or recommending the ordering, purchasing or leasing of, items or services payable, in whole or in part, by Medicare, Medicaid or any other federal healthcare program. The federal Anti-Kickback Statute is very broad in scope and many of its provisions have not been uniformly or definitively interpreted by existing case law or regulations. In addition, many states have adopted laws similar to the federal Anti-Kickback Statute that apply to activity in those states, and some of these laws are even broader than the federal Anti-Kickback Statute in that their prohibitions may apply to items or services reimbursed under Medicaid and other state programs or, in several states, apply regardless of the source of payment. Violations of the federal Anti-Kickback Statute may result in substantial criminal, civil or administrative penalties, damages, fines and exclusion from participation in federal healthcare programs.

While we believe our operations will be in compliance with the federal Anti-Kickback Statute and similar state laws, we cannot be certain that we will not be subject to investigations or litigation alleging violations of these laws, which could be time-consuming and costly to us and could divert management's attention from operating our business, which in turn could have a material adverse effect on our business. In addition, if our arrangements were found to violate the federal Anti-Kickback Statute or similar state laws, the consequences of such violations would likely have a material adverse effect on our business, results of operations and financial condition.

Risks Related To Our Fine Chemical Business

A small number of our customers account for a substantial portion of our revenue, and the loss of any of these customers would materially decrease our revenues.

In 2022, three major customers accounted for 68% of total revenues. Accounts receivable balances for these major customers represents 19% of total accounts receivable at December 31, 2022. We have a supply contract with only one of our major customers. The loss of one of these customers would materially decrease our revenues if we were unable to replace such customers.

We are dependent on certain third-party suppliers.

We purchase the Trappsol® cyclodextrin products we sell from third-party suppliers and depend on those suppliers for the cyclodextrins we use in our Aquaplex® products. We are also dependent on outside manufacturers that use lyophilization techniques for our Aquaplex® products. We purchase substantially all of our Trappsol® products from bulk manufacturers and distributors in the U.S., Japan, China, and Europe. Although products are available from multiple sources, an unexpected interruption of supply, or material increases in the price of products, for any reason, such as regulatory requirements, import restrictions, loss of certifications, power interruptions, fires, hurricanes, war or other events could have a material adverse effect on our business, results of operations, financial condition and cash flows.

We may be negatively affected by currency exchange rate fluctuations.

Our earnings and cash flows are influenced by currency fluctuations due to the geographic diversity of our suppliers, which may have a significant impact on our financial results. As we buy inventory from foreign suppliers, the change in the value of the U.S. dollar in relation to the Euro, Yen and Yuan has an effect on our cost of inventory, and will continue to do so. We buy most of our products from outside the U.S. using U.S. dollars. Our main supplier of specialty cyclodextrins and complexes, Cyclodextrin Research & Development Laboratory, is located in Hungary and its prices are set in Euros. The cost of our bulk inventory often changes due to fluctuations in the U.S. dollar. These products currently represent a significant portion of our revenues. When we experience short-term increases in currency fluctuation or supplier price increases, we are often not able to raise our prices sufficiently to maintain our historical margins and therefore, our margins on these sales may decline. If the U.S. dollar weakens against foreign currencies, the translation of these foreign currency denominated transactions may adversely affect our results of operations and financial condition.

Risks Related To Our Common Stock

The market price of our Common Stock may be highly volatile, and you could lose all or part of your investment.

The trading price of our Common Stock and warrants is likely to be volatile. This volatility may prevent you from being able to sell your securities at or above the price you paid for your securities. Our stock price and warrant price could be subject to wide fluctuations in response to a variety of factors, which include:

- whether we achieve our anticipated corporate objectives;
- changes in financial or operational estimates or projections;
- termination of the lock-up agreement or other restrictions on the ability of our stockholders and other security holders to sell shares after this offering; and
- general economic or political conditions in the United States or elsewhere.

In addition, the stock market in general, and the stock of clinical stage biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our Common Stock, regardless of our actual operating performance.

If we are delisted from The Nasdaq Capital Market, and our shares become subject to the penny stock rules, it would become more difficult to trade our shares.

The SEC has adopted rules that regulate broker-dealer practices in connection with transactions in penny stocks. Penny stocks are generally equity securities with a price of less than $5.00, other than securities registered on certain national securities exchanges or authorized for quotation on certain automated quotation systems, provided that current price and volume information with respect to transactions in such securities is provided by the exchange or system. If we do not maintain a listing on Nasdaq and if the price of our Common Stock is less than $5.00, our Common Stock will be deemed a penny stock. The penny stock rules require a broker-dealer, before a transaction in a penny stock not otherwise exempt from those rules, to deliver a standardized risk disclosure document containing specified information. In addition, the penny stock rules require that before effecting any transaction in a penny stock not otherwise exempt from those rules, a broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive (i) the purchaser's written acknowledgment of the receipt of a risk disclosure statement; (ii) a written agreement to transactions involving penny stocks; and (iii) a signed and dated copy of a written suitability statement. These disclosure requirements may have the effect of reducing the trading activity in the secondary market for our Common Stock, and therefore stockholders may have difficulty selling their shares.

Our failure to meet the continued listing requirements of The Nasdaq Capital Market could result in a de-listing of our securities.

If we fail to satisfy the continued listing requirements of Nasdaq, such as the corporate governance requirements or the minimum closing bid price requirement, Nasdaq may take steps to de-list our securities. Such a de-listing would likely have a negative effect on the price of our Common Stock and would impair your ability to sell or purchase our Common Stock when you wish to do so. In the event of a de-listing, we would take actions to restore our compliance with Nasdaq's listing requirements, but we can provide no assurance that any such action taken by us would allow our Common Stock to become listed again, stabilize the market price or improve the liquidity of our securities, prevent our Common Stock from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with Nasdaq's listing requirements.

We will indemnify and hold harmless our officers and directors to the maximum extent permitted by Nevada law.

Our bylaws provide that we will indemnify and hold harmless our officers and directors against claims arising from our activities to the maximum extent permitted by Nevada law. If we were called upon to perform under our indemnification agreement, then the portion of our assets expended for such purpose would reduce the amount otherwise available for our business.

Because we do not expect to pay dividends for the foreseeable future, investors seeking cash dividends should not purchase shares of Common Stock.

We have never declared or paid any cash dividends on our Common Stock. We currently intend to retain future earnings, if any, to finance the expansion of our business. As a result, we do not anticipate paying any cash dividends in the foreseeable future. Our payment of any future dividends will be at the discretion of our Board of Directors after taking into account various factors, including but not limited to our financial condition, operating results, cash needs, growth plans and the terms of any credit agreements that we may be a party to at the time. Accordingly, investors seeking cash dividends should not purchase our shares.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 2. Properties.

We do not currently own any real property. In December 2016, we sold our office and manufacturing facility located in Alachua, Florida for $800,000 and entered into a lease with respect to 2,500 square feet of office and warehouse space located in Gainesville, Florida for $1,600 per month. On December 16, 2020, we entered into a new lease with respect to these premises for $1,650 month, for a term ending on January 31, 2023. This lease was renewed on January 12, 2023 for an additional three years ending January 31, 2026, with a three-year renewal option, for $1,700 per month. We believe that this leased property is currently sufficient for our operating requirements, and that we will be able to find alternative space suitable for our needs in the event we are unable to renew this lease upon its expiration.

Item 3. Legal Proceedings.

From time to time, we are a party to claims and legal proceedings arising in the ordinary course of business. Our management evaluates our exposure to these claims and proceedings individually and in the aggregate and allocates additional monies for potential losses on such litigation if it is possible to estimate the amount of loss and if the amount of the loss is probable. Other than as set forth above, we are not currently involved in any litigation nor to our knowledge, is any litigation threatened against us, the outcome of which would, in our judgment based on information currently available to us, have a material adverse effect on our financial position or results of operations.

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.

Our Common Stock and warrants are traded on the Nasdaq Capital Market under the symbols “CYTH” and “CYTHW” respectively.

Holders

As of March 10, 2023, the number of holders of record of shares of Common Stock, excluding the number of beneficial owners whose securities are held in street name, was approximately 160.

Dividend Policy

The Company paid no dividends in 2022 and will not pay any cash dividends on its Common Stock in 2023 because it intends to retain its earnings to finance the expansion of its business. Any future declaration of dividends will be determined by the Board of Directors in light of conditions then existing, including without limitation the Company's financial condition, capital requirements and business condition.

Item 6. Selected Financial Data

Not applicable.

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

*This Management's Discussion and Analysis of Financial Condition and Results of Operations, and other parts of this Annual Report on Form 10-K contain forward-looking statements that involve risks and uncertainties. All forward-looking statements included in this Annual Report are based on information available to us on the date hereof, and we assume no obligation to update any such forward-looking statements. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of a number of factors, including those set forth in the section captioned "**Risk Factors**" in this Annual Report. The following should be read in conjunction with our audited financial statements included elsewhere herein.*

Overview

We are a clinical stage biotechnology company that develops cyclodextrin-based products for the treatment of neurodegenerative diseases. We filed a Type II Drug Master File with the U.S. Food and Drug Administration ("FDA") in 2014 for our lead drug candidate, Trappsol® Cyclo™ (hydroxypropyl beta cyclodextrin) as a treatment for Niemann-Pick Type C disease ("NPC"). NPC is a rare and fatal autosomal recessive genetic disease resulting in disrupted cholesterol metabolism that impacts the brain, lungs, liver, spleen, and other organs. In 2015, we launched an International Clinical Program for Trappsol® Cyclo™ as a treatment for NPC. In 2016, we filed an Investigational New Drug application ("IND") with the FDA, which described our Phase I clinical plans for a randomized, double blind, parallel group study at a single clinical site in the U.S. The Phase I study evaluated the safety and pharmacokinetics of Trappsol® Cyclo™ along with markers of cholesterol metabolism and markers of NPC during a 12-week treatment period of intravenous administration of Trappsol® Cyclo™ every two weeks to participants 18 years of age and older. The IND was approved by the FDA in September 2016, and in January 2017 the FDA granted Fast Track designation to Trappsol® Cyclo™ for the treatment of NPC. Initial patient enrollment in the U.S. Phase I study commenced in September 2017, and in May 2020 we announced Top Line data showing a favorable safety and tolerability profile for Trappsol® Cyclo™ in this study.

We have also completed a Phase I/II clinical study approved by European regulatory bodies with clinical trial centers in the United Kingdom, Sweden, and in Israel. The Phase I/II study evaluated the safety, tolerability and efficacy of Trappsol® Cyclo™ through a range of clinical outcomes, including neurologic, respiratory, and measurements of cholesterol metabolism and markers of NPC. Consistent with the 12-week phase 1 study (single US site), the European/Israel study administered Trappsol® Cyclo™ intravenously to NPC patients every two weeks in a double-blind, randomized trial, but differs in that the study period was for 48 weeks (24 doses). In March of 2021 we announced that 100% of patients who completed the trial (9 out of 12) improved or remained stable, and 89% met the efficacy outcome measure of improvement in at least two domains of the 17-domain NPC severity scale.

Additionally, in February 2020 we had a face-to-face "Type C" meeting with the FDA with respect to the initiation of our pivotal Phase III clinical trial of Trappsol® Cyclo™ based on the clinical data obtained to date. At that meeting, we also discussed with the FDA submitting a New Drug Application (NDA) under Section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for the treatment of NPC in pediatric and adult patients with Trappsol® Cyclo™. A similar request was submitted to the European Medicines Agency ("EMA") in February 2020, seeking scientific advice and protocol assistance from the EMA for proceeding with a Phase III clinical trial in Europe. In October 2020 we received a "Study May Proceed" notification from the FDA with respect to the proposed Phase III clinical trial, and in June of 2021 we commenced enrollment in TransportNPC, a pivotal Phase III study of Trappsol® Cyclo™ for the treatment of NPC.

