As filed with the Securities and Exchange Commission on September 29, 2020

Registration No. 333-

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form S-1
REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

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

Florida (prior to reincorporation) **Nevada (after reincorporation)**	**2833**	**59-3029743**
(State or other jurisdiction of incorporation or organization)	*(Primary Standard Industrial Classification Code Number)*	*(I.R.S. Employer Identification Number)*

6714 NW 16th Street, Suite B
Gainesville, FL 32653
(386) 418-8060
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

N. Scott Fine
Chief Executive Officer
Cyclo Therapeutics, Inc.
6714 NW 16th Street, Suite B
Gainesville, FL 32653
(386) 418-8060
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies of Communications to:

Alison Newman, Esq.
Zev M. Bomrind, Esq.
Fox Rothschild LLP
101 Park Avenue
New York, New York 10178
(212) 878-7997

Barry I. Grossman, Esq.
Sarah Williams, Esq.
Matthew Bernstein, Esq.
Ellenoff Grossman & Schole LLP
1345 Avenue of Americas, 11th Floor
New York, NY 10105
(212) 370-1300

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box. ☒

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer [ ]
Non-accelerated filer [X]

Accelerated filer [ ]
Smaller reporting company [X]
Emerging growth company [ ]

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Exchange Act. ☐

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Proposed Maximum Aggregate Offering Price (1)	Amount of Registration Fee
Units consisting of shares of Common Stock, par value $0.0001 per share, and Warrants to purchase shares of Common Stock, par value $0.0001 per share (2)	$ 20,000,000	$ 2,596.00
Common Stock included as part of the Units	Included with Units above	_____
Warrants to purchase shares of Common Stock included as part of the Units (3)	Included with Units above	_____
Representative's Warrant to purchase Common Stock (3)	_____	_____
Shares of Common Stock issuable upon exercise of the Warrants (4)(5)	$ 10,000,000	$ 1,298.00
Shares of Common Stock issuable upon exercise of Representative's Warrants (5)(6)	$ 1,100,000	$ 142.78
TOTAL	$ 31,100,000	$ 4,036.78

(1) Estimated solely for the purpose of calculating the registration fee in accordance with Rule 457(o) under the Securities Act of 1933, as amended.

(2) Includes stock and/or warrants that may be issued upon exercise of a 45-day option granted to the underwriters to cover over-allotments, if any.

(3) In accordance with Rule 457(g) under the Securities Act, because the shares of the common stock underlying the Warrants and Representative's warrants are registered hereby, no separate registration fee is required with respect to the warrants registered hereby.

(4) There will be issued warrant to purchase one share of common stock for every unit offered. The Warrants are exercisable at a per share price of % of the unit public offering price.

(5) Includes shares of common stock which may be issued upon exercise of additional warrants which may be issued upon exercise of 45-day option granted to the underwriters to cover over-allotment, if any.

(6) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(g) under the Securities Act of 1933, as amended, based on an estimated proposed maximum aggregate offering price of the Representative's warrants of $1,100,000, or 110% of $1,000,000 (5% of $20,000,000). Assumes the full exercise of the underwriter's over-allotment option.

In the event of a stock split, stock dividend, or similar transaction involving our common stock, the number of shares registered shall automatically be increased to cover the additional shares of common stock issuable pursuant to Rule 416 under the Securities Act.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall hereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

EXPLANATORY NOTE

Cyclo Therapeutics, Inc., the registrant whose name appears on the cover page of this registration statement, is a Florida corporation. Prior to the sale and issuance of any shares of common stock subject to this registration statement, Cyclo Therapeutics, Inc. expects to reincorporate as a Nevada corporation and retain its current name, Cyclo Therapeutics, Inc.

The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and we are not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

PRELIMINARY PROSPECTUS
SUBJECT TO COMPLETION, DATED SEPTEMBER __, 2020

Units
Each Unit Consisting of
One Share of Common Stock
and
One Warrant to Purchase One Share of Common Stock

This is a firm commitment public offering of Units at an assumed offering price of $ per unit, each Unit consisting of one share of common stock, $0.0001 par value per share, and one warrant to purchase one share of common stock, of Cyclo Therapeutics, Inc., a Nevada corporation. Each warrant is immediately exercisable for one share of common stock at an exercise price of $ per share (or % of the price of each share of common stock sold in the offering) and will expire five years from the date of issuance. The Units will not be certificated and the shares of common stock and the warrants comprising such Units are immediately separable and will be issued separately in this offering.

Our common stock is quoted for trading on the OTCQB Marketplace ("OTCQB") under the symbol "CTDH." As of September , 2020, the closing bid price for our common stock as reported on the OTCQB was $ per share. There is no established trading market for the warrants. We have applied to have our common stock and warrants listed on the Nasdaq Capital Market under the symbols "CYTH" and "CYTHW," respectively. We believe that upon the completion of the offering contemplated by this prospectus, we will meet the standards for listing on the Nasdaq Capital Market. We cannot guarantee that we will be successful in listing our common stock or our warrants on the Nasdaq Capital Market; however, we will not complete this offering unless we are so listed.

The share and per share information in this prospectus reflects, other than in our Financial Statements and the Notes thereto, a proposed reverse stock split of the authorized and outstanding common stock of 1-for-__to occur immediately following the effective date but prior to the closing of the offering.

An investment in our common stock and warrants involves a high degree of risk. Before buying any shares you should carefully read the discussion of the material risks of investing in our common stock and warrants in "Risk Factors" beginning on page 5 of this prospectus.

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

	Per Unit	Total
Public offering price	$	$
Underwriting discounts and commissions (1)	$	$
Proceeds to us before offering expenses (2)	$	$

(1) Does not reflect additional compensation to the underwriters in the form of warrants to purchase up to shares of common stock (assuming the over-allotment option is fully exercised) at an exercise price equal to 110% of the public offering price. We have also agreed to reimburse the underwriters for certain expenses. See "Underwriting" on page of this prospectus for a description of these arrangements.

(2) We estimate the total expenses of this offering will be approximately $. Assumes no exercise of the over-allotment option we have granted to the underwriters as described below.

We have granted the underwriters a 45-day option to purchase up to additional shares of common stock and/or warrants.

The underwriters expect to deliver our shares and warrants to purchasers in the offering on or about , 2020.

Sole Book-Running Manager

Maxim Group LLC

Prospectus dated [●], 2020.

TABLE OF CONTENTS

MARKET AND INDUSTRY DATA

The market data and certain other statistical information used throughout this prospectus are based on independent industry publications, governmental publications, reports by market research firms or other independent sources. Some data are also based on our good faith estimates.

BASIS OF PRESENTATION

References herein to the "Company," "Registrant," "we," "us," "our" and "our company" refer, prior to the reincorporation, to Cyclo Therapeutics, Inc., a Florida corporation, and, after the reincorporation, to Cyclo Therapeutics, Inc., a Nevada corporation.

Certain monetary amounts, percentages and other figures included in this prospectus have been subject to rounding adjustments. Accordingly, figures shown as totals in certain tables or charts and figures expressed as percentages in the text may not total 100% or, as applicable, when aggregated may not be the arithmetic aggregation of the percentages that precede them.

YOU SHOULD RELY ONLY ON THE INFORMATION CONTAINED IN THIS PROSPECTUS OR IN ANY FREE WRITING PROSPECTUS WE MAY AUTHORIZE TO BE DELIVERED OR MADE AVAILABLE TO YOU . WE HAVE NOT, AND THE UNDERWRITERS HAVE NOT, AUTHORIZED ANYONE TO PROVIDE YOU WITH DIFFERENT INFORMATION. WE ARE NOT MAKING AN OFFER OF THESE SECURITIES IN ANY STATE WHERE THE OFFER IS NOT PERMITTED. YOU SHOULD NOT ASSUME THAT THE INFORMATION PROVIDED IN THIS PROSPECTUS IS ACCURATE AS OF ANY DATE OTHER THAN THE DATE ON THE FRONT OF THIS PROSPECTUS.

No person is authorized in connection with this prospectus to give any information or to make any representations about us, the securities offered hereby or any matter discussed in this prospectus, other than the information and representations contained in this prospectus. If any other information or representation is given or made, such information or representation may not be relied upon as having been authorized by us.

PROSPECTUS SUMMARY

This summary highlights selected information contained elsewhere in this prospectus. This summary does not contain all of the information that you should consider before investing in our securities. You should read carefully the entire prospectus, including "Risk Factors" and the financial statements and notes thereto, before making an investment decision.

Corporate Overview

We are a clinical stage biotechnology company that develops cyclodextrin-based products for the treatment of disease. We filed a Type II Drug Master File with the U.S. Food and Drug Administration ("FDA") in 2014 for our lead drug candidate, Trappsol® Cyclo™ (hydroxypropyl beta cyclodextrin) as a treatment for Niemann-Pick Type C disease ("NPC"). NPC is a rare and fatal cholesterol metabolism disease that impacts the brain, lungs, liver, spleen, and other organs. In 2015, we launched an International Clinical Program for Trappsol® Cyclo™ as a treatment for NPC. In 2016, we filed an Investigational New Drug application ("IND") with the FDA, which described our Phase I clinical plans for a randomized, double blind, parallel group study at a single clinical site in the U.S. The Phase I study evaluated the safety of Trappsol® Cyclo™ along with markers of cholesterol metabolism and markers of NPC during a 14-week treatment period of intravenous administration of Trappsol® Cyclo™ every two weeks to participants 18 years of age and older. The IND was approved by the FDA in September 2016, and in January 2017 the FDA granted Fast Track designation to Trappsol® Cyclo™ for the treatment of NPC. Initial patient enrollment in the U.S. Phase I study commenced in September 2017. Enrollment in this study was completed in October 2019, and in May 2020 we announced Top Line data showing a favorable safety and tolerability profile for Trappsol® Cyclo™ in this study.

We have also filed Clinical Trial Applications for a Phase I/II clinical study with several European regulatory bodies, including those in the United Kingdom, Sweden and Italy, and in Israel, all of which have approved our applications. The Phase I/II study is evaluating the safety, tolerability and efficacy of Trappsol® Cyclo™ through a range of clinical outcomes, including neurologic, and respiratory, in addition to measurements of cholesterol metabolism and markers of NPC. The European/Israel study is similar to the U.S. study, providing for the administration of Trappsol® Cyclo™ intravenously to NPC patients every two weeks in a double-blind, randomized trial but it differs in that the study period is for 48 weeks (24 doses). The first patient was dosed in this study in July 2017, and in February 2020, we announced completion of enrollment of 12 patients in this study. In September 2020, we released positive data from the seven patients who completed the trial, supporting the efficacy of Trappsol® Cyclo™ in treating NPC patients.

Additionally, in February 2020 we had a face-to-face "Type C" meeting with the FDA with respect to the initiation of a Phase III clinical trial of Trappsol® Cyclo™ based on the clinical data obtained to date. At that meeting, we also discussed with the FDA submitting a New Drug Application (NDA) under Section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for the treatment of NPC in pediatric and adult patients with Trappsol® Cyclo™. A similar request was submitted to the European Medicines Agency ("EMA") in February 2020, seeking scientific advice and protocol assistance from the EMA for proceeding with a Phase III clinical trial in Europe. While we have not yet received the "Study May Proceed" from the FDA with respect to the proposed Phase III clinical trial, management believes the feedback from both the EMA and FDA were positive.

Preliminary data from our clinical studies suggest that Trappsol® Cyclo™ releases cholesterol from cells, crosses the blood-brain-barrier in individuals suffering from NPC, and results in clinical improvements in NPC patients. The full significance of these findings will be determined as part of the final analysis of both clinical trials.

On May 17, 2010, the FDA designated Trappsol® Cyclo™ as an orphan drug for the treatment of NPC, which would provide us with the exclusive right to sell Trappsol® Cyclo™ for the treatment of NPC for seven years following FDA drug approval. In April 2015, we also obtained Orphan Drug Designation for Trappsol® Cyclo™ in Europe, which will provide us with at least 10 years of market exclusivity following regulatory approval. On January 12, 2017, we received Fast Track Designation from the FDA, and on December 1, 2017, the FDA designated NPC a Rare Pediatric Disease and issued us a Priority Review Voucher with respect to the treatment of NPC with Trappsol® Cyclo™.

We are also exploring the use of cyclodextrins in the treatment of Alzheimer's disease. In January 2018, the FDA authorized a single patient IND expanded access program using Trappsol® Cyclo™ for the treatment of this disease. After 18 months of treatment in this geriatric patient with late-onset disease, the disease was stabilized and the drug was well tolerated. The patient also exhibited signs of improvement with less volatility and shorter latency in word-finding. In October 2019, we entered into an agreement with Worldwide Clinical Trials, a Contract Research Organization, to conduct a clinical trial to evaluate the safety and efficacy of Trappsol® Cyclo™ for the treatment of Alzheimer's disease. We prepared a synopsis for an early stage protocol using Trappsol® Cyclo™ intravenously to treat Alzheimer's Disease, and we plan to present this synopsis to the FDA in early 2021.

We filed a provisional patent application for the treatment of Alzheimer's disease with cyclodextrins with the U.S. Patent and Trademark Office in October 2018, which was amended based on additional clinical data in August 2019; and we filed a similar international patent application in October 2019 under the Patent Cooperation Treaty.

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

Listing on the Nasdaq Capital Market

Our common stock is currently quoted on the OTCQB Market. In connection with this offering, we have applied to list our common stock and warrants offered in the offering on the Nasdaq Capital Market ("Nasdaq") under the symbols "CYTH" and "CYTHW", respectively. If our listing application is approved, we expect to list our common stock and the warrants offered in the offering on Nasdaq upon consummation of the offering, at which point our common stock will cease to be traded on the OTCQB Market. No assurance can be given that our listing application will be approved. Nasdaq listing requirements include, among other things, a stock price threshold. As a result, prior to effectiveness, we will need to take the necessary steps to meet Nasdaq listing requirements, including but not limited to a reverse split of our outstanding common stock. There can be no assurance that our common stock will be listed on the Nasdaq.

Risks Associated With our Business

Our ability to execute our business strategy is subject to numerous risks, as more fully described in the section captioned "Risk Factors" immediately following this prospectus summary. You should read these risks before you invest in our common stock and warrants. In particular, risks associated with our business include, but are not limited to, the following:

- We have suffered recent losses and our future profitability is uncertain.
- Even with the proceeds from this offering, we will need additional capital to fund our operations as planned.
- We have not received approval for any drug candidate for commercial sale and, as a result, we have never generated any revenue from the sale of biopharmaceutical products, and expect to continue to incur significant financial losses in the future, which makes it difficult to assess our future viability.
- We are largely dependent upon the success of our Trappsol® Cyclo™ product, which may never receive regulatory approval.
- Even if Trappsol® Cyclo™ receives regulatory approval, we may not be successful in our commercialization efforts and Trappsol® Cyclo™ may fail to achieve the degree of market acceptance by physicians, patients, healthcare payors and others in the medical community necessary for commercial success.
- The results of our clinical trials may not support our product claims or may result in the discovery of adverse side effects.
- Clinical trials involve a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.
- 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.
- We rely in part on third parties for research and clinical trials for products using Trappsol® Cyclo™.
- We currently have no marketing and sales organization for our pharmaceutical candidates and may have to invest significant resources to develop these capabilities. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be able to generate product revenue.
- We rely upon third parties for the manufacture of Trappsol® Cyclo™ and are dependent on their quality and effectiveness.
- We face competition from well-funded companies to treat NPC.
- The rights we rely upon to protect our unpatented trade secrets may be inadequate.
- The pharmaceutical business is subject to increasing government price controls and other restrictions on pricing, reimbursement and access to drugs, which could adversely affect our future revenues and profitability.

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

Reverse Stock Split

Subject to the approval of our board of directors (the "Board"), we plan to implement a 1-for- reverse stock split of our authorized and issued and outstanding shares of common stock prior to the closing of this offering.

Corporate and other Information

We were organized as a Florida corporation on August 9, 1990, with operations beginning in July 1992. In conjunction with a restructuring in 2000, we changed our name from Cyclodextrin Technologies Development, Inc. to CTD Holdings, Inc. We changed our name to Cyclo Therapeutics, Inc. in September 2019 to better reflect our current business. Prior to the completion of this offering, we expect to reincorporate in the State of Nevada. Our principal offices are located at 6714 NW 16th Street, Suite B, Gainesville, FL 32653, and our telephone number is (386) 418-8060. We maintain a website at www.ctd-holdings.com. Information contained on our website does not constitute part of this prospectus.

