

CTD HOLDINGS INC
Form 10-K
March 17, 2017

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, 2016

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 (IRS Employer
incorporation or organization) Identification No.)

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6714 NW 16th Street, Suite B,
32563
Gainesville, Florida
(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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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

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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, or a smaller reporting company. See the definitions of 'large accelerated filer,' 'accelerated filer,' and 'smaller reporting 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

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, 2016, the aggregate market value of the registrant's Common Stock held by non-affiliates was \$11,257,948 based on the average bid and asked price of such Common Stock on such date.

As of March 1, 2017, there were 72,707,361 shares of registrant's Common Stock outstanding.

CTD HOLDINGS, INC.

ANNUAL REPORT ON FORM 10-K

For the Year Ended December 31, 2016

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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 Neimann-Pick Type C disease (“NPC”). NPC is a rare and fatal cholesterol metabolism disease found primarily in children and young adults. 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 US. 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. We have also filed Clinical Trial Applications with several European regulators, including the United Kingdom's Medicines and Healthcare Products Regulatory Agency, which approved our application. We expect to commence a U.S. clinical study in 2017 in which we will provide Trappsol® Cyclo™ intravenously to NPC patients two years of age and older in order to track biochemical markers of cholesterol metabolism and to measure effects on neurologic, lung and liver symptoms, with similar studies to be conducted in Europe.

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.

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 2008, one of our clients used our product, Trappsol® hydroxypropyl beta cyclodextrin, in an FDA approved compassionate use investigational new drug protocol for the treatment of NPC. We now sell this product for industrial use under our trademark Trappsol® Cyclo™. Our customer successfully applied to the FDA to designate Trappsol® Cyclo™ as an orphan drug in the treatment of NPC in support of an Investigational New Drug protocol for a particular U.S. patient. 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 and, if such application is approved, they have the ability to sell it exclusively for seven years, and may get clinical trial tax incentives. On May 17, 2010, the FDA designated Trappsol® Cyclo™ as an orphan drug for the treatment of NPC. To date, Trappsol® Cyclo™ has been administered to approximately 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 the sale of cyclodextrins, including bio-pharmaceuticals containing cyclodextrins, 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 APTM-Flavor product lines. The Trappsol® product line includes basic cyclodextrins, and cyclodextrins with different chemical adducts resulting in more than 100 different cyclodextrins. 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 200 different Aquaplex® products. Historically, substantially all of our sales of Aquaplex® products were to one chemical supply house, Sigma-Aldrich Fine Chemical. The APTM-Flavor product lines are cyclodextrins that contain various food flavors. Sales of Trappsol® and Aquaplex® comprise approximately 91% and 9%, respectively, of our 2016 product sales. Our sales of APTM-Flavors are not significant and are primarily targeted to the food industry. 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 service and trade marks 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 complexes (Aquaplex®) from Cyclodextrin Research & Development Laboratory, we have also begun purchasing some cyclodextrin complexes from Equinox Chemical in Albany, Georgia. 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 products directly to customers in the pharmaceutical, diagnostics, and industrial chemical industries, and to chemical supply distributors. For the year ended December 31, 2016, our revenues consisted of 48% biopharmaceuticals, 43% basic natural and chemically modified cyclodextrins, and 9% 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 2016 and 2015, one customer (UNO Healthcare, Inc.) accounted for 44% and 31% of our total revenue, respectively. Sigma-Aldrich Fine Chemical, Inc. accounts for almost 100% of our 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 informal business relationships with many of the producers and consumers of cyclodextrins worldwide and, over more than 25 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 Europe, and expect to conduct clinical trials in the U.S. to gain market authorization of our bio-pharmaceutical product for the treatment of NPC. 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. As a result of the shift in our business focus and these efforts, research and development expenses increased to approximately \$1,865,000 in 2016, from \$659,000 in 2015.

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 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 (EMA). 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. We have also filed Clinical Trial Applications with several European regulators, including the United Kingdom's Medicines and Healthcare Products Regulatory Agency, which approved our application. We expect to commence a U.S. clinical study in 2017 in which we will provide Trappsol® Cyclo™ intravenously to NPC patients two years of age and older in order to track biochemical markers of cholesterol metabolism and to measure effects on neurologic, lung and liver symptoms, with similar studies to be conducted in Europe.

There have also 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, 2016, we employed six 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 \$4.2 million and \$2.6 million for the years ended December 31, 2016 and December 31, 2015, 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.

We will need additional capital to fund our operations as planned.

For year ended December 31, 2016, our operations used approximately \$2,951,000 in cash. This cash was provided primarily by cash on hand, net proceeds of \$1,880,000 from equity issuances, and net proceeds of approximately \$256,000, after closing costs and repaying our bank indebtedness, from the sale of our office and manufacturing facility and related equipment. 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;

finest, 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 will rely on third parties to conduct certain of the research and clinical trials for products using Trappsol® Cyclo™.

We rely on contract 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 intend to 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 44% of our total sales in fiscal 2016. Our largest five customers collectively accounted for 74% of total sales in fiscal 2016. 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 99% 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 1, 2017, C.E. Rick Strattan, our founder and one of our directors, held the beneficial power to vote 20,568,385 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 28.3% of the issued and outstanding shares of Common Stock. Accordingly, Mr. Strattan has the power to influence or control 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 other key personnel, 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 and certain other key employees, including N. Scott Fine, our Executive Chairman and Chief Executive Officer, and Jeffrey L. Tate, Ph.D., our Director, Chief Operating Officer and Chief Scientific Officer. Our ability to manage our operations and meet our business objectives could be adversely affected if, for any reason, such officers or employees do not remain with us.

We do not have a majority independent board of directors or independent audit committee.

Our Board of Directors is currently comprised of eight people, four of whom are currently or were recently employed by the Company. Accordingly, our Board of Directors is not comprised of a majority of “independent directors” using the definition set forth in the NASDAQ Marketplace Rules. In addition, our audit, compensation and governance committees are not comprised exclusively of independent directors. Although our directors are subject to the fiduciary duties imposed on Board members pursuant to Florida law, our shareholders do not have the protection afforded by a board with a majority of independent directors and an independent audit committee which are some of the traditional procedural safeguards that protect the interests of minority shareholders. Our lack of independent directors on our board of directors may also make decisions of our board of directors more prone to legal claims or shareholder criticism than if made by a board of directors with a majority of independent board members.

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 January 27, 2017, we entered into a two-year lease for approximately 2,500 square feet of office and distribution warehouse space located in Gainesville, Florida for \$1,500 per month, with a two-year renewal option. We believe that this leased property is currently sufficient for our operating requirements.