Preliminary data from our completed clinical studies suggest that Trappsol® Cyclo™ clears toxic deposits of cholesterol and other lipids from cells, has a consistent pharmacokinetic profile peripherally, and crosses the blood-brain-barrier in individuals suffering from NPC, and results in neurological and neurocognitive benefits and other clinical improvements in NPC patients. The full significance of these findings will be determined as part of the final analysis of data derived from our clinical trials (both completed and ongoing).

On May 17, 2010, the FDA designated Trappsol® Cyclo™ as an orphan drug for the treatment of NPC, which would provide us with the exclusive right to sell Trappsol® Cyclo™ for the treatment of NPC for seven years following FDA drug approval. In April 2015, we also obtained Orphan Drug Designation for Trappsol® Cyclo™ in Europe, which will provide us with 10 years of market exclusivity following regulatory approval, which period will be extended to 12 years upon acceptance by the EMA's Pediatric Committee of our pediatric investigation plan (PIP) demonstrating that Trappsol® Cyclo™ addresses the pediatric population. On January 12, 2017, we received Fast Track Designation from the FDA, and on December 1, 2017, the FDA designated NPC a Rare Pediatric Disease.

We are also exploring the use of cyclodextrins in the treatment of Alzheimer's disease. In January 2018, the FDA authorized a single patient IND expanded access program using Trappsol® Cyclo™ for the treatment of Alzheimer's disease. After 18 months of treatment in this geriatric patient with late-onset disease, the disease was stabilized and the drug was well tolerated. The patient also exhibited signs of improvement with less volatility and shorter latency in word-finding. We prepared a synopsis for an early stage protocol using Trappsol® Cyclo™ intravenously to treat Alzheimer's disease that was presented to the FDA in January of 2021. We received feedback from the FDA on this synopsis in April 2021 and incorporated the feedback into an IND for a Phase II study for the treatment of Alzheimer's disease with of Trappsol® Cyclo™ that we submitted to the FDA in November 2021. In December of 2021, we received IND clearance from the FDA, allowing us to proceed with our Phase II study of Trappsol® Cyclo™ for the treatment of Alzheimer's disease. U.S. sites for the study were activated during the second half of 2022, with patient dosing beginning in the first quarter of 2023.

We filed an international patent application in October 2019 under the Patent Cooperation Treaty directed to the treatment of Alzheimer's disease with cyclodextrins, and we are pursuing national and regional stage applications based on this international application. The terms of any patents resulting from these national or regional stage applications would be expected to expire in 2039 if all the requisite maintenance fees are paid.

We also continue to operate our legacy fine chemical business, consisting of the sale of cyclodextrins and related products to the pharmaceutical, nutritional, and other industries, primarily for use in diagnostics and specialty drugs. However, our core business has transitioned to a biotechnology company primarily focused on the development of cyclodextrin-based biopharmaceuticals for the treatment of disease from a business that had been primarily reselling basic cyclodextrin products.

Year Ended December 31, 2022 Compared to Year Ended December 31, 2021

For 2022, we incurred a net loss of approximately $15,451,000, compared to a net loss in 2021 of approximately $14,287,000. Total revenues for 2022 were approximately $1,376,000 compared to approximately $1,586,000 for 2021.

Our change in the mix of our product sales for 2022 and 2021 is as follows:

Trappsol® Cyclo™ HPBCDs
First and second-generation formulations of Trappsol® Cyclo™ HPBCD (in liquid and powder form) have been sold to a single customer who exports to Brazil for compassionate use in NPC patients. Sales increased 150% to approximately $5,000 for 2022 from approximately $2,000 for 2021. This product is designated as an orphan drug; the population of patients who use the product on a compassionate basis is small.

Trappsol® HPB
Our sales of Trappsol® HPB increased 26% to approximately $852,000 for 2022 from approximately $674,000 for 2021.

Trappsol® other products
Our sales of other Trappsol® products decreased 30% to approximately $501,000 for 2022 from approximately $715,000 for 2021.

Aquaplex®
Our sales of Aquaplex® decreased to approximately $5,000 for 2022 compared to approximately $185,000 for 2021, and are primarily attributable to a single customer. The decrease in sales is representative of the periodic purchasing pattern of our primary Aquaplex® customer. Aquaplex® sales to this customer for the last five years were approximately $5,000 in 2022, $185,000 in 2021, $7,000 in 2020, $150,000 in 2019, and $111,000 in 2018.

The largest customers of our legacy fine chemical business continue to follow historical product ordering trends to place periodic large orders that represent a significant share of our annual revenue volume. In 2022, our three largest customers (Charles River Laboratories, Inc., Ventana Medical Systems, Inc., and Uno Healthcare) accounted for 68% of our revenues, and the largest accounted for 35% of our revenues. In 2021, our four largest customers (Charles River Laboratories, Inc., Ventana Medical Systems, Inc., Sigma-Aldrich Fine Chemicals, Inc., and Uno Healthcare) accounted for 73% of our revenues, and the largest accounted for 30% of our revenues. Historically, our usual smaller sales of HPB occur more frequently throughout the year compared to our large sales that we receive periodically. The timing of when we receive and are able to complete these two kinds of sales has a significant effect on our quarterly revenues and operating results and makes period to period comparisons difficult.

Our cost of products sold decreased to approximately $139,000 for 2022 compared to approximately $156,000 for 2021. Our cost of products sold as a percentage of product sales was 10% for 2022 and 2021. This percentage is a function of the sales make up by product mix as well as customer order size. Historically, the timing and product mix of sales to our large customers has had a significant effect on our sales, cost of products sold and the related margin. We did not experience any significant increases in material costs during 2022 and 2021.

Our gross margins may not be comparable to those of other entities, since some entities include all the costs related to their distribution network in cost of goods sold. Our cost of goods sold includes only the direct cost of products sold and does not include any allocation of inbound or outbound freight charges, indirect overhead expenses, warehouse and distribution expenses, or depreciation and amortization expense. Our employees provide management, receiving, inspection, warehousing and shipping operations for us. The cost of our employees is included in personnel expense. Our other costs of warehousing and shipping functions are included in office and other expense.

As we buy inventory from foreign suppliers, the change in the value of the U.S. dollar in relation to the Euro, Yen and Yuan has an effect on our cost of inventory. Our main supplier of specialty cyclodextrins and complexes, Cyclodextrin Research & Development Laboratory, is located in Hungary and its prices are set in Euros. The cost of our bulk inventory often changes due to fluctuations in the U.S. dollar. The cost of shipping from outside the U.S. also has a significant effect on our inventory acquisition costs. When we experience short-term increases in currency fluctuation or supplier price increases, we are often not able to raise our prices sufficiently to maintain our historical margins. Therefore, our margins on these sales may decline.

Personnel expenses increased 3% to approximately $3,969,000 for 2022, from approximately $3,838,000 for 2021. The increase in personnel expense is due an increase in employee bonuses based on achievements of targets approved by our Board of Directors, and an increase in the cost of employee benefits. We expect to maintain our level of employees and related costs in the near term.

Research and development expenses decreased 2% to approximately $9,000,000 for 2022, from approximately $9,154,000 for 2021. The changes in research and development expenses relate to the timing of startup costs in our clinical programs. We expect research and development costs to increase in 2023 as we continue to seek regulatory approval for the use of Trappsol® Cyclo™ in the treatment of NPC and Alzheimer's disease.

Repairs and maintenance expenses remained consistent at approximately $11,000 for 2022 and 2021. We expect our repairs and maintenance expenses to remain consistent in 2023.

Professional fees increased 64% to approximately $2,417,000 for 2022 from approximately $1,475,000 for 2021. Professional fees increased due to increased legal and consulting fees. Professional fees may continue to increase in the future due to new initiatives in raising capital and the continuation of product development.

Office and other expenses decreased 3% to approximately $1,026,000 for 2022 from approximately $1,062,000 for 2021, primarily due to a decrease in insurance costs.

Board of Directors fees and costs increased to approximately $394,000 for 2022 from approximately $123,000 for 2021. Board of Directors fees and costs include fees paid to our directors and scientific advisory board members, reimbursement of expenses of our board members, and related expenses.

Amortization and depreciation increased to approximately $19,000 for 2022 from approximately $17,000 for 2021. These expenses fluctuate slightly with equipment purchases and dispositions.

Freight and shipping expenses were approximately $13,000 for 2022 compared to approximately $18,000 for 2021. Freight and shipping is dependent on frequency of ordering products for inventory and frequency of shipping out products sold.

We increased our valuation allowance to allow for 100% of the 2022 increase in our deferred tax asset and did not recognize an income tax benefit or provision for 2022 and 2021.

Liquidity and Capital Resources

Our cash decreased to approximately $1,543,000 as of December 31, 2022, compared to approximately $16,613,000 as of December 31, 2021, primarily as the result of our research and development costs, and other operating costs. Our current assets less current liabilities were approximately $678,000 as of December 31, 2022, compared to approximately $15,605,000 at December 31, 2021. Cash used in operations was approximately $15,114,000 for the year ended December 31, 2022, compared to approximately $15,005,000 for 2021. The cash used in operations is primarily attributable to our net loss and continued expenses for clinical trials of our drug candidates. To date, we have funded our operations primarily through public and private offerings of our securities.

We borrowed approximately $158,000 under the Paycheck Protection Program in May 2020. The loan was used to fund certain qualifying expenses as described in the CARES Act. The full amount of the loan plus accrued interest was forgiven in March 2022.

On November 19, 2021 we sold an aggregate of 1,950,000 units at a price to the public of $6.00 per unit (the "Public Offering"), each unit consisting of one share of our Common Stock, pursuant to an Underwriting Agreement we entered into with Maxim Group LLC ("Maxim"). We received gross proceeds of $11,700,000 upon the initial closing of the Public Offering, before deducting underwriting discounts and commissions of seven percent (7%), and expenses. The total expenses of the Public Offering were approximately $927,000 which included Maxim's expenses relating to the offering.

In addition, subsequent to the end of 2022, on January 3, 2023, we sold to an institutional investor in a registered direct offering 930,000 shares of our common stock at a purchase price per share of $1.61, and prefunded warrants to purchase up to an aggregate of 1,678,696 shares of common stock at a purchase price of $1.6099 per pre-funded warrant. The pre-funded warrants have an exercise price of $0.0001 per share and remain exercisable until exercised in full. The net proceeds from the registered direct offering were approximately $3.7 million after deducting fees due to the placement agent in the offering and our estimated expenses. In a concurrent private placement, we also issued to the institutional investor Series A-1 warrants to purchase up to 2,608,696 shares of common stock at an exercise price of $1.36 per share, exercisable for a period of five years from the date of issuance, and Series A-2 warrants to purchase up to 2,608,696 shares of common stock at an exercise price of $1.36 per share, exercisable for a period of three years from the date of issuance.

We have continued to realize losses from operations and will need to raise additional capital in the future to support our ongoing operations and continue our clinical trials. We expect to continue to raise additional capital through the sale of our securities from time to time for the foreseeable future to fund the development of our drug product candidates through clinical development, manufacturing and commercialization. Our ability to obtain such additional capital will likely be subject to various factors, including our overall business performance and market conditions. There can be no guarantee that the Company will be successful in its ability to raise capital to fund future operational and development initiatives.

Our consolidated financial statements for the years ended December 31, 2022 and 2021 were prepared on the basis of a going concern, which contemplates that we will be able to realize assets and discharge liabilities in the normal course of business. Our ability to continue as a going concern is dependent upon the availability of equity financing as noted above.

