CTD HOLDINGS INC
Form 10-K
March 15, 2019

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, 2018

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

CTD HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Florida	59-3029743
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)
6714 NW 16th 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 Exchange Act:

None

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

Common Stock, par value $0.0001

(Title of class)

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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (section 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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	(Do not check if a smaller reporting company)	Smaller reporting company
		Emerging growth company

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

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

As of June 30, 2018, the aggregate market value of the registrant's Common Stock held by non-affiliates was $14,457,994 based on the closing price on the over-the-counter market of such Common Stock on such date.

As of March 11, 2019, there were 91,264,463 shares of registrant's Common Stock outstanding.

CTD HOLDINGS, INC.

ANNUAL REPORT ON FORM 10-K

For the Year Ended December 31, 2018

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PART I

Item 1. Business.

Overview

CTD Holdings, 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., or CTDI, to CTD Holdings, Inc.; CTDI was then incorporated as a Florida corporation and became a wholly owned subsidiary of CTD Holdings, Inc.

We are a biotechnology company that develops cyclodextrin-based products for the treatment of disease. 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 cholesterol metabolism disease 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 describes 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 will evaluate 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. 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.

We have also filed Clinical Trial Applications for a Phase I/II clinical study with several European regulatory bodies, including those in the United Kingdom, Sweden and Italy, and in Israel, all of which have approved our applications. The European Phase I/II study will evaluate the safety of Trappsol® Cyclo™ along with a range of clinical outcomes, including neurologic, hepatic, and respiratory, in addition to measurements of cholesterol metabolism and markers of NPC. The European study is similar to the U.S. study, providing for the administration of Trappsol® Cyclo™ intravenously to NPC patients every two weeks in a double-blind, randomized trial. The first patient was dosed in this study in July 2017.

Preliminary data from our clinical studies suggests that Trappsol® Cyclo™ crosses the blood-brain-barrier in individuals suffering from NPC. Following intravenous administration of Trappsol® Cyclo™ to study subjects, it was detected in subjects' cerebrospinal fluid. The clinical significance of these findings will be determined as part of the final analysis of both clinical trials.

We are also exploring the use of cyclodextrins in the treatment of Alzheimer's disease under a collaborative arrangement with Kerwin Research Center, which is funding this project. In January 2018, the FDA authorized a single patient IND expanded access program using Trappsol® Cyclo™ for the treatment of this disease, and in October 2018, we filed a patent application with respect to the use of hydroxypropyl beta cyclodextrins in the treatment of Alzheimer's disease.

We also continue to sell cyclodextrins and related products to the pharmaceutical, nutritional, and other industries, primarily for use in diagnostics and specialty drugs with continuing growth in research and new product development. 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.

We have retained Torreya Capital, LLC, as our strategic advisor to support business development.

Cyclodextrins

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. 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 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. In 2010, Trappsol® Cyclo™ was designated an orphan drug by the U.S. Food and Drug Administration for the treatment of NPC. Trappsol® Cyclo™ is the first use of a cyclodextrin as an active pharmaceutical and not just as an inactive formulation excipient.

Cyclodextrin Product Background

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.

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.

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. 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. 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.

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.

Our Cyclodextrin Products

Substantially all of our revenues are 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 88% and 12%, respectively, of our 2018 product sales. The Trappsol® and Aquaplex® products can be used in many industries, the largest being the food and pharmaceutical industries. We do not have any other registered trademarks and do not have any patents or licenses.

We have protected our Trappsol® and Aquaplex® trademarks used in our legacy fine chemical business by registering them with the U.S. Patent and Trademark Office. These trademarks add additional visibility to our products and reputation as a leader in the industry. Our website at www.cyclodex.com has grown to be an important cyclodextrin information Internet site.

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.

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, 2018, our revenues consisted of 17% biopharmaceuticals, 71% basic natural and chemically modified cyclodextrins, and 12% 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. In 2018 and 2017, one customer (UNO Healthcare, Inc.) accounted for 15% and 23% of our total revenue, respectively. Sigma-Aldrich Fine Chemical, Inc. accounts for almost 95% of our 2018 and 2017 annual sales 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.

Competition

We face competition in the commercialization of our Trappsol® Cyclo™ orphan drug product. An effort to pursue a similar product has been announced by another company, and the disclosed team is composed of professionals in the finance and pharmaceutical industries. We believe our longstanding efforts, 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.

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 the Company. 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 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 increased to approximately $2,711,000 in 2018, from $2,293,000 in 2017.

We also conduct research and development focused on the improvement of our manufacturing processes. We occasionally initiate research to develop a new product such as a novel cyclodextrin complex that has promising applications and is not otherwise available. We do not currently conduct, nor have we historically conducted, research and development activities or on behalf of or jointly with our customers. Our clients bear their own research and development costs.

Government Regulation

The development, production and marketing of biological products, which include the proposed use of Trappsol® Cyclo™ to treat disease, including NPC, are subject to regulation for safety, efficacy and quality by numerous governmental authorities in the U.S. and other countries. In the U.S., the development, manufacturing and marketing of pharmaceuticals are subject to extensive regulation under the Federal Food, Drug, and Cosmetic Act. The FDA, and comparable agencies in foreign countries, not only assesses the safety and efficacy of these products but also regulate, among other things, the testing, manufacture, labeling, storage, record-keeping, advertising and promotion of such products. The process of obtaining FDA and foreign regulatory approval for a new pharmaceutical is costly and time-consuming.

Under the Federal Food, Drug and Cosmetic Act, the FDA is also given comprehensive authority to regulate the development, production, distribution, labeling and promotion of food and food additives. The FDA's authority includes the regulation of the labeling and purity of our food additive and nutraceutical products. In the event the FDA believes any company is not in compliance with the law, the FDA can institute proceedings to detain or seize products, enjoin future violations or assess civil and/or criminal penalties against that Company.

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. All of our other products are sold for our customers' research and development purposes only, and do not require FDA approval. Any use in humans as a drug or food product would require compliance with FDA regulations. Under present FDA regulations, FDA defines drugs as "articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man." In 2014, the Company submitted a Type II Drug Master File (DMF) to the FDA for Trappsol® Cyclo™ and it was accepted for filing. This DMF (#028889) can now be cited by researchers seeking IND approval for use of Trappsol® Cyclo™ in the treatment of disease. This same product is also the focus of a clinical program to achieve market authorization in Europe. As such it will be subject to the regulatory authorities in that jurisdiction including, but not limited to, the European Medicines Agency (EMEA). Trappsol® Cyclo™ has also been designated an orphan drug in Europe.

Our IND for Trappsol® Cyclo™ as a treatment for NPC 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. We have also filed Clinical Trial Applications for a Phase I/II clinical study with several European regulatory bodies, including those in the United Kingdom, Sweden and Italy, and in Israel, all of which have approved our applications. The European Phase I/II study will evaluate the safety of Trappsol® Cyclo™ along with a range of clinical outcomes, including neurologic, hepatic, and respiratory, in addition to measurements of cholesterol metabolism and markers of NPC. The European study is similar to the U.S. study, providing for the administration of Trappsol® Cyclo™ intravenously to NPC patients every two weeks in a double-blind, randomized trial. The first patient was dosed in this study in July 2017.

There have been a number of federal and state legislative changes made over the last few years regarding the pricing of pharmaceutical products, government control and other changes to the healthcare system of the U.S. It is uncertain how such legislative changes will be adopted or what actions federal, state or private payers for medical goods and services may take in response to such legislation. We cannot predict the effect such healthcare changes will have on our business, and no assurance can be given that any such reforms will not have a material adverse effect.

Employees

As of December 31, 2018, we employed five 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.

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

We have incurred net losses of approximately $4.3 million and $3.8 million for the years ended December 31, 2018 and December 31, 2017, respectively. Our recent losses have predominantly resulted from research and development expenses for our Trappsol® Cyclo™ product and other general operating expenses, including board advisory fees. 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. 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.

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

While we sell cyclodextrins for use and research in numerous industries, 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 in the United States and Europe. We plan 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. The potential population of 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 deemed by the regulatory agencies of any jurisdiction to be effective and safe in the treatment of NPC or any other disease. 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.

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, 2018, 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 will need additional capital to fund our operations as planned.

For year ended December 31, 2018, our operations used approximately $3,188,000 in cash. This cash was provided primarily by cash on hand and net proceeds of $4,102,000 from equity issuances. 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.

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

Our primary drug candidate 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 rely in part on third parties for research and clinical trials for products using Trappsol® Cyclo™.

We rely on contact research organizations, 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 face competition from well-funded companies in the use of cyclodextrins 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 different classes of cyclodextrins for the same NPC indications. 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.

One of our customers accounts for a substantial portion of our revenue, and the loss of this customer would have a material adverse effect on our results of operations and reduce our ability to service our debt obligations.

Our single largest customer accounted for 18% of our total sales in fiscal 2018. Our largest four customers collectively accounted for 57% of total sales in fiscal 2018. We have a supply contract with only one of our major customers. The loss of any one of these customers would have a material adverse effect on our financial results 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 manufacturers 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 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.

We are significantly influenced by one person who controls a significant majority of our voting stock.

As of March 11, 2019, C.E. Rick Strattan, our founder and one of our directors, held the beneficial power to vote 20,608,385 shares of Common Stock (including 630,738 shares of Common Stock owned by a tax exempt organization over which Mr. Strattan has sole voting and dispositive power), or approximately 23% of the issued and outstanding shares of Common Stock. Accordingly, Mr. Strattan has the power to influence the outcome of important corporate decisions or matters submitted to a vote of our shareholders. Although Mr. Strattan owes the Company certain fiduciary duties as a director of the Company, the personal interests of Mr. Strattan may conflict with, or differ from, the interests of other holders of our capital stock. Under a Voting Agreement between Mr. Strattan and us dated February 19, 2014, he has agreed to vote his shares of Common Stock for the slate of directors nominated by the Company's board for seven (7) years, which slate will be required to include two representatives of investors in the private placement consummated on the same date. This arrangement could have the effect of preventing a change of control of the Company. So long as Mr. Strattan has the power to vote a substantial number of shares of our Common Stock, he will have the power to significantly influence and/or control all our corporate decisions and will be able to effect or inhibit changes in control of the Company.