The Offering

Securities offered:	$ of Units, each Unit consisting of one share of our common stock and one warrant to purchase one share of our common stock. Each warrant will have an exercise price of $ per share (% of the public offering price of the common stock), is exercisable immediately and will expire five (5) years from the date of issuance. The Units will not be certificated or issued in stand-alone form. The shares of our common stock and the warrants comprising the Units are immediately separable upon issuance and will be issued separately in this Offering.
Common stock outstanding prior to this offering (1)	169,982,602 shares
Number of shares of common stock offered by us:	shares
Number of warrants offered by us:	warrants
Public offering price:	$ per Unit
Common stock outstanding after this offering (1)	shares (assuming none of the warrants issued in this offering are exercised).
Use of proceeds	We estimate that we will receive net proceeds from this offering of approximately $ million based upon an assumed public offering price of $ per Unit, after deducting underwriting discounts and estimated offering expenses payable by us. We currently intend to use the net proceeds we receive from this offering to (i) proceed with our proposed Phase III trial for the treatment of NPC with Trappsol® Cyclo™, (ii) fund further development of our preclinical programs towards IND filings and/or into clinical trials for the treatment of Alzheimer's disease with Trappsol® Cyclo™ and (iii) fund working capital and general corporate purposes using any remaining amounts. See "Use of Proceeds" on page .
Representative's warrants	The registration statement of which this prospectus is a part also registers for sale warrants (the "Representative's Warrants") to purchase shares of our common stock to Maxim Group LLC (the "Representative"), as the representative of the several underwriters, as a portion of the underwriting compensation payable to the underwriters in connection with this offering. The Representative's Warrants will be exercisable commencing six months following the effective date of the registration statement of which this prospectus is a part and expiring on the fifth anniversary of the commencement of sales of this offering at an exercise price of $ (110% of the public offering price of the Units). Please see "Underwriting — Representative's Warrants" for a description of these warrants.
Over-allotment option:	The Underwriting Agreement provides that we will grant to the underwriters an option, exercisable within 45 days after the closing of this offering, to acquire up to an additional 15% of the total number of shares of common stock and/or warrants to be offered by us pursuant to this offering, solely for the purpose of covering over-allotments.
Lock-Up	Our directors, executive officers, and certain stockholders have agreed with the Representative not to offer for sale, issue, sell, contract to sell, pledge or otherwise dispose of any of our common stock or securities convertible into common stock for a period of 6 months commencing on the date of this prospectus.

Risk Factors	You should carefully read the "Risk Factors" section of this prospectus beginning on page 5 for a discussion of factors that you should consider before deciding to invest in our common stock.
Trading Symbol and Listing	Our common stock is presently quoted on the OTCQB Market under the symbol "CTDH". We have applied to have our common stock and warrants listed on the NASDAQ Capital Market under the symbols "CYTH" and "CYTHW," respectively.

(1) Unless we indicate otherwise, the number of shares of our common stock outstanding after this offering is based on 169,982,602 shares of common stock outstanding on September __, 2020, does not give effect to the potential reverse stock split, and excludes the following:

- shares of our common stock reserved for issuance under our 2019 Omnibus Equity Incentive Plan; and
- 93,622,864 shares of our common stock issuable upon the exercise of warrants, with a weighted-average exercise price of $ per share.

Unless otherwise noted, the information in this prospectus assumes:

- that the public offering price of our Units is $ per Unit (the assumed public offering price is $ per share of common stock and $ per accompanying warrant);
- no exercise of the outstanding warrants described above;
- no exercise of the warrants included in the Units;
- no exercise of the Representative's Warrants; and
- no exercise of the underwriters' option to purchase additional shares and/or warrants from us in this offering.

RISK FACTORS

An investment in our securities involves a high degree of risk. You should carefully consider the following risk factors in addition to other information in this prospectus before purchasing our securities. The risks and uncertainties described below are those that we currently deem to be material and that we believe are specific to our company, our industry and our securities. In addition to these risks, our business may be subject to risks currently unknown to us. If any of these or other risks actually occurs, our business may be adversely affected, the trading price of our securities may decline and you may lose all or part of your investment.

Risks Related to our Financial Position and Capital Needs

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

We have incurred net losses of approximately $7.5 million and $4.3 million for the years ended December 31, 2019 and December 31, 2018, and $4.8 million for the six months ended June 30, 2020. Our recent losses have predominantly resulted from research and development expenses for our Trappsol® Cyclo™ product and other general operating expenses, including personnel costs. We believe our expenses will continue to increase as we conduct clinical trials and continue to seek regulatory approval for the use of Trappsol® Cyclo™ in the treatment of NPC and Alzheimer's disease. As a result, we expect our operating losses to continue until such time, if ever, that product sales, licensing fees, royalties and other sources generate sufficient revenue to fund our operations. We cannot predict when, if ever, we might achieve profitability and cannot be certain that we will be able to sustain profitability, if achieved.

Even with the proceeds from this offering, wewill need additional capital to fund our operations as planned.

For the year ended December 31, 2019, our operations used approximately $6,589,000 in cash, and for the six months ended June 30, 2020, our operations used $3,870,000 in cash. Cash used in operations consisted of cash on hand and cash raised through private placements of our securities. At June 30, 2020, the Company had a cash balance of approximately $1,008,000 and current liabilities exceeded current assets by $1,969,000. Although we raised additional gross proceeds of approximately $2,831,000 from a private placement of our securities in August 2020 and expect to raise additional funds from the offering, 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.

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

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

- continue our ongoing and planned development of Trappsol® Cyclo™ for multiple indications;
- initiate, conduct and complete ongoing, anticipated or future preclinical studies and clinical trials for our current and future product candidates;
- seek marketing approvals for product candidates that successfully complete clinical trials; and
- establish a sales, marketing and distribution infrastructure to commercialize products for which we may obtain marketing approval.

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

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

Our auditors, WithumSmith+Brown, PC, have indicated in their report on our consolidated financial statements for the fiscal year ended December 31, 2019, that conditions exist that raise substantial doubt about our ability to continue as a going concern due to our recurring losses from operations and significant accumulated deficit. In addition, we continue to experience negative cash flows from operations. Notwithstanding the funds we expect to raise in this offering, our auditors may again provide a "going concern" opinion with respect to our future audited financial statements. A going concern opinion could impair our ability to finance our operations through the sale of equity. Our ability to continue as a going concern will depend upon the availability of equity financing which represents the primary source of cash flows that will permit us to meet our financial obligations as they come due and continue our research and development efforts.

Risks Related to Product Development, Regulatory Approval and Commercialization

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

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

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

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

- its efficacy;
- limitations or warnings or any restrictions on the use of Trappsol® Cyclo™, together with other medications, and the prevalence and severity of any side effects;
- the availability and efficacy of alternative treatments;
- the effectiveness of sales and marketing efforts and the strength of marketing and distribution support;
- the cost-effectiveness of Trappsol® Cyclo™ compared to alternative therapies and the ability to offer such drug for sale at competitive prices; and
- availability and amount of coverage and reimbursement from government payors, managed care plans and other third-party payors.

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

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

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

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

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

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

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

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

- refusals or delays in the approval of applications or supplements to approved applications;
- refusal of a regulatory authority to review pending market approval applications or supplements to approved applications;
- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market or voluntary or mandatory product recalls or seizures;
- fines, warning letters, or holds on clinical trials;

- import or export restrictions;
- injunctions or the imposition of civil or criminal penalties;
- restrictions on product administration, requirements for additional clinical trials, or changes to product labeling requirements; or
- recommendations by regulatory authorities against entering into governmental contracts with us.

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

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

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

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

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

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

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

- we may not be able to attract and build an effective marketing department or sales force;
- the cost of establishing a marketing department or sales force may exceed our available financial resources and the revenue generated by our product candidates that we may develop, in-license or acquire; and
- our direct sales and marketing efforts may not be successful.

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

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

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

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

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

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

We are subject to risks arising from the recent global outbreak of the COVID-19 coronavirus.

The recent outbreak of the COVID-19 coronavirus has spread across the globe and is impacting worldwide economic activity. A pandemic, including COVID-19 or other public health epidemic, poses the risk that we or our employees, CROs, suppliers, manufacturers and other partners may be prevented from conducting business activities for an indefinite period of time, including due to the spread of the disease or shutdowns that may be requested or mandated by governmental authorities. While it is not possible at this time to estimate the full impact that COVID-19 could have on our business, the continued spread of COVID-19 could disrupt our clinical trials, supply chain and the manufacture or shipment of our cyclodextrin products, and other related activities, which could have a material adverse effect on our business, financial condition and results of operations. COVID-19 has also had an adverse impact on global economic conditions which could impair our ability to raise capital when needed. While we have not yet experienced any disruptions in our business or other negative consequences relating to COVID-19, the extent to which the COVID-19 pandemic impacts our results will depend on future developments that are highly uncertain and cannot be predicted.

Risks Related to Our Intellectual Property

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

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

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

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

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

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

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

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

There is a substantial amount of litigation over patent and other intellectual property rights in the biotechnology industry. Whether or not a product infringes a patent involves complex legal and factual considerations, the determination of which is often uncertain. Our management is presently unaware of any other parties' patents and proprietary rights which our products under development would infringe. Searches typically performed to identify potentially infringed patents of third parties are often not conclusive and, because patent applications can take many years to issue, there may be applications now pending, which may later result in issued patents which our current or future products may infringe or be alleged to infringe. In addition, our competitors or other parties may assert that our product candidates and the methods employed may be covered by patents held by them. If any of our products infringes a valid patent, we could be prevented from manufacturing or selling such product unless we are able to obtain a license or able to redesign the product in such a manner as to avoid infringement. A license may not always be available or may require us to pay substantial royalties. We also may not be successful in any attempt to redesign our product to avoid infringement, nor does a later redesign protect the Company from prior infringement. Infringement and other intellectual property claims, with or without merit, can be expensive and time-consuming to litigate and can divert our management's attention from operating our business.

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

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

Risks Related to Legal and Regulatory Compliance Matters

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

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

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

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

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

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

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

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

Risks Related to Employee Matters

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

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

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

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

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

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

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

Risks Related To Our Fine Chemical Business

A small number of our customers account for a substantial portion of our revenue, and the loss of this customer would have a material adverse effect on our results of operations.

Our single largest customer accounted for 25% of our total sales in fiscal 2019 and our largest four customers collectively accounted for 70% of total sales in fiscal 2019. During the six months ended June 30, 2020, our two largest customers accounted for 60% of our sales; the largest accounted for 42% of sales. 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 suppliers for the cyclodextrins we use in our Aquaplex® products. We are also dependent on outside manufacturers that use lyophilization techniques for our Aquaplex ® products. We purchase substantially all of our Trappsol® products from bulk manufacturers and distributors in the U.S., Japan, China, and Europe. Although products are available from multiple sources, an unexpected interruption of supply, or material increases in the price of products, for any reason, such as regulatory requirements, import restrictions, loss of certifications, power interruptions, fires, hurricanes, war or other events could have a material adverse effect on our business, results of operations, financial condition and cash flows.

We may be negatively affected by currency exchange rate fluctuations.

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

Risks Related To Our Common Stock and This Offering

Our executive officers and certain stockholders possess the majority of our voting power, and through this ownership, control the Company and our corporate actions.

Our current directors and executive officers, together with our largest stockholder, which is affiliated with one of our directors, hold approximately 51.1% of the voting power of our outstanding shares prior to this offering. These stockholders have a controlling influence in determining the outcome of any corporate transaction or other matters submitted to our stockholders for approval, including mergers, consolidations and the sale of all or substantially all of our assets, election of directors, and other significant corporate actions. As such, our executive officers and these investors have the power to prevent or cause a change in control; therefore, without their consent we could be prevented from entering into transactions that could be beneficial to us. The interests of our executive officers may give rise to a conflict of interest with the Company and the Company's stockholders.

Our management has broad discretion as to the use of the net proceeds from this offering.

We will use the net proceeds from this offering primarily to fund our proposed Phase III trial for the treatment of NPC with Trappsol® Cyclo™ and to fund further development of our preclinical programs and clinical trials for the treatment of Alzheimer's disease with Trappsol ® Cyclo™. Our management will have broad discretion in the application of the net proceeds, including for any of the purposes described in "Use of Proceeds." Accordingly, you will have to rely upon the judgment of our management with respect to the use of the proceeds. Our management may spend a portion or all of the net proceeds from this offering in ways that holders of our common stock may not desire or that may not yield a significant return or any return at all. The failure by our management to apply these funds effectively could harm our business. Pending their use, we may also invest the net proceeds from this offering in a manner that does not produce income or that loses value.

There is a limited existing market for our common stock and we do not know if a more liquid market for our common stock will develop to provide you with adequate liquidity.

Prior to this offering, there has been a limited public market for our common stock. We cannot assure you that a more active trading market for our common stock or warrants will develop following this offering, or if it does develop, that it will be maintained. You may not be able to sell your securities quickly or at the market price if trading in our securities is not active. The public offering price for the securities will be determined by negotiations between us and the representatives of the underwriters and may not be indicative of prices that will prevail in the trading market. Upon closing of this offering, our common stock and warrants will be listed on the Nasdaq Capital Market, however, we cannot ensure that an active public market for our common stock and warrants will develop after this offering, or that if it does develop, it will be sustained. In the absence of an active public trading market:

- you may not be able to resell your securities at or above the public offering price;
- the market price of our common stock may experience more price volatility; and
- there may be less efficiency in carrying out your purchase and sale orders.

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

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

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

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

As a "thinly-traded" stock, large sales can place downward pressure on our stock price.

Our stock experiences periods when it could be considered "thinly traded". Financing transactions resulting in a large number of newly issued shares that become readily tradable, or other events that cause current stockholders to sell shares, could place further downward pressure on the trading price of our stock. In addition, the lack of a robust resale market may require a stockholder who desires to sell a large number of shares to sell the shares in increments over time to mitigate any adverse impact of the sales on the market price of our stock.

You will experience immediate and substantial dilution as a result of this offering and may experience additional dilution in the future.

You will incur immediate and substantial dilution as a result of this offering. After giving effect to the sale by us of Units in this offering at an assumed public offering price of $ per Unit, after deducting underwriter discounts and commissions and estimated offering expenses payable by us, investors in this offering can expect an immediate dilution of $ per share, or % at the assumed public offering price. For a further description of the dilution that investors in this offering may experience, see "Dilution."

In the past, we have issued shares of common stock and warrants in private placements of our securities, and we have issued shares of common stock as compensation to our officers and directors. Our issuance of shares of common stock in the future, and the exercise of outstanding warrants or warrants that we may issue in the future, may result in additional dilution to investors in this offering.

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

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

If our securities are listed on Nasdaq, our failure to meet the continued listing requirements of The Nasdaq Capital Market could result in a de-listing of our securities.

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

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

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

Substantial future sales of shares of our common stock in the public market could cause our stock price to fall.

Except for shares of our common stock held by our affiliates, all of our outstanding shares of common are currently freely trading or eligible for resale without restriction under Rule 144, except for shares of common stock sold in our August 27, 2020 private placement, of which shares held by non-affiliates of ours will be eligible for resale without restriction under Rule 144 on February 24, 2021. In addition, the lock-up agreements which our officers, directors, and principal stockholders entered into with the underwriter expire six months after the closing of this offering. Upon the expiration of those lock-up agreements, the outstanding shares of common stock covered by them become eligible for resale in the open market (subject to Rule 144 volume limitations applicable to executive officers, directors and 10% or more stockholders), resulting in more shares eligible for sale and potentially causing selling in the market to increase and our stock price to decline. Additional sales of a substantial number of our shares of our common stock in the public market, or the perception that sales could occur, could have a material adverse effect on the price of our common stock.

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

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

Risks Associated with Our Reverse Stock Split

The one-for-__ reverse stock split could cause our stock price to decline relative to its value before the split.

We plan to effect a one-for-__ reverse stock split of our authorized, issued and outstanding common stock immediately following the effectiveness but prior to the closing of this offering in order to achieve a sufficient increase in our stock price to enable us to qualify for listing on Nasdaq. There is no assurance that the reverse split will not cause an actual decline in the value of our outstanding common stock.

Following our planned one for__ reverse stock split, we cannot assure you that we will be able to continue to comply with the minimum bid price requirement of The Nasdaq Capital Market.