At December 31, 2022, we had approximately $42,395,000 in net state and federal operating loss carryforwards expiring from 2024 through 2037, including $33,997,000 that will not expire, that can be used to offset our current and future taxable net income and reduce our income tax liabilities. We have provided a 100% valuation allowance on our deferred tax asset based on our expected future expenses related to our clinical trials and other development initiatives.

We had no off-balance sheet arrangements as of December 31, 2022.

Critical Accounting Policies and Estimates

The results of operations are based on the preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States. The preparation of consolidated financial statements requires management to select accounting policies for critical accounting areas as well as make estimates and assumptions that affect the amounts reported in the consolidated financial statements. The Company's accounting policies are more fully described in Note 1 of Notes to Consolidated Financial Statements for our year ended December 31, 2022. Significant changes in assumptions and/or conditions in our critical accounting policies could materially impact the operating results. We have identified the following accounting policies and related judgments as critical to understanding the results of our operations.

Revenue Recognition

Revenues are recognized when our customer obtains control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. We recognize revenues following the five step model prescribed under ASU No. 2014-09: (i) identify contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenues when (or as) we satisfy the performance obligation.

Product Revenues

In the U.S. we sell our products to the end user or wholesale distributors. In other countries, we sell our products primarily to wholesale distributors and other third-party distribution partners. These customers subsequently resell our products to health care providers and patients.

Revenues from product sales are recognized when the customer obtains control of our product, which occurs at a point in time, typically upon delivery to the customer. We expense incremental costs of obtaining a contract as and when incurred if the expected amortization period of the asset that we would have recognized is one year or less or the amount is immaterial. We treat shipping and handling costs performed after a customer obtains control of the product as a fulfillment cost. We have identified one performance obligation in our contracts with customers which is the delivery of product to our customers. The transaction price is recognized in full when we deliver the product to our customer, which is the point at which we have satisfied our performance obligation.

Reserves for Discounts and Allowances

Revenues from product sales are recorded net of reserves established for applicable discounts and allowances that are offered within contracts with our customers, health care providers or payors, including those associated with the implementation of pricing actions in certain of the international markets in which we operate. Our process for estimating reserves established for these variable consideration components do not differ materially from our historical practices.

Product revenue reserves, which are classified as a reduction in product revenues, are generally characterized in the following categories: discounts, contractual adjustments and returns. These reserves are based on estimates of the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable (if the amount is payable to our customer) or a liability (if the amount is payable to a party other than our customer). Our estimates of reserves established for variable consideration typically utilize the most likely method and reflect our historical experience, current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns. The transaction price, which includes variable consideration reflecting the impact of discounts and allowances, may be subject to constraint and is included in the net sales price only to the extent that it is probable that a significant reversal of the amount of the cumulative revenues recognized will not occur in a future period. Actual amounts may ultimately differ from our estimates. If actual results vary, we adjust these estimates, which could have an effect on earnings in the period of adjustment.

Valuation Allowance on Deferred Tax Assets

At December 31, 2022, we fully reserved for our net deferred tax asset with an approximately $23,167,000 valuation allowance. We increased our valuation allowance by approximately $5,464,000 in 2022 to reduce our recognized deferred tax asset to zero.

We have determined it is more likely than not that we will not realize our temporary deductible differences and net operating loss carryforwards, and we have provided a 100% valuation allowance at December 31, 2022.

Current accounting standards require that deferred tax assets be evaluated for future realization and reduced by the extent to which we believe a portion will not be realized. We consider many factors when assessing the likelihood of future realization of our deferred tax assets including our recent cumulative earnings (loss) experience, expectations of future expenses from research and development and product development, expectations of future taxable income, the carry-forward periods available to us for tax reporting purposes, and other relevant factors. The range of possible judgments relating to the valuation of our deferred tax asset is very wide. Significant judgment is required in making this assessment, and it is very difficult to predict when, if ever, our assessment may conclude our deferred tax assets are realizable.

Research and Development

The Company's research and development activities and expenses are related to our International Clinical Trial Program. We expense our research and development costs as incurred.

Stock Based Compensation

The value we assign to the options that we issue is based on the fair market value as calculated by the Black-Scholes pricing model. To perform a calculation of the value of our options, we determine an estimate of the volatility of our stock. We need to estimate volatility because there has not been enough trading of our stock to determine an appropriate measure of volatility. We believe our estimate of volatility is reasonable, and we review the assumptions used to determine this whenever we issue new equity instruments. If we have a material error in our estimate of the volatility of our stock, our expenses could be understated or overstated. All stock-based awards are expensed on a straight-line basis over the vesting period of the options.

Forward-looking Statements

This Annual Report on Form 10-K contains forward-looking statements that reflect our current expectations about our future results, performance, prospects and opportunities. These forward-looking statements are subject to significant risks, uncertainties, and other factors, including those identified in "Risk Factors" above, which may cause actual results to differ materially from those expressed in, or implied by, any forward-looking statements. The forward-looking statements within this Form 10-K may be identified by words such as "believes," "anticipates," "expects," "intends," "may," "would," "will" and other similar expressions. However, these words are not the exclusive means of identifying these statements. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances are forward-looking statements. Except as expressly required by the federal securities laws, we undertake no obligation to publicly update or revise any forward-looking statements to reflect events or circumstances occurring subsequent to the filing of this Form 10-K with the SEC or for any other reason. You should carefully review and consider the various disclosures we make in this report and our other reports filed with the SEC that attempt to advise interested parties of the risks, uncertainties and other factors that may affect our business.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Not applicable.

Item 8. Financial Statements and Supplementary Data.

CYCLO THERAPEUTICS, INC. AND SUBSIDIARY
CONSOLIDATED FINANCIAL STATEMENTS

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders
Cyclo Therapeutics, Inc**.**

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Cyclo Therapeutics, Inc. and Subsidiary, (the “Company”) as of December 31, 2022 and 2021, and the related consolidated statements of operations, stockholders’ equity, and cash flows for each of the years in the two-year period ended December 31, 2022, and the related consolidated notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2022, in conformity with accounting principles generally accepted in the United States of America.

Substantial Doubt Regarding Going Concern

The accompanying consolidated financial statements have been prepared assuming that the entity will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the entity has suffered recurring losses from operations, has experienced cash used from operations in excess of its current cash position, and has an accumulated deficit, that raise substantial doubt about its ability to continue as a going concern. Management’s plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. Our opinion is not modified with respect to this matter.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on these consolidated 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 audits to obtain reasonable assurance about whether the consolidated 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 consolidated 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 consolidated 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 consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

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

Research and Development Expenses, Accrued Clinical Trial Liabilities, and Prepaid Research and Development Costs

Description of the Matter

The Company recognizes research and development expenses as incurred. Advance payments for future research and development activities are deferred and expensed as the related services are performed. The Company recognizes its clinical trial expenses based on the services performed pursuant to contracts with research institutions and clinical research organizations (collectively, "CROs") that conduct and manage clinical trials on the Company's behalf. Total research and development expenses for the year ended December 31, 2022 was approximately $9,000,000. Prepaid clinical expenses as of December 31, 2022 was approximately $2,205,000 and the clinical trial liabilities included in accounts payable and accrued expenses as of December 31, 2022 was approximately $1,239,000.

At each balance sheet date, the Company reconciles prepaid research and development costs and accrued clinical trial liabilities by obtaining reporting from CROs, discussing progress or stage of completion of services with internal personnel and external service providers, and comparing this information to payments made, invoices received, and the agreed-upon fee to be paid for such services in the applicable contract, statements of work, or purchase orders. The reconciliation of the amount of work completed is primarily based on the status and timing of services performed, the number of patients enrolled, and the rate of patient enrollment.

We identified research and development expenses, accrued clinical trial liability, and prepaid research and development costs as a critical audit matter given the estimation involved in accounting for research and development expenses, accrued clinical trial liabilities, and prepaid research and development costs. This required extensive audit effort related to the estimation of research and development expenses, accrued clinical trial liabilities and prepaid clinical expenses.

How We Addressed the Matter in Our Audit

Our audit procedures related to research and development expenses, accrued clinical trial liabilities and prepaid clinical expenses included the following, among others:

- We selected a sample of amounts recognized as research and development expense, the accrued clinical trial liability and prepaid research development expenses and performed the following procedures for each item selected:
    - We obtained and read related master service agreements, statements of work, purchase orders or other supporting agreements with the CRO.
    - We performed corroborating inquiries with the Company's clinical operations personnel responsible for the oversight of the activities regarding the nature and status of work performed.
    - We inspected evidence from the third-party vendor regarding the payments made and the status and timing of services performed.
    - We compared the data and evidence obtained from internal and external sources to the inputs used in the Company's analysis and recalculated the related research and development expense, prepaid research and development expense, and the accrued clinical liability balances.
    - We tested the completeness and accuracy of the underlying data.
    - We physically observed the Company's clinical trial materials located at a third-party logistics location.

We have served as the Company's auditor since 2011.

/s/ WithumSmith+Brown, PC

East Brunswick, New Jersey
March 17, 2023

PCAOB ID Number 100

CYCLO THERAPEUTICS, INC. AND SUBSIDIARY
CONSOLIDATED BALANCE SHEETS

	December 31, 2022	December 31, 2021
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 1,543,418	$ 16,612,711
Accounts receivable, net	54,991	493,113
Inventory, net	254,491	227,437
Current portion of mortgage note receivable	-	45,977
Prepaid insurance and services	101,135	42,246
Prepaid clinical expenses	2,204,520	2,014,851
Total current assets	4,158,555	19,436,335
FURNITURE AND EQUIPMENT, NET	55,188	59,583
RIGHT-TO-USE LEASE ASSET, NET	1,470	17,636
MORTGAGE NOTE RECEIVABLE, LESS CURRENT PORTION	-	7,279
TOTAL ASSETS	$ 4,215,213	$ 19,520,833
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Current portion of lease liability	$ -	$ 19,245
Current portion of note payable	-	133,712
Accounts payable and accrued expenses	3,480,669	3,677,979
Total current liabilities	3,480,669	3,830,936
LONG-TERM LIABILITIES		
Long-term note payable, less current portion	-	18,034
STOCKHOLDERS' EQUITY		
Common stock, par value $.0001 per share, 20,000,000 shares authorized, 8,481,848 and 8,403,869 shares issued and outstanding at December 31, 2022 and 2021, respectively	849	841
Preferred stock, par value $.0001 per share, 5,000,000 shares authorized, 0 outstanding	-	-
Additional paid-in capital	64,533,074	64,019,513
Accumulated deficit	(63,799,379)	(48,348,491)
Total stockholders' equity	734,544	15,671,863
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 4,215,213	$ 19,520,833

See accompanying Notes to Consolidated Financial Statements.

CYCLO THERAPEUTICS, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended December 31,	
	2022	**2021**
REVENUES		
Product sales	$ 1,375,760	$ 1,585,756
EXPENSES		
Personnel	3,968,681	3,838,477
Cost of products sold (exclusive of direct and indirect overhead and handling costs)	138,929	156,080
Research and development	8,999,543	9,153,780
Repairs and maintenance	11,019	10,708
Professional fees	2,417,017	1,474,911
Office and other	1,025,635	1,061,937
Board of Directors fees and costs	394,009	122,833
Depreciation	19,481	16,827
Freight and shipping	13,060	18,336
Bad debt expense	10,272	21,927
Total operating expenses	16,997,646	15,875,816
LOSS FROM OPERATIONS	(15,621,886)	(14,290,060)
OTHER INCOME		
Investment and other income, net	12,474	(3,405)
Gain on forgiveness of PPP loan	158,524	-
LOSS BEFORE PROVISION FOR INCOME TAXES	(15,450,888)	(14,286,655)
PROVISION FOR INCOME TAXES	-	-
NET LOSS	$ (15,450,888)	$ (14,286,655)
BASIC AND DILUTED NET LOSS PER COMMON SHARE	$ (1.83)	$ (2.24)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING	8,439,177	6,370,073

See accompanying Notes to Consolidated Financial Statements.