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 Dr. Sharon Hrynkow, our Chief Scientific 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.

Broker-dealers may be discouraged from effecting transactions in our Common Stock because it is considered a penny stock and is subject to the penny stock rules.

Our Common Stock currently constitutes "penny stock." Subject to certain exceptions, for the purposes relevant to us, "penny stock" includes any equity security that has a market price of less than $5.00 per share or with an exercise price of less than $5.00 per share. Rules 15g-1 through 15g-9 promulgated under the Securities Exchange Act of 1934, as amended, impose sales practice and disclosure requirements on certain brokers-dealers who engage in certain transactions involving a "penny stock." In particular, a broker-dealer selling penny stock to anyone other than an established customer or "accredited investor" (generally, an individual with net worth in excess of $1,000,000 or an annual income exceeding $200,000, or $300,000 together with his or her spouse), must make a special suitability determination for the purchaser and must receive the purchaser's written consent to the transaction prior to sale, unless the broker-dealer or the transaction is otherwise exempt. In addition, the penny stock regulations require the broker-dealer to deliver, prior to any transaction involving a penny stock, a disclosure schedule prepared by the Securities and Exchange Commission ("SEC") relating to the penny stock market, unless the broker-dealer or the transaction is otherwise exempt. A broker-dealer is also required to disclose commissions payable to the broker-dealer and the registered representative and current quotations for the securities. Finally, a broker-dealer is required to send monthly statements disclosing recent price information with respect to the penny stock held in a customer's account and information with respect to the limited market in penny stocks.

The additional sales practice and disclosure requirements imposed upon broker-dealers may discourage broker-dealers from effecting transactions in our shares, which could severely limit the market liquidity of the shares and impede the sale of our shares in the secondary market.

As an issuer of "Penny Stock" the protection provided by the federal securities laws relating to forward looking statements does not apply to us.

Although the federal securities laws provide a safe harbor for forward-looking statements made by a public company that files reports under the federal securities laws, this safe harbor is not available to issuers of penny stocks. As a result, if we are a penny stock, we will not have the benefit of this particular safe harbor protection in the event of any claim that the material provided by us contained a material misstatement of fact or was misleading in any material respect because of our failure to include any statements necessary to make the statements not misleading.

We have a limited market for our securities.

Although certain market makers facilitate trades of our Common Stock on the OTCQB tier of the OTC Markets Group ("OTCQB"), there is currently a limited market for shares of our Common Stock and we cannot be certain that an active market will develop. The lack of an active public market could have a material adverse effect on the price and liquidity of our Common Stock. Broker-dealers often decline to trade in OTCQB stocks given that the market for such securities is often limited, the stocks are more volatile, and the risk to investors is greater. Consequently, selling our Common Stock may be difficult because smaller quantities of shares can be bought and sold, transactions can be delayed and securities analyst and news media coverage of our Company may be reduced. These factors could result in lower prices and larger spreads in the bid and ask prices for shares of our Common Stock as well as lower trading volume. Investors should realize that they may be unable to sell shares of our Common Stock that they purchase. Accordingly, investors must be able to bear the financial risk of losing their entire investment in our Common Stock.

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. On November 26, 2018, we exercised a two-year renewal option, commencing February 2019, with respect to our lease of approximately 2,500 square feet of office and warehouse space located in Gainesville, Florida for $1,600 per month. We believe that this leased property is currently sufficient for our operating requirements.

Item 3. Legal Proceedings.

On November 30, 2017, we filed a Complaint against the National Institutes of Health (the "NIH") in the United States District Court for the Northern District of Florida, Gainesville Division. Pursuant to the Complaint, we are seeking an order requiring the NIH to provide the Company with records responsive to a request originally made by us under the Freedom of Information Act on October 19, 2016 (the "FOIA Request"). Subsequent to the filing of the Complaint, we received documents from the NIH with substantial redactions. We are currently reviewing those documents and our options in connection with this proceeding.

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 currently trades on the OTCQB under the symbol CTDH. Since the commencement of trading of the company's securities, there has been an extremely limited market for its securities. The following table sets forth high and low bid quotations for the quarters indicated as reported by the OTCQB.

		High	Low
2017	First Quarter	$0.80	$0.41
	Second Quarter	$0.62	$0.37
	Third Quarter	$0.55	$0.27
	Fourth Quarter	$0.51	$0.25
2018	First Quarter	$0.45	$0.25
	Second Quarter	$0.40	$0.25
	Third Quarter	$0.77	$0.30
	Fourth Quarter	$1.18	$0.50

Over-the-counter market quotations reflect inter-dealer prices, without retail mark-up, mark-down or commissions and may not represent actual transactions.

Holders

As of March 11, 2019, 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 140.

Dividend Policy

The Company paid no dividends in 2018 and will not pay any cash dividends on its Common Stock in 2019 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

Overview

We are a biotechnology company that develops cyclodextrin-based products for the treatment of disease. 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 cholesterol metabolism disease 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 describes 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 will evaluate 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. 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.

We have also filed Clinical Trial Applications for a Phase I/II clinical study with several European regulatory bodies, including those in the United Kingdom, Sweden and Italy, and in Israel, all of which have approved our applications. The European Phase I/II study will evaluate the safety of Trappsol® Cyclo™ along with a range of clinical outcomes, including neurologic, hepatic, and respiratory, in addition to measurements of cholesterol metabolism and markers of NPC. The European study is similar to the U.S. study, providing for the administration of Trappsol® Cyclo™ intravenously to NPC patients every two weeks in a double-blind, randomized trial. The first patient was dosed in this study in July 2017.

Preliminary data from our clinical studies suggests that Trappsol® Cyclo™ crosses the blood-brain-barrier in individuals suffering from NPC. Following intravenous administration of Trappsol® Cyclo™ to study subjects, it was detected in subjects' cerebrospinal fluid. The clinical significance of these findings will be determined as part of the final analysis of both clinical trials.

We are also exploring the use of cyclodextrins in the treatment of Alzheimer's disease under a collaborative arrangement with Kerwin Research Center, which is funding this project. In January 2018, the FDA authorized a single patient IND expanded access program using Trappsol® Cyclo™ for the treatment of this disease, and in October 2018, we filed a patent application with respect to the use of hydroxypropyl beta cyclodextrins in the treatment of Alzheimer's disease.

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 with continuing growth in research and new product development. 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.

Substantially all of our revenues are 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®, Aquaplex®, and AP™-Flavor product lines. We currently sell our products directly to customers in the pharmaceutical, diagnostics, and industrial chemical industries, and to chemical supply distributors.

Trappsol® Cyclo™

At the end of 2009, we provided Trappsol® Cyclo™ (our first generation product) to a customer for compassionate use as an Investigational New Drug to treat a set of twins in the U.S. who were diagnosed NPC, also known as Childhood Alzheimer’s. NPC is a fatal disease caused by a genetic defect that prevents proper handling of cholesterol in the body’s

cells. The patient's treatment with our Trappsol® Cyclo™ product proved to provide an ameliorative benefit. On May 17, 2010, the FDA granted orphan drug status for Trappsol® Cyclo™ for the treatment of NPC. Trappsol® Cyclo™ (first generation and second generation product) has been administered to more than 20 NPC patients in compassionate use programs around the world, including in the U.S., Brazil and Spain. Our annual sales of Trappsol® Cyclo™ decreased to $167,000 for 2018 from $342,000 for 2017. In 2012, we began to offer 100ml vials of Trappsol® Cyclo™ in a liquid form from a contract manufacturer (second generation product). In 2014, we completed validation of the proprietary Trappsol® Cyclo™ manufacturing process and submitted a Type II Drug Master File to the FDA. In 2015, we established an International Clinical Program that includes a team of experienced drug development companies and individuals. Our third generation product of Trappsol® Cyclo™ in liquid form is in clinical trials. We hold Orphan Drug Designation for Trappsol® Cyclo™ in both the U.S. and Europe.

Resale of Cyclodextrin and Cyclodextrin Complexes

Our sales of cyclodextrins and cyclodextrin complexes are primarily to chemical supply houses around the world, to pharmaceutical companies, to food companies for research and development and to diagnostics companies.

We acquire our products principally from outside the United States, including from Wacker Biosolutions, a division of Wacker Chemie AG (Germany), with a production facility located in Adrian, Michigan and Hangzhou Pharma and Chem Co. (China), Quian Hui (China), and Cyclodextrin Research & Development Laboratory (Hungary), and are gradually finding supply sources in the United States. While we enjoy lower supply prices from outside the United States, changes in shipping costs for our current order quantities and currency exchange rates are making domestic sources more competitively priced. We make patent information about cyclodextrins available to our customers. We also offer our customers our knowledge of the properties and potential new uses of cyclodextrins and complexes.

As most of our customers use our cyclodextrin products in their research and development activities, the timing, product mix, and volume of their orders from us are unpredictable. We also have four large customers (each of whom has historically purchased from us annually and, depending upon the year, may account for greater than 10% of our annual revenues) who have a significant effect on our revenues when they increase or decrease their research and development activities that use cyclodextrins. We keep in constant contact with these customers as to their cyclodextrin needs so we can maintain the proper inventory composition and quantity in anticipation of their needs. The sales to large customers and the product mix and volume of products sold has a significant effect on our revenues and product margins. These factors contribute to our revenue volatility from quarter to quarter and year to year.

Liquidity and Capital Resources

Our cash increased to $2,217,000 as of December 31, 2018, from $1,271,000 at December 31, 2017. Our current assets less current liabilities was $844,000 at December 31, 2018 compared to $953,000 at December 31, 2017. Cash used in operations for 2018 increased to $3,188,000 compared to $3,062,000 for 2017. Our increase in cash and working capital is due to equity issuances. The increase in cash used in operations is due primarily to our net loss and increasing expenses for our drug development and expansion strategy, which we intend to continue funding with the capital we raised.

During the year ended December 31, 2018, we generated net proceeds of approximately $4,102,000 from the sale of our equity securities in two private placements, and approximately $130,000 in addition in January 2019 following the initial closing of our December 2018 private placement.

We plan to use the proceeds of our stock transactions primarily for the development of our Trappsol® Cyclo™ orphan drug product, including in connection with our continuing International Clinical Program and U.S. clinical trials, and other general corporate purposes.