Item 3. Legal Proceedings.

From time to time, we are a party to claims and legal proceedings arising in the ordinary course of business. Our management evaluates our exposure to these claims and proceedings individually and in the aggregate and allocates additional monies for potential losses on such litigation if it is possible to estimate the amount of loss and if the amount of the loss is probable. 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
2015	First Quarter	\$0.71	\$0.52
	Second Quarter	\$0.67	\$0.39
	Third Quarter	\$0.78	\$0.41
	Fourth Quarter	\$0.72	\$0.46
2016	First Quarter	\$0.50	\$0.25
	Second Quarter	\$0.57	\$0.29
	Third Quarter	\$0.53	\$0.33
	Fourth Quarter	\$0.51	\$0.40

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

Holder

As of March 1, 2017, 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 112.

Dividend Policy

The Company paid no dividends in 2016 and will not pay any cash dividends on its Common Stock in 2017 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 FDA in 2014 for our lead drug candidate, Trappsol® Cyclo™ (hydroxypropyl beta cyclodextrin) as a treatment for Neimann-Pick Type C disease ("NPC"), a rare and fatal cholesterol metabolism disease found primarily in children and young adults. 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 US, which was approved by the FDA in September 2016. In January 2017 the FDA granted Fast Track designation to Trappsol® Cyclo™ for the treatment of NPC. We have also filed Clinical Trial Applications with several European regulators, including the United Kingdom's Medicines and Healthcare Products Regulatory Agency, which approved our application. We expect to commence a U.S. clinical study in 2017 in which we will provide Trappsol® Cyclo™ intravenously to NPC patients two years of age and older in order to track biochemical markers of cholesterol metabolism and to measure effects on neurologic, lung and liver symptoms, with similar studies to be conducted in Europe.

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.

Substantially all of our revenues are derived from the sale of cyclodextrins, including bio-pharmaceuticals containing cyclodextrins, cyclodextrin complexes, 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 2008, we provided Trappsol® Cyclo™ 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 to our customer for Trappsol® Cyclo™ for the treatment of NPC. To date, Trappsol® Cyclo™ has been administered to approximately 20 NPC patients in compassionate use programs around the world, including in the U.S., Brazil and Spain. Our annual sales of Trappsol® Cyclo™ increased to \$697,000 for 2016 from \$352,000 for 2015. In 2012, we began to offer 100ml vials of Trappsol® Cyclo™ in a liquid form from a contract manufacturer. In 2014, we completed validation of the 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. We have also obtained Orphan Drug Designation for Trappsol® Cyclo™ in both the U.S. and Europe.

Most recently, we obtained regulatory approval of both the IND we filed with the FDA for Trappsol® Cyclo™ as a treatment for NPC, and the Clinical Trial Application we filed with the United Kingdom's Medicines and Healthcare Products Regulatory Agency. As a result, we expect to conduct multiple U.S. and international clinical studies in which we will provide Trappsol® Cyclo™ intravenously to NPC patients in order to track biochemical markers of cholesterol metabolism and to measure effects on neurologic, lung and liver symptoms.

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), but are gradually finding satisfactory 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 decreased to \$960,000 as of December 31, 2016, from \$1,842,000 at December 31, 2015. Our working capital was \$1,293,000 at December 31, 2016 compared to \$1,528,000 at December 31, 2015. We repaid all of our bank debt in 2016 with proceeds from the sales of our real property and manufacturing facility. Our bank debt had been classified as current at December 31, 2015 due to our non-compliance with a loan covenant. Cash used in operations for 2016 increased to \$2,951,000 compared to \$1,989,000 for 2015. Our decrease in cash and working capital is due to our net loss. 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, 2016, we generated net proceeds of \$1,880,000 from the sale of our equity securities in a private placement, and net proceeds of approximately \$256,000 from the sale of our office and manufacturing facility and related equipment, including our pulse dryer, after closing costs and repaying our bank indebtedness. We also sold real property located in High Springs, Florida during 2016, which had been previously classified on our balance sheets as property held for sale, with a carrying value of \$275,000. Pursuant to the terms of that sale, the buyer paid us \$10,000 in cash at closing and issued us a promissory note in the principal amount of \$265,000 secured by a mortgage in our favor on the property. The promissory note provides for monthly payments to us of \$3,653, including principal and interest at 4.25%, over a seven-year period that commenced March 1, 2016.

On February 23, 2017, subsequent to the year ended December 31, 2016, we generated additional net proceeds of \$1,879,000 from the sale of our equity securities in a private placement.

During the year ended December 31, 2015, we generated net proceeds of \$1,911,000 from the sale of our equity securities in private placements and received \$78,616 upon the exercise of outstanding warrants.

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

In January, 2017, we entered into a two-year lease for our offices and distribution warehouse space for \$1,500 per month, with a two-year renewal option.

We presently believe the Company has sufficient cash to meet its anticipated operating costs and capital expenditure requirements for at least the next twelve months. 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.

At December 31, 2016, we had approximately \$6,166,000 in net state and federal operating loss carryforwards expiring from 2020 through 2036 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, 2016.

Results of Operations - 2016 compared to 2015

For 2016, we incurred a net loss of \$4,224,000, compared to a net loss in 2015 of \$2,551,000. Total revenues for 2016 were \$1,503,000 compared to \$950,000 for 2015.

Our change in the mix of our product sales for 2016 and 2015 is as follows:

Trappsol® Cyclo™

Our sales of Trappsol® Cyclo™ increased 98% to \$697,000 for 2016 from \$352,000 for 2015. Our sales to a customer who exports Trappsol® Cyclo™ to South America were \$669,000 (96% of total sales of Trappsol® Cyclo™) for 2016. Our 2015 sales to this customer were \$296,000 (84% of total 2015 sales of Trappsol® Cyclo™). This product is designated as an orphan drug; the population of patients is small and while we expect our future sales to increase, the timing of sales will be unpredictable and our ability to market the drug for use other than research is severely constrained by regulatory restrictions.

Trappsol® HPB

Our sales of Trappsol® HPB increased 12% to \$433,000 for 2016 from \$388,000 for 2015.

Trappsol® other products

Our sales of other Trappsol® products increased by 62%, to \$201,000 from \$124,000 for 2016 and 2015, respectively.

Aquaplex®

Our sales of Aquaplex® increased to \$136,000 for 2016 compared to \$75,000 for 2015, 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 \$133,813 in 2016, \$75,474 in 2015, \$34,027 in 2014, \$2,907 in 2013, and \$77,569 in 2012.