CYCLO THERAPEUTICS, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
YEARS ENDED DECEMBER 31, 2022 AND 2021

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par Value			
Balance, December 31, 2020	4,770,761	477	44,513,841	(34,061,836)	10,452,482
Stock issued to employees	70,991	7	396,299	-	396,306
Stock issued to nonemployees	10,000	1	50,299	-	50,300
Exercise of warrants, net	1,602,117	161	7,990,940	-	7,991,101
Stock based compensation	-	-	295,578	-	295,578
Sale of common stock, net of issuance fees	1,950,000	195	10,772,556	-	10,772,751
Net loss	-	-	-	(14,286,655)	(14,286,655)
Balance, December 31, 2021	8,403,869	841	64,019,513	(48,348,491)	15,671,863
Stock issued to employees	7,500	-	15,750		15,750
Stock issued to nonemployees	70,479	8	143,755		143,763
Stock based compensation	-	-	354,056		354,056
Net loss				(15,450,888)	(15,450,888)
Balance, December 31, 2022	8,481,848	$ 849	$ 64,533,074	$ (63,799,379)	$ 734,544

See accompanying Notes to Consolidated Financial Statements.

CYCLO THERAPEUTICS, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended December 31,	
	2022	**2021**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (15,450,888)	$ (14,286,655)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	19,481	16,827
Gain on forgiveness of PPP loan	(158,524)	-
Provision for doubtful accounts	10,272	21,927
Stock compensation to employees	15,750	124,998
Stock compensation to nonemployees	143,763	50,300
Stock-based compensation	354,056	295,578
Increase or decrease in:		
Accounts receivable, net	427,850	(444,023)
Inventory, net	(27,054)	10,472
Prepaid clinical expenses	(189,669)	(1,286,899)
Prepaid insurance and services	(58,889)	84,228
Other	-	(297)
Accounts payable and accrued expenses	(200,389)	408,246
Total adjustments	336,647	(718,643)
NET CASH USED IN OPERATING ACTIVITIES	(15,114,241)	(15,005,298)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of furniture and equipment	(15,086)	(22,500)
Collections from mortgage note receivable	53,256	37,322
NET CASH PROVIDED BY INVESTING ACTIVITIES	38,170	14,822
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from sale of common stock and warrants, net of issuance costs	-	18,763,852
Payments on PPP loan	(8,159)	(6,778)
Refund of PPP loan payments	14,937	-
NET CASH PROVIDED BY FINANCING ACTIVITIES	6,778	18,757,074
NET INCREASE / (DECREASE) IN CASH AND CASH EQUIVALENTS	(15,069,293)	3,766,598
CASH AND CASH EQUIVALENTS, beginning of year	16,612,711	12,846,113
CASH AND CASH EQUIVALENTS, end of year	$ 1,543,418	$ 16,612,711
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION		
Cash paid for interest	$ -	$ 3,525
SUPPLEMENTAL DISCLOSURE OF NON-CASH INVESTING AND FINANCING ACTIVITIES		
Issuance of common stock for services	$ 159,513	$ 446,606

See accompanying Notes to Consolidated Financial Statements

(1) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:

The following is a summary of the more significant accounting policies of Cyclo Therapeutics, Inc. (the "Company," "we," "our" or "us") that affect the accompanying consolidated financial statements:

(a) ORGANIZATION AND OPERATIONS—The Company was incorporated in August 1990 as a Florida corporation, under the name Cyclodextrin Technologies Development, Inc. with operations beginning in July 1992. In conjunction with a restructuring in 2000, we changed our name to CTD Holdings, Inc. We changed our name to Cyclo Therapeutics, Inc. in September 2019 to better reflect our current business and on November 6, 2020, we reincorporated from the State of Florida to the State of Nevada.

We are a clinical stage biotechnology company that develops cyclodextrin-based products for the treatment of neurodegenerative diseases. We filed a Type II Drug Master File with the U.S. Food and Drug Administration ("FDA") in 2014 for our lead drug candidate, Trappsol® Cyclo™ (hydroxypropyl beta cyclodextrin) as a treatment for Niemann-Pick Type C disease ("NPC"). NPC is a rare and fatal autosomal recessive genetic disease resulting in disrupted cholesterol metabolism that impacts the brain, lungs, liver, spleen, and other organs. In 2015, we launched an International Clinical Program for Trappsol® Cyclo™ as a treatment for NPC. In 2016, we filed an Investigational New Drug application ("IND") with the FDA, which described our Phase I clinical plans for a randomized, double blind, parallel group study at a single clinical site in the U.S. The Phase I study evaluated the safety and pharmacokinetics of Trappsol® Cyclo™ along with markers of cholesterol metabolism and markers of NPC during a 12-week treatment period of intravenous administration of Trappsol® Cyclo™ every two weeks to participants 18 years of age and older. The IND was approved by the FDA in September 2016, and in January 2017 the FDA granted Fast Track designation to Trappsol® Cyclo™ for the treatment of NPC. Initial patient enrollment in the U.S. Phase I study commenced in September 2017, and in May 2020 we announced Top Line data showing a favorable safety and tolerability profile for Trappsol® Cyclo™ in this study.

We have also completed a Phase I/II clinical study approved by European regulatory bodies with clinical trial centers in the United Kingdom, Sweden, and in Israel. The Phase I/II study evaluated the safety, tolerability and efficacy of Trappsol® Cyclo™ through a range of clinical outcomes, including neurologic, respiratory, and measurements of cholesterol metabolism and markers of NPC. Consistent with the 12-week phase 1 study (single US site), the European/Israel study administered Trappsol® Cyclo™ intravenously to NPC patients every two weeks in a double-blind, randomized trial, but differs in that the study period was for 48 weeks (24 doses). In March of 2021 we announced that 100% of patients who completed the trial (9 out of 12) improved or remained stable, and 89% met the efficacy outcome measure of improvement in at least two domains of the 17-domain NPC severity scale.

Additionally, in February 2020 we had a face-to-face "Type C" meeting with the FDA with respect to the initiation of our pivotal Phase III clinical trial of Trappsol® Cyclo™ based on the clinical data obtained to date. At that meeting, we also discussed with the FDA submitting a New Drug Application (NDA) under Section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for the treatment of NPC in pediatric and adult patients with Trappsol® Cyclo™. A similar request was submitted to the European Medicines Agency ("EMA") in February 2020, seeking scientific advice and protocol assistance from the EMA for proceeding with a Phase III clinical trial in Europe. In October 2020 we received a "Study May Proceed" notification from the FDA with respect to the proposed Phase III clinical trial, and in June of 2021 we commenced enrollment in TransportNPC, a pivotal Phase III study of Trappsol® Cyclo™ for the treatment of NPC.

We are also exploring the use of cyclodextrins in the treatment of Alzheimer's disease. In January 2018, the FDA authorized a single patient IND expanded access program using Trappsol® Cyclo™ for the treatment of Alzheimer's disease. After 18 months of treatment in this geriatric patient with late-onset disease, the disease was stabilized and the drug was well tolerated. The patient also exhibited signs of improvement with less volatility and shorter latency in word-finding. We prepared a synopsis for an early stage protocol using Trappsol® Cyclo™ intravenously to treat Alzheimer's disease that was presented to the FDA in January of 2021. We received feedback from the FDA on this synopsis in April 2021 and incorporated the feedback into an IND for a Phase II study for the treatment of Alzheimer's disease with of Trappsol® Cyclo™ that we submitted to the FDA in November 2021. In December of 2021, we received IND clearance from the FDA, allowing us to proceed with our Phase II study of Trappsol® Cyclo™ for the treatment of Alzheimer's disease. U.S. sites for the study were activated during the second half of 2022, with patient dosing beginning in the first quarter of 2023.

(1) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES: (CONTINUED)

We also continue to operate our legacy fine chemical business, consisting of the sale of cyclodextrins and related products to the pharmaceutical, nutritional, and other industries, primarily for use in diagnostics and specialty drugs. However, our core business has transitioned to a biotechnology company primarily focused on the development of cyclodextrin-based biopharmaceuticals for the treatment of disease from a business that had been primarily reselling basic cyclodextrin products.

(b) BASIS OF PRESENTATION—The consolidated financial statements include the Company and its wholly owned subsidiary. All significant intercompany accounts and transactions have been eliminated in consolidation.

(c) CASH AND CASH EQUIVALENTS—Cash and cash equivalents consist of cash and any highly liquid investments with an original purchased maturity of three months or less.

(d) ACCOUNTS RECEIVABLE—Accounts receivable are unsecured and non-interest bearing and stated at the amount we expect to collect from outstanding balances. Customer account balances with invoices dated over 90 days old are considered past due. The Company does not accrue interest on past due accounts. Customer payments are allocated to the specific invoices identified on the customer's remittance advice or, if unspecified, applied to the oldest unpaid invoices. Accounts receivable at January 1, 2021 was approximately $ 71,000 .

The carrying amount of accounts receivable are reduced by an allowance for credit losses that reflects management's best estimate of the amounts that will not be collected. The Company reviews each customer balance where all or a portion of the balance exceeds 90 days from the invoice date. Based on the Company's assessment of the customer's current creditworthiness, the Company estimates the portion, if any, of the balance that will not be collected, and writes off receivables as a charge to the allowance for credit losses when, in management's estimation, it is probable that the receivable is worthless. The Company has estimated an allowance for doubtful accounts of $ 10,300 and $ 21,800 at December 31, 2022 and 2021, respectively.

(e) INVENTORY AND COST OF PRODUCTS SOLD—Inventory consists of our pharmaceutical drug Trappsol® Cyclo™, cyclodextrin products and chemical complexes purchased for resale recorded at the lower of cost (first-in, first-out) or net realizable value. Cost of products sold includes the acquisition cost of the products sold and does not include any allocation of inbound or outbound freight charges, indirect overhead expenses, warehouse and distribution expenses, or depreciation and amortization expense. The Company records a specific reserve for inventory items that are determined to be obsolete. The reserve for obsolete inventory was approximately $ 52,900 at December 31, 2022 and 2021.

The Company's reserve for obsolete inventory is based on the Company's best estimates of product sales and customer demands. It is reasonably possible that the estimates used by the Company to determine its provisions for inventory write-downs will be materially different from actual write-downs. These differences could result in materially higher than expected inventory provisions and related costs, which could have a materially adverse effect on the Company's results of operations and financial condition in the near term.

(f) PREPAID CLINICAL EXPENSES—Prepaid clinical expenses consist of our pharmaceutical drug Trappsol® Cyclo™ expected to be used in our clinical trial program recorded at cost. In addition, advance payments for goods or services for future research and development activities are included as prepaid clinical expenses. Prepaid clinical expenses are expensed as research and development costs as the goods are delivered or the related services are performed.

(g) MORTGAGE NOTE RECEIVABLE—The mortgage note receivable is stated at amortized value, which is the amount we expect to collect. The mortgage note receivable was paid in full as of December 31, 2022

(h) FURNITURE AND EQUIPMENT—Furniture and equipment are recorded at cost, less accumulated depreciation. Depreciation is computed using primarily the straight-line method over the estimated useful lives of the assets (generally three to five years for computers and vehicles and seven to ten years for machinery, equipment and office furniture). We periodically review our long-lived assets to determine if the carrying value of assets may not be recoverable. If an impairment is identified, we recognize a loss for the difference between the carrying amount and the estimated fair value of the asset.

(1) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES: (CONTINUED)

(i) REVENUE RECOGNITION—Revenues are recognized when our customer obtains control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. We recognize revenues following the five step model prescribed under Accounting Standard Update ("ASU") No. 2014-09: (i) identify contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenues when (or as) we satisfy the performance obligation.