We will need to raise additional capital to support our ongoing operations and continue our clinical trials. While we presently lack sufficient cash to meet our anticipated operating costs and capital expenditure requirements through April 2020, 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. Our need for additional capital as described above raises 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.

Our consolidated financial statements for the years ended December 31, 2018 and 2017 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. We have incurred losses from operations in each of our last five fiscal years. Our ability to continue as a going concern is dependent upon the availability of equity financing as noted above.

At December 31, 2018, we had approximately $11,903,000 in net state and federal operating loss carryforwards expiring from 2020 through 2037, including $3,260,000 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, 2018.

Results of Operations - 2018 compared to 2017

For 2018, we incurred a net loss of $4,255,000, compared to a net loss in 2017 of $3,833,000. Total revenues for 2018 were $1,011,000 compared to $1,238,000 for 2017.

Our change in the mix of our product sales for 2018 and 2017 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 decreased 51% to $167,000 for 2018 from $342,000 for 2017. Our 2017 sales to this customer were $287,000 (84% of total 2017 sales of Trappsol® Cyclo™) with the remainder sold to individual institutions in approved compassionate use programs in Europe. The population of patients who use the product on a compassionate basis is small.

Trappsol® HPB

Our sales of Trappsol® HPB decreased 32% to $484,000 for 2018 from $711,000 for 2017.

Trappsol® other products

Our sales of other Trappsol® products increased 79% to $234,000 for 2018 from $131,000 for 2017.

Aquaplex®

Our sales of Aquaplex® increased to $117,000 for 2018 compared to $18,000 for 2017, and are primarily attributable to a single customer. The increase 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 $110,674 in 2018, $16,512 in 2017, $133,813 in 2016, $75,474 in 2015, and $34,027 in 2014.

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 2018, our five largest customers (Ventana Medical Systems, Inc., Uno Healthcare, Siemens Medical Solutions USA, Inc., Sigma-Aldrich Fine Chemicals, Inc., and BAS Evansville, Inc.) accounted for 61% of our revenues, and the largest accounted for 18% of our revenues. In 2017, our five largest customers (Charles River Laboratories, Inc., Uno Healthcare, Ventana Medical Systems, Inc., Thermofisher Scientific Diagnostics, Inc., and Siemens Medical Solutions USA, Inc.) accounted for 73% of our revenues, and the largest accounted for 25% 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 (excluding any allocation of direct and indirect overhead and handling costs) decreased to $105,000 for 2018 compared to $133,000 for 2017. Our cost of products sold as a percentage of product sales was 10% for 2018 and 11% for 2017. 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 (excluding any allocation of direct and indirect overhead and handling costs) and the related margin. We did not experience any significant increases in material costs during 2018 or 2017.

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 decreased 1% to $1,172,000 for 2018, from $1,183,000 for 2017. The decrease in personnel expense is due to a slight decrease in employee benefits. We expect to maintain our level of employees and related costs in the near term.

Research and development expenses increased 18% to $2,711,000 for 2018, from $2,293,000 for 2017. Our research and development expenses are due to our International Clinical Program. We expect research and development costs to increase in 2019 as we continue to seek regulatory approval for the use of Trappsol® Cyclo™ in the treatment of NPC.

Repairs and maintenance expenses decreased 64% to $4,000 for 2018 from $11,000 for 2017. This decrease is due to low levels of maintenance required on equipment and rental facilities. We expect our repairs and maintenance expenses to remain consistent in 2019.

Professional fees decreased 10% to $809,000 for 2018 from $903,000 for 2017. The decrease from 2017 was due to reduced activity in 2018 in our lawsuit against the NIH, and reduced intellectual property related expenses. Professional fees may increase in the future due to new initiatives in raising capital and the continuation of product development.

Office and other expenses decreased 16% to $354,000 for 2018 from $421,000 for 2017.

Board of Directors fees and costs decreased to $95,000 for 2018 from $118,000 for 2017. Board of Directors fees and costs include fees paid to our non-employee directors and scientific advisory board members, reimbursement of expenses of our board members, and related expenses.

Amortization and depreciation increased 11% to $10,000 for 2018 from $9,000 for 2017. This increase is due to the purchase of new equipment in 2018.

Freight and shipping decreased 25% to $6,000 for 2018 from $8,000 for 2017. Freight and shipping is dependent on frequency of ordering products for inventory and frequency of shipping out products sold.

We recorded an impairment expense for slow moving inventory of $12,150 and $5,500 for 2018 and 2017, respectively.

We increased our valuation allowance to allow for 100% of the 2018 increase in our deferred tax asset and did not recognize an income tax benefit or provision for 2018 and 2017.

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. 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, 2018, we fully reserved for our net deferred tax asset with a $6,235,000 valuation allowance. We increased our valuation allowance by $1,575,000 in 2018 to reduce our recognized deferred tax asset to zero.

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.

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, 2018.

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.

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.

CTD HOLDINGS, INC. AND SUBSIDIARIES

CONSOLIDATED FINANCIAL STATEMENTS

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders

CTD Holdings, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of CTD Holdings, Inc. and subsidiaries (the "Company") as of December 31, 2018 and 2017, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2018, and the related notes (collectively referred to as the "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, 2018 and 2017, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2018, 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 Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has suffered recurring losses from operations and has a significant accumulated deficit. In addition, the Company continues to experience negative cash flows from operations. These factors raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The accompanying financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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

Our audits included performing procedures to assess the risks of material misstatement of the 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.

/s/ WithumSmith+Brown, PC

We have served as the Company’s auditor since 2011.
Orlando, Florida

March 15, 2019

CTD HOLDINGS, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

	December 31, 2018	2017
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$*2,217,412*	$*1,270,973*
Accounts receivable	*80,044*	*56,860*
Inventory, net	*416,531*	*471,221*
Current portion of mortgage note receivable	*37,439*	*35,884*
Other	*18,185*	*60,846*
Total current assets	*2,769,611*	*1,895,784*
FURNITURE AND EQUIPMENT, NET	*18,571*	*25,736*
MORTGAGE NOTE RECEIVABLE, LESS CURRENT PORTION	*129,674*	*167,128*
TOTAL ASSETS	$*2,917,856*	$*2,088,648*
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued expenses	$*1,925,332*	$*943,030*
STOCKHOLDERS' EQUITY		
Common stock, par value $.0001 per share, 500,000,000 and 100,000,000 shares authorized at December 31, 2018 and 2017, respectively, 90,759,324 and 72,999,361 shares issued and outstanding at December 31, 2018 and 2017, respectively	*9,075*	*7,299*
Preferred stock, par value $.0001 per share, 0 and 5,000,000 shares authorized at December 31, 2018 and 2017, respectively, Series B – 50,000 shares designated, convertible 0 and 15,500 shares issued and outstanding at December 31, 2018 and 2017, liquidation preference $0 and $1,550,000 December 31, 2018 and 2017, respectively	-	*2*
Additional paid-in capital	*18,701,211*	*14,470,984*
Stock subscription receivable	*(130,062)*	-
Accumulated deficit	*(17,587,700)*	*(13,332,667)*
Total stockholders' equity	*992,524*	*1,145,618*
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$*2,917,856*	$*2,088,648*

See accompanying Notes to Consolidated Financial Statements.

CTD HOLDINGS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31,	
	2018	**2017**
REVENUES		
Product sales	$*1,011,477*	$*1,237,756*
EXPENSES		
Personnel	*1,171,941*	*1,183,441*
Cost of products sold (exclusive of depreciation and amortization, shown separately below)	*105,026*	*132,918*
Research and development	*2,711,275*	*2,292,892*
Repairs and maintenance	*3,821*	*10,500*
Professional fees	*808,770*	*902,714*
Office and other	*354,102*	*421,256*
Board of Directors fees and costs	*95,431*	*117,555*
Depreciation	*10,124*	*9,271*
Freight and shipping	*5,643*	*7,847*
Loss (gain) on disposal of equipment	-	*(2,817)*
Inventory write down	*12,150*	*5,500*
Total expenses	*5,278,283*	*5,081,077*
LOSS FROM OPERATIONS	*(4,266,806)*	*(3,843,321)*
OTHER INCOME		
Investment and other income	*11,773*	*10,261*
Total other income	*11,773*	*10,261*
LOSS BEFORE INCOME TAXES	*(4,255,033)*	*(3,833,060)*
PROVISION FOR INCOME TAXES	-	-
NET LOSS	$*(4,255,033)*	$*(3,833,060)*
BASIC AND FULLY DILUTED NET LOSS PER COMMON SHARE	$*(0.05)*	$*(0.05)*
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING	*81,756,839*	*72,037,167*

See accompanying Notes to Consolidated Financial Statements.

CTD HOLDINGS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

YEARS ENDED DECEMBER 31, 2018 AND 2017

	Common Stock		Preferred Stock Series B		Additional			Total
	Shares	Par Value	Units	Par Value	Paid-In Capital	Subscription Receivable	Accumulated Deficit	Stockholders' Equity
Balance, December 31, 2016	*66,952,529*	$*6,695*	-	$ -	$*11,018,915*	$ -	$*(9,499,607)*	$*1,526,003*
Sale of common stock, net of issuance fees	*5,754,832*	*575*	-	-	*1,850,480*	-	-	*1,851,055*
Sale of preferred stock units, net of issuance fees	-	-	*15,500*	*2*	*1,489,998*	-	-	*1,490,000*
Stock compensation	*292,000*	*29*	-	-	*111,591*	-	-	*111,620*
Net loss	-	-	-	-	-	-	*(3,833,060)*	*(3,833,060)*
Balance, December 31, 2017	*72,999,361*	*7,299*	*15,500*	*2*	*14,470,984*	-	*(13,332,667)*	*1,145,618*
Sale of preferred stock units, net of issuance fees	-	-	*20,100*	*2*	*1,959,998*	-	-	*1,960,000*
Conversion of preferred stock units to common stock	*14,240,000*	*1,424*	*(35,600)*	*(4)*	*(1,420)*	-	-	-
	3,519,963	*352*	-	-	*2,271,649*	*(130,062)*	-	*2,141,939*

Sale of common stock, net of issuance fees								
Net loss	-	-	-	-	-		*(4,255,033)*	*(4,255,033)*
Balance, December 31, 2018	*90,759,324*	$*9,075*	-	$ -	$*18,701,211*	$*(130,062)*	$*(17,587,700)*	$*992,524*

See accompanying Notes to Consolidated Financial Statements.