Our largest customers continue to follow historical product ordering trends to place periodic large orders that represent a significant share of our annual revenue volume. In 2016, our five largest customers (Uno Healthcare, Thermofisher Scientific Diagnostics, Inc., Inc., Sigma-Aldrich Fine Chemicals, Inc., Siemens Medical Solutions USA, Inc., and Peregrine Pharmaceuticals, Inc.) accounted for 74% of our revenues, and the largest accounted for 44% of our revenues. In 2015, our five largest customers (Uno Healthcare, Inc., Siemens Medical Solutions USA, Inc., Sigma-Aldrich Fine Chemicals, Inc., Thermofisher Scientific Diagnostics, Inc., and Charles River Laboratories, Inc.) accounted for 59% of our revenues, and the largest accounted for 31% 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) increased to \$198,000 for 2016 compared to \$124,000 for 2015. Our cost of products sold as a percentage of product sales was 13% for both 2016 and 2015. 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 2016 or 2015.

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 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. We have four employees who provide receiving,

inspection, warehousing and shipping operations for us. The cost of these employees, and our other employees, are included in personnel expense. Our other costs of warehousing and shipping functions are included in office and other expense.

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

Personnel expenses increased 40% to \$1,274,000 for 2016, from \$908,000 for 2015. The increase in personnel expense is due to an increase in the number of employees and employee healthcare benefits. We expect personnel costs to continue to increase in 2017 as the result of additional employees and our International Clinical Program product development activities.

Research and development expenses increased 183% to \$1,865,000 for 2016, from \$659,000 for 2015. The increase in research and development expense is due to the International Clinical Program. We expect research and development costs to increase in 2017 as we continue to seek regulatory approval for the use of Trappsol® Cyclo™ in the treatment of NPC.

Repairs and maintenance expenses decreased 28% to \$24,000 for 2016 from \$33,000 for 2015. We expect our repairs and maintenance expenses to further decrease in 2017 due to the sale of our office and manufacturing facility.

Professional fees increased 32% to \$603,000 for 2016 from \$456,000 for 2015. Professional fees may further increase due to new initiatives in raising capital and the continuation of product development.

Office and other expenses increased 76% to \$585,000 for 2016 from \$333,000 for 2015.

Board of Directors fees and costs decreased to \$136,000 for 2016 from \$526,000 for 2015. This decrease is due to our Chairman of the Board (who now serves as our Chief Executive Officer) becoming an employee in 2016. 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 decreased 37% to \$107,000 for 2016 from \$169,000 for 2015. We expect our amortization and depreciation expense to further decrease in 2017 due to the sale of our office and manufacturing facility.

Freight and shipping decreased 5% to \$7,000 for 2016 from \$8,000 for 2015. Freight and shipping is dependent on frequency of ordering products for inventory and frequency of shipping out products sold.

We recorded an expense for slow moving inventory of \$5,000 in 2016 and \$17,000 for 2015.

We recorded an impairment expense on our property held for sale of \$810,000 in 2016 and \$125,000 for 2015.

Interest expense decreased to \$29,000 for 2016, from \$31,000 for 2015. We expect our interest expense to further decrease in 2017 due to the payoff of our bank debt in 2016.

We increased our valuation allowance to 100% of our deferred tax deferred tax asset and did not recognize an income tax benefit or provision for 2016. We increased our valuation allowance to 100% of our deferred tax deferred tax asset and recognized \$120,000 income tax expense in 2015.

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.

Valuation Allowance on Deferred Tax Assets

At December 31, 2016, we fully reserved for our net deferred tax asset with a \$3,616,000 valuation allowance. We increased our valuation allowance by \$2,376,000 in 2016 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, 2016.

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.

We have audited the accompanying consolidated balance sheets of CTD Holdings, Inc. and subsidiaries (the “Company”) as of December 31, 2016 and 2015, and the related consolidated statements of operations, stockholders’ equity, and cash flows for each of the years in the two-year period ended December 31, 2016. 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 conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall consolidated financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of CTD Holdings, Inc. and subsidiaries as of December 31, 2016 and 2015, and the results of their operations and their cash flows for each of the years in the two-year period ended December 31, 2016, in conformity with accounting principles generally accepted in the United States of America.

/s/ WithumSmith+Brown, PC
Orlando, Florida
March 17, 2017

CTD HOLDINGS, INC. AND SUBSIDIARIES**CONSOLIDATED BALANCE SHEETS**

	December 31,	
	2016	2015
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$960,197	\$1,842,233
Accounts receivable	89,667	55,636
Inventory	497,397	610,166
Current portion of mortgage note receivable	34,393	-
Other current assets	53,879	14,851
Total current assets	1,635,533	2,522,886
PROPERTY AND EQUIPMENT, NET	29,984	1,892,943
OTHER ASSETS		
Mortgage note receivable, less current portion	203,028	-
Property held for sale	-	275,000
Deferred costs	-	50,000
Total other assets	203,028	325,000
TOTAL ASSETS	\$1,868,545	\$4,740,829
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued expenses	\$342,542	\$257,537
Notes payable	-	703,313
Line of credit	-	34,296
Total current liabilities	342,542	995,146
STOCKHOLDERS' EQUITY		
Common stock, par value \$.0001 per share, 100,000,000 shares authorized, 66,952,529 and 58,670,347 shares issued and outstanding at December 31, 2016 and 2015, respectively	6,695	5,867
Preferred stock, par value \$.0001 per share, 5,000,000 shares authorized; no shares outstanding	-	-
Additional paid-in capital	11,018,915	9,015,582
Accumulated deficit	(9,499,607)	(5,275,766)
Total stockholders' equity	1,526,003	3,745,683
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$1,868,545	\$4,740,829

See accompanying Notes to Consolidated Financial Statements.

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CTD HOLDINGS, INC. AND SUBSIDIARIES**CONSOLIDATED STATEMENTS OF OPERATIONS**

	Year Ended December 31,	
	2016	2015
REVENUES		
Product sales	\$ 1,502,908	\$ 950,455
EXPENSES		
Personnel	1,274,313	907,744
Cost of products sold (exclusive of depreciation and amortization, shown separately below)	198,429	124,425
Research and development	1,864,726	658,505
Repairs and maintenance	23,857	32,985
Professional fees	602,715	456,636
Office and other	630,704	332,531
Board of Directors fees and costs	136,128	526,480
Amortization and depreciation	107,096	169,030
Freight and shipping	7,159	7,569
Loss (gain) on disposal of equipment	48,668	(700)
Inventory write down	5,000	17,000
Impairment on property held for sale	810,000	125,000
	5,708,795	3,357,205
LOSS FROM OPERATIONS	(4,205,887)	(2,406,750)
OTHER INCOME (EXPENSE)		
Investment and other income	10,649	6,670
Interest expense	(28,603)	(31,290)
Total other income (expense)	(17,954)	(24,620)
LOSS BEFORE INCOME TAXES	(4,223,841)	(2,431,370)
PROVISION FOR INCOME TAXES	-	(120,000)
NET LOSS	\$(4,223,841)	\$(2,551,370)
BASIC AND FULLY DILUTED NET LOSS PER COMMON SHARE	\$(0.07)	\$(0.05)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING	63,354,494	56,209,420

See accompanying Notes to Consolidated Financial Statements.