There can be no assurance that the market price of our common stock following the reverse stock split will remain at the level required for continuing compliance with that requirement. It is not uncommon for the market price of a company's common stock to decline in the period following a reverse stock split. If the market price of our common stock declines following the effectuation of the reverse stock split, the percentage decline may be greater than would occur in the absence of a reverse stock split. In any event, other factors unrelated to the number of shares of our common stock outstanding, such as negative financial or operational results, could adversely affect the market price of our common stock and jeopardize our ability to meet or maintain The Nasdaq Capital Market's minimum bid price requirement.

The reverse stock split may decrease the liquidity of the shares of our common stock

The liquidity of the shares of our common stock may be affected adversely by the reverse stock split given the reduced number of shares that will be outstanding following the reverse stock split, especially if the market price of our common stock does not increase as a result of the reverse stock split. In addition, the reverse stock split may increase the number of stockholders who own odd lots (less than 100 shares) of our common stock, creating the potential for such stockholders to experience an increase in the cost of selling their shares and greater difficulty effecting such sales.

Following the reverse stock split, the resulting market price of our common stock may not attract new investors, including institutional investors, and may not satisfy the investing requirements of those investors. Consequently, the trading liquidity of our common stock may not improve.

Although we believe that a higher market price of our common stock may help generate greater or broader investor interest, there can be no assurance that the reverse stock split will result in a share price that will attract new investors, including institutional investors. In addition, there can be no assurance that the market price of our common stock will satisfy the investing requirements of those investors. As a result, the trading liquidity of our common stock may not necessarily improve.

DISCLOSURE REGARDING FORWARD-LOOKING STATEMENTS

The information contained in this prospectus contains certain forward-looking statements. All statements other than statements of historical facts contained or incorporated by reference in this prospectus, including statements regarding our future financial position, business strategy and plans and objectives of management for future operations, are forward-looking statements. The words “anticipate,” “believe,” “estimate,” “will,” “may,” “future,” “plan,” “intend” and “expect” and similar expressions generally identify forward-looking statements. These forward-looking statements are not guarantees and are subject to known and unknown risks, uncertainties and assumptions that may cause our actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by such forward-looking statements. Although we believe that our plans, intentions and expectations reflected in the forward-looking statements are reasonable, we cannot be sure that they will be achieved. Particular uncertainties that could cause our actual results to be materially different than those expressed in our forward-looking statements include: our history of losses; our inability to receive regulatory approval for our products; later discovery of previously unknown problems; reliance on third parties; competition between us and other companies in the industry; delays in the development of products; our ability to raise additional capital; continued services of our executive management team; and statements of assumption underlying any of the foregoing, as well as other factors set forth under the caption **“Risk Factors”** on page 5 of this prospectus. All subsequent written and oral forward-looking statements attributable to us, or persons acting on our behalf, are expressly qualified in their entirety by the foregoing. Except as required by law, we undertake no obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise.

USE OF PROCEEDS

We estimate that the net proceeds from this offering will be approximately $ based on assumed offering price of $ per Unit after deducting estimated underwriting discounts and estimated offering expenses payable by us and excluding the proceeds, if any, from the exercise of the warrants issued as part of the Units. If the underwriters' over-allotment option is exercised in full, we estimate that our net proceeds will be approximately $ after deducting estimated underwriting discounts and estimated offering expenses payable by us and excluding the proceeds, if any, from the exercise of the warrants issued as part of the Units.

We currently intend to use the net proceeds we receive from this offering (i) to proceed with our proposed Phase III trial for the treatment of NPC with Trappsol® Cyclo™, (ii) to fund further development of our preclinical programs towards IND filings and/or into clinical trials for the treatment of Alzheimer's disease with Trappsol® Cyclo™ and (iii) to fund working capital and general corporate purposes using any remaining amounts.

Based on our planned use of the net proceeds, we estimate such funds, together with our existing cash and cash equivalents, will be sufficient for us to fund our operating expenses and capital expenditure requirements through at least . We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we expect.

The expected use of the net proceeds from the offering represents our intentions based upon our current plans and business conditions. The amounts we actually expend in these areas, and the timing thereof, may vary significantly from our current intentions and will depend on a number of factors, including the success of research and product development efforts, cash generated from future operations and actual expenses to operate our business.

The amounts and timing of our preclinical and clinical expenditures and the extent of preclinical and clinical development may vary significantly depending on numerous factors, including the status, results and timing of our current preclinical studies and the preclinical studies and clinical trials which we may commence in the future, the product approval process with the FDA and other regulatory agencies, and any new collaborations we may enter into with third parties and any unforeseen cash needs. As a result, we cannot predict with any certainty all of the particular uses for the net proceeds or the amounts that we will actually spend on the uses set forth above. Accordingly, our management will have broad discretion in the application of the net proceeds, and investors will be relying on the judgment of our management regarding the application of the net proceeds of this offering.

The expected net proceeds of this offering will not be sufficient for us to fund any of our product candidates through regulatory approval, and we will need to raise substantial additional capital to complete the development and commercialization of our product candidates.

DIVIDEND POLICY

We have never declared or paid any cash dividends on our common stock and do not anticipate paying any cash dividends on our common stock at any time in the foreseeable future. We currently intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any dividends on our common stock in the foreseeable future. Any future determination to declare dividends will be made at the discretion of our Board and will depend on, among other factors, our financial condition, operating results, capital requirements, general business conditions, the terms of any future credit agreements and other factors that our Board may deem relevant. In addition, our current financing arrangements effectively prohibit us from paying cash dividends on our capital stock for the foreseeable future.

CAPITALIZATION

The following table sets forth our cash and cash equivalents, debt obligations, and capitalization as of June 30, 2020:

- on an actual basis; and
- on a pro forma as adjusted basis to give effect to the issuance and sale of shares of our common stock and public warrants in this offering at an assumed public offering price of $ per share, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

	As of June 30, 2020	
	Actual	Pro Forma As Adjusted[1]
Cash and cash equivalents	$ 1,008,355	$ 0
Capitalization:		
Equipment financing	-	-
Stockholders' (deficit) equity:		
Common stock, par value $0.0001 per share, 1,000,000,000 shares authorized, 141,671,462 shares issued and outstanding, and pro forma, as adjusted	14,155	
Preferred stock, par value $0.001 per share, 5,000,000 shares authorized	-	-
Additional paid-in capital	28,012,423	
Accumulated deficit	(29,946,617)	
Total stockholders' deficit	(1,920,039)	
Total capitalization	$ (1,920,039)	$ 0

(1) Each $0.50 increase (decrease) in the assumed public offering price of $ per Unit would increase (decrease) cash and cash equivalents, working capital, total assets, total liabilities, additional paid-in capital and total stockholders' (deficit) equity by $, assuming that the number of Units offered by us, as set forth on the cover page of this prospectus, remains the same, after deducting the estimated underwriting discounts and commissions. Similarly, each increase (decrease) of 500,000 Units offered by us would increase (decrease) each of cash and cash equivalents, working capital, total assets, additional paid-in capital and total stockholders' (deficit) equity by $, assuming the assumed public offering price of $ per Unit remains the same, and after deducting the estimated underwriting discounts and commissions.

The foregoing pro forma as adjusted information is illustrative only, and our capitalization following the completion of this offering will be adjusted based on the actual public offering price and other terms of this offering determined at pricing. The pro forma as adjusted information also gives effect to 28,311,140 shares of common stock we issued in our August 2020 private placement. You should read this table together with our financial statements and the related notes appearing elsewhere in this prospectus and the "Selected Financial Data" and "Management's discussion and analysis of financial condition and results of operations" sections of this prospectus.

The table and discussion above does not give effect to the potential reverse stock split, or include:

- shares of our common stock reserved for issuance under our 2019 Omnibus Equity Incentive Plan; and
- 93,622,864 shares of our common stock issuable upon the exercise of warrants, with a weighted-average exercise price of $ per share.

DILUTION

If you invest in our Units in this offering, your interest will be diluted to the extent of the difference between the assumed public offering price per share of common stock that is part of the Unit and the pro forma as adjusted net tangible book value per share of common stock immediately after this offering.

Our net tangible book value is the amount of our total tangible assets less our total liabilities. Our net tangible book value as of June 30, 2020 was $, or $ per share of common stock. Pro forma net tangible book value gives effect to receipt of $2,831,000 net cash proceeds from our August 2020 private placement.

Pro forma as adjusted net tangible book value is our pro forma net tangible book value, plus the effect of the sale of Units in this offering at the assumed public offering price of $ per Unit and after deducting the underwriting discounts and commissions and other estimated offering expenses payable by us. Our pro forma as adjusted net tangible book value as of June 30, 2020 would have been approximately $, or $ per share. This amount represents an immediate increase in pro forma as adjusted net tangible book value of approximately $ per share to our existing stockholders, and an immediate dilution of $ per share to new investors participating in this offering. Dilution per share to new investors is determined by subtracting pro forma as adjusted net tangible book value per share after this offering from the public offering price per share paid by new investors.

The following table illustrates this per share dilution:

Assumed public offering price per share (attributing no value to the warrants)	$
Net tangible book value per share as of June 30, 2020	$
Increase in as adjusted net tangible book value per share attributable to the August 2020 private placement	$
Pro forma net tangible book value per share as of June 30, 2020	$
Increase in pro forma as adjusted net tangible book value per share after this offering	$
Pro forma as adjusted net tangible book value per share after giving effect to this offering	$
Dilution in pro forma as adjusted net tangible book value per share to new investors	$

Each $0.50 increase (decrease) in the assumed public offering price of $ per Unit would increase (decrease) the pro forma as adjusted net tangible book value per share by $, and the dilution per share to new investors in this offering by $, assuming the number of Units offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. Each increase of 500,000 in the number of Units sold in this offering would increase (decrease) our pro forma as adjusted net tangible book value by approximately $ and the dilution per share to new investors in this offering by $, assuming that the assumed public offering price per Unit remains the same and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The information above assumes that the Representative does not exercise its over-allotment option. If the Representative exercises its over-allotment option in full, the pro forma as adjusted net tangible book value will increase to $ per share, representing an immediate increase to existing stockholders of $ per share and an immediate dilution of $ per share to new investors.

The foregoing discussion and table do not take into account further dilution to new investors that could occur upon the exercise of outstanding warrants having a per share exercise or conversion price less than the per share offering price to the public in this offering.

We may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

The table and discussion above does not give effect to the potential reverse stock split, or include:

- shares of our common stock reserved for issuance under our 2019 Omnibus Equity Incentive Plan; and
- 93,622,864 shares of our common stock issuable upon the exercise of warrants, with a weighted-average exercise price of $ per share.

OUR BUSINESS

Overview

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

We are a clinical stage biotechnology company that develops cyclodextrin-based products for the treatment of disease. We filed a Type II Drug Master File with the U.S. Food and Drug Administration ("FDA") in 2014 for our lead drug candidate, Trappsol® Cyclo™ (hydroxypropyl beta cyclodextrin) as a treatment for Niemann-Pick Type C disease ("NPC"). NPC is a rare and fatal cholesterol metabolism disease that impacts the brain, lungs, liver, spleen, and other organs. In 2015, we launched an International Clinical Program for Trappsol® Cyclo™ as a treatment for NPC. In 2016, we filed an Investigational New Drug application ("IND") with the FDA, which described our Phase I clinical plans for a randomized, double blind, parallel group study at a single clinical site in the U.S. The Phase I study evaluated the safety of Trappsol® Cyclo™ along with markers of cholesterol metabolism and markers of NPC during a 14-week treatment period of intravenous administration of Trappsol® Cyclo™ every two weeks to participants 18 years of age and older. The IND was approved by the FDA in September 2016, and in January 2017 the FDA granted Fast Track designation to Trappsol ® Cyclo™ for the treatment of NPC. Initial patient enrollment in the U.S. Phase I study commenced in September 2017. Enrollment in this study was completed in October 2019, and in May 2020 we announced Top Line data showing a favorable safety and tolerability profile for Trappsol® Cyclo™ in this study.

We have also filed Clinical Trial Applications for a Phase I/II clinical study with several European regulatory bodies, including those in the United Kingdom, Sweden and Italy, and in Israel, all of which have approved our applications. The Phase I/II study is evaluating the safety, tolerability and efficacy of Trappsol ® Cyclo™ through a range of clinical outcomes, including neurologic, and respiratory, in addition to measurements of cholesterol metabolism and markers of NPC. The European/Israel study is similar to the U.S. study, providing for the administration of Trappsol® Cyclo™ intravenously to NPC patients every two weeks in a double-blind, randomized trial but it differs in that the study period is for 48 weeks (24 doses). The first patient was dosed in this study in July 2017, and in February 2020, we announced completion of enrollment of 12 patients in this study. In September 2020, we released positive data from the seven patients who completed the trial, supporting the efficacy of Trappsol® Cyclo™ in treating NPC patients.

Additionally, in February 2020 we had a face-to-face "Type C" meeting with the FDA with respect to the initiation of a Phase III clinical trial of Trappsol® Cyclo™ based on the clinical data obtained to date. At that meeting, we also discussed with the FDA submitting a New Drug Application (NDA) under Section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for the treatment of NPC in pediatric and adult patients with Trappsol® Cyclo™. A similar request was submitted to the European Medicines Agency ("EMA") in February 2020, seeking scientific advice and protocol assistance from the EMA for proceeding with a Phase III clinical trial in Europe. While we have not yet received the "Study May Proceed" from the FDA with respect to the proposed Phase III clinical trial, management believes the feedback from both the EMA and FDA were positive.

Preliminary data from our clinical studies suggest that Trappsol® Cyclo™ releases cholesterol from cells, crosses the blood-brain-barrier in individuals suffering from NPC, and results in clinical improvements in NPC patients. The full significance of these findings will be determined as part of the final analysis of both clinical trials.

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

We are also exploring the use of cyclodextrins in the treatment of Alzheimer's disease. In January 2018, the FDA authorized a single patient IND expanded access program using Trappsol® Cyclo™ for the treatment of this disease. After 18 months of treatment in this geriatric patient with late-onset disease, the disease was stabilized and the drug was well tolerated. The patient also exhibited signs of improvement with less volatility and shorter latency in word-finding. In October 2019, we entered into an agreement with Worldwide Clinical Trials, a Contract Research Organization, to conduct a clinical trial to evaluate the safety and efficacy of Trappsol® Cyclo™ for the treatment of Alzheimer's disease. We prepared a synopsis for an early stage protocol using Trappsol ® Cyclo™ intravenously to treat Alzheimer's Disease, and we plan to present this synopsis to the FDA in early 2021.

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

Niemann-Pick Type C Disease

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

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

We estimate the incidence of NPC to be one in 100,000 live births and that there are currently 3,000 existing NPC patients worldwide, with approximately 1,370 new NPC cases each year.

Treatment Options for NPC

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

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

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

Cyclodextrins

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

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.

Use of Cyclodextrins to Treat NPC

Natural cyclodextrins have been confirmed to be generally recognized as safe (GRAS) in most of the world, including the U.S. Moreover, approvals of products containing cyclodextrins by the FDA since 2001 suggest that regulatory approval for new products may be easier to obtain in the future. In 2001, Janssen Pharmaceutica, now a subsidiary of Johnson & Johnson, received FDA approval to market Sporanox®, an antifungal which contained hydroxypropyl beta cyclodextrin as an excipient. In 2009, one of our products was used in an FDA approved compassionate use investigational new drug protocol for the treatment of NPC. Under the Orphan Drug Act, companies that develop a drug for a disorder affecting fewer than 200,000 people in the United States may seek designation as an orphan drug. If such designation is approved, a company will have the ability to sell the drug exclusively for seven years following FDA drug approval, and the company may receive clinical trial tax incentives. On May 17, 2010, the FDA designated Trappsol® Cyclo™ as an orphan drug for the treatment of NPC. We have also obtained Orphan Drug Designation for Trappsol® Cyclo™ in Europe. Trappsol® Cyclo™ has been administered to more than 20 NPC patients in compassionate use programs around the world, including in the U.S., Brazil and Spain. The doctors and patients participating in these programs, including patients that have been administered Trappsol® Cyclo™ intravenously for more than five years, have made their data available to us, which we used to design our clinical studies in the U.S. and abroad.

Use of Cyclodextrins to Treat Alzheimer's Disease

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

In January 2018, the FDA authorized a single patient IND expanded access program using Trappsol® Cyclo™ for the treatment of Alzheimer's disease. After 18 months of monthly intravenous infusions, the patient's disease did not progress as measured with standard cognitive tools, and the patient and family reported less volatility and greater word-finding ability. In October 2018, we filed a patent application with respect to the use of hydroxypropyl beta cyclodextrins in the treatment of Alzheimer's disease. In October 2019, we entered into an agreement with Worldwide Clinical Trials, a Contract Research Organization, to conduct a clinical trial to evaluate the safety and efficacy of Trappsol® Cyclo™ for the treatment of Alzheimer's disease. We prepared a synopsis for an early stage protocol using Trappsol® Cyclo™ intravenously for Alzheimer's Disease and plan to present it to FDA in early 2021.