CTD HOLDINGS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31, 2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$*(4,255,033)*	$*(3,833,060)*
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	*10,124*	*9,271*
Gain on disposal of equipment	*-*	*(2,817)*
Stock compensation to employees	*19,400*	*65,205*
Stock compensation to nonemployees	*64,020*	*53,475*
Inventory valuation allowance	*12,150*	*5,500*
Increase or decrease in:		
Accounts receivable	*(23,184)*	*32,807*
Inventory	*42,540*	*20,676*
Other current assets	*42,661*	*(6,967)*
Accounts payable and accrued expenses	*898,882*	*593,428*
Total adjustments	*1,066,593*	*770,578*
NET CASH USED IN OPERATING ACTIVITIES	*(3,188,440)*	*(3,062,482)*
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of furniture and equipment	*(2,959)*	*(6,856)*
Proceeds from mortgage note receivable	*35,899*	*34,409*
Proceeds from sale of property and equipment, net of closing costs	*-*	*4,650*
NET CASH PROVIDED BY INVESTING ACTIVITIES	*32,940*	*32,203*
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from sale of common stock, preferred stock and warrants, net of issuance costs	*4,101,939*	*3,341,055*
NET CASH PROVIDED BY FINANCING ACTIVITIES	*4,101,939*	*3,341,055*
NET INCREASE IN CASH AND CASH EQUIVALENTS	*946,439*	*310,776*
CASH AND CASH EQUIVALENTS, beginning of year	*1,270,973*	*960,197*
CASH AND CASH EQUIVALENTS, end of year	$*2,217,412*	$*1,270,973*
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION		
Cash paid for interest	$-	$-

Cash paid for income taxes	$-	$-
SUPPLEMENTAL DISCLOSURE OF NONCASH INVESTING AND FINANCING ACTIVITIES		
Common stock issued in exchange for a subscription receivable	$*130,062*	$-
Conversion of preferred stock into common stock	$*1,424*	$-

See accompanying Notes to Consolidated Financial Statements

CTD HOLDINGS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2018 AND 2017

(*1*) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:

The following is a summary of the more significant accounting policies of CTD Holdings, Inc. and subsidiaries (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, with operations beginning in *July 1992.* We are a biotechnology company that develops cyclodextrin-based products for the treatment of disease. We have filed a Type II Drug Master File with the U.S. Food and Drug Administration ("FDA") for our lead drug candidate, Trappsol® Cyclo™ as a treatment for Niemann-Pick Type C disease ("NPC"), a rare and fatal cholesterol metabolism disease that impacts the brain, lungs, liver, spleen, and other organs. The FDA approved our Investigational New Drug application (IND) which describes our Phase I clinical plans in the U.S. for Trappsol® Cyclo™ 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.* We have also filed Clinical Trial Applications with several European regulatory bodies, including those in the United Kingdom, Sweden and Italy, and in Israel, all of which have approved our applications. The *first* patient was dosed in our European study in *July 2017.*

We also sell cyclodextrins and related products to the pharmaceutical, nutritional, and other industries, primarily for use in diagnostics and specialty drugs with continuing growth in research and new product development. 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 which had been primarily reselling basic cyclodextrin products.

(b) BASIS OF PRESENTATION—The consolidated financial statements include the Company and its wholly owned subsidiaries. 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.

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. Based on management's assessment of the credit history with customers having outstanding balances and current relationships with them, an allowance for doubtful accounts was *not* deemed necessary at *December 31, 2018* and *2017.*

(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 *$39,700* and *$27,500* at *December 31, 2018* and *2017,* respectively.

(f) MORTGAGE NOTE RECEIVABLE—The mortgage note receivable is stated at amortized value, which is the amount we expect to collect.

CTD HOLDINGS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2018* AND *2017

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

(g) 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.

(h) REVENUE RECOGNITION— Effective *January 1, 2018,* the Company adopted the provisions of ASC *606* using the modified retrospective method. The adoption of the new revenue standards as of *January 1, 2018* did *not* change the Company's revenue recognition as the majority of its revenues continues to be recognized when the customer takes control of the product. As the Company did *not* identify any accounting changes that impacted the amount of reported revenues with respect to its product revenues, *no* adjustment to retained earnings was required upon adoption.

Under the new revenue standards, 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.

CTD HOLDINGS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2018* AND *2017

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

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

(i) 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.

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

(k) RESEARCH AND DEVELOPMENT COSTS—Research and development costs are expensed as incurred.

(l) 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.

The Tax Cut and Jobs Act (the “Tax Act”) was enacted on *December 22, 2017.* The Tax Act contains several key provisions including, among other things, reducing the U.S. federal corporate tax rate from *35%* to *21%.* Changes in tax law are accounted for in the period of enactment. In addition, federal net operating losses (“NOLs”) generated during future periods will be carried forward indefinitely, but will be subject to an *80%* utilization against taxable income. The carryback provision has been revoked for NOLs after *January 1, 2018.*

(m) 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 convertible preferred stock and outstanding warrants to purchase *32,192,294* and *28,500,478* common shares were antidilutive for *2018* and *2017,* respectively.

(n) STOCK BASED COMPENSATION—The Company periodically awards stock to employees, directors, 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.

(o) FAIR VALUE MEASUREMENTS AND DISCLOSURES–The Fair Value Measurements and Disclosures topic of the Accounting Standards Codification ("ASC") 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.

CTD HOLDINGS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2018* AND *2017

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

We have *no* assets or liabilities that are required to have their fair value measured on a recurring basis at *December 31, 2018* or *2017.* 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, 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, 2018* and *2017,* the carrying value of the mortgage note receivable approximates fair value.

(p) LIQUIDITY AND GOING CONCERN— For the year ended *December 31, 2018* and *2017,* the Company incurred net losses of *$4,255,000* and *$3,833,000,* respectively. The Company has an accumulated deficit of approximately *$17,588,000* at *December 31, 2018.* Our recent losses have predominantly resulted from research and development expenses for our Trappsol® Cyclo™ product and other general operating expenses, including board advisory fees. 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.

For year ended *December 31, 2018,* our operations used approximately *$3,188,000* in cash. This cash was provided primarily by cash on hand and net proceeds of *$4,102,000* from equity issuances. At *December 31, 2018,* the Company had a cash balance of *$2,217,000* and current assets less current liabilities of *$844,000.* 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.

The Company has incurred losses from operations in each of the last *five* years. We will need 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. 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 year ended *December 31, 2018* and *2017* 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. We have incurred losses from operations in each of our last *five* fiscal years. Our ability to continue as a going concern is dependent upon the availability of equity financing as noted above. We will need to raise additional capital to support our ongoing operations and continue our clinical trials. 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.

(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. 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 *August 2016,* the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") *2016-15,* "Classification of Certain Cash Receipts and Cash Payments (a consensus of the Emerging Issues Task Force)." The amendments in this ASU relate to *eight* specific types of cash receipts and cash payments which current U.S. generally accepted accounting principles ("U.S. GAAP") either is unclear or does *not* include specific guidance on the cash flow classification issues. The amendments in this ASU are effective for public business entities for fiscal years beginning after *December 15, 2017,* and interim periods within those fiscal years. The Company adopted this ASU effective *January 1, 2018* and there was *no* significant impact on its consolidated financial statements and disclosures.

CTD HOLDINGS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2018* AND *2017

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

In *February 2016,* the FASB issued ASU *2016-02,* Leases (Topic *842*), which requires that lessees recognize assets and liabilities for leases with lease terms greater than *12* months in the statement of financial position. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. This update also requires improved disclosures to help users of financial statements better understand the amount, timing and uncertainty of cash flows arising from leases. The update is effective for fiscal years beginning after *December 15, 2018,* including interim reporting periods within that reporting period. The Company will adopt this ASU effective *January 1, 2019* and does *not* expect a significant impact on its consolidated financial statements and disclosures.

Between *May 2014* and *December 2016,* the FASB issued several ASUs on Revenue from Contracts with Customers (Topic *606*). These updates will supersede nearly all existing revenue recognition guidance under current U.S. GAAP. The core principle is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration to which an entity expects to be entitled for those goods or services. A *five*-step process has been defined to achieve this core principle, and, in doing so, more judgment and estimates *may* be required within the revenue recognition process than are required under existing U.S. GAAP. The standards are effective for annual periods beginning after *December 15, 2017,* and interim periods therein, using either of the following transition methods: (i) a full retrospective approach reflecting the application of the standards in each prior reporting period with the option to elect certain practical expedients, or (ii) a retrospective approach with the cumulative effect of initially adopting the standards recognized at the date of adoption (which includes additional footnote disclosures). Effective *January 1, 2018,* the Company adopted the provisions of ASC *606* using the modified retrospective method. The adoption of the new revenue standards as of *January 1, 2018* did *not* change the Company's revenue recognition as the majority of its revenues continues to be recognized when the customer takes control of the product. As the Company did *not* identify any accounting changes that impacted the amount of reported revenues with respect to its product revenues, *no* adjustment to retained earnings was required upon adoption.

(*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. 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. The Company adopted the requirements of ASC *606* on *January 1, 2018* using the modified retrospective method. See Note *1*(h) – Revenue Recognition for additional discussion.

Revenues by product are summarized as follows:

	Year Ended December 31,	
	2018	**2017**
Trappsol® Cyclo™	$*166,596*	$*342,231*
Trappsol® HPB	*484,101*	*710,939*
Trappsol® Fine Chemical	*233,910*	*130,982*
Aquaplex®	*116,806*	*17,760*
Other	*10,064*	*35,844*
Total revenues	$*1,011,477*	$*1,237,756*

All of our sales of Trappsol® Cyclo™ for the year ended *December 31, 2018* and *84%* of our sales of Trappsol® Cyclo™ for the year ended *December 31, 2017* were to a single customer who exports the drug to South America. Substantially all of our Aquaplex® sales are to *one* customer.