Product revenues
In the U.S. we sell our products to the end user or wholesale distributors. In other countries, we sell our products primarily to wholesale distributors and other third-party distribution partners. These customers subsequently resell our products to health care providers and patients.

Revenues from product sales are recognized when the customer obtains control of our product, which occurs at a point in time, typically upon delivery to the customer. We expense incremental costs of obtaining a contract as and when incurred if the expected amortization period of the asset that we would have recognized is one year or less or the amount is immaterial. We treat shipping and handling costs performed after a customer obtains control of the product as a fulfillment cost. We have identified one performance obligation in our contracts with customers which is the delivery of product to our customers. The transaction price is recognized in full when we deliver the product to our customer, which is the point at which we have satisfied our performance obligation.

Reserves for Discounts and Allowances
Revenues from product sales are recorded net of reserves established for applicable discounts and allowances that are offered within contracts with our customers, health care providers or payors, including those associated with the implementation of pricing actions in certain of the international markets in which we operate. Our process for estimating reserves established for these variable consideration components do not differ materially from our historical practices.

Product revenue reserves, which are classified as a reduction in product revenues, are generally characterized in the following categories: discounts, contractual adjustments and returns. These reserves are based on estimates of the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable (if the amount is payable to our customer) or a liability (if the amount is payable to a party other than our customer). Our estimates of reserves established for variable consideration typically utilize the most likely method and reflect our historical experience, current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns. The transaction price, which includes variable consideration reflecting the impact of discounts and allowances, may be subject to constraint and is included in the net sales price only to the extent that it is probable that a significant reversal of the amount of the cumulative revenues recognized will not occur in a future period. Actual amounts may ultimately differ from our estimates. If actual results vary, we adjust these estimates, which could have an effect on earnings in the period of adjustment.

For additional information on our revenues, please read Note 2, Revenues, to these consolidated financial statements.

(j) SHIPPING AND HANDLING FEES—Shipping and handling fees, if billed to customers, are included in product sales. Shipping and handling costs associated with inbound and outbound freight are expensed as incurred and included in freight and shipping expense.

(k) ADVERTISING—Advertising costs are charged to operations when incurred. We incur minimal advertising expenses.

(l) RESEARCH AND DEVELOPMENT COSTS— In addition, advance payments for goods or services for future research and development activities are included as prepaid clinical expenses. Prepaid clinical expenses are expensed as research and development costs as the goods are delivered or the related services are performed.

(1) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES: (CONTINUED)

(m) INCOME TAXES—Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective income tax bases. Deferred tax assets and liabilities are measured using enacted rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. In addition,
tax benefits related to positions considered uncertain are recognized only when it is more likely than not the position will be sustained upon examination by the tax authorities. Such tax positions shall initially and subsequently be measured as the largest amount of tax benefit that has a greater than 50% likelihood of being realized upon ultimate settlement with the tax authority assuming full knowledge of the position and relevant facts. As of December 31, 2022 and 2021, the Company has recorded a full valuation allowance against its deferred tax assets.

(n) NET LOSS PER COMMON SHARE—Basic and fully diluted net loss per common share is computed using a simple weighted average of common shares outstanding during the periods presented, as outstanding warrants to purchase 2,045,846 and 2,048,186 common shares were antidilutive for 2022 and 2021, respectively, and outstanding stock options outstanding to purchase 425,646 and 222,700 common shares were antidilutive for the years ended December 31, 2022 and 2021, respectively.

(o) STOCK BASED COMPENSATION— The Company periodically awards stock to employees, directors, and consultants. In the case of employees and consultants, an expense is recognized equal to the fair value of the stock determined using the closing trading price of the stock on the award date. With respect to directors, the Company accrues stock compensation expense on a quarterly basis based on the Company's historical director compensation policies, and each quarter recognizes such expense based on the trading price of the common stock during such quarter. This expense is then trued up at the time the shares are issued to directors based on the trading price at the time of issuance.

The Company periodically issues stock options under its 2021 Equity Incentive Plan. The Company uses the Black-Scholes valuation method to estimate the fair value of stock options at grant date. Compensation expense is recognized on the straight-line basis over the requisite service period, which is generally the vesting period.

(p) FAIR VALUE MEASUREMENTS AND DISCLOSURES—The Fair Value Measurements and Disclosures topic of the Accounting Standards Codification ("ASC") (Topic 820) requires companies to determine fair value based on the price that would be received to sell the asset or paid to transfer the liability to a market participant. The Fair Value Measurements and Disclosures topic emphasizes that fair value is a market-based measurement, not an entity-specific measurement.

The guidance requires that assets and liabilities carried at fair value be classified and disclosed in one of the following categories:

- Level 1: Quoted market prices in active markets for identical assets or liabilities.
- Level 2: Observable market based inputs or unobservable inputs that are corroborated by market data.
- Level 3: Unobservable inputs that are not corroborated by market data.

We have no assets or liabilities that are required to have their fair value measured on a recurring basis at December 31, 2022 or 2021. Long-lived assets are measured at fair value on a non-recurring basis and are subject to fair value adjustments when there is evidence of impairment.

For short-term classes of our financial instruments, which include cash and cash equivalents, accounts receivable and accounts payable, and which are not reported at fair value, the carrying amounts approximate fair value due to their short-term nature. The fair value of the mortgage note receivable is estimated based on the present value of the underlying cash flows discounted at current rates. At December 31, 2022 the mortgage note receivable was paid in full. At December 31, 2021, the carrying value of the mortgage note receivable approximated fair value.

(1) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES: (CONTINUED)

(q) USE OF ESTIMATES—The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. The Company's most significant estimate relates to inventory obsolescence and deferred tax valuation allowance. Although management bases its estimates on historical experience and assumptions that are believed to be reasonable under the circumstances, actual results could significantly differ from these estimates.

(r) RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS— In June 2016, the FASB issued ASU 2016- 13, Financial Instruments – Credit Losses (Topic 326), which provides guidance on how an entity should measure credit losses on financial instruments. The ASU is effective for smaller reporting companies for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. The Company does not expect this ASU to have a material impact on its consolidated financial statements.

(s) WARRANTS— The Company accounts for its warrants as either equity-classified or liability-classified instruments based on an assessment of the specific terms of the warrants considering the authoritative guidance in ASC 480 , "Distinguishing Liabilities from Equity" ("ASC 480") and ASC 815 , "Derivatives and Hedging" ("ASC 815"). The assessment considers whether the warrants meet the definition of a liability pursuant to ASC 480 , and 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 satisfy additional conditions for equity classification. Warrants that are liability-classified are measured at fair value at each reporting date in accordance with the guidance in ASC 820 , "Fair Value Measurement," with any subsequent changes in fair value recognized in the statement of operations in the period of change. The fair value of liability classified warrants was not material at December 31, 2022 and 2021 .

(t) LIQUIDITY AND GOING CONCERN—For the years ended December 31, 2022 and 2021, the Company incurred net losses of $ 15,450,888 and $ 14,286,655 , respectively. The Company has an accumulated deficit of $ 63,799,379 at December 31, 2022. Our recent losses have predominantly resulted from research and development expenses for our Trappsol® Cyclo™ product and other general operating expenses, including personnel expenses and board advisory fees. We believe our expenses will continue to increase as we continue to conduct clinical trials and seek regulatory approval for the use of Trappsol® Cyclo™ in the treatment of NPC and Alzheimer's disease.

For the year ended December 31, 2022, the Company's operations used $ 15,114,241 in cash, and at December 31, 2022, the Company had a cash balance of $ 1,543,418 and current assets less current liabilities of $ 677,886 . We will need to raise additional capital for the foreseeable future to fund the development of our drug product candidates through clinical development, manufacturing and commercialization. As further discussed in Note 17, subsequent to year end, the Company generated net proceeds of approximately $ 3.7 million from the sale of securities to an institutional investor in a registered direct offering and concurrent private placement of the Company's securities.

We intend to continue to raise such capital through the sale of equity securities from time to time, the issuance of debt securities, the sale or licensing of existing assets or assets in development, or from other non-dilutive funding mechanisms. Our ability to obtain such additional capital will likely be subject to various factors, including our overall business performance and market conditions. If we cannot raise the additional funds required for our anticipated operations, we may be required to reduce the scope of or eliminate our research and development programs, delay our clinical trials and the ability to seek regulatory approvals, downsize our general and administrative infrastructure, or seek alternative measures to avoid insolvency. If we raise additional funds through future offerings of shares of our Common Stock or other securities, such offerings would cause dilution of current stockholders' percentage ownership in the Company, which could be substantial. Future offerings also could have a material and adverse effect on the price of our Common Stock.

Our consolidated financial statements for the years ended December 31, 2022 and 2021 were prepared on the basis of a going concern, which contemplates that we will be able to realize assets and discharge liabilities in the normal course of business. Our ability to continue as a going concern is dependent upon the availability of equity financing as noted above. These factors raise substantial doubt about our ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of these uncertainties.

(2) REVENUES:

The Company operates in one business segment, which primarily focuses on the development and commercialization of innovative cyclodextrin-based products for the treatment of people with serious and life threatening rare diseases and medical conditions. However, substantially all of the Company's revenues are derived from the sale of cyclodextrins and related products to the pharmaceutical, nutritional, and other industries, primarily for use in diagnostics and specialty drugs. Currently, a small portion of the Company's revenues is generated by sales of Trappsol® Cyclo™ to South America (Brazil) for the treatment of NPC patients.

The Company considers there to be revenue concentration risks for regions where net product revenues exceed 10% of consolidated net product revenues. The concentration of the Company's net product revenues within the regions below may have a material adverse effect on the Company's revenues and results of operations if sales in the respective regions experience difficulties.

Revenues by product are summarized as follows:

	Year Ended December 31,	
	2022	2021
Trappsol® Cyclo™	$ 5,118	$ 2,245
Trappsol® HPB	851,756	673,916
Trappsol® Fine Chemical	501,295	714,662
Aquaplex®	5,460	185,004
Other	12,131	9,929
Total revenues	$ 1,375,760	$ 1,585,756

Substantially all of our sales of Trappsol® Cyclo™ for the years ended December 31, 2022 and 2021 were to a single customer who exports the drug to South America. Substantially all of our Aquaplex® sales are to one customer.

(3) MAJOR CUSTOMERS AND SUPPLIERS:

Our revenues are derived primarily from chemical supply and pharmaceutical companies located primarily in the United States. In 2022, three major customers accounted for 68 % of total revenues. Accounts receivable balances for these major customers represent 19 % of total accounts receivable at December 31, 2022. Accounts receivable balances for three customers accounted for 94 % of total accounts receivable at December 31, 2022. In 2021, four major customers accounted for 73 % of total revenues. Accounts receivable balances for these major customers represent 94 % of total accounts receivable at December 31, 2021.

Substantially all inventory purchases were from three vendors in 2022 and 2021. These vendors are located primarily outside the United States.

We have three sources for our Aquaplex® products. There are multiple sources for our Trappsol® products.

For the year ended December 31, 2022, the product mix of our revenues consisted of 99 % basic natural and chemically modified cyclodextrins and 1 % cyclodextrin complexes. For the year ended December 31, 2021, the product mix of our revenues consisted of 88 % basic natural and chemically modified cyclodextrins and 12 % cyclodextrin complexes.

(4) MORTGAGE NOTE RECEIVABLE:

On January 21, 2016, the Company sold its real property located in High Springs, Florida to an unrelated party. Pursuant to the terms of the sale, at the closing, the buyer paid $ 10,000 in cash, less selling costs and settlement charges, and delivered to the Company a promissory note in the principal amount of $ 265,000 , and a mortgage in our favor securing the buyer's obligations under the promissory note. The promissory note provides for monthly payments of $ 3,653 , including principal and interest at 4.25 %, over a seven-year period that commenced March 1, 2016, with the unpaid balance due in February 2023. In August 2022, the buyer paid the remaining balance in full.