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CTD HOLDINGS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
FOR THE YEARS ENDED DECEMBER 31, 2016 AND 2015

	Common Stock Shares	Par Value	Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
Balance, December 31, 2014	54,420,882	\$5,442	\$7,088,891	\$(2,724,396)	\$4,369,937
Sale of common stock	3,900,000	390	1,831,589	-	1,831,979
Exercise of common stock warrants	314,465	31	78,585	-	78,616
Stock compensation	35,000	4	16,517	-	16,521
Net loss	-	-	-	(2,551,370)	(2,551,370)
Balance, December 31, 2015	58,670,347	5,867	9,015,582	(5,275,766)	3,745,683
Sale of common stock	8,000,000	800	1,879,200	-	1,880,000
Stock compensation	282,182	28	124,133	-	124,133
Net loss	-	-	-	(4,223,841)	(4,223,841)
Balance, December 31, 2016	66,952,529	\$6,695	\$11,018,915	\$(9,499,607)	\$1,526,003

See accompanying Notes to Consolidated Financial Statements.

CTD HOLDINGS, INC. AND SUBSIDIARIES**CONSOLIDATED STATEMENTS OF CASH FLOWS**

	Year Ended December 31,	
	2016	2015
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	\$(4,223,841)	\$(2,551,370)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	107,096	169,030
Loss (gain) on disposal of equipment	48,668	(700)
Impairment on property held for sale	810,000	125,000
Inventory valuation allowance	5,000	17,000
Write off deferred costs	50,000	-
Deferred income taxes	-	120,000
Stock compensation to employees	54,050	48,200
Stock compensation to nonemployees	67,410	26,400
Other	3,305	-
Increase or decrease in:		
Accounts receivable	(34,031)	25,345
Inventory	112,727	(45,557)
Other current assets	(39,028)	(1,574)
Accounts payable and accrued expenses	87,706	78,812
Total adjustments	1,272,903	561,956
NET CASH USED IN OPERATING ACTIVITIES	(2,950,938)	(1,989,414)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of property and equipment	(9,343)	(419,239)
Proceeds from mortgage note receivable	27,579	-
Proceeds from sale of property and equipment, net of closing costs	924,699	700
NET CASH PROVIDED BY (USED IN) INVESTING ACTIVITIES	942,935	(418,539)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from sale of common stock and warrants, net of issuance costs	1,880,000	1,910,595
Principal payments on notes payable	(719,737)	(74,759)
Proceeds from line of credit	-	54,796
Principal payments on line of credit	(34,296)	(20,500)
NET CASH PROVIDED BY FINANCING ACTIVITIES	1,125,967	1,870,132
NET DECREASE IN CASH AND CASH EQUIVALENTS	(882,036)	(537,821)

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CASH AND CASH EQUIVALENTS, beginning of period	1,842,233	2,380,054
CASH AND CASH EQUIVALENTS, end of period	\$960,197	\$1,842,233
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION		
Cash paid for interest	\$28,603	\$31,290
Cash paid for income taxes	\$-	\$-
SUPPLEMENTAL DISCLOSURE OF NONCASH INVESTING AND FINANCING		
Exchange of property held for sale for a mortgage note receivable	\$265,000	\$-

See accompanying Notes to Consolidated Financial Statements

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CTD HOLDINGS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2016 AND 2015

(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”) 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. In 2014 we 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”). The FDA recently approved our Investigational New Drug application (IND) which describes our Phase I clinical plans in the US for Trappsol® Cyclo™. We have also filed Clinical Trial Applications with the United Kingdom's Medicines and Healthcare Products Regulatory Agency and other European regulators, and launched an International Clinical Program for Trappsol® Cyclo™.

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 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, it has concluded that realization losses on balances outstanding at year-end will be immaterial.

(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 market. 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.

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

(g) **PROPERTY AND EQUIPMENT**—Property and equipment are recorded at cost. Depreciation on property and equipment 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, seven to ten years for machinery and furniture, fifteen years for certain land improvements, and forty years for buildings and building improvements). 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. The Company recorded an impairment of \$810,000 in 2016 with respect to property and equipment that was sold in 2016. No impairments were identified or recorded in 2015.

CTD HOLDINGS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2016 AND 2015

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

(h) **PROPERTY HELD FOR SALE**— In 2015, property held for sale consists of 40 acres of land and buildings located in High Springs, Florida. This property was used for operations and our corporate offices through September 30, 2011, and was sold in 2016. Property is classified as held for sale when management's intent is to sell the property and the applicable accounting criteria are satisfied. This determination requires management to make estimates and assumptions, including assessing the probability that potential sales transactions may or may not occur. Actual results could differ from those assumptions. Upon designation as held for sale, the carrying values of the assets are recorded at the lower of the carrying value or the estimated fair value, less estimated selling costs. Assets held for sale are no longer depreciated. We periodically review our property held for sale to determine if the carrying value of assets may not be recoverable. If we identify impairment, a loss is recognized for the difference between the carrying amount and the estimated market value of the assets. In 2015, an impairment loss of \$125,000 was recorded on this property to adjust its carrying value to \$275,000. This property was sold in January 2016 for \$275,000.

(i) **REVENUE RECOGNITION**—We recognize revenue from product sales when the following four revenue recognition criteria are met: persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the selling price is fixed or determinable, and collectability is reasonably assured. Product sales and shipping revenues, net of any discounts or return allowances, are recorded when the products are shipped and title passes to customers. Sales to customers are made pursuant to a sales contract that provides for transfer of both title and risk of loss upon our delivery to the carrier. Return allowances, which reduce product revenue, have been historically infrequent, and are recorded when they become known. Amounts received in advance are deferred and recognized as revenue when all four revenue recognition criteria have been met. At December 31, 2016 and 2015, there is no deferred revenue.