CTD HOLDINGS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2018* AND *2017

(*3*) MAJOR CUSTOMERS AND SUPPLIERS:

Our revenues are derived primarily from chemical supply and pharmaceutical companies located primarily in the United States. In *2018, four* major customers accounted for *57%* of total revenues. Accounts receivable balances for these major customers represent *31%* of total accounts receivable at *December 31, 2018.* In *2017, three* major customers accounted for *59%* of total revenues. Accounts receivable balances for these major customers represent *27%* of total accounts receivable at *December 31, 2017.*

Substantially all inventory purchases were from *three* vendors in *2018* and *2017.* 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, 2018,* the product mix of our revenues consisted of *17%* biopharmaceuticals, *71%* basic natural and chemically modified cyclodextrins, and *12%* cyclodextrin complexes. For the year ended *December 31, 2017,* the product mix of our revenues consisted of *28%* biopharmaceuticals, *71%* basic natural and chemically modified cyclodextrins, and *1%* 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.* Scheduled debt principal collections on this mortgage for the next *five* years

and thereafter are as follows:

Year Ending December 31,	Principal
2019	$*37,439*
2020	*39,061*
2021	*40,754*
2022	*42,520*
2023	*7,339*
Thereafter	-
	$*167,113*

(*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. The bank accounts *may* exceed federally insured levels; however, we have *not* experienced any losses in such accounts.

CTD HOLDINGS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2018* AND *2017

(*6*) FURNITURE AND EQUIPMENT:

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

	2018	**2017**
Machinery and equipment	$*16,089*	$*14,764*
Office furniture	*52,820*	*51,186*
	68,909	*65,950*
Less: accumulated depreciation	*50,338*	*40,214*
Furniture and equipment, net	$*18,571*	$*25,736*

(*7*) EQUITY TRANSACTIONS:

The Company expensed *$83,420* and *$118,680* in employee and board member stock compensation in *2018* and *2017,* respectively. These shares were valued using quoted market values. The Company accrues stock compensation expense over the period earned for employees and board members. In *2018,* the Company did *not* issue shares of Common Stock as a bonus. In *2017,* the Company issued *292,000* shares of Common Stock to *eight* board members, the Company's secretary, and to employees as a bonus.

In *April 2014,* we entered into a *one*-year agreement with Scarsdale Equities, LLC ("Scarsdale"), which was subsequently extended, to act as our financial advisor and exclusive placement agent. Under the agreement, Scarsdale is entitled to a fee with respect to each private placement of debt or equity securities of the Company in an amount equal to *6%* of the proceeds of such financing raised by Scarsdale, and a *seven*-year warrant to purchase *6%* of the securities issued as a part of such financing raised by Scarsdale, with an exercise price equal to *100%* of the offering price of the securities sold during the term of the agreement. The foregoing compensation terms were modified for private placements effected in *2017,* resulting in the compensation described in more detail below. The agreement also provides for payment of the above fees for any financing within *one* year of the expiration of the term, with investors identified by Scarsdale during the term. N. Scott Fine, the Company's Chief Executive Officer and Chairman of the

Board, was a principal of Scarsdale at the time we initially retained Scarsdale as our financial adviser, and his son is currently employed by Scarsdale, is active on our account and serves as our Secretary.

On *February 23, 2017,* the Company issued *5,754,832* "Units" at a purchase price of *$0.35* per Unit in a private placement, each Unit consisting of *one* share of Common Stock, and a *seven*-year warrant to purchase an additional share of Common Stock at an exercise price of *$0.35,* for aggregate gross proceeds to the Company of approximately *$2* million. Scarsdale acted as financial advisor to the Company in connection with the private placement and was paid a cash fee of approximately *$153,000,* and it and its designees were issued *seven*-year warrants to purchase *164,074* Units at an exercise price of *$0.35* per Unit. A *$10,000* cash fee was also paid to another party with respect to this private placement.

In *October 2017,* the Company completed a private placement of *15,500* preferred stock "Units" at a purchase price of *$100* per Unit, each Unit consisting of *one* share of Series B Convertible Preferred Stock ("Series B Preferred Stock") convertible into *400* shares of Common Stock, and *seven*-year warrants to purchase *400* shares of Common Stock at an exercise price of *$0.25* per share. The Series B Preferred Stock was automatically converted into Common Stock on *May 23, 2018,* when the Company increased its authorized shares of Common Stock, which resulted in the Company having a sufficient number of authorized and unissued shares of Common Stock to permit the conversion or exercise, as applicable, of all outstanding shares of preferred stock, warrants and other convertible securities. The Series B Preferred Stock had a liquidation preference of *$100* per share, was *not* redeemable, and did *not* entitle the holder to special dividends. Scarsdale acted as financial advisor to the Company in connection with the private placement and was paid a cash fee of *$60,000,* and it and its designees were issued *seven*-year warrants to purchase *600* Units at an exercise price of *$100* per Unit.

CTD HOLDINGS, INC. AND SUBSIDIARIES

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(*7*) EQUITY TRANSACTIONS: (CONTINUED)

In *April 2018,* the Company completed a private placement of *20,100* "Units", at a price of *$100* per Unit, resulting in gross proceeds to the Company of *$2,010,000.* Each Unit consisted of *one* share of Series B Preferred Stock convertible into *400* shares of Common Stock, and *seven*-year warrants to purchase *400* shares of Common Stock at an exercise price of *$0.25* per share. Prior to *March 31, 2018,* the Company received *$74,983* in advance from these investors. Scarsdale acted as financial advisor to the Company in connection with the private placement and was paid a cash fee of *$50,000.*

On *May 23, 2018,* at a special meeting of shareholders, the Company's shareholders approved amendments to the Company's Articles of Incorporation increasing the number of authorized shares of Common Stock from *100,000,000* shares to *500,000,000* shares, and deleting references to the Series A Preferred Stock, which was *no* longer outstanding. Following the meeting, the Company filed Articles of Amendment to its Article of Incorporation which resulted in the automatic conversion of each outstanding share of Series B Preferred Stock into *400* shares of Common Stock, increasing the number of outstanding shares of Common Stock by *14,240,000.*

In *December 2018,* the Company completed a private placement of *3,519,963* common stock "Units" at a price of *$0.65* per Unit, resulting in gross proceeds to the Company of *$2,342,034,* of which *$130,063* was received in *January 2019* and is reflected in the accompanying balance sheet as a stock subscription receivable. Each Unit consisted of *one* share of common stock and a *seven*-year warrant to purchase *one* share of common stock at an exercise price of *$0.65* per share.

The following table presents the number of Common Stock warrants outstanding:

Warrants outstanding, December 31, 2016	*8,677,500*
Issued	*11,954,831*
Exercised	-
Expired	-
Warrants outstanding, December 31, 2017	*20,632,331*
Issued	*11,559,963*

Exercised	-
Expired	-
Warrants outstanding, December 31, 2018	*32,192,294*

The following table presents the number of Common Stock warrants outstanding, their exercise price, and expiration dates at *December 31, 2018:*

Warrants Issued	**Exercise Price**	**Expiration Date**
240,000	$ *0.25*	April 2021
103,500	$ *1.00*	July 2021
156,000	$ *0.50*	July 2022
78,000	$ *0.50*	August 2022
8,100,000	$ *0.25*	June 2023
5,754,831	$ *0.35*	February 2024
6,200,000	$ *0.25*	October 2024
8,040,000	$ *0.25*	April 23, 2025
3,519,963	$ *0.65*	December 2025
32,192,294		

In addition, there are *seven*-year warrants outstanding at *December 31, 2018* to purchase *480,000* Units sold in our *May 2016* private placement at an exercise price of *$0.25* per Unit, *164,074* Units sold in our *February 2017* private placement at an exercise price of *$0.35* per Unit, and *600* Units sold in our *October 2017* private placement at an exercise price of *$100* per Unit.

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(*8*) PREFERRED STOCK:

The Company's Articles of Incorporation provide for *5,000,000* shares of "blank check" preferred stock. At *December 31, 2018, no* shares of preferred stock were outstanding or designated.

In *October 2017,* the Company designated *50,000* shares of preferred stock as Series B Convertible Preferred Stock and issued an aggregate of *35,600* of such shares in connection with the private placements described in Note *7* above. Each share of Series B Preferred Stock was convertible into *400* shares of Common Stock, had a liquidation preference of *$100* per share, and did *not* entitle the holder to special dividends. The Series B Preferred Stock automatically converted into common stock in *2018.* Please read Note *7,* Equity Transactions, to these consolidated financial statements.

(*9*) 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 *$6,235,000* 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, 2018,* 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 recent 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.

We have available at *December 31, 2018,* unused federal and state net operating loss carryforwards totaling approximately *$11,903,000* that *may* be applied against future taxable income.

CTD HOLDINGS, INC. AND SUBSIDIARIES
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(*9*) INCOME TAXES: (CONTINUED)

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

Year Ending December 31,	**Amount**
2020	$*174,000*
2021	*71,000*
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	*3,260,000*
Total	$*11,903,000*

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. At *December 31, 2018,* the amount of net operating losses subject to an annual Section *382* limitation has *not* been determined.

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 *$3,085,000* at *December 31, 2018.*

For *2018,* we did *not* recognize a benefit or provision for income taxes. The net deferred tax asset before the valuation allowance increased *$1,575,000* from *2017* to *2018,* which is primarily the result of an additional net operating loss for *2018.* We increased our valuation allowance to offset this increase in our deferred tax asset.

For *2017,* we did *not* recognize a benefit or provision for income taxes. The net deferred tax asset before the valuation allowance increased *$1,044,000* from *2016* to *2017,* which is primarily the result of an additional net operating loss for *2017.* We increased our valuation allowance to offset this increase in our deferred tax asset.