(5) CONCENTRATIONS OF CREDIT RISK:

Significant concentrations of credit risk for all financial instruments owned by the Company are as follows:

DEMAND DEPOSITS—We maintain bank accounts in Federal credit unions and other financial institutions, which are insured up to the Federal Deposit Insurance Corporation limits of $250,000. The bank accounts may exceed federally insured levels.

The Company does not any off-balance sheet concentrations of credit risk, such as foreign currency exchange contracts, option contracts or other hedging arrangements.

(6) FURNITURE AND EQUIPMENT:

Furniture and equipment consists of the following as of December 31:

	2022	2021
Machinery and equipment	$ 75,137	$ 67,151
Office furniture	81,590	74,490
	156,727	141,641
Less: accumulated depreciation	101,539	82,058
Furniture and equipment, net	$ 55,188	$ 59,583

Depreciation expense for the years ended December 31, 2022 and 2021 was $ 19,481 and $ 16,827 , respectively.

(7) LEASES:

Right-of-use assets and lease liabilities are recognized based on the present value of the future minimum lease payments over the lease terms at the commencement dates. The Company uses its incremental borrowing rates as the discount rate for its leases, which is equal to the rate of interest the Company would have to pay on a collateralized basis to borrow an amount equal to the lease payments under similar terms. The incremental borrowing rate for all existing leases as of the opening balance sheet date was based upon the remaining terms of the leases; the incremental borrowing rate for all new or amended leases is based upon the lease terms. The lease terms for all the Company's leases include the contractually obligated period of the leases, plus any additional periods covered by a Company option to extend the leases that the Company is reasonably certain to exercise.

Operating lease expense is recognized on a straight-line basis over the lease term and is included in operating costs or general and administrative expense. Variable lease payments are expensed as incurred. The Company determines if an arrangement is or contains a lease at contract inception and recognizes a right-of-use asset and a lease liability at the lease commencement date. Leases with an initial term of 12 months or less but greater than one month are not recorded on the balance sheet for select asset classes. The lease liability is measured at the present value of future lease payments as of the lease commencement date. The right-of-use asset recognized is based on the lease liability adjusted for prepaid and deferred rent and unamortized lease incentives.

Certain leases provide that the lease payments may be increased annually based on the fixed rate terms or adjustable terms such as the Consumer Price Index. Future base rent escalations that are not contractually quantifiable as of the lease commencement date are not included in our lease liability.

The Company has one office lease for a two-year term ending on January 31, 2023, which is as an operating lease and included in the right-of-use asset, current portion of lease liability, and long-term lease liability captions on the Company's consolidated balance sheet. The lease liability was paid in full as of December 31, 2022.

Operating lease assets are recorded net of accumulated amortization of $ 66,552 as of December 31, 2022. Lease expense for lease payments are recognized on a straight-line basis over the lease term. Lease expense was $ 16,166 and $ 17,636 for the years ended December 31, 2022 and 2021, respectively.

(7) LEASES: (CONTINUED)

As further described in Note 17, the Company entered into a new three-year lease for the same office space with payments commencing on February 1, 2023.

(8) NOTE PAYABLE:

On May 4, 2020, the Company's wholly owned subsidiary, Cyclodextrin Technologies Development, Inc., borrowed $ 158,524 from BBVA USA under the Paycheck Protection Program (PPP) which was established under the Coronavirus Aid, Relief and Economic Security Act ("CARES Act"). The loan matured on May 4, 2022 and bore interest at a rate of 1% per annum, payable monthly commencing on September 5, 2021. Under the Paycheck Protection Program, because the loan was used to fund certain qualifying expenses as described in the CARES Act, the full amount of the loan, including accrued interest was forgiven in March 2022. As a result, the balance forgiven is presented separately as gain on the forgiveness of PPP loan in the accompanying consolidated statement of operations.

(9) EQUITY TRANSACTIONS:

On June 24, 2021, following the approval of the Company's stockholders at its annual meeting, the Company's Articles of Incorporation were amended to increase the number of authorized shares of common stock from 10,000,000 to 20,000,000 .

The Company expensed $ 15,750 in employee stock compensation in 2022 relating to the issuance 7,500 shares to an employee. In 2021, the Company expensed $ 124,998 in employee stock compensation relating to the issuance of 17,053 shares to an officer upon her hiring in September 2021. These shares were valued using quoted market values.

The Company issued 5,000 shares with a value of $ 10,500 to a member of the scientific advisory board in 2022. In 2021, the Company did not issue shares to any members of the scientific advisory board.

The Company accrues stock compensation expense over the period earned for employees and board members. Stock compensation expense for board members is included in "Board of Directors fees and costs" on our consolidated statement of operations, and stock compensation expense for officers and employees that are not board members is included in "Personnel" on our consolidated statement of operations. In 2022, the Company issued 65,479 shares to board members with a value of $ 133,263 , at the time of issuance. Compensation expense for 11,327 of these shares issued to board members with a value of $ 41,004 at the time of issuance had been accrued as of December 31, 2021.

In January 2021, the Company issued 10,000 shares of common stock with a value of $ 50,300 to a consultant for services. In January 2021, the Company issued 53,938 shares of common stock with a value of $ 271,308 to employees for compensation that had been accrued as of December 31, 2020.

During 2021, warrants to purchase an aggregate of 1,599,204 shares of common stock were exercised, resulting in gross proceeds to the Company of $ 7,991,101 .

In March 2021, warrants to purchase an aggregate of 9,436 shares of common stock were exercised on a cashless basis, resulting in the issuance of 2,913 shares of common stock.

On November 19, 2021 the Company sold 1,950,000 shares of common stock in a public offering underwritten by Maxim, at a price to the public of $ 6.00 per share, resulting in gross proceeds of $ 11,700,000 , before deducting underwriting discounts and commissions of seven percent (7 %), and expenses. The total expenses of this offering were approximately $ 927,000 , which included Maxim's expenses relating to the offering.

On December 29, 2022, the Company entered into a securities purchase agreement with an institutional investor, pursuant to which the Company agreed to sell and issue in a registered direct offering (i) 930,000 shares of the Company's common stock, par value $ 0.0001 per share at a purchase price per share of $ 1.61 and (ii) pre-funded warrants to purchase up to an aggregate of 1,678,696 shares of common stock at a purchase price of $ 1.6099 per Pre-Funded Warrant.

(9) EQUITY TRANSACTIONS: (CONTINUED)

Pursuant to the purchase agreement, in a concurrent private placement, the Company has also agreed to sell and issue to the investor Series A-1 warrants to purchase up to 2,608,696 shares of common stock at an exercise price of $ 1.36 per share, exercisable for a period of five years from the date of issuance, and Series A-2 warrants to purchase up to 2,608,696 shares of common stock at an exercise price of $ 1.36 per share, exercisable for a period of three years from the date of issuance. The transaction closed in January 2023, as disclosed in Note 17.

The following table presents the number of common stock warrants outstanding:

Warrants outstanding, December 31, 2020	3,662,661
Issued	-
Exercised	(1,599,204)
Expired	(15,271)
Warrants outstanding, December 31, 2021	2,048,186
Issued	-
Exercised	-
Expired	(2,340)
Warrants outstanding, December 31, 2022	2,045,846

The following table presents the number of common stock warrants outstanding, their exercise price, and expiration dates at December 31, 2022:

Warrants Issued	Exercise Price	Expiration Date
1,000	$ 55	June 2023
84,800	$ 25	June 2023
60,837	$ 35	February 2024
2,400	$ 25	October 2024
57,600	$ 25	October 2024
302,379	$ 9.37	November 2024
80,000	$ 25	April 2025
35,200	$ 65	December 2025
2,223	$ 11	September 2025
283,111	$ 15	September 2027
1,078,796	$ 5	December 2025
57,500	$ 6.25	December 2025
2,045,846		

In addition, there are currently outstanding seven-year warrants to purchase (i) 4,800 Units sold in our May 2016 private placement at an exercise price of $ 25.00 per Unit, (ii) 1,641 Units sold in our February 2017 private placement at an exercise price of $ 35.00 per Unit, and (iii) 2,400 Units sold in our October 2017 private placement at an exercise price of $ 25.00 per Unit. The exercise in full of these warrants to purchase units (including exercise of the warrants underlying these warrants) would result in the issuance of 17,682 additional shares of our common stock at an aggregate exercise price of $ 474,870 .

(10) PREFERRED STOCK:

The Company's Articles of Incorporation provide for 5,000,000 shares of "blank check" preferred stock. At December 31, 2022 and 2021, no shares of preferred stock were outstanding or designated.

(11) INCOME TAXES:

If all of our net operating loss carryforwards and temporary deductible differences were used, we would realize a net deferred tax asset of approximately $ 23,167,000 based upon expected income tax rates. Under ASC 740, deferred tax assets must be reduced by a valuation allowance if it is likely that all or a portion of it will not be realized. At December 31, 2022, we have determined it is more likely than not that we will not realize our temporary deductible differences and net operating loss carryforwards, and have provided a 100 % valuation allowance on our net deferred tax asset.

Positive evidence we evaluated in the order of significance and weighting in our evaluation includes the amount of net operating loss carryforward utilized against current income tax liabilities in four of the prior ten years, and the length of time the net operating loss carryforwards are available before they expire. Negative evidence we considered in the order of significance and weighting in our evaluation include our recent net losses, our plans for continued clinical trial and product development expenses, the timing of expiration of the net operating loss carryforwards prior to being utilized, unpredictability of future sales and profitability, competition from others, and new government regulations. We determined greatest weight should be given to our plans for continued clinical trial and product development expenses, trend of increasing expenses, and net operating losses in our evaluation. We re-measure our valuation allowance each quarter based on changes in our current and expected future sales and margins, and changes in the other factors of both positive and negative evidence.

At December 31, 2022, we have unused federal and state net operating loss carryforwards totaling approximately $ 42,395,000 that may be applied against future taxable income.

If not used, the net operating loss carryforwards will expire as follows:

Year Ending December 31,	Amount
2024	$ 66,000
2028	7,000
2030	160,000
2031	73,000
2032	48,000
2034	727,000
2035	1,969,000
2036	2,867,000
2037	2,481,000
Indefinite	33,997,000
Total	$ 42,395,000

A change in ownership pursuant to Section 382 of the Internal Revenue Code occurred during 2014. As a result, net operating losses in existence as of the date of the ownership change are subject to an annual Section 382 limitation.

The Company has expenses that qualify for the Orphan Drug Credit. The Orphan Drug Credit may be used to offset any current tax liabilities. Unused credits may be carried forward for 20 years. If the credit has not been used by the end of the 20 year carryforward period, it can be deducted as an expense for federal income tax purposes. The cumulative unused credit carryforward was $ 10,354,000 at December 31, 2022.

For 2022 we did not recognize a benefit or provision for income taxes. The net deferred tax asset before the valuation allowance increased $ 5,464,000 from 2021 to 2022, which is primarily the result of an additional net operating loss for 2022. We increased our valuation allowance to offset this increase in our deferred tax asset. For 2021 we did not recognize a benefit or provision for income taxes. The net deferred tax asset before the valuation allowance increased $ 5,500,000 from 2020 to 2021, which is primarily the result of an additional net operating loss for 2021. We increased our valuation allowance to offset this increase in our deferred tax asset.