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

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

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

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

(n) NET LOSS PER COMMON SHARE—Basic and fully diluted net loss per common share is computed using a simple weighted average of common shares outstanding during the periods presented, as outstanding warrants to purchase 9,057,500 and 577,500 common shares were antidilutive for 2016 and 2015, respectively.

(o) 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.

CTD HOLDINGS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2016 AND 2015

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

(p) **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.

We have no assets or liabilities that are required to have their fair value measured on a recurring basis at December 31, 2016 or 2015. 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. As disclosed above, we recorded an impairment of \$810,000 on property and equipment in 2016, and an impairment of \$125,000 in 2015. The impairment was determined based on actual transactions of similar property, a Level 2 input.

For short-term classes of our financial instruments 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, 2016, the carrying value of the mortgage note receivable approximates fair value. The fair value of our long-term debt is estimated based on the present value of the underlying cash flows discounted at current rates offered the Company for similar debt. At December 31, 2015, the carrying value of long-term debt approximated fair value. We had no long-term debt at December 31, 2016.

(q) **LIQUIDITY**—For the year ended December 31, 2016, the Company incurred a net loss of \$4,224,000 and used \$2,951,000 of cash flows in its operations. At December 31, 2016, the Company had a cash balance of \$960,000 and working capital of \$1,293,000. On February 23, 2017, subsequent to the year ended December 31, 2016, the Company generated additional net proceeds of \$1,879,000 from the sale of equity securities in a private placement. Regarding the aforementioned loss and the cash used from operating activities, the Company was able to obtain equity financing, which it concluded represents the primary source of cash flows that will permit the Company to meet its financial obligations as they come due through March 2018. The Company is actively seeking to raise capital through the sale of its common stock. In the event that the Company cannot raise sufficient capital, management may be required to reduce expenditures related to its operations.

(r) **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.

(s) **RECLASSIFICATIONS**—Certain amounts in the 2015 financial statements have been reclassified to conform to the 2016 presentation. These reclassifications had no effect on previously reported net income or stockholders equity.

(t) **NEW ACCOUNTING PRONOUNCEMENTS**—The Financial Accounting Standards Board (FASB) has issued various Accounting Standards Updates (ASUs), including ASU 2014-09, Revenue from Contracts with Customers, as subsequently amended; ASU 2014-15, Presentation of Financial Statements-Going Concern; ASU No. 2015-11, Simplifying the Measurement of Inventory, ASU 2015-17, Balance Sheet Classification of Deferred Taxes; and ASU 2016-02, Leases, which are effective in future fiscal years. We do not expect the adoption of these standards to have a material effect on our financial position or results of operations.

CTD HOLDINGS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2016 AND 2015

(2) MAJOR CUSTOMERS AND SUPPLIERS:

Our revenues are derived primarily from chemical supply and pharmaceutical companies located primarily in the United States. In 2016, two major customers accounted for 54% of total revenues. In 2015, one major customer accounted for 31% of total revenues.

Substantially all inventory purchases were from three vendors in 2016 and 2015. These vendors are located primarily outside the United States.

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

For the year ended December 31, 2016, our revenues consisted of 48% biopharmaceuticals, 43% basic natural and chemically modified cyclodextrins, and 9% cyclodextrin complexes. For the year ended December 31, 2015, our revenues consisted of 38% biopharmaceuticals, 34% basic natural and chemically modified cyclodextrins, and 8% cyclodextrin complexes.

(3) MORTGAGE NOTE RECEIVABLE

On January 21, 2016, the Company sold its real property located in High Springs, Florida to an unrelated party. This property was previously classified on our balance sheet as property held for sale, with a carrying value of \$275,000. 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	
2017	\$ 34,393
2018	35,884
2019	37,439
2020	39,061
2021	40,772
Thereafter	49,872
	\$237,241

(4) CONCENTRATIONS OF CREDIT RISK:

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

(a) 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.

(b) ACCOUNTS RECEIVABLE—Our accounts receivable consist of amounts due primarily from chemical supply and pharmaceutical companies located primarily in the United States. Two customers accounted for 81% of the accounts receivable balance at December 31, 2016. Five customers accounted for 89% of the accounts receivable balance at December 31, 2015. We have no policy requiring collateral or other security to support our accounts receivable.

CTD HOLDINGS, INC. AND SUBSIDIARIES**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2016 AND 2015****(5) PROPERTY AND EQUIPMENT:**

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

	2016	2015
Land	\$-	\$92,181
Building and improvements	-	656,835
Machinery and equipment	21,861	1,455,010
Office Furniture and equipment	49,409	49,409
	71,270	2,253,435
Less: accumulated depreciation	41,286	632,279
	29,984	1,621,156
Building improvements not in service	-	271,787
Property and equipment, net	\$29,984	\$1,892,943

(6) NOTES PAYABLE:

In connection with the December 16, 2016 sale of the Company's office and manufacturing facility, the mortgage and equipment bank loans described below were repaid in full. As a result, at December 31, 2016 the Company did not have any outstanding notes payable.

At December 31, 2015, The Company owed \$516,685, on a mortgage note payable, collateralized by land and a building acquired in September 2010. Monthly payments of \$3,506, including principal and interest at 3.99%, were due, with a final balloon payment of approximately \$350,000 due in July 2023. The note was secured by a mortgage on our Alachua property. We were not in compliance with a debt coverage ratio covenant for the year ending December 31, 2015. As a result, the principal due beyond one year was classified as current in the accompanying 2015 balance sheet.

The Company also owed this lender \$203,052 at December 31, 2015, under an equipment loan. Monthly payments of \$4,051, including principal and interest at 3.99%, were due through and including July 2020. The note was collateralized by all of our equipment. The principal due under this loan was also reclassified as current in the accompanying 2015 balance sheet due to our non-compliance with the loan covenant referred to above.

The Company had a \$100,000 line of credit which was collateralized by our inventory, accounts receivable, equipment, general intangibles and fixtures. The credit line was also cross collateralized with our mortgage and equipment loans. There was a \$34,296 balance outstanding at December 31, 2015.

The notes payable balance was reduced by unamortized deferred financing costs of \$16,424 at December 31, 2015.

(7) EQUITY TRANSACTIONS:

The Company expensed \$121,460 and \$74,600 in employee and board member stock compensation in 2016 and 2015, respectively. The Company accrues stock compensation expense over the period earned for employees and board members. The Company issued 264,000 shares of common stock due to an employee, seven board members, and the Company's secretary on July 22, 2016. On January 21, 2015, the Company awarded 35,000 shares of Common Stock to a consultant for past services.