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

	2018	**2017**
Deferred tax assets:		
Net operating loss carryforwards	$*3,017,000*	$*2,206,000*
Tax credits	*3,085,000*	*2,397,000*
Impairment allowances	*10,000*	*7,000*
Stock compensation	*64,000*	*20,000*
Other	*62,000*	*35,000*
Less valuation allowance	*(6,235,000)*	*(4,660,000)*
Deferred tax asset, net of valuation	*3,000*	*5,000*
Deferred tax liabilities:		
Property and equipment	*(3,000)*	*(5,000)*
Deferred tax liabilities	*(3,000)*	*(5,000)*
Net tax assets	$-	$-

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(*9*) INCOME TAXES: (CONTINUED)

On *December 22, 2017,* the President of the United States signed into law the Tax Cuts and Jobs Act (H.R. *1*) (the "Act"). The Act includes a number of changes in existing tax law impacting businesses including, among other things, a permanent reduction in the corporate income tax rate from *34%* to *21%,* effective *January 1, 2018.*

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. The Company's net tax asset as of *December 31, 2018* was determined based on the current enacted federal tax rate of *34%* prior to the passage of the Act. As a result of the reduction in the corporate income tax rate to *21%* from *34%* under the Act, the Company revalued its net deferred tax assets and liabilities as of *January 1, 2018.* The impact of the reduction of the income tax rate was a reduction of deferred tax asset and the corresponding valuation allowance of approximately *$768,000.*

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, 2018* and *34%* at *December 31, 2017,* is summarized as follows:

	2018	**2017**
Tax benefit (expense) at Federal statutory rate	$*894,000*	$*1,303,000*
Effect of State taxes	*185,000*	*139,000*
Tax credits	*676,000*	*1,135,000*
Nondeductible expenses	*(180,000)*	*(435,000)*
Tax Cuts and Jobs Act rate decrease	-	*(1,098,000)*
Valuation allowance – deferred tax assets	*(1,575,000)*	*(1,044,000)*
Total tax benefit (provision)	$-	$-

The Company files income tax returns in the U.S. Federal jurisdiction, and in the State of Florida. The Company is *no* longer subject to U.S. Federal or state income tax examinations by tax authorities for years before *2015.*

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.

(*10*) EMPLOYEE BENEFIT PLAN:

The Company maintains a *401*(k) plan available to all employees who have satisfied certain eligibility requirements. 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 *2018* and *2017,* the Company elected to match the employee's contribution, *not* to exceed *4%* of compensation. The Company's *401*(k) contributions were *$24,765* and *$14,235* for *2018* and *2017,* respectively.

(*11*) COMMITMENTS AND CONTINGENCIES:

During *2017,* the Company filed a Complaint against the National Institutes of Health (the "NIH") in the United States District Court for the Northern District of Florida, Gainesville Division. Pursuant to the Complaint, the Company is seeking an order requiring the NIH to provide the Company with records responsive to a request originally made by the Company to the NIH under the Freedom of Information Act on *October 19, 2016.* Subsequent to the filing of the Complaint, the Company received documents from the NIH with substantial redactions. Legal counsel is currently reviewing those documents and our options in connection with this proceeding.

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(*11*) COMMITMENTS AND CONTINGENCIES: (CONTINUED)

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.

On *November 26, 2018,* we entered a new *two*-year lease for approximately *2,500* square feet of office and distribution warehouse space located in Gainesville, Florida for *$1,600* per month, with a *two*-year renewal option.

(*12*) RELATED PARTY TRANSACTIONS:

As discussed in Note *7* above, N. Scott Fine, our Chief Executive Officer and Chairman of the Board, was a principal of Scarsdale at the time we initially retained Scarsdale as our financial adviser, and his son is currently employed by Scarsdale, is active on our account and serves as our Corporate Secretary.

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.

During *2017,* Rebecca A. Fine, Mr. Fine’s daughter, was employed by us as an Executive Assistant and was paid an annual salary of *$60,000.* During *2018,* she was engaged by us as a contractor to provide those services at the rate of *$5,000* per month and received a bonus of *$5,000.* She is currently engaged by us as a contractor at the rate of *$5,800* per month.

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 increased from *$90,000* to *$100,000* in *November 2017* and to his current salary of *$107,200* in *October 2018.* In addition, he received a bonus of *$10,000* in *2018.*

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. During *2017* she was paid an annual salary of *$48,000.* In *January 2018,* her annual salary increased to *$72,000.* In *January 2019* her annual salary increased to *$78,000* her current salary. In addition, she received a bonus of *$5,000* in *2018.*

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, 2018. 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, 2018.

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.

The following table contains information regarding the current members of the Board of Directors and executive officers. The ages of individuals are provided as of March 11, 2019:

Name	Age	Positions and Offices With Registrant	Year First Became Director
N. Scott Fine	62	Director, Chief Executive Officer	2014
Jeffrey L. Tate, Ph.D.	61	Director, Chief Operating Officer	2010
C.E. Rick Strattan	73	Director	1990
Markus W. Sieger	53	Director	2014
F. Patrick Ostronic	63	Director	2014
Judge Joseph J. Farnan	73	Director	2015
William S. Shanahan	78	Director	2016
Dr. Randall M. Toig	68	Director	2018
Dr. Sharon H. Hrynkow	58	Chief Scientific Officer and SVP for Medical Affairs	N/A

N. Scott Fine has been a Director of the Company since February 2014, and became our Chief Executive Officer on September 14, 2015. From 2004 until 2014, he was a principal at Scarsdale Equities, an investment banking firm located in New York City. Mr. Fine has been involved in investment banking for over 35 years working on a multitude of debt and equity financings, buy and sell side M&A, strategic advisory work and corporate restructurings. The majority of his time has been focused on transactions in the healthcare and consumer products area, including time with The Tempo Group of Jakarta, Indonesia when Mr. Fine and his family resided in Jakarta for a period of two years.

Mr. Fine currently serves on the board of directors of Kenon Holdings Ltd, a spin-off from the Israel Corporation Ltd., and Pacific Drilling S.A., all of which are public companies. Additionally, Mr. Fine serves on the board of Global Virus Network. Mr. Fine also served as Sole Director of Better Place Inc. from 2013 until 2015, where he successfully managed the global wind down of the company.

Mr. Fine was a director of Central European Distribution Corporation, a multi-billion dollar alcohol company, from 1996 until 2014, during which time he led the CEDC Board's successful efforts in 2013 to restructure the company

through a pre-packaged Chapter 11 process whereby CEDC was acquired by the Russian Standard alcohol group.

Mr. Fine's relationships within the financial community in New York and around the world, as well as his significant experience with equity and debt financing, make him a valuable contributor as a Director. Mr. Fine was appointed to the Board of Directors in connection with a private placement of Common Stock by the Company in February 2014, and has the right to be nominated to our Board (or to have a representative nominated to our Board) for up to seven years from the date of that offering.

Dr. Jeffrey L. Tate has served as a Director of the Company since August 2010 and since September 14, 2015 has served as our Chief Operating Officer. Prior to Mr. Fine's appointment as Chief Executive Officer, Dr. Tate served as our President (from August 2010) and Chief Executive Officer (from July 2014). From January 2007 to February 2010, he was president of J-Jireh Products, Incorporated, a company that develops and markets industrial, food, cosmetic and nutritional products manufactured using pulse drying technology. From January 1995 to December 2006, Dr. Tate served as a principal of J. Benson Tate Consultants LLC, a management consulting company. From July 1999 to January 2005, Dr. Tate served as Vice President of Scientific and Regulatory Affairs of Natural Biologics, LLC, a pharmaceutical company. Dr. Tate received his B.Sc. from the University of Minnesota Department of Botany and his M.Sc. and Ph.D. from the University of Minnesota Graduate School in Management of Technology and Plant Physiology, respectively.

Dr. Tate was selected to serve as a member of our Board of Directors because of his position with CTD Holdings, Inc. and his experience with biopharmaceutical development, manufacturing and regulatory compliance.

C.E. Rick Strattan has served as Director of the Company since 1990. Mr. Strattan served as Chairman and CEO from 1990 to 2014, and as treasurer of the Company from August 1990 to May 1995. From November 1987 through July 1989, Mr. Strattan was with Pharmatec, Inc., where he served as Director of Marketing and Business Development for cyclodextrins. Mr. Strattan was responsible for cyclodextrin sales and related business development efforts. From November, 1985 through May, 1987, Mr. Strattan served as Chief Technical Officer for Boots-Celltech Diagnostics, Inc. He also served as Product Sales Manager for American Bio-Science Laboratories, a Division of American Hospital Supply Corporation. Mr. Strattan is a graduate of the University of Florida receiving a B.S. degree in chemistry and mathematics, and has also received an MS degree in pharmacology, and an MBA degree in Marketing/Computer Information Sciences, from the same institution. Mr. Strattan has written and published numerous articles and a book chapter on the subject of cyclodextrins.

Mr. Strattan was selected to serve as a member of our Board of Directors because of his extensive experience with cyclodextrins, his years of executive level experience, and his advanced degrees in pharmacology.

Markus W. Sieger has been a Director of the Company since February 2014. Mr. Sieger holds a degree in Economics from the University of Applied Sciences for Business and Administration Zurich. He started his career in 1981 with Zurich Insurance Group where he specialized in information systems and organizational projects, which he managed in Switzerland and in the United States. In 1994, he joined fincoord where he built a track record of negotiating and closing complex merger and acquisition transactions and building up, strategically repositioning and reorganizing companies in both emerging and Western markets. Since 2013, Mr. Sieger has been an investor and principal at Sieger & Sieger Ltd. and Consiglio AG, focusing on strategic advisory mandates and investments. He is member of the boards of directors of various public and private companies in Western/Central and Eastern Europe. Since June 2016 Mr. Sieger has been the President and CEO of Polpharma Group, one of the leading pharmaceutical generics players in the CEE/CIS region, which is also active in the development and production of biosimilar products.

Mr. Sieger’s extensive experience in strategic, operational and investment roles make him a valuable member of our Board of Directors. Mr. Sieger was appointed to the Board of Directors in connection with a private placement of Common Stock by the Company in February 2014, and has the right to be nominated to our Board (or to have a representative nominated to our Board) for up to seven years from the date of that offering.

F. Patrick Ostronic has been a director since April 2014. Mr. Ostronic has been an officer of US Pharmacia International, Inc., a subsidiary of USP, since November 2006, and also serves as the Chief Financial Officer of The USP Group. Mr. Ostronic is also a director of Novit US, Inc., the general partner of Novit.

Mr. Ostronic’s extensive experience in finance and the pharmaceutical industry make him a valuable member of the Board of Directors. Mr. Ostronic was appointed to the Board in connection with a private placement of Common Stock by the Company in April 2014.