(11) INCOME TAXES: (CONTINUED)

Significant components of our deferred Federal income taxes were as follows:

	2022	2021
Deferred tax assets:		
Net operating loss carryforwards	$ 10,761,000	$ 9,570,000
Tax credits	10,354,000	8,104,000
Impairment allowances	19,000	13,000
Stock-based compensation	45,000	-
Other	105,000	99,000
Accrued bonuses	245,000	-
Research and development expenses, net	1,642,000	-
Less valuation allowance	(23,167,000)	(17,703,000)
Deferred tax asset, net of valuation	4,000	83,000
Deferred tax liabilities:		
Property and equipment	(4,000)	(8,000)
Stock-based compensation	-	(75,000)
Deferred tax liabilities	(4,000)	(83,000)
Net tax assets	$ -	$ -

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. Effective January 1, 2021, the Florida corporate state income tax rate was reduced from 4.458 % to 3.535 %. Effective January 1, 2022, the Florida corporate state income tax rate increased to 5.5 %. The impact of these rate changes in 2021 was a reduction in the Company's deferred tax asset and the corresponding valuation allowance of approximately $ 399,000 . There was no impact on 2022.

The differences between the effective income tax rate reflected in the benefit (provision) for income taxes and the amounts, which would be determined by applying federal statutory income tax rate of 21% at December 31, 2022 and 2021, is summarized as follows:

	2022	2021
Tax benefit (expense) at Federal statutory rate	21%	21%
Effect of State taxes	3%	3%
Effect of tax rate change	-%	3%
Tax credits	15%	16%
Nondeductible expenses	(3)%	(3)%
Valuation allowance – deferred tax assets	(36)%	(39)%
Total tax benefit (provision)	$ -	$ -

The Company files income tax returns in the U.S. Federal jurisdiction, and three states. The Company is no longer subject to U.S. Federal or state income tax examinations by tax authorities for years before 2019.

The Company has reviewed and evaluated the relevant technical merits of each of its tax positions in accordance with accounting principles generally accepted in the United States of America for accounting for uncertainty in income taxes, and determined that there are no uncertain tax positions that would have a material impact on the financial statements of the Company. When applicable, interest and penalties will be reflected as a component of income tax expense.

(12) EMPLOYEE BENEFIT PLAN:

The Company's employees who have satisfied certain eligibility requirements are entitled to participate in a 401(k) plan through the Company's professional employer organization (PEO). Employee contributions are discretionary. The Company may match employee contributions and may also make discretionary contributions for all eligible employees based upon their total compensation. For 2022 and 2021, the Company elected to match the employee's contribution, not to exceed 4 % of compensation. The Company's 401(k) contributions were $ 61,168 and $ 49,165 for 2022 and 2021, respectively.

(13) EQUITY INCENTIVE PLANS:

On August 29, 2019, the Company's stockholders approved the Company's 2019 Omnibus Equity Incentive Plan at a special meeting of stockholders (the "2019 Plan"). The 2019 Plan provides for the issuance of up to 68,437 shares of common stock pursuant to the grant of shares of common stock, stock options or other awards, to employees, officers or directors of, and consultants to, the Company and its subsidiary. Options granted under the Incentive Plan may either be intended to qualify as incentive stock options under the Internal Revenue Code of 1986, or may be non-qualified options, and are exercisable over periods not exceeding ten years from date of grant. As of December 31, 2022, we had awarded 68,437 shares of common stock as awards under the 2019 Plan, with no shares of common stock remaining available for future awards under the 2019 Plan.

On June 24, 2021, the Company's stockholders approved the Company's 2021 Equity Incentive Plan at its annual meeting of stockholders (the "2021 Plan"). The 2021 Plan provides for the issuance of up to 3,000,000 shares of common stock pursuant to the grant of shares of common stock, stock options or other awards, to employees, officers or directors of, and consultants to, the Company and its subsidiary. Options granted under the Incentive Plan may either be intended to qualify as incentive stock options under the Internal Revenue Code of 1986, or may be non-qualified options, and are exercisable over periods not exceeding ten years from date of grant. During the year ended December 31, 2021 we awarded 17,053 shares of common stock and granted 222,700 stock options under the 2021 plan. During the year ended December 31, 2022, we had awarded 77,979 shares of common stock and granted 226,746 stock options under the 2021 Plan, and 23,800 options were forfeited, with 2,479,322 shares of common stock remaining available for future awards.

The Company uses the Black-Scholes valuation model to estimate the fair value of stock options at grant date. This valuation model uses the option exercise price as well as estimates and assumptions related to the expected price volatility of the Company's stock, the rate of return on risk-free investments, the expected period during which the options will be outstanding, and the expected dividend yield for the Company's common stock to estimate the fair value of a stock option at the date of grant. The valuation assumptions were determined as follows:

- *Expected stock price volatility:* There is a limited market for the Company's common stock providing a basis to estimate the expected volatility of the Company's stock prices for the purpose of valuing stock options granted. Alternatively, the Company uses the historical volatility of certain publicly traded companies that represents the primary industry sector within which the Company operates.

- *Risk-free interest rate:* The Company bases the risk-free interest rate on the interest rate payable on U.S. Treasury securities in effect at the time of grant for a period that is commensurate with the assumed expected option term.

- *Expected term of options:* The expected term of options represents the period of time options are expected to be outstanding.

- *Expected annual dividends:* The estimate for annual dividends is $ 0 because the Company has not historically paid and does not intend to pay dividends in the foreseeable future.

Share-based compensation expense is recorded on a straight-line basis over the requisite service period, which is generally the vesting period.

(13) EQUITY INCENTIVE PLANS: (CONTINUED)

The following table summarizes weighted-average assumptions used in our calculations of fair value for the years ended December 31, 2022 and 2021:

	2022	2021
Dividend yield	-%	-%
Expected volatility	90.5 – 92.3%	91.5 – 92.7%
Risk-free interest rate	1.83 – 2.76%	0.43%
Expected lives (years)	5 - 6.25	5 - 6.25

The weighted-average fair value of options granted during the year ended December 31, 2022, as determined under the Black-Scholes valuation model, was $ 1.60 - $ 2.47 per share. The weighted-average fair value of options granted during the year ended December 31, 2021, as determined under the Black-Scholes valuation model, was $ 5.28 and $ 5.64 per share.

The following is a summary of the stock option activity for the years ended December 31, 2022 and 2021:

	Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value	Weighted Average Remaining Contractual Life
Stock options outstanding at December 31, 2020	-	$ -	$ -	
Granted	222,700	7.45	3,094	
Exercised	-	-	$ -	
Forfeited/Expired	-	-	-	
Stock options outstanding at December 31, 2021	222,700	7.45	$ 3,094	9.7
Granted	226,746	3.18		
Exercised	(-)	-	$ -	
Expired	(-)			
Forfeited	(23,800)	7.45	-	
Stock options outstanding at December 31, 2022	425,646	$ 5.17	$ -	8.9
Stock options exercisable at December 31, 2022	150,495	$ 5.81	$ -	8.9

Unrecognized compensation expense related to unvested stock options was $ 1,000,914 as of December 31, 2022, which is expected to be recognized over a weighted-average period of 8.9 years and will be adjusted for forfeitures as they occur.

(14) NET LOSS PER SHARE:

The following table sets forth the computation of basic and diluted net loss per common share.

	As of December 31, 2022	2021
Numerator		
Net loss	$ (15,450,888)	$ (14,286,655)
Denominator		
Weighted-average common shares outstanding, basic and diluted	8,439,177	6,370,073
Net loss per share, basic and diluted	$ (1.83)	$ (2.24)

(14) NET LOSS PER SHARE: (CONTINUED)

The Company reported a net loss in 2022 and 2021, therefore, the basic and diluted net loss per share are the same in the respective periods because of the inclusion of potential common shares would have an anti-dilutive effect. Potential shares of common stock that are excluded from the computation of diluted weighted-average shares outstanding are as follows:

	For the Year Ended December 31,	
	2022	2021
Stock options	425,646	222,700
Warrants	2,045,846	2,048,186

(15) COMMITMENTS AND CONTINGENCIES:

From time to time, the Company is a party to claims and legal proceedings arising in the ordinary course of business. Our management evaluates our exposure to these claims and proceedings individually and in the aggregate and records an expense for potential losses on such litigation if it is possible to estimate the amount of loss and if the amount of the loss is probable.

In connection with an agreement executed in January 2022 with Ashland, Inc., the Company committed to purchase minimum amounts of goods used in its normal operations based on completion of certain milestones. Future annual minimum purchases remaining under the agreement are $ 2,940,000 . During 2022, no purchases were made under the agreement.

(16) RELATED PARTY TRANSACTIONS:

Since October 2016, we have paid a monthly fee of $ 5,000 to a non-profit organization of which C.E. Rick Strattan is the Executive Director, in consideration of consulting services provided to us by Mr. Strattan. Mr. Strattan is our founder, former Chief Executive Officer and one of our directors.

In June 2019, we engaged Joshua M. Fine, the son of our Chief Executive Officer, to serve as our Chief Financial Officer. Mr. Fine received an annual salary of $ 335,780 and $ 275,333 in 2022 and 2021, respectively. In addition, he was awarded a cash bonus of $ 134,312 and $ 75,000 in 2022 and 2021, respectively. Joshua Fine was awarded stock options with a value of $ 76,752 in 2022 and $ 134,288 in 2021 that vest over 4 years.

Rebecca A. Fine, the daughter of our Chief Executive Officer, provides executive assistant services. In 2022, Ms. Fine received a salary of $ 107,700 and a cash bonus of $ 16,155 . In 2021, Ms. Fine received a salary of $ 90,000 and a cash bonus of $ 15,000 .

Kevin J. Strattan, the son of C.E. Rick Strattan, has been employed by us since 2008, and since 2014 has been our Vice President, Finance – Compensation. His annual salary was $ 180,250 and $ 149,800 in 2022 and 2021, respectively. In addition, he received cash bonuses of $ 54,075 and $ 30,000 in 2022 and 2021, respectively. In 2022 and 2021 Mr. Strattan was also awarded stock options with a value of $ 41,509 and $ 72,787 , respectively, that vest over 4 years.

Corey E. Strattan, the daughter-in-law of C.E. Rick Strattan, has been employed by us since 2011 as a documentation specialist and logistics coordinator, at an annual salary of $ 92,700 in 2022. In addition, she received a cash bonus of $ 13,905 in 2022. In 2021, Ms. Strattan received an annual salary of $ 90,000 and a cash bonus of $ 15,000 .

(17) SUBSEQUENT EVENTS:

On January 3, 2023, the Company sold to an institutional investor in a registered direct offering 930,000 shares of common stock at a purchase price per share of $ 1.61 , and prefunded warrants to purchase up to an aggregate of 1,678,696 shares of common stock at a purchase price of $ 1.6099 per pre-funded warrant. The pre-funded warrants have an exercise price of $ 0.0001 per share and remain exercisable until exercised in full. The net proceeds from the registered direct offering were approximately $ 3.7 million after deducting fees due to the placement agent in the offering and our estimated expenses.

In a concurrent private placement, the Company also issued to the investor Series A- 1 warrants to purchase up to 2,608,696 shares of common stock at an exercise price of $ 1.36 per share, exercisable for a period of five years from the date of issuance, and Series A- 2 warrants to purchase up to 2,608,696 shares of common stock at an exercise price of $ 1.36 per share, exercisable for a period of three years from the date of issuance.

H.C. Wainwright & Co., LLC acted as placement agent to the Company in connection with the registered direct offering and concurrent private placement and was paid a cash fee equal to 7.5 % of the gross proceeds of the offering, a management fee equal to 1.0 % of the gross proceeds of the offering, and was reimbursed by the Company for its non-accountable expenses in the amount of $ 35,000 , for fees and expenses of its legal counsel, for other out-of-pocket expenses in the amount of $ 50,000 , and for its clearing expenses in the amount of $ 15,950 . The Company also issued to designees of the placement agent five-year warrants to purchase an aggregate of 156,522 shares of common stock at an exercise price of $ 2.0125 per share.