CTD HOLDINGS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2016 AND 2015

(7) EQUITY TRANSACTIONS: (CONTINUED)

In April 2014, we entered into 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, and a seven-year warrant to purchase 6% of the securities issued as a part of such financing, with an exercise price equal to 100% of the offering price of the securities sold during the term of the agreement. 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, a director of the Company, 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 July 10, 2015, the Company entered into a Securities Purchase Agreement under which it issued 2.6 million shares of its Common Stock in a private placement, at a purchase price of \$0.50 per share, for aggregate gross proceeds to the Company of \$1.3 million. Scarsdale acted as financial advisor to the Company in connection with the private placement and was paid a cash fee in an amount equal to 6% of the gross proceeds of the private placement and was issued seven-year warrants to purchase 156,000 shares of Common Stock at an exercise price of \$0.50 per share.

On July 28, 2015, the Company received \$78,616 from the exercise of previously outstanding warrants for 314,465 shares of Common Stock at an exercise price of \$0.25 per share.

On August 20, 2015, the Company issued 1.3 million shares of its Common Stock in a private placement, at a purchase price of \$0.50 per share, for aggregate gross proceeds to the company of \$650,000. Scarsdale acted as financial advisor to the company in connection with the private placement and was paid a cash fee in an amount equal to 6% of the gross proceeds of the private placement and it and its designees were issued seven-year warrants to purchase 78,000 shares of Common Stock at an exercise price of \$0.50 per share.

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On June 6, 2016, the Company issued 8 million units (“Units”) at a purchase price of \$0.25 per Unit in a private placement, each Unit consisting of one share of its common stock, and a seven-year warrant to purchase an additional share of common stock at an exercise price of \$0.25, for aggregate gross proceeds to the Company of \$2 million. Scarsdale acted as financial advisor to the Company in connection with the private placement and was paid a cash fee in an amount equal to 6% of the gross proceeds of the private placement, and it and its designees were issued seven-year warrants to purchase 480,000 Units at an exercise price of \$0.25 per Unit.

The following table presents the number common stock warrants outstanding at year end December 31, 2016 and 2015.

Warrants outstanding, December 31, 2014	657,965
Issued	234,000
Exercised	(314,465)
Expired	-
Warrants outstanding, December 31, 2015	577,500
Issued	8,000,000
Exercised	-
Expired	-
Warrants outstanding, December 31, 2016	8,577,500

CTD HOLDINGS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2016 AND 2015

(7) EQUITY TRANSACTIONS: (CONTINUED)

The following table presents the number of common stock warrants outstanding, their exercise price, and expiration dates at December 31, 2016:

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
8,000,000	\$ 0.25	June 2023
8,577,500		

In addition, there are seven-year warrants outstanding at December 31, 2016 to purchase 480,000 Units at an exercise price of \$0.25 per Unit.

(8) PREFERRED STOCK:

In 2004, the Company amended its Articles of Incorporation authorizing a class of “blank check” preferred stock consisting of 5,000,000 shares and created a Series A Preferred Stock consisting of one share and set forth its designations, rights and preferences. The more significant right is the Series A share votes together with the holders of the Common Stock on all matters submitted to a vote of company holders of Common Stock, with the share of Series A Preferred Stock being entitled to one vote more than one-half of all votes entitled to be cast by all holders of voting capital stock of the Company on any matter submitted to common shareholders so as to ensure that the votes entitled to be cast by the holder of the Series A Preferred Stock are equal to at least a majority of the total of all votes entitled to be cast by all shareholders. Each share of Series A Preferred Stock has a par value and liquidation preference of \$.0001. There was no preferred stock outstanding in 2015 or 2016.

(9) INCOME TAXES:

Differences between accounting rules and tax laws cause differences between the basis of certain assets and liabilities for financial reporting purposes and tax purposes. The tax effect of these differences, to the extent they are temporary, is recorded as deferred tax assets and liabilities. Income tax expense is the tax payable or refundable for the period plus or minus the change during the period in deferred assets and liabilities. Temporary differences which give rise to deferred tax assets and liabilities consist of net operating loss carryforwards, stock compensation expense not deducted for tax purposes until trading restrictions are removed and declared as compensation by the recipient, and accelerated depreciation methods for income tax purposes.

If all of our net operating loss carryforwards and temporary deductible differences were used, we would realize a net deferred tax asset of approximately \$3,616,000 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, 2016, 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.

CTD HOLDINGS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2016 AND 2015

(9) INCOME TAXES: (CONTINUED)

The income tax disclosures for the year ended December 31, 2015 have been revised to reflect the inclusion of tax credits that were not included in the prior year financial statement disclosures. This correction had no effect on assets, liabilities, stockholder's equity and net income as originally reported for the year ended December 31, 2015. The Company has determined that the impact of these revisions on its previously filed consolidated financial statements was not material.

For 2015, we calculated our deferred tax asset using the temporary deductible timing differences plus the net operating loss carryforward multiplied by our expected effective income tax rate. We estimated our future taxable income based on historical results and expected future trends in sales and margins. We estimated the timing of deducting our temporary deductible differences. We estimated the amount of our net operating loss carryforward we would be able to utilize prior to expiration. We increased our valuation allowance to 100% and recorded income tax expense of \$120,000. 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, 2016, unused federal and state net operating loss carryforwards totaling approximately \$6,166,000 that may be applied against future taxable income.

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

Year Ending	Amount
December 31,	
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	2,871,000
Total	\$6,166,000

The Company believes 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, 2016, the amount of net operating losses subject to an annual Section 382 limitation has not been determined.

In 2015 and 2016, the Company had expenses that qualified 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 for federal income tax purposes. The unused credit carryforwards were \$329,663 and \$1,262,026 for 2015 and 2016 respectively.

For 2016, the Company did not recognize a benefit or provision for income taxes. The net deferred tax asset before the valuation allowance increased \$2,164,000 from 2015 to 2016, which is primarily the result of an additional net operating loss for 2016. We increased our valuation allowance to offset this increase in our deferred tax asset. For 2015, we recognized a \$120,000 provision for income taxes, which was due to the increase in our valuation allowance to 100% of net deferred tax assets. Our net deferred tax asset before the valuation allowance increased \$1,242,000 from 2014 to 2015, which is primarily the result of an additional net operating loss for 2015. We increased our valuation allowance to offset this increase in our deferred tax asset as well as our previously recognized deferred tax assets.