Joseph J. Farnan has been a director since October 2015. Judge Farnan served as a United States District Judge for the District of Delaware from 1985 to 2010 and as Chief Judge from 1997 to 2001. During his tenure, Judge Farnan presided over hundreds of bench and jury trials involving patents and complex commercial disputes. His current law practice focuses on patent litigation and consulting, and complex commercial matters. Additionally, Judge Farnan serves as an arbitrator and mediator in complex disputes.

Judge Farnan’s experience in complex legal matters makes him a valuable member of the Board of Directors.

William S. Shanahan has been a director since June 2016. Mr. Shanahan is currently retired and served as the President of Colgate-Palmolive Company from 1992 until to September 30, 2005. More recently he was employed as a Management Advisor to ValueAct Capital LLC of San Francisco and as a Consultant for Life Technologies Corporation.

Mr. Shanahan’s vast experience will greatly benefit the Company as it seeks to execute its global growth plan, and makes him a valuable member of the Board of Directors.

Dr. Randall M. Toig has been a director since March 2018. Dr. Toig has been a practicing physician for more than 35 years in obstetrics, gynecology and gynecological surgery, and practices at Gold Coast Gynecology in Chicago. He is also an associate professor of clinical obstetrics and gynecology at Northwestern University. He previously served at Northwestern Memorial Hospital practicing, teaching and serving on active staff. Dr. Toig is consistently listed in the Top Doctors of Chicago and Guide to America's Top Doctors in his fields.

Dr. Toig’s medical experience makes him a valuable member of the Board of Directors.

Dr. Sharon H. Hrynkow has served as our Chief Scientific Officer since February 2019, and as our Senior Vice President for Medical Affairs since September 2015. Prior to that, she served as the President of Global Virus Network, a nonprofit organization working to combat pandemic viral disease. She previously served as a Senior Executive at the National Institutes of Health (NIH), where she was the Deputy Director and Acting Director of the Fogarty International Center, the focal point for international research and training and for diplomatic relations for the NIH. Dr. Hrynkow also served as Associate Director of the National Institute on Environmental Health Sciences and Senior Advisor to the NIH Deputy Director. Dr. Hrynkow serves on many advisory committees for national and international organizations, and has been recognized for her contributions to global health and global science by scientific and political leaders and organizations, including with the US President's Merit Award for Senior Executives, the Order of Merit from the King of Norway and election as Fellow of the American Association for the Advancement of Science. She is an elected member of the Council on Foreign Relations. Dr. Hrynkow received her PhD in Neuroscience from the University of Connecticut Health Center and her B.A. in Biology from Rhode Island College.

Board Committee Structure

Our Board of Directors has Audit, Compensation and Governance Committees as standing committees. Currently, N. Scott Fine, F. Patrick Ostronic and Jeffrey L. Tate serve as the members of our Audit Committee; Markus W. Sieger, F. Patrick Ostronic and C.E. Rick Strattan serve as the members of our Compensation Committee; and Markus W. Sieger and N. Scott Fine serve as the members of our Governance Committee.

Audit Committee Financial Expert

The Board of Directors has determined that F. Patrick Ostronic qualifies as an audit committee financial expert within the meaning of SEC regulations.

Code of Ethics

We have adopted a code of ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. Our code of ethics will be provided to any person without charge, upon request. Requests should be addressed to Investor Relations Department, c/o CTD Holdings, Inc., PO Box 1180, Alachua, Florida 32616-1180.

Section 16(a) Beneficial Ownership Reporting Compliance

We are required to identify each person who was an officer, director or beneficial owner of more than 10% of our registered equity securities during our most recent fiscal year and who failed to file on a timely basis reports required by Section 16(a) of the Securities Exchange Act of 1934.

Based solely upon a review of Forms 3 and 4 and amendments thereto filed with the SEC during the year ended December 31, 2018, no person who, at any time during the year ended December 31, 2018 was a director, officer or beneficial owner of more than 10 percent of the Company's Common Stock failed to file on a timely basis, as disclosed in the above forms, reports required by Section 16(a) of the Exchange Act during the year ended December 31, 2018, except for a late a Form 3 filing by Dr. Randall M. Toig, and two late Form 4 filings by Novit, LP.

Item 11. Executive Compensation.

Executive Compensation

The following table contains information concerning the compensation paid during our fiscal years ended December 31, 2018 and 2017 to (i) the person who served as our Chief Executive Officer during 2018, and (ii) our executive officers as of December 31, 2018 whose compensation exceeded $100,000 (collectively, our "Named Executive Officers").

SUMMARY COMPENSATION TABLE

Name & Principal Position	Year	Salary ($)	Stock Awards ($) (1)	All Other Compensation ($) (2)	Total ($)
N. Scott Fine	2018	400,000	4,294	62,347	466,641
CEO	2017	400,000	16,170	24,673	440,843
Jeffrey L. Tate	2018	186,667	4,294	27,233	218,194
COO	2017	155,000	16,170	17,371	188,541
Dr. Sharon H. Hrynkow	2018	232,000	-	7,947	239,947
Chief Scientific Officer (3)					

(1) Reflects award of 20,000 shares to each Named Executive Officer in 2018 and 2017 as compensation for services as a member of the Company's board of directors in 2018 and 2017, respectively. Also reflects award of 20,000 shares in 2017 as compensation for services in the form of an employee bonus. All of the shares were fully vested upon issuance. The stock award figure represents the value of the stock award at grant date as calculated under FASB ASC Topic 718.

(2) Reflects matching contributions made under the Company's 401(k) plan, and insurance premiums for health, dental, and vision.

(3) Dr. Sharon H. Hrynkow was designated an executive officer of the Company by our Board of Directors on June 29, 2018.

Outstanding Equity Awards at Fiscal Year End

As of December 31, 2018, our Named Executive Officers had no outstanding unexercised options, unvested stock or other unvested equity incentive plan awards.

Employment Agreements

Currently, N. Scott Fine and Dr. Sharon H. Hrynkow are our only Named Executive Officer who are parties to employment agreements with us.

We entered into an Employment Agreement with Mr. Fine dated as of September 14, 2015, and amended on November 7, 2017, pursuant to which Mr. Fine serves as our Chief Executive Officer. Under the Employment Agreement:

- Mr. Fine's employment as Chief Executive Officer is for an initial term ending on September 14, 2020, subject to automatic one-year extensions unless either party notifies the other party prior to the expiration of the then term.
- Mr. Fine receives an initial base salary of $400,000 per annum.
- Mr. Fine is entitled to an annual bonus based on financial performance and personal performance targets to be established by the Board of Directors or a committee thereof.

In the event of the termination of Mr. Fine's employment by the Company without Cause (as defined in the Employment Agreement), Mr. Fine will be entitled to continued payment of his base salary for a period of one-year following termination, and the payment of any bonus previously earned by Mr. Fine but not yet paid.

We entered into an Employment Agreement with Dr. Hrynkow dated as of September 14, 2015, and amended on November 8, 2017. Under the Employment Agreement:

Dr. Hrynkow employment with us is for an initial term ending on September 14, 2019, subject to automatic one-year extensions unless either party notifies the other party prior to the expiration of the then term.

Dr. Hrynkow is entitled to a base salary of $200,000 per annum, which has been increased to $248,000.

Dr. Hrynkow is entitled to an annual bonus based on financial performance and personal performance targets.

In the event of the termination of Dr. Hrynkow's employment by the Company without Cause (as defined in the Employment Agreement), Dr. Hrynkow will be entitled to continued payment of her base salary for a period of one-year following termination, and the payment of any bonus previously earned by Dr. Hrynkow but not yet paid.

Compensation of Directors

Directors of the Company are entitled to such compensation for their services as the board may from time to time determine, and reimbursements for their reasonable expenses incurred in attending meetings of directors. We did not compensate our directors for their services during 2018 or 2017, other than the issuance of 20,000 shares of common stock to each of our directors in March 2017 in consideration of their services to the Company during 2016. We expect to issue 40,000 shares of common stock in 2019 to each of our directors in consideration of their services to the Company during 2017 and 2018.

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

The following table shows the ownership of the Common Stock of the Company on March 11, 2019, by (i) those persons known by the Company to be beneficial owners of more than 5% of the Company's outstanding Common Stock; (ii) each current executive officer named in the Summary Compensation Table; (iii) each director; and (iv) all directors and executive officers as a group. Unless otherwise noted, shares are subject to the sole voting and investment power of the indicated person. Beneficial ownership is determined in accordance with the rules of the SEC. Shares of Common Stock subject to options or warrants currently exercisable or exercisable within 60 days of March 11, 2019 are deemed outstanding for computing the percentage ownership of the stockholder holding the options or warrants, but are not deemed outstanding for computing the percentage ownership of any other stockholder. Percentage of ownership is based on 91,264,463 shares of Common Stock outstanding as of March 11, 2019.

Names and Address of Individual or Identity of Group(1)	**Number of Shares Beneficially Owned**		**Approximate Percent of Class**	
Officers and Directors				
C.E. Rick Strattan	20,608,385	(2)	22.6	%
Jeffrey L. Tate	1,090,972	(3)	1.2	%
N. Scott Fine	7,952,966	(4)	8.6	%
Markus Sieger	4,365,714	(5)	4.8	%
F. Patrick Ostronic	1,214,780	(6)	1.3	%
Judge Joseph J. Farnan	1,970,000	(7)	2.1	%
William S. Shanahan	2,545,020	(8)	2.8	%
Dr. Randall M. Toig	2,215,540	(9)	2.4	%
Dr. Sharon Hrynkow	515,000	(10)	*	
All Directors and Executive Officers as a Group (9 Persons)	42,478,377	(11)	43.7	%
5% Holders				

Novit, L.P. 966 Hungerford Drive Rockville, Maryland 20850	11,535,164 (12)	12.3	%
Scarsdale Equities LLC 10 Rockefeller Plaza, Suite 720 New York, NY 10020	10,946,290 (13)	11.4	%

* Less than one percent.

(1) Unless otherwise indicated, the business address of each officer and director of the Company is c/o CTD Holdings, Inc., 6714 NW 16th Street, Suite B, Gainesville, Florida 32653.