Intellectual Property

We have filed a U.S. and international patent application with respect to the treatment of Alzheimer's disease with cyclodextrins. In addition, the designation of Trappsol® Cyclo™ as an orphan drug for the treatment of NPC by the FDA and European regulators would provide us with seven years, and 10 to 12 years, of market exclusivity, respectively, following regulatory approval. We also believe that our formulation and manufacturing process for Trappsol ® Cyclo™ is protected by trade secrets. We have also protected our Trappsol® and Aquaplex® trademarks by registering them with the U.S. Patent and Trademark Office.

Competition

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

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

Research and Development

We are currently pursuing clinical programs in the U.S., Europe, and Israel in an effort to gain market authorization of our bio-pharmaceutical product for the treatment of NPC. We have made a substantial investment in the research and development of our Trappsol® Cyclo™ product as we seek approval for marketing the product for the treatment of NPC. We are also exploring the use of cyclodextrins in the treatment of Alzheimer's disease. We will continue to expend substantial funds in support of these efforts with the progression of our clinical trials, which we commenced in 2017. Research and development expenses increased to approximately $4,869,000 in 2019, from $2,711,000 in 2018.

Government Regulation

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

United States Government Regulation

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

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

- completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's good laboratory practice regulations;
- completion of the manufacture, under cGMP conditions, of the drug substance and drug product that the sponsor intends to use in clinical trials along with required analytical and stability testing;
- submission to the FDA of an investigational new drug, or IND, application for clinical trials, which must become effective before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, at each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled clinical trials, in accordance with good clinical practice, or GCP, requirements to establish the safety, potency, purity and efficacy of the proposed drug for each proposed indication;
- payment of user fees;
- preparation and submission to the FDA of an NDA requesting marketing for one or more proposed indications, including submission of detailed information on the manufacture and composition of the product in clinical development and proposed labelling;
- satisfactory completion of an FDA advisory committee review, if applicable;

- satisfactory completion of an FDA inspection of the manufacturing facility or facilities, including those of third parties at which the product, or components thereof, are produced to assess compliance with cGMP requirements, and to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- satisfactory completion of an FDA inspection of selected clinical sites to assure compliance with GCPs and the integrity of the clinical data;
- FDA review and approval of the NDA; and
- compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy, or REMS, and any post-approval studies or other post-marketing commitments required by the FDA.

Preclinical Studies

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

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

Expanded Access to an Investigational Drug for Treatment Use

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

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

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

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

Clinical Trials

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

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

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

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

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

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

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

Compliance with cGMP Requirements

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

Marketing Approval

Assuming successful completion of the required clinical testing, the results of the preclinical studies and clinical trials, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the product for one or more indications. In most cases, the submission of an NDA is subject to a substantial application user fee. Under the PDUFA guidelines that are currently in effect, the FDA has a goal of ten months to review and act on a standard NDA and six months to review and act on a priority NDA, measured from the date of "filing" of a standard NDA for a NME. This review typically takes eight months from the date the NDA is submitted to the FDA because the FDA has approximately two months to make a "filing" decision.

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

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

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

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

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

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

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

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

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

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

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

Orphan Drug Designation

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

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

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

Special FDA Expedited Review and Approval Programs; Priority Review Voucher

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

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

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

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

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

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

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

Coverage and Reimbursement

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

Impact of Healthcare Reform on our Business

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

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

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

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

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

Other Healthcare Laws

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

Our Legacy Fine Chemical Business

Substantially all of our revenues are currently derived from our legacy fine chemical business, consisting of the sale of cyclodextrins, including cyclodextrin complexes, the resale of cyclodextrins manufactured by others for our clients to their specifications, and our own licensed cyclodextrin products. We have trademarked certain products under our Trappsol® and Aquaplex® product lines. The Trappsol® product line includes basic cyclodextrins, and cyclodextrins with different chemical adducts resulting in more than 261 different cyclodextrins products available for sale from us. The Aquaplex® product line includes various cyclodextrins combined with more than 80 different active ingredients that, only as a complex, then become water soluble; we currently list for sale more than 116 different Aquaplex® products. Historically, substantially all of our sales of Aquaplex® products were to one chemical supply house, Sigma-Aldrich Fine Chemical. Sales of Trappsol® and Aquaplex® comprise approximately 85% and 15%, respectively, of our 2019 product sales. The Trappsol® and Aquaplex® products can be used in many industries, the largest being the food and pharmaceutical industries.

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

Cyclodextrin Product Background

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

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

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

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

Other Cyclodextrin Uses

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

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

Customers

We currently sell our legacy fine chemical products directly to customers in the pharmaceutical, diagnostics, and industrial chemical industries, and to chemical supply distributors. For the year ended December 31, 2019, our revenues consisted of 10% biopharmaceuticals, 75% basic natural and chemically modified cyclodextrins, and 15% cyclodextrin complexes.

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

The majority of our revenues are from five to ten customers who have historically been repeat purchasers. For the years ended December 31, 2019 and 2018, one customer (UNO Healthcare, Inc.) that has historically been a large customer, accounted for 14% and 15% of our total revenue, respectively. In addition, another customer that was not previously a large customer accounted for 25% of our total revenue in 2019. Sigma-Aldrich Fine Chemical, Inc. accounted for almost 100% and 95% of our 2019 and 2018 annual sales, respectively, of Aquaplex®. In a given year, we typically sell to fewer than 200 individual customers. Our industrial customers buy products from us as needed primarily for product research and development purposes. Therefore, it is difficult to predict future sales from these customers, as it is dependent on the current cyclodextrin related research and development activities of others, which we have monitored in the past by following the issuance and applications of patents in the US and elsewhere.

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

Employees

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

Description Of Property

We do not currently own any real property. In December 2016, we sold our office and manufacturing facility located in Alachua, Florida for $800,000. On November 26, 2018, we exercised a two-year renewal option, commencing February 2019, with respect to our lease of approximately 2,500 square feet of office and warehouse space located in Gainesville, Florida for $1,600 per month. We believe that this leased property is currently sufficient for our operating requirements, and that we will be able to find alternative space suitable for our needs in the event we are unable to renew this lease upon its expiration.

Legal Proceedings

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

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*This Management's Discussion and Analysis of Financial Condition and Results of Operations, and other parts of this prospectus contain forward-looking statements that involve risks and uncertainties. All forward-looking statements included in this prospectus are based on information available to us on the date hereof, and we assume no obligation to update any such forward-looking statements. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of a number of factors, including those set forth in the section captioned "**Risk Factors**" on page 5 of this prospectus. The following should be read in conjunction with our audited financial statements included elsewhere herein.*

Overview

We are a clinical stage biotechnology company that develops cyclodextrin-based products for the treatment of disease. We filed a Type II Drug Master File with the U.S. Food and Drug Administration ("FDA") in 2014 for our lead drug candidate, Trappsol® Cyclo™ (hydroxypropyl beta cyclodextrin) as a treatment for Niemann-Pick Type C disease ("NPC"). NPC is a rare and fatal cholesterol metabolism disease that impacts the brain, lungs, liver, spleen, and other organs. In 2015, we launched an International Clinical Program for Trappsol® Cyclo™ as a treatment for NPC. In 2016, we filed an Investigational New Drug application ("IND") with the FDA, which described our Phase I clinical plans for a randomized, double blind, parallel group study at a single clinical site in the U.S. The Phase I study evaluated the safety of Trappsol® Cyclo™ along with markers of cholesterol metabolism and markers of NPC during a 14-week treatment period of intravenous administration of Trappsol® Cyclo™ every two weeks to participants 18 years of age and older. The IND was approved by the FDA in September 2016, and in January 2017 the FDA granted Fast Track designation to Trappsol ® Cyclo™ for the treatment of NPC. Initial patient enrollment in the U.S. Phase I study commenced in September 2017. Enrollment in this study was completed in October 2019, and in May 2020 we announced Top Line data showing a favorable safety and tolerability profile for Trappsol® Cyclo™ in this study.

We have also filed Clinical Trial Applications for a Phase I/II clinical study with several European regulatory bodies, including those in the United Kingdom, Sweden and Italy, and in Israel, all of which have approved our applications. The Phase I/II study is evaluating the safety, tolerability and efficacy of Trappsol ® Cyclo™ through a range of clinical outcomes, including neurologic, and respiratory, in addition to measurements of cholesterol metabolism and markers of NPC. The European/Israel study is similar to the U.S. study, providing for the administration of Trappsol® Cyclo™ intravenously to NPC patients every two weeks in a double-blind, randomized trial but it differs in that the study period is for 48 weeks (24 doses). The first patient was dosed in this study in July 2017, and in February 2020, we announced completion of enrollment of 12 patients in this study. In September 2020, we released positive data from the seven patients who completed the trial, supporting the efficacy of Trappsol® Cyclo™ in treating NPC patients.

Additionally, in February 2020 we had a face-to-face "Type C" meeting with the FDA with respect to the initiation of a Phase III clinical trial of Trappsol® Cyclo™ based on the clinical data obtained to date. At that meeting, we also discussed with the FDA submitting a New Drug Application (NDA) under Section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for the treatment of NPC in pediatric and adult patients with Trappsol® Cyclo™. A similar request was submitted to the European Medicines Agency ("EMA") in February 2020, seeking scientific advice and protocol assistance from the EMA for proceeding with a Phase III clinical trial in Europe. While we have not yet received the "Study May Proceed" from the FDA with respect to the proposed Phase III clinical trial, management believes the feedback from both the EMA and FDA were positive.

Preliminary data from our clinical studies suggest that Trappsol® Cyclo™ releases cholesterol from cells, crosses the blood-brain-barrier in individuals suffering from NPC, and results in clinical improvements in NPC patients. The full significance of these findings will be determined as part of the final analysis of both clinical trials.

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

We are also exploring the use of cyclodextrins in the treatment of Alzheimer's disease. In January 2018, the FDA authorized a single patient IND expanded access program using Trappsol® Cyclo™ for the treatment of this disease. After 18 months of treatment in this geriatric patient with late-onset disease, the disease was stabilized and the drug was well tolerated. The patient also exhibited signs of improvement with less volatility and shorter latency in word-finding. In October 2019, we entered into an agreement with Worldwide Clinical Trials, a Contract Research Organization, to conduct a clinical trial to evaluate the safety and efficacy of Trappsol® Cyclo™ for the treatment of Alzheimer's disease. We prepared a synopsis for an early stage protocol using Trappsol ® Cyclo™ intravenously to treat Alzheimer's Disease, and we plan to present this synopsis to the FDA in early 2021.

We filed a provisional patent application for the treatment of Alzheimer's disease with cyclodextrins with the U.S. Patent and Trademark Office in October 2018, which was amended based on additional clinical data in August 2019; and we filed a similar international patent application in October 2019 under the Patent Cooperation Treaty.

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

Results of Operations

Six Months Ended June 30, 2020 Compared to Six Months Ended June 30, 2019

We reported a net loss of $(4,826,000) for the six months ended June 30, 2020, compared to net loss of $(3,272,000) for the six months ended June 30, 2019.

Total revenues for the six month period ended June 30, 2020 increased 8% to $535,000 compared to $494,000 for the same period in 2019. Our change in the mix of our product sales for the six months ended June 30, 2020 and 2019 is as follows:

Trappsol® Cyclo
Our sales of Trappsol® Cyclo™ increased by 15% for the six month period ended June 30, 2020, to $30,000 from $26,000 for the six month period ended June 30, 2019. Substantially all of our sales of Trappsol® Cyclo™ for the six months ended June 30, 2020 and 2019 were to a particular customer who exports the drug to South America. Our annual 2019 sales to this customer were $104,000 (100% of total 2019 sales of Trappsol® Cyclo™). This product is designated as an orphan drug; the population of patients who use the product on a compassionate basis is small.

Trappsol® HPB
Our sales of Trappsol® HPB increased by 77% for the six month period ended June 30, 2020, to $366,000 from $207,000 for the six months ended June 30, 2019.

Trappsol® other products
Our sales of other Trappsol® products increased for the six month period ended June 30, 2020, to $134,000 from $105,000 for the six months ended June 30, 2019.

Aquaplex®
Our sales of Aquaplex® were $1,000 for the six month period ended June 30, 2020 compared to $150,000 for the six month period ended June 30, 2019.

The largest customers for our legacy fine chemical business continue to follow historical product ordering trends by placing periodic large orders that represent a significant share of our annual sales volume. During the six months ended June 30, 2020, our two largest customers accounted for 60% of our sales; the largest accounted for 42% of sales. During the six months ended June 30, 2019, our four largest customers accounted for 65% of our sales; the largest accounted for 28% of sales. 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) for the six month period ended June 30, 2020 increased 5% to $39,000 from $37,000 for the same period in 2019. Our cost of products sold (excluding any allocation of direct and indirect overhead and handling costs) as a percentage of sales was 7% for the six months ended June 30, 2020 and 2019. 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 2019, or the first six months of 2020.

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

As we buy inventory from foreign suppliers, the change in the value of the U.S. dollar in relation to the Euro and Yuan may from time to time have 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. There were no purchases of inventory from Hungary during the six months ended June 30, 2020. The cost of shipping from outside the U.S. also has a significant effect on our inventory acquisition costs. In addition, unpredictable changes in United States import tariffs also impacts our costs for raw materials. When we experience short-term increases in currency fluctuation, tariff increases, 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 by 25%, to $903,000 for the six months ended June 30, 2020 from $721,000 for the six months ended June 30, 2019. The increase in personnel expense is due to additional personnel added during the middle of 2019. We expect to maintain our level of employees and related costs in the near term.

Research and development expenses increased 77% to $3,773,000 for the six months ended June 30, 2020, from $2,130,000 for the six months ended June 30, 2019. Research and development expenses as a percentage of our total operating expenses increased to 70% for the six months ended June 30, 2020 from 56% for the six months ended June 30, 2019. The increase in research and development expense is due to increased activity in our International Clinical Program and U.S. clinical trials. We expect future research and development costs to further increase as we continue to seek regulatory approval for the use of Trappsol® Cyclo™ in the treatment of NPC and Alzheimer's disease.

Professional fees decreased 21% to $363,000 for the six months ended June 30, 2020, compared to $461,000 for the six months ended June 30, 2019. Professional fees may increase in the future due to new initiatives in raising capital and the continuation of product development.

Office and other expenses decreased 26% to $258,000 for the six months ended June 30, 2020, compared to $350,000 for the six months ended June 30, 2019. Office and other expenses include costs for travel to, and participation in, industry conferences and similar events, which vary from period to period.

Board of Directors fees and costs decreased to $29,000 for the six months ended June 30, 2020, compared to $65,000 for the six months ended June 30, 2019. Board of Directors fees and costs include fees (generally in the form of stock compensation) paid to our non-employee directors and scientific advisory board members, reimbursement of expenses of our board members, and related expenses. The reduction in Board of Directors fees and costs for the six months ended June 30, 2020 compared to the same period in the prior year was due to a decrease in the market price of the Company's common stock.

We increased our valuation allowance to offset the increase in our deferred tax asset from our net operating loss and did not recognize an income benefit or provision for the six months ended June 30, 2020, and 2019, respectively.

Year Ended December 31, 2019 Compared to Ended December 31, 2018

For 2019, we incurred a net loss of $7,532,500, compared to a net loss in 2018 of $4,255,000. Total revenues for 2019 were $1,007,000 compared to $1,011,000 for 2018.

Our change in the mix of our product sales for 2019 and 2018 is as follows:

Trappsol® Cyclo™ HPBCDs
First and second-generation formulations of Trappsol® Cyclo™ HPBCD (in liquid and powder form) have been sold to a single customer who exports to Brazil for compassionate use in NPC patients. Sales decreased 38% to $104,000 for 2019 from $167,000 for 2018. The population of patients who use the product on a compassionate basis is small.

Trappsol® HPB
Our sales of Trappsol® HPB decreased 1% to $481,000 for 2019 from $484,000 for 2018.

Trappsol® other products
Our sales of other Trappsol® products increased 14% to $266,000 for 2019 from $234,000 for 2018.

Aquaplex®

Our sales of Aquaplex® increased to $150,000 for 2019 compared to $117,000 for 2018, 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 $149,250 in 2019, $111,000 in 2018, $17,000 in 2017, $134,000 in 2016, and $75,000 in 2015.