CTD HOLDINGS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2016 AND 2015

(9) INCOME TAXES: (CONTINUED)

The components of our (provision) for income taxes are as follows for the years ended December 31:

	2016	2015
Current:		
Federal	\$ -	\$-
State	-	-
Total Current	\$ -	\$-
Deferred:		
Federal	\$ -	\$(102,460)
State	-	(17,540)
Total Deferred	-	(120,000)
Total tax expense	\$ -	\$(120,000)

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

	2016	2015
Deferred tax assets:		
Net operating loss carryforwards	\$2,321,000	\$1,240,000
Tax credits	1,262,000	330,000
Impairment allowances	8,000	89,000
Stock compensation	27,000	28,000
Other	6,000	-
Less valuation allowance	(3,616,000)	(1,452,000)
Deferred tax assets, net of valuation	8,000	235,000
Deferred tax liabilities:		
Property and equipment	(8,000)	(235,000)
Deferred tax liabilities	(8,000)	(235,000)
Net tax assets	\$-	\$-

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 34% is summarized as follows:

	2016	2015
Tax benefit (expense) at Federal statutory rate	\$ 1,436,000	\$ 827,000
Effect of State taxes	153,000	88,000
Tax credits	932,000	330,000
Nondeductible expenses	(357,000)	(123,000)
Other	215,000	-
Valuation allowance – deferred tax assets	(2,164,000)	(1,242,000)
Total tax benefit (provision)	\$-	\$(120,000)

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CTD HOLDINGS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2016 AND 2015

(9) INCOME TAXES: (CONTINUED)

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 2013.

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 2016 and 2015, the Company elected to match the employee's contribution, not to exceed 4% of compensation. The Company's 401(k) contributions were \$16,294 and \$16,597 for 2016 and 2015, respectively.

(11) SALE OF PROPERTY AND EQUIPMENT:

On January 21, 2016, the Company closed on the sale of its real property located in High Springs, Florida, which had been previously classified on the Company's balance sheets as property held for sale, with a carrying value of \$275,000. Pursuant to the terms of the sale, at the closing, the buyer paid \$10,000 in cash and delivered to the Company a promissory note in the principal amount of \$265,000, and a mortgage in favor of the Company 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. The Company previously recorded valuation allowances on this property in the amount of \$220,455, and recorded a loss of \$4,489 in 2016 on the sale.

On December 16, 2016, the Company completed the sale of its office and manufacturing facility located in Alachua, Florida for an aggregate purchase price of \$980,000. The assets sold consisted of the Company's real property, sold for a purchase price of \$800,000, and substantially all of the Company's manufacturing equipment at such location, including the Company's pulse dryer, sold for a purchase price of \$180,000. The Company previously recorded valuation allowances on these properties in the amount of \$810,000 in 2016, and recorded a loss of \$44,179 in 2016 on the sale. The Company used \$664,800 of the proceeds of the sale to repay in full all of its outstanding indebtedness to Regions Bank, which consisted of a mortgage loan secured by the real property sold to the buyer, and an equipment loan secured by the equipment sold to the buyer, thereby terminating the Company's loan agreements with Regions Bank. Net cash proceeds to the Company from the sale, after giving effect to repayment of the indebtedness to Regions Bank as described above and the payment of transaction expenses, amounted to \$255,690.

(12) SUBSEQUENT EVENTS:

On January 27, 2017, the Company entered into a two-year lease for approximately 2,500 square feet of office and distribution warehouse space located in Gainesville, Florida for \$1,500 per month, with a two-year renewal option.

On February 23, 2017, the Company issued 5,754,832 units ("Units") at a purchase price of \$0.35 per Unit in a private placement, each Unit consisting of one share of its 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 \$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 272,455 Units at an exercise price of \$0.35 per Unit.

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, 2016. 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, 2016.

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 17, 2016:

Name	Age	Positions and Offices With Registrant	Year First Became Director
N. Scott Fine	60	Director, Chief Executive Officer	2014
Jeffrey L. Tate, Ph.D.	59	Director, Chief Operating Officer, Chief Scientific Officer	2010
George L. Fails	72	Director	2001
C.E. Rick Strattan	71	Director	1990
Markus W. Sieger	51	Director	2014
F. Patrick Ostronic	61	Director	2014
Judge Joseph J. Farnan	71	Director	2015
William S. Shanahan	76	Director	2016

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., Forward Industries, Inc., 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). Dr. Tate has been President and CEO of NanoSonic Products, Inc., and Sphingo Biotechnology, Inc., wholly-owned subsidiaries of the Company since 2010. From January 2007 to February 2010, he was president of J-Jireh Products, Incorporated, a company that develops and markets 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 NanoSonic Products, Inc. and his experience with pulse drying technology.

George L. Fails served as Executive Vice President, Operations Manager and a Director of the Company from 2001 until his retirement in November 2016. He served as President of Cyclodextrin Technologies Development, Inc. (CTD, Inc.), a wholly-owned subsidiary of the Company, and Operations Manager of CTD, Inc. from 2000 to 2014. Prior to joining the Company, Mr. Fails served as a Detective Sergeant with the Veterans Administration Hospital in Gainesville, Florida, with special duties as a Predator officer with the U.S. Marshall's service. From 1965 until his retirement in 1986, Mr. Fails served with the U.S. Army Special Forces, including several tours in Vietnam, Salvador, and Angola. Mr. Fails also served two years with a United States intelligence arm. Mr. Fails received his B.A. from the University of the Philippines, and has also received degrees from 43 Military schools, as well as the Federal Police Academy in Little Rock, Arkansas.

Mr. Fails was selected to serve as a member of our Board of Directors because of his experience with CTD, Inc.

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 and marketing/computer information sciences.

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 make him a valuable member of the Board of Directors.

William S. Shanahan became a director in 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.

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, N. Scott Fine and George L. Fails 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

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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, 2016, no person who, at any time during the year ended December 31, 2016 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, 2016.

Item 11. Executive Compensation.**Executive Compensation**

The following table contains information concerning the compensation paid during our fiscal years ended December 31, 2016 and 2015 to (i) the person who served as our Chief Executive Officer during 2016, and (ii) our executive officer as of December 31, 2016 whose compensation exceeded \$100,000 (collectively, our “Named Executive Officers”).

SUMMARY COMPENSATION TABLE

Name & Principal Position	Year	Salary (\$)	Stock Awards (\$ (2))	All Other Compensation (\$ (4))	Total (\$)
N. Scott Fine CEO	2016	373,058	8,360	-	381,778
	2015	392,500(1)	-	-	392,500
Jeffrey L. Tate COO and Chief Scientific Officer (3)	2016	152,000	8,360	6,080	166,440
	2015	147,328	-	5,518	152,846

Reflects compensation paid to Mr. Fine following his appointment as Chief Executive Officer on September 14, (1)2015 in the amount of \$158,915, as well as compensation paid to him for the period prior thereto during 2015 for serving as our Chairman of the Board.