(2) Based solely on a Schedule 13D/A filed by Mr. Strattan with the SEC on October 20, 2015, and Form 4s filed by Mr. Strattan on June 8, 2016, July 26, 2016, April 4, 2017 and February 5, 2018. Includes currently exercisable warrants to purchase 40,000 shares of Common Stock and 630,738 shares of Common Stock owned by TFBU, Inc. (“TFBU”), a tax exempt organization under Section 501(c)(3) of the Internal Revenue Code. Mr. Strattan has sole voting and dispositive power with respect to the shares of Common Stock issued in the name of TFBU.

(3) Includes currently exercisable warrants to purchase 225,000 shares of Common Stock.

(4) Includes currently exercisable warrants to purchase 1,676,483 shares of Common Stock.

(5) Includes currently exercisable warrants to purchase 342,857 shares of Common Stock.

(6) Includes currently exercisable warrants to purchase 509,890 shares of Common Stock.

(7) Includes currently exercisable warrants to purchase 630,000 shares of Common Stock.

(8) Includes currently exercisable warrants to purchase 1,239,560 shares of Common Stock.

(9) Includes currently exercisable warrants to purchase 1,107,770 shares of Common Stock.

(10) Includes currently exercisable warrants to purchase 240,000 shares of Common Stock.

(11) Includes currently exercisable warrants to purchase 6,011,560 shares of Common Stock.

(12) Based on a Schedule 13D/A filed by Novit, LP and its affiliates with the SEC on July 21, 2015. Novit U.S., Inc. is the general partner of Novit, L.P. and Katarzyna Kusmierz is the trustee of the NAP Trust, which owns all of the outstanding partnership interests in Novit, L.P. Each of Novit US, Inc. and Ms. Kusmierz share voting and dispositive power over the shares Common Stock owned by Novit, L.P. and may be deemed to own such shares of Common Stock. Includes currently exercisable warrants to purchase 2,817,582 shares of Common Stock.

(13) Based on a Schedule 13G/A filed by Scarsdale Equities, LLC with the SEC on February 19, 2019. Includes 6,506,290 shares of Common Stock held in accounts managed by Scarsdale and 4,440,000 shares of Common Stock issuable upon the exercise of warrants held in such managed accounts.

Equity Compensation Plan Information

Plan Category	Number of Securities to be issued upon exercise of outstanding options, warrants and rights (a) (#)	Weighted average exercise price of outstanding options, warrants and rights (b) ($)	Number of securities remaining available for issuance under equity compensation plans (excluding securities reflected in column (a)) (c) (#)
Equity compensation plans not approved by security holders (1)	2,345,647	$ 0.32	0
Equity compensation plans approved by security holders	None	Not Applicable	Not Applicable
Total:	2,345,647	$ 0.32	0

(1) Consists of (i) seven-year warrants to purchase 240,000 shares of Common Stock at an exercise price of $0.25 per share, issued to Scarsdale Equities and its affiliates for services provided in connection with our April 2014 private placement, (ii) seven-year warrants to purchase 103,500 shares of Common Stock at an exercise price of $1.00 per share, issued to Scarsdale Equities and its affiliates for services provided in connection with our July 2014 private placement, (iii) seven-year warrants to purchase 156,000 shares of Common Stock at an exercise price of $0.50 per share, issued to Scarsdale Equities and its affiliates for services provided in connection with our July 2015 private placement, (iv) seven-year warrants to purchase 78,000 shares of Common Stock at an exercise price of $0.50 per share, issued to Scarsdale Equities and its affiliates for services provided in connection with our August 2015 private placement, (v) seven-year warrants to purchase 480,000 Units at an exercise price of $0.25, each Unit consisting of one share of Common Stock and one warrant for one additional share of Common Stock at an

exercise price of $0.25 per share, issued to Scarsdale Equities and its affiliates for services provided in connection with our June 2016 private placement, (vi) seven-year warrants to purchase 164,074 Units at an exercise price of $0.35, each Unit consisting of one share of Common Stock and one warrant for one additional share of Common Stock at an exercise price of $0.35 per share, issued to Scarsdale Equities and its affiliates for services provided in connection with our February 2017 private placement, and (vii) seven-year warrants to purchase 600 Units at an exercise price of $100, each Unit consisting of one share of Series B Convertible Preferred Stock convertible into 400 shares of Common Stock and one warrant for one additional 400 shares of Common Stock at an exercise price of $0.25 per share, issued to Scarsdale Equities and its affiliates for services provided in connection with our October 2017 private placement.

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

Related Party Transactions

N. Scott Fine was a principal at Scarsdale Equities and a director of ours when we initially retained Scarsdale Equities as our financial adviser and exclusive placement agent in April 2014. Mr. Fine ceased to be affiliated with Scarsdale Equities on October 6, 2014. However, Mr. Fine’s son is currently employed by Scarsdale Equities, is active on our account, and serves as our Secretary. During 2018, we paid Scarsdale Equities cash fees of approximately $66,000. During 2017 we paid Scarsdale Equities cash fees of approximately $213,000 and issued it and its designees warrants to purchase (A) 164,074 Units at an exercise price of $0.35, each such Unit consisting of one share of Common Stock and one warrant for one additional share of Common Stock at an exercise price of $0.35 per share, and (B) 600 Units at an exercise price of $100, each such Unit consisting of one share of Series B Preferred Stock and one warrant to purchase 400 shares of Common Stock at an exercise price of $0.25 per share, in connection with private placements of our Common Stock.

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.

During 2017, Rebecca A. Fine, Mr. Fine's daughter, was employed by us as an Executive Assistant and was paid an annual salary of $60,000. During 2018, she was engaged by us as a contractor to provide those services at the rate of $5,000 per month and received a bonus of $5,000. She is currently engaged by us as a contractor at the rate of $5,800 per month.

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 increased from $90,000 to $100,000 in November 2017 and to his current salary of $107,200 in October 2018. In addition, he received a bonus of $10,000 in 2018.

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. During 2017 she was paid an annual salary of $48,000. In January 2018, her annual salary increased to $72,000. In January 2019 her annual salary increased to $78,000.00, her current salary. In addition, she received a bonus of $5,000 in 2018.

Director Independence

Our Board of Directors is comprised of eight individuals, two of whom are or were in the last three years employed by the Company. We have determined that of our other directors, Mr. Sieger, Mr. Ostronic, Judge Farnan, Mr. Shanahan and Dr. Toig, are "independent" using the definition set forth in the NYSE MKT Company Guide, which we have chosen to use for purposes of evaluating board independence as if we were listed on such exchange. We also do not have an independent audit committee, compensation committee or governance committee, since members of the Board who do not qualify as "independent" under the standards of the NYSE MKT Company Guide serve on each of those committees.

Item 14. Principal Accountant Fees and Services.

Audit Fees

The aggregate fees billed in 2018 and 2017 for professional services rendered by the principal accountant, WithumSmith+Brown, PC for the audit of the Company's annual financial statements, the review of financial statements included in the Company's Form 10-Q or services that are normally provided by the accountant in connection with statutory and regulatory filings or engagements was $53,645 and $52,200, respectively.

Audit-Related Fees

No fees were billed during either of the last two fiscal years for any assurance and related services by WithumSmith+Brown, PC that are not reported under the caption "Audit Fees".

Tax Fees

No fees were billed during either of the last two fiscal years for professional services rendered by WithumSmith+Brown, PC for tax compliance, tax advice, or tax planning.

All Other Fees

No other fees were billed during either of the last two fiscal years for professional services provided by WithumSmith+Brown, PC.

Audit Committee Pre-Approval Policies

The Company's Audit Committee has not adopted a policy for the pre-approval of services provided by its independent auditors. However, the Company's independent auditors are generally engaged only to audit the Company's annual financial statements and review the Company's interim financial statements.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

Exhibits

3.1	Amended and Restated Articles of Incorporation filed June 29, 2018 (incorporated by reference to the Company's Form 10-Q filed with the Securities and Exchange Commission on August 14, 2018).
3.2	By-Laws (incorporated by reference to the Company's Form 10-SB filed with the Securities and Exchange Commission on February 1, 1994).
4.1	Form of Warrant issued to investors (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed June 8, 2016).
10.1	Conversion Agreement dated as of February 19, 2014 between CTD Holdings, Inc. and C.E. Rick Strattan (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed February 20, 2014).
10.2	Voting Commitment Letter dated as of February 19, 2014 between CTD Holdings, Inc. and C.E. Rick Strattan (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K filed February 20, 2014).
10.3	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).
10.4†	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).
10.5†	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).
10.6	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).
10.7	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).
10.8	

	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).
10.9	Form of Securities Purchase Agreement between CTD Holdings, Inc. and investors in the October 2017 private placement (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed October 20, 2017).
10.10†	Employment Agreement between the Company and Dr. Sharon H. Hrynkow, dated as of September 14, 2015.*
10.11†	Amendment to Employment Agreement between the Company and Dr. Sharon H. Hrynkow, dated as of November 8, 2017.*

21.1	Subsidiaries (incorporated by reference to Exhibit 21.1 to the Company's Annual Report on Form 10-K filed April 16, 2018).
31.1	Rule 13a-14(a)/15d-14a(a) Certifications *
32.1	Section 1350 Certifications *
101.INS	XBRL Instance Document*
101.SCH	XBRL Taxonomy Extension Schema Document*
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document*
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document*
101.LAB	XBRL Taxonomy Extension Label Linkbase Document*
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document*

*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.

CTD HOLDINGS, INC.

By: /s/ N. Scott Fine
N. SCOTT FINE

Chief Executive Officer

(principal executive, financial and accounting officer)

Date: March 15, 2019

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, financial and accounting officer)

Date: March 15, 2019

By: /s/ C.E. Rick Strattan
C.E. RICK STRATTAN

Director

Date: March 15, 2019

By: /s/ Jeffrey L. Tate
JEFFREY L. TATE

By: /s/ Joseph J. Farnan
JOSEPH J. FARNAN
Director

Date: March 15, 2019

By: /s/ William S. Shanahan
WILLIAM S. SHANAHAN

Director

Date: March 15, 2019

By: /s/ F. Patrick Ostronic
F. PATRICK OSTRONIC

Chief Operating Officer; Director
Date: March 15, 2019

By: /s/ Markus W. Sieger

MARKUS W. SIEGER

Director
Date: March 15, 2019

Director
Date: March 15, 2019

By: /s/ Randall M. Toig

RANDALL M. TOIG

Director
Date: March 15, 2019

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