The largest customers of our legacy fine chemical business continue to follow historical product ordering trends to place periodic large orders that represent a significant share of our annual revenue volume. In 2019, our five largest customers (Charles River Laboratories, Inc., Ventana Medical Systems, Inc., Sigma-Aldrich Fine Chemicals, Inc., Uno Healthcare, and Thermofisher Scientific Diagnostics, Inc.) accounted for 78% of our revenues, and the largest accounted for 25% of our revenues. In 2018, our five largest customers (Ventana Medical Systems, Inc., Uno Healthcare, Siemens Medical Solutions USA, Inc., Sigma-Aldrich Fine Chemicals, Inc., and BAS Evansville, Inc.) accounted for 61% of our revenues, and the largest accounted for 18% of our revenues. Historically, our usual smaller sales of HPB occur more frequently throughout the year compared to our large sales that we receive periodically. The timing of when we receive and are able to complete these two kinds of sales has a significant effect on our quarterly revenues and operating results and makes period to period comparisons difficult.

Our cost of products sold decreased to $75,500 for 2019 compared to $105,000 for 2018. Our cost of products sold as a percentage of product sales was 7.5% for 2019 and 10% for 2018. This percentage is a function of the sales make up by product mix as well as customer order size. Historically, the timing and product mix of sales to our large customers has had a significant effect on our sales, cost of products sold and the related margin. We did not experience any significant increases in material costs during 2019 or 2018.

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

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

Personnel expenses increased 63% to $1,906,000 for 2019, from $1,172,000 for 2018. In June 2019 we hired a Chief Financial Officer on a part-time basis, and in September 2019 we hired a Global Head of Regulatory Affairs. Increased personnel expenses reflect compensation expense and stock awards. We expect to maintain our level of employees and related costs in the near term.

Research and development expenses increased 80% to $4,869,000 for 2019, from $2,711,000 for 2018. The increase in research and development expenses is due to increased activity in our International Clinical Program and U.S. clinical trials. We expect research and development costs to further increase in 2020 as we continue to seek regulatory approval for the use of Trappsol® Cyclo™ in the treatment of NPC and Alzheimer's disease.

Repairs and maintenance expenses increased 117% to $8,000 for 2019 from $4,000 for 2018. This increase is due to varying levels of maintenance required on equipment and rental facilities. We expect our repairs and maintenance expenses to remain consistent in 2020.

Professional fees decreased 29% to $572,000 for 2019 from $809,000 for 2018. In 2019 there was reduced activity in our lawsuit against the NIH, which we have discontinued, and reduced intellectual property related expenses. Professional fees may increase in the future due to new initiatives in raising capital and the continuation of product development.

Office and other expenses increased 139% to $845,000 for 2019 from $354,000 for 2018. Office and other expenses include costs for travel to, and participation in, industry conferences and similar events, which vary from period to period, and investor relations expenses.

Board of Directors fees and costs increased to $109,000 for 2019 from $95,000 for 2018. Board of Directors fees and costs include fees (generally in the form of stock compensation) 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 to $6,000 for 2019 from $10,000 for 2018. These expenses fluctuate slightly with equipment purchases and dispositions.

Freight and shipping expenses were $6,000 for 2019 and 2018. Freight and shipping is dependent on frequency of ordering products for inventory and frequency of shipping out products sold.

We recorded an impairment expense for slow moving and expired inventory of $154,000 and $12,150 for 2019 and 2018, respectively.

We increased our valuation allowance to allow for 100% of the 2019 increase in our deferred tax asset and did not recognize an income tax benefit or provision for 2019 and 2018.

Liquidity and Capital Resources

Our cash increased to $2,784,000 as of December 31, 2019, from $2,217,000 at December 31, 2018, primarily as the result of net proceeds of approximately $6,990,000 generated by the sale of our equity securities in the private placement we closed in May 2019. Our current assets less current liabilities was approximately $817,000 at December 31, 2019 compared to approximately $844,000 at December 31, 2018. Cash used in operations for 2019 increased to $6,589,000 compared to $3,188,000 for 2018. 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 raise.

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

Our cash decreased to approximately $1,008,000 as of June 30, 2020, compared to $2,784,000 as of December 31, 2019. Our current assets less current liabilities were $(1,969,000) as of June 30, 2020, compared to $817,000 at December 31, 2019. Cash used in operations was $3,870,000 for the six months ended June 30, 2020, compared to $2,747,000 for the same period in 2019. 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 raise.

On May 31, 2019, we completed a private placement of our securities to a group of accredited investors that included several directors of the Company and members of management. Investors in the private placement purchased a total of 29,770,000 units at a price per unit of $0.25, each unit consisting of one share of Common Stock and one warrant to purchase a share of Common Stock, resulting in gross proceeds to us of $7,442,500, before deducting placement agent fees and offering expenses.

In April 2020, we completed a private placement in which we raised $2,000,000 from the sale of 20,000,000 shares of Common Stock, at a price $0.10 per share, and in August 2020, we completed a private placement in which we raised an additional $2,831,114 from the sale of 28,311,140 units at a price of $0.10 per unit, each unit consisting of one share of Common Stock and a seven-year warrant to purchase one share of Common Stock at an exercise price of $0.15 per share.

We also borrowed $158,524 under the Paycheck Protection Program in May 2020, and plan to apply for forgiveness of the loan in accordance with the terms of the CARES Act. While we currently believe that our use of the loan proceeds met or will meet the conditions for forgiveness of the loan, there can be no assurance in that regard.

The Company has continued to realize losses from operations. Upon the closing of this offering, we believe we will have sufficient cash to meet our anticipated operating costs and capital expenditure requirements through . However, we will need to raise additional capital to support our ongoing operations and continue our clinical trials. We expect to continue to raise additional capital through the sale of our securities from time to time for the foreseeable future to fund the development of our drug product candidates through clinical development, manufacturing and commercialization. Our ability to obtain such additional capital will likely be subject to various factors, including our overall business performance and market conditions. There can be no guarantee that the Company will be successful in its ability to raise capital to fund future operational and development initiatives. Our need for additional capital as described above raises substantial doubt about our ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of these uncertainties.

At December 31, 2019, we had approximately $18,335,000 in net state and federal operating loss carryforwards expiring from 2020 through 2037, including $9,692,000 that will not expire, that can be used to offset our current and future taxable net income and reduce our income tax liabilities. We have provided a 100% valuation allowance on our deferred tax asset based on our expected future expenses related to our clinical trials and other development initiatives.

We have no off-balance sheet arrangements at June 30, 2020 and December 31, 2019.

Critical Accounting Policies and Estimates

The results of operations are based on the preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States. The preparation of consolidated financial statements requires management to select accounting policies for critical accounting areas as well as make estimates and assumptions that affect the amounts reported in the consolidated financial statements. The Company's accounting policies are more fully described in Note 1 of Notes to Consolidated Financial Statements for our year ended December 31, 2019. Significant changes in assumptions and/or conditions in our critical accounting policies could materially impact the operating results. We have identified the following accounting policies and related judgments as critical to understanding the results of our operations.

Revenue Recognition

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

Product Revenues

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

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

Reserves for Discounts and Allowances

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

Product revenue reserves, which are classified as a reduction in product revenues, are generally characterized in the following categories: discounts, contractual adjustments and returns.

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

Valuation Allowance on Deferred Tax Assets

At December 31, 2019, we fully reserved for our net deferred tax asset with a $8,881,000 valuation allowance. We increased our valuation allowance by $2,645,000 in 2019 to reduce our recognized deferred tax asset to zero.

We have determined it is more likely than not that we will not realize our temporary deductible differences and net operating loss carryforwards, and we have provided a 100% valuation allowance at December 31, 2019.

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

Research and Development

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

MANAGEMENT

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 September , 2020:

Name	Age	Positions and Offices With Registrant	Year First Became Director
N. Scott Fine	63	Director, Chief Executive Officer	2014
Jeffrey L. Tate, Ph.D.	62	Director, Chief Operating Officer	2010
C.E. Rick Strattan (2)	74	Director	1990
Markus W. Sieger (1) (3)	55	Director and Chairman of the Board of Directors	2014
F. Patrick Ostronic (1)	65	Director and Vice Chairman of the Board of Directors	2014
William S. Shanahan (2) (3)	80	Director	2016
Dr. Randall M. Toig (1)	70	Director	2018
Joshua M. Fine	38	Chief Financial Officer and Secretary	N/A
Dr. Sharon H. Hrynkow	59	Chief Scientific Officer and SVP for Medical Affairs	N/A
Michael Lisjak	47	Chief Regulatory Officer and SVP for Business Development	N/A

(1) Member of the audit committee.
(2) Member of the corporate governance and nominating committee.
(3) Member of the compensation committee.

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. Much of his time has been focused on transactions in the healthcare and consumer products area. Mr. Fine has led global transactions in healthcare, including medical devices, generic pharmaceuticals, and genetics. He also worked with The Tempo Group of Jakarta, Indonesia when Mr. Fine and his family resided in Jakarta. Mr. Fine was Chairman of the Board of The Global Virus Network (GVN), and he also was the lead investment banker on the initial public offering of Green Mountain Coffee Roasters, Inc. and Central European Distribution Corporation ("CEDC"), a multi-billion-dollar alcohol company. Mr. Fine continued his involvement with CEDC serving as a director from 1996 until 2014, during which time he led the CEDC Board in its 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. Recently, Mr. Fine served as Vice Chairman and Chairman of the Restructuring Committee of Pacific Drilling from 2017 to 2018 where he successfully led the independent directors to a successful reorganization. He also served as sole director of Better Place Inc. from 2013 until 2015. In his role there, Mr. Fine successfully managed the global wind down of the company in a timely and efficient manner which was approved by both the Delaware and Israeli Courts.

Mr. Fine currently serves on the board of directors of Kenon Holdings Ltd. (NYSE: KEN). Mr. Fine also devotes time to several non-profit organizations, including through his service on the Board of Trustees for the IWM American Air Museum in Britain. Mr. Fine has been a guest lecturer at Ohio State University's Moritz School of Law.

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. Mr. Fine is the father of Joshua M. Fine, our Chief Financial Officer.

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

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

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

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

Markus W. Sieger has been a Director of the Company since February 2014 and serves as the Chairman of the Company's Board of Directors. 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. Mr. Sieger holds a Bachelor's Degree in Economics from the University of Applied Sciences for Business and Administration, Zurich, and completed the Stanford Graduate School of Business Executive Program.

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 holds a B.A. in Economics and Accounting from Holy Cross University, an M.S. in Accounting from Old Dominion University, and a J.D. from the University of Maryland School of Law, and was previously licensed as a Certified Public Accountant.

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.

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

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

Dr. Randall M. Toig has been a director since March 2018. Until his recent retirement from private practice, Dr. Toig was a practicing physician for more than 35 years in obstetrics, gynecology and gynecological surgery at Gold Coast Gynecology, of which he was the Chief Executive Officer. Dr. Toig is currently an associate professor of clinical obstetrics and gynecology at Northwestern University, Northwestern Memorial Hospital and Northwestern Medical School Prentice Women's Hospital. He previously served at Northwestern Memorial Hospital practicing, teaching and serving on active staff. Dr. Toig holds a B.S. from University of Michigan and received his M.D. from the University of Pittsburgh.

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

Joshua M. Fine was appointed our Chief Financial Officer on June 11, 2019, and has been our Secretary since 2014. From 2011 until his appointment as our Chief Financial Officer, he served as the Vice President/Director, Healthcare Capital Markets, of Scarsdale Equities. Mr. Fine is also currently the Vice President of Finance and Operations for Icagen, Inc., a biotechnology company, a position he has held since 2017. From 2009 until 2011, Mr. Fine served as the Vice President, Capital Markets of Emerging Growth Equities, a boutique investment banking firm. Mr. Fine holds a Bachelor of Arts in Political Science from Hartwick College. Mr. Fine is the son of N. Scott Fine, our Chief Executive Officer.

Dr. Sharon H. Hrynkow has served as our Chief Scientific Officer since February 2019, and as our Senior Vice President for Medical Affairs since September 2015. Prior to that, she served as the President of Global Virus Network, a nonprofit organization working to combat pandemic viral disease. She previously served as a Senior Executive at the National Institutes of Health (NIH), where she was the Deputy Director and Acting Director of the Fogarty International Center, the focal point for international research and training and for diplomatic relations for the NIH. Dr. Hrynkow also served as Associate Director of the National Institute on Environmental Health Sciences and Senior Advisor to the NIH Deputy Director. Dr. Hrynkow serves on many advisory committees for national and international organizations, and in 2019 was appointed to the President's Council of Advisors on Science and Technology. She is an elected member of the Council on Foreign Relations. Dr. Hrynkow received her PhD in Neuroscience from the University of Connecticut Health Center and her B.A. in Biology from Rhode Island College.

Michael Lisjak joined us as our Global Head of Regulatory Affairs and Senior Vice President for Business Development in July 2019, and was appointed our Chief Regulatory Officer in September 2020. He has more than 20 years of regulatory strategy and operations experience within the biopharmaceutical and consulting industries for multiple therapeutic areas, including cardiovascular, metabolic, neuroscience and pain and inflammation. Prior to joining the Company, Mr. Lisjak was the Director of Global Regulatory Affairs at Sanofi from July 2015 to June 2016, leading the Endocrinology and Neuromuscular Rare Disease Area, and then served as Sanofi's Head of Global Regulatory Affairs for Established Products and Global Health until July 2019. Prior to Sanofi, Mr. Lisjak served as the Global Regulatory Services Lead for Accenture's Life Sciences group accountable for the growth and strategic oversight for Accenture's global regulatory offerings, capabilities and go-to-market strategy. Before Accenture, he held multiple leadership roles at Pfizer and Wyeth with responsibility for developing, maintaining and directing global regulatory strategies and resources in the provision of regulatory guidance and filings ensuring optimal regulatory interactions with global/regional Health Authorities. Mr. Lisjak holds a B.A. in Biology from Rochester Institute of Technology.

Director Independence

Our board of directors currently consists of seven directors, five of whom are "independent" as defined under the rules of the Nasdaq Capital Market because they are not employees or executive officers of the Company, and have not been paid more than $120,000 of compensation by the Company in any consecutive 12-month period during the past three years. N. Scott Fine, our Chief Executive Officer, and Dr. Jeffrey L. Tate, our Chief Operating Officer, are not independent directors due to their employment by us as executive officers.

Audit Committee

Our audit committee is comprised of Patrick Ostronic, Markus Sieger and Dr. Randall Toig. Patrick Ostronic serves as the chairman of our audit committee. Our Board has determined that each member of our audit committee meets the requirements for independence and financial literacy under the applicable rules and regulations of the SEC and the listing standards of the Nasdaq. Our Board has also determined that Patrick Ostronic is an "audit committee financial expert" as defined in the rules of the SEC and has the requisite financial sophistication as defined under the listing standards of the Nasdaq. The responsibilities of our audit committee include, among other things:

- selecting and hiring the independent registered public accounting firm to audit our financial statements;
- overseeing the performance of the independent registered public accounting firm and taking those actions as it deems necessary to satisfy itself that the accountants are independent of management;
- reviewing financial statements and discussing with management and the independent registered public accounting firm our annual audited and quarterly financial statements, the results of the independent audit and the quarterly reviews, and the reports and certifications regarding internal control over financial reporting and disclosure controls;
- preparing the audit committee report that the SEC requires to be included in our annual proxy statement;
- reviewing the adequacy and effectiveness of our internal controls and disclosure controls and procedures;
- overseeing our policies on risk assessment and risk management;
- reviewing related party transactions; and
- approving or, as required, pre-approving, all audit and all permissible non-audit services and fees to be performed by the independent registered public accounting firm.

Our audit committee operates under a written charter which satisfies the applicable rules and regulations of the SEC and the listing standards of Nasdaq.

Compensation Committee

Our compensation committee is comprised of Markus Sieger and William Shanahan. Mr. Sieger serves as the chairman of our compensation committee. Our Board has determined that each member of our compensation committee meets the requirements for independence under the applicable rules and regulations of the SEC and listing standards of Nasdaq. Each member of the compensation committee is a non-employee director, as defined in Rule 16b-3 promulgated under the Exchange Act. The purpose of our compensation committee is to oversee our compensation policies, plans and benefit programs and to discharge the responsibilities of our Board relating to compensation of our executive officers. The responsibilities of our compensation committee include, among other things:

- reviewing and approving or recommending to the Board for approval compensation of our executive officers and directors;
- overseeing our overall compensation philosophy and compensation policies, plans and benefit programs for service providers, including our executive officers;
- reviewing, approving and making recommendations to our Board regarding incentive compensation and equity plans; and
- administering our equity compensation plans.