Reflects award of 20,000 shares to each Named Executive Officer in 2016 as compensation for services as a (2)member of the Company’s board of directors in 2015. 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.

(3)Prior to September 14, 2015, Mr. Tate served as our Chief Executive Officer and President.

(4)Reflects matching contributions made under the Company’s 401(k) plan.

Outstanding Equity Awards at Fiscal Year End

As of December 31, 2016, our Named Executive Officers had no outstanding unexercised options, unvested stock or other unvested equity incentive plan awards.

Employment Agreements

Currently, N. Scott Fine is our only Named Executive Officer who is a party to an employment agreement with us.

We entered into an Employment Agreement with Mr. Fine dated as of September 14, 2015, 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 of three years, subject to automatic one-year extensions unless either party notifies the other party at least 60 days 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.

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 are also entitled to reimbursements for reasonable expenses incurred in attending meetings of directors. We did not compensate our directors for their services during the year ended December 31, 2016 other than the issuance of 20,000 shares of common stock to each of our directors in July 2016 in consideration of their services to the Company during 2015.

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 1, 2017, 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 1, 2017 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. No such options or warrants are currently held by the persons in the table below. Percentage of ownership is based on 72,707,361 shares of Common Stock outstanding as of March 1, 2017.

Names and Address of Individual or Identity of Group(1)	Number of Shares Beneficially Owned	Approximate Percent of Class	
C.E. Rick Strattan	20,568,385 (2)	28.3	%
Novit, L.P. 966 Hungerford Drive Rockville, Maryland 20850	7,042,856 (3)	9.6	%
Jeffrey L. Tate	780,972 (4)	1.1	%
George L. Fails	1,665,221	2.3	%
N. Scott Fine	5,831,428 (5)	8.0	%

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Markus Sieger	3,825,714	(6)	5.3	%
F. Patrick Ostronic	697,856	(7)	*	
Judge Joseph J. Farnan	710,000	(8)	1.0	%
William S. Shanahan	1,397,328	(9)	1.9	%
All Directors and Executive Officers as a Group (8 Persons)	35,476,904	(10)	47.6	%

* 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 32563.

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 and July 26, 2016. Includes currently exercisable warrants to purchase 40,000 shares (2) 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.

- 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
- (3) 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 571,428 shares of Common Stock.
- (4) Includes currently exercisable warrants to purchase 100,000 shares of Common Stock.
- Includes currently exercisable warrants to purchase 645,714 shares of Common Stock. Includes 285,714 shares of
- (5) common stock and warrants to 285,714 shares of common stock held of record FYD Holdings, LLC, of which Mr. Fine is the sole member.
- (6) Includes currently exercisable warrants to purchase 142,857 shares of Common Stock.
- (7) Includes currently exercisable warrants to purchase 271,428 shares of Common Stock.
- (8) Includes currently exercisable warrants to purchase 20,000 shares of Common Stock.
- (9) Includes currently exercisable warrants to purchase 685,714 shares of Common Stock.
- (10) Includes currently exercisable warrants to purchase 1,905,713 shares of Common Stock.

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) (#)(3)
Equity compensation plans not approved by security holders (1)	1,537,500	\$0.27	0
Equity compensation plans approved by security holders	None	Not Applicable	Not Applicable
Total:	1,537,500	\$0.27	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, and (v) seven-year warrants to purchase 480,000 Units and 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.

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 2016 we paid Scarsdale Equities cash fees of \$120,000 and issued it and its designees 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 in connection with a private placement of our Common Stock, and during 2015 we paid Scarsdale Equities cash fees of \$117,000 and issued it and its designees warrants to purchase 234,000 shares of Common Stock at an exercise price of \$0.50 per share in connection with private placements of our Common Stock.

Director Independence

Our Board of Directors is comprised of eight individuals, four of whom are or were in the last three years employed by the Company. We have determined that our other directors, Mr. Sieger, Mr. Ostronic, Judge Farnan, and Mr. Shanahan, 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 2016 and 2015 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 \$52,000 and \$42,900, 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 Articles of Incorporation filed August 9, 1990 (incorporated by reference to the Company's Form 10-SB filed with the Securities and Exchange Commission on February 1, 1994).
- 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).
- 3.3 Certificates of Amendment to the Articles of Incorporation filed November 18, 1993 and September 24, 1993 (incorporated by reference to the Company's Form 10-SB filed with the Securities and Exchange Commission on February 1, 1994).
- 3.4 Certificate of Amendment to the Articles of Incorporation filed May 10, 2004 (incorporated by reference to the Company's Form 10-K/A filed with the Securities and Exchange Commission on February 2, 2011).
- 3.5 Certificate of Amendment to the Articles of Incorporation filed September 27, 2004 (incorporated by reference to the Company's Form 10-K/A filed with the Securities and Exchange Commission on February 2, 2011).
- 4.1 Form of Warrant issued to investors in the Company's June 2016 private placement (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed June 6, 2016).
- 10.1 Securities Purchase Agreement dated as of February 19, 2014 between and among CTD Holdings, Inc. and the purchasers named therein (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed February 20, 2014).
- 10.2 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).
- 10.3 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).
- 10.4 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).
- 10.5

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Securities Purchase Agreement dated as of July 21, 2014 by and among CTD Holdings and the investors named therein (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed July 22, 2014).

10.6 Securities Purchase Agreement dated as of July 21, 2014 by and among CTD Holdings and the investors named therein (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed July 22, 2014).

10.7 Securities Purchase Agreement dated as of July 10, 2015, between and among CTD Holdings, Inc. and the purchasers named therein (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed July 13, 2015).

Exhibits

- 10.8 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).
- 10.9 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).
- 10.10 Mortgage, 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).
- 10.11 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).
- 21.1 Subsidiaries (incorporated by reference to the Company's Form 10-K filed with the Securities and Exchange Commission on March 27, 2015).
- 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.

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 17, 2017

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 17, 2017

By: /s/ Joseph J. Farnan

JOSEPH J. FARNAN
Director

Date: March 17, 2017

By: /s/ George L. Fails
GEORGE L. FAILS

Director

Date: March 17, 2017

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

Director

Date: March 17, 2017

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

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

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Director

Director

Date: March 17, 2017

Date: March 17, 2017

By: /s/ Jeffrey L. Tate
JEFFREY L. TATE
Chief Operating Officer; Director

By: /s/ Markus W. Sieger
MARKUS W. SIEGER
Director

Date: March 17, 2017

Date: March 17, 2017