On January 12, 2023, the Company entered into a three-year lease extension for approximately 1,500 square feet of office and distribution warehouse space located in Gainesville, Florida for $ 1,700 per month, with a three-year renewal option.

On January 25, 2023, the investor exercised a portion of its pre-funded warrants and acquired 400,696 shares of common stock for an aggregate exercise price of $ 40 , and on February 27, 2023, the investor exercised an additional portion of its pre-funded warrants and acquired 741,000 shares of common stock for an aggregate exercise price of $ 74 .

On March 3, 2023, following the approval of the Company's stockholders at a special meeting, the Company's Articles of Incorporation were amended to increase the number of authorized shares of common stock from 20,000,000 to 50,000,000 .

On March 7, 2023, the Company awarded options to purchase (i) an aggregate of 329,131 shares of common stock to its officers and employees, with an exercise price of $ 1.28 , vesting over a four-year period in equal monthly installments, and (ii) 3,350 shares of common stock to each of its five non-employee directors, with an exercise price of $ 1.28 , vesting over a one-year period in equal monthly installments.

Item 9. Changes In and Disagreements With Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures.

Disclosure controls and procedures are the Company's controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934, as amended (the "Exchange Act") is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the possible controls and procedures.

Our management has evaluated, with the participation of our principal executive officer and principal financial officer, the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this report. Based upon this evaluation, our management, including our principal executive officer and principal financial officer, has concluded that, as of the end of the period covered by this report, the Company's disclosure controls and procedures were effective at the reasonable assurance level.

Management's Annual Report on Internal Control over Financial Reporting

Company management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed by, or under the supervision of, our principal executive and principal financial officers and effected by the Company's 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:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the Company;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

Because of inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2022. In making this assessment, management used the criteria set forth in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our assessment, management has concluded that our internal control over financial reporting was effective as of December 31, 2022.

Changes in Internal Control.

We made no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) identified in connection with the evaluation of our internal controls that occurred during our last fiscal quarter that has materially affected, or which is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers, Promoters, Control Persons and Corporate Governance.

Information with respect to this item will be set forth in the Proxy Statement for the 2023 Annual Meeting of Stockholders ("Proxy Statement") under the headings "Directors," "Executive Officers," "Delinquent Section 16 Reports" and "Corporate Governance" or an amendment to this Annual Report on Form 10-K ("Form 10-K/A"), and is incorporated herein by reference. The Proxy Statement or Form 10-K/A, as the case may be, will be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

Item 11. Executive Compensation.

Information with respect to this item will be set forth in the Proxy Statement under the headings "Executive Compensation" and "Director Compensation," or the Form 10-K/A, and is incorporated herein by reference.

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

Information with respect to this item will be set forth in the Proxy Statement under the headings "Security Ownership of Certain Beneficial Owners and Management" and "Executive Compensation—Securities Authorized for Issuance Under Equity Compensation Plans" or the Form 10-K/A, and is incorporated herein by reference.

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

Information with respect to this item will be set forth in the Proxy Statement under the headings "Related Party Transactions" and " Director Independence" and is incorporated herein by reference or the Form 10-K/A.

Item 14. Principal Accountant Fees and Services.

Information with respect to this item will be set forth in the Proxy Statement under the headings "Audit and Non-Audit Related Fees" and "Pre-Approval Policy" and is incorporated herein by reference or the Form 10-K/A.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

Exhibits	
2.1	Agreement and Plan of Merger, dated November 4, 2020, by and between Cyclo Therapeutics, Inc., a Florida corporation, and Cyclo Therapeutics, Inc., a Nevada corporation (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 10, 2020).
3.1	Articles of Incorporation of Cyclo Therapeutics, Inc., a Nevada corporation (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 10, 2020).
3.2	Certificate of Amendment to Articles of Incorporation of Cyclo Therapeutics, Inc., filed June 24, 2021 (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on June 24, 2021).
3.3	Bylaws of Cyclo Therapeutics, Inc., a Nevada corporation (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 10, 2020).
4.1	Form of Series A-1 Warrant issued to Armistice Capital Master Fund Ltd. (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 3, 2023).
4.2	Form of Series A-2 Warrant issued to Armistice Capital Master Fund Ltd. (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 3, 2023)
4.3	Form of Warrant issued to investors in private placements conducted in 2016, 2017 and 2018 (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed June 8, 2016).
4.4	Form of Warrant, dated May 31, 2019, issued by CTD Holdings, Inc. to investors and ThinkEquity, a division of Fordham Financial Management, Inc., and its designees (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed June 4, 2019).
4.5	Form of Warrant, dated August 27, 2020, issued by Cyclo Therapeutics, Inc. to investors in a private placement conducted in August 2020 (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed September 2, 2020).
4.6	Form of Public Warrant (incorporated by reference to Exhibit 4.5 to Company's Registration Statement on S-1 filed November 16, 2020)
4.7	Form of Warrant Agency Agreement between the Company and vStock Transfer LLC (incorporated by reference to Exhibit 4.6 to Company's Registration Statement on S-1 filed November 16, 2020)
4.8	Form of Representative's Warrant. (incorporated by reference to Exhibit 4.7 to Company's Registration Statement on S-1 filed November 16, 2020)
4.9	Form of Pre-Funded Warrant issued January 3, 2023 to Armistice Capital Master Fund Ltd. (incorporated by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 3, 2023).
4.10	Form of Placement Agent Warrant issued January 3, 2023 (incorporated by reference to Exhibit 4.4 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 3, 2023).
4.11	Description of Registrant's Securities (incorporated by reference to Exhibit 4.3 to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 12, 2021).
10.1	Securities Purchase and Collaboration Agreement dated as of April 9, 2014 between CTD Holdings, Inc. and Novit, L.P. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed April 15, 2014).
10.2†	Employment Agreement between the Company and N. Scott Fine, dated as of September 14, 2015 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed October 16, 2015).

10.3†	Amendment to Employment Agreement between the Company and N. Scott Fine, dated as of November 7, 2017 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed November 8, 2017).
10.4	Promissory Note in the original principal amount of $265,000, dated January 21, 2016, by Crit, Inc. DBA Commercial Gates & Electric, in favor of CTD Holdings, Inc. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed January 27, 2016).
10.5	Mortgage, dated January 21, 2016, by Crit, Inc. DBA Commercial Gates & Electric, in favor of CTD Holdings, Inc. (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed January 27, 2016).
10.6	Commercial Contract between Alchem Laboratories Corporation and Nanosonic Products Inc., entered into September 6, 2016 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed December 20, 2016).
10.7†	2019 Omnibus Equity Incentive Plan (incorporated by reference to Appendix B to the Company's Proxy Statement on Schedule 14A filed July 19, 2019).
10.8†	2021 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed June 24, 2021).
10.9	Promissory Note, dated May 4, 2020, by Cyclodextrin Technologies Development, Inc., a wholly-owned subsidiary of the Company, in favor of BBVA USA (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed May 6, 2020).
10.10†	Employment Agreement between the Company and N. Scott Fine, dated as of February 28, 2022 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed March 2, 2022).
10.11†	Employment Agreement between the Company and Lise Kjems, dated as of September 27, 2021 (incorporated by reference to Exhibit 10.13 to the Company's Annual Report on Form 10-K filed March 11, 2022).
10.12†	Employment Agreement between the Company and Michael Lisjak, dated as of February 28, 2022 (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed March 2, 2022).
10.13†	Employment Agreement between the Company and Joshua Fine, dated as of February 28, 2022 (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed March 2, 2022).
10.14†	Employment Agreement between the Company and Jeffrey Tate, dated as of February 28, 2022 (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed March 2, 2022).
10.15	Securities Purchase Agreement dated December 29, 2022 between the Company and Armistice Capital Master Fund Ltd. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 3, 2023)
21.1	Subsidiaries*
23.1	Consent of WithumSmith+Brown, PC*
31.1	Rule 13a-14(a)/15d-14a(a) Certification of Principal Executive Officer*
31.2	Rule 13a-14(a)/15d-14a(a) Certification of Principal Financial Officer*
32.1	Section 1350 Certification of Principal Executive Officer *
32.2	Section 1350 Certification of Principal Financial Officer *
101.INS***	Inline XBRL Instance Document
101.SCH***	Inline XBRL Taxonomy Extension Schema Document
101.CAL***	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF***	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB***	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE***	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL and contained in Exhibit 101)

* Filed herewith.
† Management contract or compensatory plan or arrangement

SIGNATURES

In accordance with Section 13 or 15(d) of the Exchange Act, the Registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

CYCLO THERAPEUTICS, INC.

By: /s/ N. Scott Fine
N. SCOTT FINE
Chief Executive Officer
(principal executive officer)
Date: March 17, 2023

In accordance with the Exchange Act, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

By: /s/ N. Scott Fine
N. SCOTT FINE
Chief Executive Officer; Director
(principal executive officer)
Date: March 17, 2023

By: /s/ C.E. Rick Strattan
C.E. RICK STRATTAN
Director
Date: March 17, 2023

By: /s/ Jeffrey L. Tate
JEFFREY L. TATE
Chief Operating Officer; Director
Date: March 17, 2023

By: /s/ Markus W. Sieger
MARKUS W. SIEGER
Chairman of the Board, Director
Date: March 17, 2023

By: /s/ Joshua M. Fine
JOSHUA M. FINE
Chief Financial Officer
(principal financial and accounting officer)
Date: March 17, 2023

By: /s/ William S. Shanahan
WILLIAM S. SHANAHAN
Director
Date: March 17, 2023

By: /s/ F. Patrick Ostronic
F. PATRICK OSTRONIC
Director
Date: March 17, 2023

By: /s/ Randall M. Toig
RANDALL M. TOIG
Director
Date: March 17, 2023

EXHIBIT 21.1

SUBSIDIARIES OF CYCLO THERAPEUTICS, INC.

The following is the sole subsidiary of Cyclo Therapeutics, Inc.:

Name	Ownership	State of Incorporation
Cyclodextrin Technologies Development, Inc.	100.00%	Florida

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-1 (Registration No. 333-269437) and Form S-3 (Registration No. 333-254496) of Cyclo Therapeutics, Inc. ("the Company") of our report dated March 17, 2023, which includes an explanatory paragraph relating to the Company's ability to continue as a going concern, relating to the consolidated financial statements of the Cyclo Therapeutics, Inc. and Subsidiary as of and for the years ended December 31, 2022 and 2021, which appear in this Form 10-K.

/s/ WithumSmith+Brown, PC

East Brunswick, New Jersey
March 17, 2023

EXHIBIT 31.1

CERTIFICATION PURSUANT TO RULE 13a-14(a)/15d-14(a)
OF THE SECURITIES EXCHANGE ACT OF 1934

I, N. Scott Fine, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 17, 2023

By: */s/ N. Scott Fine*
N. Scott Fine
Chief Executive Officer

EXHIBIT 31.2

CERTIFICATION PURSUANT TO RULE 13a-14(a)/15d-14(a)
OF THE SECURITIES EXCHANGE ACT OF 1934

I, Joshua M. Fine, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 17, 2023

By: */s/ Joshua M. Fine*
Joshua M. Fine
Chief Financial Officer

EXHIBIT 32.1

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

In connection with this Annual Report on Form 10-K of Cyclo Therapeutics, Inc. (the "Company") for the fiscal year ended December 31, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, N. Scott Fine, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: March 17, 2023

/s/ *N. Scott Fine*
N. Scott Fine
Chief Executive Officer

EXHIBIT 32.2

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

In connection with this Annual Report on Form 10-K of Cyclo Therapeutics, Inc. (the "Company") for the fiscal year ended December 31, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Joshua M. Fine, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: March 17, 2023

/s/ Joshua M. Fine
Joshua M. Fine
Chief Financial Officer