Our compensation committee operates under a written charter which satisfies the applicable rules and regulations of the SEC and the listing standards of Nasdaq.

Corporate Governance and Nominating Committee

The corporate governance and nominating committee is comprised of William Shanahan and C.E. Rick Strattan. William Shanahan serves as chairman of our corporate governance and nominating committee. Our Board has determined that all members of our corporate governance and nominating committee meet the requirements for independence under the applicable rules and regulations of the SEC and listing standards of the NYSE. The responsibilities of our corporate governance and nominating committee include, among other things:

- identifying, evaluating and selecting, or making recommendations to our Board regarding, nominees for election to our Board and its committees;
- evaluating the performance of our Board and of individual directors;
- considering and making recommendations to our Board regarding the composition of our Board and its committees; and
- developing and making recommendations to our Board regarding corporate governance guidelines and matters.

Our corporate governance and nominating committee operates under a written charter which satisfies the applicable rules and regulations of the SEC and the listing standards of Nasdaq.

Code of Ethics

The Board adopted a Code of Business Conduct and Ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions and agents and representatives, including consultants. Following the completion of this offering, a copy of the code of ethics and conduct will be available on our website at www.cyclotherapeutics.com. We intend to disclose future amendments to such code, or any waivers of its requirements, applicable to any principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions or our directors on our website identified above. The inclusion of our website address in this prospectus does not include or incorporate by reference the information on our website into this prospectus.

EXECUTIVE COMPENSATION

The following table contains information concerning the compensation paid during our fiscal years ended December 31, 2019 and 2018 to (i) the person who served as our Chief Executive Officer during 2019, and (ii) our executive officers as of December 31, 2019 whose compensation exceeded $100,000 (collectively, our "Named Executive Officers").

SUMMARY COMPENSATION TABLE

Name & Principal Position	Year	Salary ($)	Stock Awards ($) (1)	All Other Compensation ($) (2)	Total ($)
N. Scott Fine	2019	400,000	10,000	79,579	489,579
CEO	2018	400,000	4,294	62,347	466,641
Jeffrey L. Tate, Ph.D.	2019	220,974	29,500	31,959	282,433
COO	2018	186,667	4,294	27,233	218,194
Sharon H. Hrynkow, Ph.D.	2019	248,000	19,500	89,084	356,584
Chief Scientific Officer	2018	232,000	-	7,947	239,947

(1) Reflects award of 20,000 shares to Mr. Fine and Dr. Tate as compensation for services as a member of the Company's board of directors in 2019 and 2018, respectively. Also reflects award of 100,000 shares in 2019 as compensation for services in the form of an employee bonus to each of Drs. Tate and Hrynkow. All of the shares were fully vested upon issuance. The stock award figure represents the value of the stock award at grant date as calculated under FASB ASC Topic 718.

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

Outstanding Equity Awards at Fiscal Year End

As of December 31, 2019, our Named Executive Officers had no outstanding unexercised options, unvested stock or other unvested equity incentive plan awards.

Employment Agreements

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

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

- Mr. Fine's employment as Chief Executive Officer is for an initial term ending on September 14, 2020, subject to automatic one-year extensions unless either party notifies the other party prior to the expiration of the then term.
- Mr. Fine receives an initial base salary of $400,000 per annum.
- Mr. Fine is entitled to an annual bonus based on financial performance and personal performance targets to be established by the Board of Directors or a committee thereof.
- In the event of the termination of Mr. Fine's employment by the Company without Cause (as defined in the Employment Agreement), Mr. Fine will be entitled to continued payment of his base salary for a period of one-year following termination, and the payment of any bonus previously earned by Mr. Fine but not yet paid.

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

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

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

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

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

Both Mr. Fine's and Dr. Hrynkow's employment agreements automatically renewed for a one-year term in September 2020.

Compensation of Directors

Directors of the Company are entitled to such compensation for their services as the Board may from time to time determine, and reimbursements for their reasonable expenses incurred in attending meetings of directors. In addition, we pay cash compensation of $15,000 per annum to Markus W. Sieger for acting as our Chairman of the Board of Directors. We did not compensate our other directors for their services during 2019, but expect to award each of them 20,000 shares of Common Stock in consideration of their services to the Company during 2019.

CERTAIN RELATIONSHIPS AND 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. In addition, Mr. Fine's son, Joshua M. Fine, was employed by Scarsdale at the time of its initial engagement by us and active on our account until his appointment as our Chief Financial Officer in June 2019. During 2018, we paid Scarsdale Equities cash fees of approximately $66,000.

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

In June 2019, we engaged Joshua M. Fine, the son of our Chief Executive Officer, to serve as our Chief Financial Officer on a part-time basis. Mr. Fine receives an annual salary of $125,000. In addition, he was awarded a stock bonus of 50,000 shares in September 2019.

During 2017, Rebecca A. Fine, the daughter of our Chief Executive Officer, provided executive assistant services at the rate of $5,000 per month. From January through May 2019, she provided these services at the rate of $5,800 per month. In June 2019, Ms. Fine was employed by us as a full-time employee serving as an executive assistant with an annual salary of $69,600. Ms. Fine also received a stock bonus of 25,000 shares in September 2019.

Kevin J. Strattan, the son of C.E. Rick Strattan, has been employed by us since 2008, and since 2014 has been our Vice President, Finance – Compensation. His annual salary increased from $100,000 to $107,200 in October 2018. In addition, he received cash bonuses of $10,000 and $12,500 in 2018 and 2019, respectively. Mr. Strattan also received a stock bonus of 50,000 shares in September 2019.

Corey E. Strattan, the daughter-in-law of C.E. Rick Strattan, has been employed by us since 2011 as a documentation specialist and logistics coordinator. Her annual salary increased from $72,000 in 2018, to $78,000 in 2019. In addition, she received a cash bonus of $5,000 in 2018. Ms. Strattan also received a stock bonus of 25,000 shares in September 2019.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following table sets forth certain information with respect to the beneficial ownership of our common stock as of September , 2020, as adjusted to reflect the sale of common stock offered by us in this offering, for:

- each person, or group of affiliated persons, who we know to beneficially own more than 5% of our common stock;
- each of our named executive officers;
- each of our directors and director nominees; and
- all of our executive officers and directors as a group.

The percentage of beneficial ownership information shown in the table is based on 169,982,602 shares of common stock outstanding as of September , 2020, and assumes no participation in this offering by the parties below. The percentage of beneficial ownership shown in the table after this offering is based upon shares of common stock outstanding after the close of this offering, assuming the sale of shares of common stock by us in the offering and no exercise of the underwriter's option to purchase additional shares of our common stock in this offering.

Information with respect to beneficial ownership has been furnished by each director, officer or beneficial owner of more than 5% of our common stock. We have determined beneficial ownership in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. In addition, the rules include shares of our common stock issuable pursuant to the exercise of warrants that are either immediately exercisable or exercisable within 60 days of September , 2020. These shares are deemed to be outstanding and beneficially owned by the person holding those warrants for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to applicable community property laws.

Names and Address of Individual or Identity of Group(1)	Number of Shares Beneficially Owned	Beneficial Ownership Prior to the Offering (%)	Beneficial Ownership After the Offering (%)
Officers and Directors			
C.E. Rick Strattan	20,608,385(2)	12.1%	
Jeffrey L. Tate	1,240,972(3)	*	
N. Scott Fine	10,542,996(4)	6.11%	
Markus Sieger	7,365,714(5)	4.29%	
F. Patrick Ostronic	4,065,780(6)	2.37%	
William S. Shanahan	7,107,220(7)	4.11%	
Dr. Randall M. Toig	3,715,540(8)	2.14%	
Dr. Sharon Hrynkow	915,000(9)	*	
All Directors and Executive Officers as a Group (10 Persons)	58,141,266(10)	32.01%	
5% Holders			
Novit, L.P.	35,135,164(11)	19.14%	
966 Hungerford Drive Rockville, Maryland 20850			
Scarsdale Equities LLC 10 Rockefeller Plaza, Suite 720 New York, NY 10020	8,829,000(12)	5.03%	
Armistice Capital Master Fund Ltd.	25,849,892(13)	14.36%	

* Less than one percent.

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

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

(3) Includes currently exercisable warrants to purchase 225,000 shares of Common Stock.
(4) Includes currently exercisable warrants to purchase 2,576,483 shares of Common Stock.
(5) Includes currently exercisable warrants to purchase 1,592,857 shares of Common Stock.
(6) Includes currently exercisable warrants to purchase 1,209,890 shares of Common Stock.
(7) Includes currently exercisable warrants to purchase 2,739,560 shares of Common Stock.
(8) Includes currently exercisable warrants to purchase 1,307,770 shares of Common Stock.
(9) Includes currently exercisable warrants to purchase 280,000 shares of Common Stock.
(10) Includes 11,651,219 shares that may be issued under currently exercisable warrants, including warrants to purchase Common Stock underlying warrants to purchase "Units" of the Company's securities.
(11) Novit U.S., Inc. is the general partner of Novit, L.P. and Katarzyna Kusmierz is the trustee of the NAP Trust and VN Trust, which own all of the outstanding partnership interests in Novit, L.P. Each of Novit US, Inc. and Ms. Kusmierz share voting and dispositive power over the shares Common Stock owned by Novit, L.P. and may be deemed to own such shares of Common Stock. Includes currently exercisable warrants to purchase 3,617,582 shares of Common Stock.
(12) Based on a Schedule 13G/A filed by Scarsdale Equities, LLC with the SEC on February 19, 2019 and information provided by Scarsdale to the Company. Includes 8,422,900 shares of Common Stock held in accounts managed by Scarsdale and 5,440,000 shares of Common Stock issuable upon the exercise of warrants held in such managed accounts.
(13) Includes a currently exercisable warrant to purchase 10,000,000 shares of Common Stock, but excludes a warrant to purchase 12,000,000 shares of Common Stock that may be issued on exercise of a warrant, as such warrant includes a provision precluding the exercise thereof if the warrant holder would beneficially own in excess of 4.99% of the Company's outstanding shares of Common Stock. Armistice Capital, LLC, the investment manager of Armistice Capital Master Fund Ltd., or Armistice, and Steven Boyd, the managing member of Armistice Capital, LLC, hold shared voting and dispositive power over the shares held by Armistice. Each of Armistice Capital, LLC and Steven Boyd disclaims beneficial ownership of the securities listed except to the extent of their pecuniary interest therein. The principal business address of Armistice is c/o Armistice Capital, LLC, 510 Madison Avenue, 7th Floor, New York, NY, 10022.

DETERMINATION OF OFFERING PRICE

The offering price has been negotiated between the representatives of the Underwriter and us. In determining the offering price of the Units, the following factors were considered:

- prevailing market conditions;
- our historical performance and capital structure;
- estimates of our business potential and earnings prospects;
- an overall assessment of our management; and
- the consideration of these factors in relation to market valuation of companies in related businesses.

Our common stock is quoted on the OTCQB under the symbol "CTDH." We have applied to The Nasdaq Capital Market to list our common stock under the symbol "CYTH", and the warrants being sold in this offering under the symbol "CYTHW". On September , 2020, the last reported sale price of our common stock on the OTCQB was $ per share.

DESCRIPTION OF SECURITIES

We are currently incorporated in Florida and expect to reincorporate in Nevada prior to the completion of this offering. We expect to adopt Nevada articles of incorporation and bylaws in connection with the reincorporation and prior to the completion of this offering. The following description of our capital stock and provisions of our amended and restated articles of incorporation and bylaws are summaries and are qualified by reference to the articles of incorporation and bylaws that will become effective prior to the pricing of this offering. Copies of these documents have been filed with the SEC as exhibits to the registration statement of which this prospectus forms a part. The description of our capital stock reflects changes to our capital structure that will occur upon the closing of this offering.

Description of Existing Securities

Common Stock

After accounting for our planned one-for- reverse stock split of our authorized common stock, we are authorized to issue shares of Common Stock, $.0001 par value per share, of which shares were outstanding on the date of this prospectus. Holders of shares of our Common Stock are entitled to one vote per share on all matters submitted to a vote of the stockholders and are not entitled to cumulative voting rights. Our shares of our Common Stock do not carry any preemptive, conversion or subscription rights, and there are no sinking fund or redemption provisions applicable to the shares of our Common Stock. Holders of our Common Stock are entitled to receive dividends and other distributions in cash, stock or property as may be declared by our Board of Directors from time to time out of our assets or funds legally available for dividends or other distributions, subject to dividend or distribution preferences that may be applicable to any then outstanding shares of preferred stock. In the event of our voluntary or involuntary liquidation, dissolution or winding up, holders of shares of our Common Stock are entitled to share ratably in the assets legally available for distribution to stockholders after payment of all debts and other liabilities and satisfaction of the liquidation preference, if any, granted to the holders of any preferred stock then outstanding. All outstanding shares of our Common Stock are fully paid and nonassessable.

Preferred Stock

We are authorized to issue 5,000,000 shares of preferred stock, $0.001 par value per share, of which no shares are outstanding on the date of this prospectus. Our certificate of incorporation authorizes our Board of Directors to establish one or more series of preferred stock (including convertible preferred stock). Unless required by law, the authorized shares of preferred stock will be available for issuance without further action by you. Our Board of Directors is able to determine, with respect to any series of preferred stock, the powers (including voting powers), preferences and relative, participating, optional or other special rights, and the qualifications, limitations or restrictions thereof, including, without limitation:

- the designation of the series;
- the number of shares of the series, which our Board of Directors may, except where otherwise provided in the preferred stock designation, increase (but not above the total number of authorized shares of the class) or decrease (but not below the number of shares then outstanding);
- whether dividends, if any, will be cumulative or non-cumulative and the dividend rate of the series;
- the dates at which dividends, if any, will be payable;
- the redemption rights and price or prices, if any, for shares of the series;
- the terms and amounts of any sinking fund provided for the purchase or redemption of shares of the series;
- the amounts payable on shares of the series in the event of any voluntary or involuntary liquidation, dissolution or winding-up of our affairs;
- whether the shares of the series will be convertible into shares of any other class or series, or any other security, of the Company or any other corporation, and, if so, the specification of the other class or series or other security, the conversion price or prices or rate or rates, any rate adjustments, the date or dates as of which the shares will be convertible and all other terms and conditions upon which the conversion may be made;
- restrictions on the issuance of shares of the same series or of any other class or series; and
- the voting rights, if any, of the holders of the series.

We could issue a series of preferred stock that could, depending on the terms of the series, impede or discourage an acquisition attempt or other transaction that some, or a majority, of the holders of our Common Stock might believe to be in their best interests or in which the holders of our Common Stock might receive a premium for your Common Stock over the market price of the Common Stock. Additionally, the issuance of preferred stock may adversely affect the holders of our Common Stock by restricting dividends on the Common Stock, diluting the voting power of the Common Stock or subordinating the liquidation rights of the Common Stock. As a result of these or other factors, the issuance of preferred stock could have an adverse impact on the market price of our Common Stock.

Warrants

Assuming the effectiveness of the planned one-for- reverse stock split, we currently have warrants outstanding to purchase a total of shares of our common stock, exercisable until various dates ranging from April 2021 to May 2027 at exercise prices ranging from $ per share to $ per share. The following table presents the number of warrants outstanding, their exercise prices, and expiration dates at September __, 2020:

Warrants Issued	Exercise Price	Expiration Date
	$	April 2021
	$	July 2021
	$	July 2022
	$	August 2022
	$	June 2023
	$	February 2024
	$	October 2024
	$	November 2024
	$	April 2025
	$	December 2025
	$	May 2027

In addition, there are currently outstanding seven-year warrants to purchase (i) 480,000 Units sold in our May 2016 private placement at an exercise price of $0.25 per Unit, (ii) 164,074 Units sold in our February 2017 private placement at an exercise price of $0.35 per Unit, and (iii) 600 Units sold in our October 2017 private placement at an exercise price of $100 per Unit. After giving effect to the planned one-for- reverse stock split, the exercise in full of these warrants to purchase units (including exercise of the warrants underlying these warrants) would result in the issuance of __ additional shares of our common stock at an aggregate exercise price of $.

Description of Securities in this Offering

Units. We are offering _____ Units, each Unit consists of one share of our common stock, par value $0.0001 per share, and one warrant (the “Warrants”) to purchase one share of our common stock. The shares of our common stock and related Warrants will be issued separately. We are also registering the shares of our common stock issuable upon exercise of the Warrants offered hereby.

Common Stock. The material terms and provisions of our common stock are described under the caption "Description of Existing Securities".

Public Warrants. Upon completion of this offering we expect to have an additional Warrants outstanding (if the Units reserved for the over-allotment are sold), each Warrant is exercisable for one share of common stock at an exercise price of % of the price of each unit sold in the offering and is exercisable at any time up for a period of five years following the date of issuance.

The number of Warrants outstanding, and the exercise price of those securities, will be adjusted proportionately in the event of a reverse or forward stock split of our common stock, a recapitalization or reclassification of our common stock, payment of dividends or distributions in common stock to our common stock holders, or similar transactions. In the event that the Company effects a rights offering to its common stock holders or a pro rata distribution of its assets among its common stock holders, then the holder of the Warrants will have the right to participate in such distribution and rights offering to the extent of their pro rata share of the Company's outstanding common stock assuming they owned the number of shares of common stock issuable upon the exercise of their Warrants. In the event of a "Fundamental Transaction" by the Company, such as a merger or consolidation of it with another company, the sale or other disposition of all or substantially all of the Company's assets in one or a series of related transactions, a purchase offer, tender offer or exchange offer, or any reclassification, reorganization or recapitalization of the Company's common stock, then the Warrant holder will have the right to receive, for each share of common stock issuable upon the exercise of the Warrant, at the option of the holder, the number of shares of common stock of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration payable as a result of the Fundamental Transaction, that would have been issued or conveyed to the Warrant holder had the holder exercised the Warrant immediately preceding the closing of the Fundamental Transaction. In lieu of receiving such common stock and additional consideration in the Fundamental Transaction, the Warrant holder may elect to have the Company or the successor entity purchase the Warrant holder's Warrant for its fair market value measured by the Black Scholes method.

The Company will promptly notify the Warrant holders in writing of any adjustment to the exercise price or to the number of the outstanding Warrants, declaration of a dividend or other distribution, a special non-recurring cash dividend on or a redemption of the common stock, the authorization of a rights offering, the approval of the stock holders required for any proposed reclassification of the common stock, a consolidation or merger by the Company, sale of all or substantially all of the assets of the Company, any compulsory share exchange, or the authorization of any voluntary or involuntary dissolution, liquidation, or winding up of the Company.

The Warrants contain a contractual provision stating that all questions concerning the construction, validity, enforcement and interpretation of the Warrants are governed by and construed and enforced in accordance with the internal laws of the State of New York, without regard to the principles of conflicts of law.

Representative's Warrants. We also expect to have up to an additional common stock purchase warrants outstanding (if the Units reserved for the over-allotment are sold), issuable to the underwriter of this offering ("Underwriter's Warrants"). Each Underwriter's Warrant is exercisable for one share of common stock on a cash or cashless basis at an exercise price of 110% of the price of each unit share of sold in the offering). The Underwriter's Warrants will be non-exercisable for six (6) months after the effective date (the "Effective Date") of the registration statement of which this Prospectus forms a part of this offering, and will expire five years after such Effective Date. The Underwriter's Warrants will contain provisions for one demand registration of the shares underlying the Underwriter's Warrants at the Company's expense and one registration of the Underwriter's Warrants at the Representative's expense for a period of five years from the Effective Date, and unlimited piggyback registration rights for a period of five years after the Effective Date at the Company's expense.

The number of Underwriter's Warrants outstanding and the exercise price of those securities will be adjusted proportionately, as permitted by FINRA Rule 5110(f)(2)(G), in the event of a reverse or forward stock split of our common stock, a recapitalization or reclassification of our common stock, payment of dividends or distributions in common stock to our common stock holders, or similar transactions. In the event that the Company effects a rights offering to its common stock holders or a pro rata distribution of its assets among its common stock holders, then the holder of the Underwriter's Warrants will have the right to participate in such distribution and rights offering to the extent of their pro rata share of the Company's outstanding common stock assuming they owned the number of shares of common stock issuable upon the exercise of their warrants. In the event of a "Fundamental Transaction" by the Company, such as a merger or consolidation of it with another company, the sale or other disposition of all or substantially all of the Company's assets in one or a series of related transactions, a purchase offer, tender offer or exchange offer, or any reclassification, reorganization or recapitalization of the Company's common stock, then the warrant holder will have the right to receive, for each share of common stock issuable upon the exercise of the warrant, at the option of the holder, the number of shares of common stock of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration payable as a result of the Fundamental Transaction that would have been issued or conveyed to the warrant holder had the holder exercised the warrant immediately preceding the closing of the Fundamental Transaction. In lieu of receiving such common stock and additional consideration in the Fundamental Transaction, the warrant holder may elect to have the Company or the successor entity purchase the warrant holder's warrant for its fair market value measured by the Black Scholes method.

The Company will promptly notify the holders of the Underwriter's Warrants in writing of any adjustment to the exercise price or to the number of the outstanding warrants, declaration of a dividend or other distribution, a special non-recurring cash dividend on or redemption of the common stock, the authorization of a rights offering, the approval of the stock holders required for any proposed reclassification of the common stock, a consolidation or merger by the Company, sale of all or substantially all of the assets of the Company, any compulsory share exchange, or the authorization of any voluntary or involuntary dissolution, liquidation, or winding up of the Company.

Nevada Anti-Takeover Statutes

The following provisions of the Nevada Revised Statutes ("NRS") could, if applicable, have the effect of discouraging takeovers of our company.

Transactions with Interested Stockholders. The NRS prohibits a publicly-traded Nevada company from engaging in any business combination with an interested stockholder for a period of three years following the date that the stockholder became an interested stockholder unless, prior to that date, the board of directors of the corporation approved either the business combination itself or the transaction that resulted in the stockholder becoming an interested stockholder.

An "interested stockholder" is defined as any entity or person beneficially owning, directly or indirectly, 10% or more of the outstanding voting stock of the corporation and any entity or person affiliated with, controlling, or controlled by any of these entities or persons. The definition of "business combination" is sufficiently broad to cover virtually any type of transaction that would allow a potential acquirer to use the corporation's assets to finance the acquisition or otherwise benefit its own interests rather than the interests of the corporation and its stockholders.

In addition, business combinations that are not approved and therefore take place after the three year waiting period may also be prohibited unless approved by the board of directors and stockholders or the price to be paid by the interested stockholder is equal to the highest of (i) the highest price per share paid by the interested stockholder within the 3 years immediately preceding the date of the announcement of the business combination or in the transaction in which he or she became an interested stockholder, whichever is higher; (ii) the market value per common share on the date of announcement of the business combination or the date the interested stockholder acquired the shares, whichever is higher; or (iii) if higher for the holders of preferred stock, the highest liquidation value of the preferred stock.

Acquisition of a Controlling Interest. The NRS contains provisions governing the acquisition of a "controlling interest" and provides generally that any person that acquires 20% or more of the outstanding voting shares of an "issuing corporation," defined as Nevada corporation that has 200 or more stockholders at least 100 of whom are Nevada residents (as set forth in the corporation's stock ledger); and does business in Nevada directly or through an affiliated corporation, may be denied voting rights with respect to the acquired shares, unless a majority of the disinterested stockholder of the corporation elects to restore such voting rights in whole or in part.

The statute focuses on the acquisition of a "controlling interest" defined as the ownership of outstanding shares sufficient, but for the control share law, to enable the acquiring person, directly or indirectly and individually or in association with others, to exercise (i) one-fifth or more, but less than one-third; (ii) one-third or more, but less than a majority; or (iii) a majority or more of the voting power of the corporation in the election of directors.

The question of whether or not to confer voting rights may only be considered once by the stockholders and once a decision is made, it cannot be revisited. In addition, unless a corporation's articles of incorporation or bylaws provide otherwise (i) acquired voting securities are redeemable in whole or in part by the issuing corporation at the average price paid for the securities within 30 days if the acquiring person has not given a timely information statement to the issuing corporation or if the stockholders vote not to grant voting rights to the acquiring person's securities; and (ii) if voting rights are granted to the acquiring person, then any stockholder who voted against the grant of voting rights may demand purchase from the issuing corporation, at fair value, of all or any portion of their securities.

The provisions of this section do not apply to acquisitions made pursuant to the laws of descent and distribution, the enforcement of a judgment, or the satisfaction of a security interest, or acquisitions made in connection with certain mergers or reorganizations.

SHARES ELIGIBLE FOR FUTURE SALE

Future sales of substantial amounts of our common stock in the public market, including shares issued upon the exercise of outstanding options or warrants, or the anticipation of these sales, could adversely affect market prices prevailing from time to time and could impair our ability to raise capital through sales of equity securities. Except for shares of our common stock held by our affiliates, all of our outstanding shares of common are currently freely trading or eligible for resale without restriction under Rule 144, except for the shares of common stock sold in our August 27, 2020 private placement, , of which shares held by non-affiliates of ours will be eligible for resale without restriction under Rule 144 on February 24, 2021.

Upon completion of this offering we estimate that we will have outstanding shares of our common stock, calculated as of September , 2020, assuming no further exercise of outstanding warrants, and no sale of shares reserved for the underwriter for over-allotment allocation, if any.

Sale of Restricted Securities

The shares of our common stock sold pursuant to this offering will be registered under the Securities Act or 1933, as amended, and therefore freely transferable, except for such shares held by our affiliates. Our affiliates will be deemed to own "control" securities that are not registered for resale under the registration statement covering this prospectus. Individuals who may be considered our affiliates after the offering include individuals who control, are controlled by or are under common control with us, as those terms generally are interpreted for federal securities law purposes. These individuals may include some or all of our directors and executive officers. Individuals who are our affiliates are not permitted to resell their shares of our common stock unless such shares are separately registered under an effective registration statement under the Securities Act of 1933, as amended, or an exemption from the registration requirements of the Securities Act of 1933, as amended, is available, such as Rule 144.

Rule 144

In general, under Rule 144 as currently in effect, a person (or persons whose shares are aggregated), including an affiliate, who beneficially owns "restricted securities" (i.e. securities that are not registered by an effective registration statement) of a "reporting company" may not sell these securities until the person has beneficially owned them for at least six months. Thereafter, affiliates may not sell within any three-month period a number of shares in excess of the greater of: (i) 1% of the then outstanding shares of Common Stock as shown by the most recent report or statement published by the issuer; and (ii) the average weekly reported trading volume in such securities during the four preceding calendar weeks.

Sales under Rule 144 by our affiliates will also be subject to restrictions relating to manner of sale, notice and the availability of current public information about us and may be affected only through unsolicited brokers' transactions.

Persons not deemed to be affiliates who have beneficially owned "restricted securities" for at least six months but for less than one year may sell these securities, provided that current public information about the Company is "available," which means that, on the date of sale, we are current in our Exchange Act filings. After beneficially owning "restricted securities" for one year, our non-affiliates may engage in unlimited re-sales of such securities.

Shares purchased by our affiliates in this offering may be "controlled securities" rather than "restricted securities." "Controlled securities" are subject to the same volume limitations as "restricted securities" but are not subject to holding period requirements.

MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS

The following is a summary of the material U.S. federal income tax considerations relating to the purchase, ownership and disposition of our units, common stock and warrants purchased in this offering, which we refer to collectively as our securities, but is for general information purposes only and does not purport to be a complete analysis of all the potential tax considerations. The holder of a unit generally should be treated, for U.S. federal income tax purposes, as the owner of the underlying one share of common stock and one warrant to purchase one share of common stock that underlie the unit, as the case may be. As a result, the discussion below with respect to actual holders of common stock and warrants should also apply to holders of units (as the deemed owners of the underlying common stock and warrants that comprise the units). This summary is based upon the provisions of the Internal Revenue Code of 1986, as amended (the "Code"), existing and proposed Treasury regulations promulgated thereunder, administrative rulings and judicial decisions, all as of the date hereof. These authorities may be changed, possibly retroactively, so as to result in U.S. federal income and estate tax consequences different from those set forth below. There can be no assurance that the Internal Revenue Service (the "IRS") will not challenge one or more of the tax consequences described herein, and we have not obtained, and do not intend to obtain, an opinion of counsel or ruling from the IRS with respect to the U.S. federal income tax considerations relating to the purchase, ownership or disposition of our securities.

This summary does not address the tax considerations arising under the laws of any U.S. state, local or any non-U.S. jurisdiction, or under U.S. federal non-income tax laws, or the potential application of the Medicare contribution tax on net investment income. In addition, this discussion does not address tax considerations applicable to an investor's particular circumstances or to investors that may be subject to special tax rules, including, without limitation:

- banks, insurance companies, regulated investment companies, real estate investment trusts or other financial institutions;
- persons subject to the alternative minimum tax;
- tax-exempt organizations or governmental organizations;
- controlled foreign corporations, passive foreign investment companies and corporations that accumulate earnings to avoid U.S. federal income tax;
- brokers or dealers in securities or currencies;
- traders in securities that elect to use a mark-to-market method of accounting for their securities holdings;
- partnerships or other entities or arrangements classified as partnerships for U.S. federal income tax purposes or other pass-through entities (and investors therein);
- persons that own, or are deemed to own, more than five percent of our common stock (except to the extent specifically set forth below);
- certain former citizens or long-term residents of the United States;
- persons whose functional currency is not the U.S. dollar;
- persons who hold our common stock or warrants as a position in a hedging transaction, "straddle," "conversion transaction" or other risk reduction transaction or integrated investment;
- persons subject to special tax accounting rules as a result of any item of gross income with respect to our common stock or warrants being taken into account in an applicable financial statement within the meaning of 451(b) of the Code;
- persons who hold or receive our common stock or warrants pursuant to the exercise of any employee stock option or otherwise as compensation;
- persons who hold or receive our common stock or warrants pursuant to conversion rights under convertible instruments;
- persons who do not hold our common stock or warrants as a capital asset within the meaning of Section 1221 of the Code (generally, for investment purposes); or
- persons deemed to sell our common stock or warrants under the constructive sale provisions of the Code.

For the purposes of this discussion, a "U.S. holder" means a beneficial owner of our common stock or warrants that is, for U.S. federal income tax purposes: (a) an individual who is a citizen or resident of the United States, (b) a corporation (or other entity taxable as a corporation for U.S. federal income tax purposes), created or organized in or under the laws of the United States, any state thereof or the District of Columbia, (c) an estate the income of which is subject to U.S. federal income taxation regardless of its source, or (d) a trust if it (1) is subject to the primary supervision of a court within the United States and one or more U.S. persons (within the meaning of Section 7701(a)(30) of the Code) have the authority to control all substantial decisions of the trust or (2) has a valid election in effect under applicable U.S. Treasury regulations to be treated as a U.S. person. A "non-U.S. holder" is, for U.S. federal income tax purposes, a beneficial owner of common stock or warrants that is not a U.S. holder or an entity or arrangement treated as a partnership for U.S. federal income tax purposes.

If a partnership or entity classified as a partnership for U.S. federal income tax purposes holds our common stock or warrants, the tax treatment of a partner generally will depend on the status of the partner and upon the activities of the partnership. Accordingly, partnerships that hold our common stock or warrants, and partners in such partnerships, should consult their tax advisors.

You are urged to consult your tax advisor with respect to the application of the U.S. federal income tax laws to your particular situation, as well as any tax consequences of the purchase, ownership and disposition of our common stock or warrants arising under the U.S. federal estate or gift tax laws or under the laws of any state, local, non-U.S. or other taxing jurisdiction or under any applicable tax treaty. In addition, significant changes in U.S. federal income tax laws were recently enacted. You should consult with your tax advisor with respect to such changes in U.S. tax law as well as potentially conforming changes in state tax laws.

Investment Unit

For U.S. federal income tax purposes, the shares of common stock and warrants acquired in this offering will be treated as an "investment unit" consisting of one share of common stock and a warrant to acquire one share of our common stock. The purchase price for each investment unit will be allocated between these two components in proportion to their relative fair market values at the time the unit is purchased by the holder. This allocation of the purchase price for each unit will establish the holder's initial tax basis for U.S. federal income tax purposes in the share of common stock and the warrant included in each unit. The separation of the common stock and warrant components of each unit should not be a taxable event for U.S. federal income tax purposes. Each holder should consult his, her or its own tax advisor regarding the allocation of the purchase price for a unit.

U.S. Holders

Exercise and Expiration of Warrants

In general, a U.S. holder will not recognize gain or loss for U.S. federal income tax purposes upon exercise of a warrant. The U.S. holder will take a tax basis in the shares acquired on the exercise of a warrant equal to the exercise price of the warrant, increased by the U.S. holder's adjusted tax basis in the warrant exercised (as determined pursuant to the rules discussed above). The U.S. holder's holding period in the shares of our common stock acquired on exercise of the warrant will begin on the date of exercise of the warrant, and will not include any period for which the U.S. holder held the warrant.

In certain limited circumstances, a U.S. holder may be permitted to undertake a cashless exercise of warrants into our common stock. The U.S. federal income tax treatment of a cashless exercise of warrants into our common stock is unclear, and the tax consequences of a cashless exercise could differ from the consequences upon the exercise of a warrant described in the preceding paragraph. U.S. holders should consult their own tax advisors regarding the U.S. federal income tax consequences of a cashless exercise of warrants.

The lapse or expiration of a warrant will be treated as if the U.S. holder sold or exchanged the warrant and recognized a capital loss equal to the U.S. holder's tax basis in the warrant. The deductibility of capital losses is subject to limitations.

Certain Adjustments to and Distributions on Warrants

Under Section 305 of the Code, an adjustment to the number of shares of common stock issued on the exercise of the warrants or an adjustment to the exercise price of the warrants may be treated as a constructive distribution to a U.S. holder of the warrants if, and to the extent that, such adjustment has the effect of increasing such U.S. holder's proportionate interest in our "earnings and profits" or assets, depending on the circumstances of such adjustment (for example, if such adjustment is to compensate for a distribution of cash or other property to our stockholders). An adjustment made pursuant to a bona fide reasonable adjustment formula that has the effect of preventing dilution should generally not be considered to result in a constructive distribution. Any such constructive distribution would be taxable whether or not there is an actual distribution of cash or other property to the holders of warrants. In certain circumstances, if we were to make a distribution in cash or other property with respect to our common stock after the issuance of the warrants, then we may make a corresponding distribution to the holders of the warrants. The taxation of a distribution received with respect to a warrant is unclear. It is possible such a distribution would be treated as a distribution (or constructive distribution), although other treatments are possible. For more information regarding the U.S. federal income tax considerations related to distributions, see the discussion below regarding "-Distributions." U.S. holders should consult their tax advisors regarding the proper treatment of any adjustments to the warrants and any distributions with respect to the warrants.

Distributions

As described in the section captioned "Dividend Policy," we have never paid cash distributions on our common stock and do not anticipate doing so in the foreseeable future. In the event that we do make distributions on our common stock to a U.S. holder, those distributions generally will constitute dividends for U.S. tax purposes to the extent paid out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles). Distributions in excess of our current and accumulated earnings and profits will constitute a return of capital that is applied against and reduces, but not below zero, a U.S. holder's adjusted tax basis in our common stock. Any remaining excess will be treated as gain realized on the sale or exchange of our common stock as described below under the section titled "- Disposition of Our Common Stock or Warrants." Under current law, if certain requirements are met, a preferential U.S. federal income tax rate will apply to any dividends paid to a beneficial owner of our common stock who is an individual U.S. holder and meets certain holding period requirements.

Distributions constituting dividends for U.S. federal income tax purposes that are made to U.S. holders that are corporate stockholders may qualify for the dividends received deduction, or DRD, which is generally available to corporate stockholders. No assurance can be given that we will have sufficient earnings and profits (as determined for U.S. federal income tax purposes) to cause any distributions to be eligible for a DRD. In addition, a DRD is available only if certain holding periods and other taxable income requirements are satisfied.

Disposition of Our Common Stock or Warrants

Upon a sale or other taxable disposition of our common stock or warrants, a U.S. holder generally will recognize capital gain or loss in an amount equal to the difference between the amount realized and the U.S. holder's adjusted tax basis in the common stock or warrants. Capital gain or loss will constitute long-term capital gain or loss if the U.S. holder's holding period for the common stock or warrants exceeds one year. The deductibility of capital losses is subject to certain limitations. U.S. holders who recognize losses with respect to a disposition of our common stock or warrants should consult their own tax advisors regarding the tax treatment of such losses.

Information Reporting and Backup Withholding

Information reporting requirements generally will apply to payments of dividends (including constructive dividends) on the common stock and warrants and to the proceeds of a sale or other disposition of common stock and warrants paid by us to a U.S. holder unless such U.S. holder is an exempt recipient, such as a corporation. Backup withholding will apply to those payments if the U.S. holder fails to provide the holder's taxpayer identification number, or certification of exempt status, or if the holder otherwise fails to comply with applicable requirements to establish an exemption.

Backup withholding is not an additional tax. Rather, any amounts withheld under the backup withholding rules will be allowed as a refund or a credit against the U.S. holder's U.S. federal income tax liability provided the required information is timely furnished to the IRS. U.S. holders should consult their own tax advisors regarding their qualification for exemption from information reporting and backup withholding and the procedure for obtaining such exemption.

Non-U.S. Holders

Exercise and Expiration of Warrants

In general, a non-U.S. holder will not recognize gain or loss for U.S. federal income tax purposes upon the exercise of warrants into shares of our common stock. The U.S. federal income tax treatment of a cashless exercise of warrants into our common stock is unclear. A non-U.S. holder should consult his, her, or its own tax advisor regarding the U.S. federal income tax consequences of a cashless exercise of warrants.

The expiration of a warrant will be treated as if the non-U.S. holder sold or exchanged the warrant and recognized a capital loss equal to the non-U.S. holder's tax basis in the warrant. However, a non-U.S. holder will not be able to utilize a loss recognized upon expiration of a warrant against the non-U.S. holder's U.S. federal income tax liability unless the loss is effectively connected with the non-U.S. holder's conduct of a trade or business within the United States (and, if an income tax treaty applies, is attributable to a permanent establishment or fixed base in the United States) or is treated as a U.S.-source loss and the non-U.S. holder is present 183 days or more in the taxable year of disposition and certain other conditions are met.

Certain Adjustments to and Distributions on Warrants

As described under "-U.S. Holders -Certain Adjustments to and Distributions on Warrants," an adjustment to the warrants could result in a constructive distribution to a non-U.S. holder, which would be treated as described under "-Distributions" below, and the tax treatment of distributions on the warrants is unclear. Any resulting withholding tax attributable to deemed dividends would be collected from other amounts payable or distributable to the non-U.S. holder. Non-U.S. holders should consult their tax advisors regarding the proper treatment of any adjustments to and distributions on the warrants.

Distributions

As described in the section captioned "Dividend Policy," we have never paid cash distributions on our common stock and do not anticipate doing so in the foreseeable future. However, if we do pay cash distributions on our common stock, those payments will constitute dividends for U.S. tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. To the extent those distributions exceed both our current and our accumulated earnings and profits, they will constitute a return of capital and will first reduce your basis in our common stock, but not below zero, and then will be treated as gain from the sale of common stock (see "Disposition of Our Common Stock or Warrants" below).

Subject to the discussion below on effectively connected income, backup withholding and foreign accounts, any distribution (including constructive distributions) that is treated as a dividend paid to a non-U.S. holder generally will be subject to U.S. withholding tax either at a rate of 30% of the gross amount of the dividend or such lower rate as may be specified by an applicable income tax treaty. In order to receive a reduced treaty rate, a non-U.S. holder generally must provide the applicable withholding agent with an IRS Form W-8BEN, IRS Form W-8BEN-E or other appropriate version of IRS Form W-8 certifying the non-U.S. holder's entitlement to benefits under that treaty.

We generally are not required to withhold tax on dividends paid (or constructive dividends deemed paid) to a non-U.S. holder that are effectively connected with the holder's conduct of a U.S. trade or business (and, if required by an applicable income tax treaty, attributable to a permanent establishment or fixed base maintained by the holder in the United States) if a properly executed IRS Form W-8ECI stating that the dividends are so connected, is furnished to us (or, if stock is held through a financial institution or other agent, to the applicable withholding agent). Such effectively connected dividends, although not subject to withholding tax, are taxed at the same graduated rates applicable to U.S. persons, net of certain deductions and credits, subject to an applicable income tax treaty providing otherwise. In addition, a corporate non-U.S. holder receiving effectively connected dividends may also be subject to a branch profits tax at a rate of 30% or such lower rate as may be specified by an applicable income tax treaty. You should consult your tax advisor regarding any applicable tax treaties that may provide for different rules.

If a non-U.S. holder holds stock through a financial institution or other agent acting on the holder's behalf, the holder will be required to provide appropriate documentation to such agent. The holder's agent may then be required to provide certification to the applicable withholding agent, either directly or through other intermediaries. If you are eligible for a reduced rate of U.S. withholding tax under an income tax treaty, you should consult with your own tax advisor to determine if you are able to obtain a refund or credit of any excess amounts withheld by timely filing an appropriate claim for a refund with the IRS.

Disposition of Our Common Stock or Warrants

In general, subject to the discussion below under "Backup Withholding and Information Reporting," a non-U.S. holder generally will not be subject to U.S. federal income tax or withholding tax on any gain realized upon the sale or other disposition of our common stock or warrants unless:

- the gain is effectively connected with the non-U.S. holder's conduct of a U.S. trade or business (and, if required by an applicable income tax treaty, the gain is attributable to a permanent establishment or fixed base maintained by the non-U.S. holder in the United States);

- the non-U.S. holder is a non-resident alien individual who is present in the United States for a period or periods aggregating 183 days or more during the calendar year in which the sale or disposition occurs and certain other conditions are met; or

- our common stock constitutes a United States real property interest by reason of our status as a "United States real property holding corporation," or USRPHC, for U.S. federal income tax purposes at any time within the shorter of the five-year period preceding the non-U.S. holder's disposition of, or their holding period for, our common stock.

We believe that we are not currently and will not become a USRPHC. However, because the determination of whether we are a USRPHC depends on the fair market value of our U.S. real property relative to the fair market value of our other business assets, there can be no assurance that we will not become a USRPHC in the future. Even if we become a USRPHC, however, as long as our common stock is regularly traded on an established securities market, your common stock will be treated as U.S. real property interests only if you actually or constructively hold more than five percent of such regularly traded common stock at any time during the shorter of the five-year period preceding your disposition of, or your holding period for, our common stock.

A non-U.S. holder described in the first bullet above will be required to pay tax on the net gain derived from the sale under regular graduated U.S. federal income tax rates and in the manner applicable to U.S. persons, and a corporate non-U.S. holder described in the first bullet above also may be subject to the branch profits tax at a 30% rate, or such lower rate as may be specified by an applicable income tax treaty. A non-U.S. holder described in the second bullet above will be subject to tax at 30% (or such lower rate specified by an applicable income tax treaty) on the gain derived from the sale, which gain may be offset by U.S. source capital losses for the year (provided such holder has timely filed U.S. federal income tax returns with respect to such losses). You should consult any applicable income tax or other treaties that may provide for different rules.

Backup Withholding and Information Reporting

Generally, we must report annually to the IRS the amount of distributions (including constructive distributions) on our common stock or warrants paid to each non-U.S. holder, their name and address, and the amount of tax withheld, if any. A similar report will be sent to the applicable non-U.S. holder. Pursuant to applicable income tax treaties or other agreements, the IRS may make these reports available to tax authorities in the non-U.S. holder's country of residence.

Payments of dividends (including constructive dividends) or of proceeds on the disposition of our common stock or warrants made to a non-U.S. holder may be subject to information reporting and backup withholding at a current rate of 24% unless the non-U.S. holder establishes an exemption, for example, by properly certifying their non-U.S. status on an IRS Form W-8BEN, IRS Form W-8BEN-E or another appropriate version of IRS Form W-8. Notwithstanding the foregoing, backup withholding and information reporting may apply if either we or our paying agent has actual knowledge, or reason to know, that a holder is a U.S. person.

Under current U.S. federal income tax law, U.S. information reporting and backup withholding requirements generally will apply to the proceeds of a disposition of our common stock or warrants effected by or through a U.S. office of any broker, U.S. or foreign, except that information reporting and such requirements may be avoided if the holder provides a properly executed and appropriate IRS Form W-8 or otherwise meets documentary evidence requirements for establishing non- U.S. holder status or otherwise establishes an exemption. Generally, U.S. information reporting and backup withholding requirements will not apply to a payment of disposition proceeds to a non-U.S. holder where the transaction is effected outside the U.S. through a non-U.S. office of a non-U.S. broker. Information reporting and backup withholding requirements may, however, apply to a payment of disposition proceeds if the broker has actual knowledge, or reason to know, that the holder is, in fact, a U.S. person. For information reporting purposes, certain brokers with substantial U.S. ownership or operations will generally be treated in a manner similar to U.S. brokers.

Backup withholding is not an additional tax; rather, the U.S. federal income tax liability of persons subject to backup withholding will be reduced by the amount of tax withheld. If withholding results in an overpayment of taxes, you may be able to obtain a refund or credit from the IRS, provided that the required information is furnished to the IRS in a timely manner.

Foreign Account Tax Compliance Act

The Foreign Account Tax Compliance Act and the rules and regulations promulgated thereunder, collectively FATCA, generally impose withholding tax at a rate of 30% on dividends (including constructive dividends) on, and gross proceeds from the sale or other disposition of, our common stock or warrants if paid to a "foreign financial institution" (as specially defined under these rules), unless such institution enters into an agreement with the U.S. government to, among other things, withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding the U.S. account holders of such institution (which includes certain equity and debt holders of such institution, as well as certain account holders that are foreign entities with U.S. owners) or otherwise establishes an exemption. FATCA also generally imposes a U.S. federal withholding tax of 30% on dividends (including constructive dividends) on and gross proceeds from the sale or other disposition of our common stock or warrants if paid to a "non-financial foreign entity" (as specially defined under these rules) unless such entity provides the withholding agent with a certification identifying certain substantial direct and indirect U.S. owners of the entity, certifies that there are none or otherwise establishes an exemption. The withholding provisions under FATCA generally apply to dividends (including constructive dividends) on our common stock and warrants. The Treasury Secretary has issued proposed regulations providing that the withholding provisions under FATCA do not apply with respect to payment of gross proceeds from a sale or other disposition of our common stock or warrants, which may be relied upon by taxpayers until final regulations are issued. Under certain circumstances, a non-U.S. holder might be eligible for refunds or credits of such taxes. An intergovernmental agreement between the United States and an applicable foreign country may modify the requirements described in this paragraph. You should consult your tax advisors regarding the possible implications of FACTA on your investment in our common stock and warrants.

The preceding discussion of U.S. federal tax considerations is for general information only. It is not tax advice. Each prospective investor should consult its tax advisor regarding the particular U.S. federal, state and local and non-U.S. tax consequences of purchasing, holding and disposing of our common stock and warrants, including the consequences of any proposed change in applicable laws.

UNDERWRITING

We have entered into an underwriting agreement with Maxim Group LLC as the sole representative of the underwriters ("Maxim" or the "Representative"), with respect to the shares and warrants being offered. Maxim is the sole book running manager for the offering. Subject to the terms and conditions of an underwriting agreement between us and the Representative, we have agreed to sell to each underwriter named below, and each underwriter named below has severally agreed to purchase, at the public offering price less the underwriting discounts set forth on the cover page of this prospectus, the number of shares of common stock and warrants listed next to its name in the following table:

Name of Underwriter	Number of Shares	Number of Warrants
Maxim Group LLC		
[_____]xxx		
Total		

The underwriters are committed to purchase all the shares of common stock and warrants offered by this prospectus if they purchase any shares of common stock and warrants. The underwriting agreement also provides that if an underwriter defaults, the purchase commitments of non-defaulting underwriters may be increased or the offering may be terminated. The underwriters are not obligated to purchase the shares of common stock and/or warrants covered by the underwriters' over-allotment option described below. The underwriters are offering the shares of common stock and warrants, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel, and other conditions contained in the underwriting agreement, such as the receipt by the underwriters of officer's certificates and legal opinions. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

Over-Allotment Option

We have granted to the underwriters an option, exercisable no later than 45 calendar days after the date of the underwriting agreement, to purchase up to shares of common stock and/or warrants at the public offering price listed on the cover page of this prospectus, less underwriting discounts and commissions. The underwriters may exercise this option only to cover over-allotments, if any, made in connection with this offering. To the extent the option is exercised and the conditions of the underwriting agreement are satisfied, we will be obligated to sell to the underwriters, and the underwriters will be obligated to purchase, these additional shares of common stock and/or warrants.

Representative's Warrants

We have agreed to grant to Maxim Group LLC, warrants to purchase a number of shares equal to five percent (5%) of the total number of shares of common stock sold in this offering, at an exercise price equal to 110% of the price per unit sold in this offering. The warrants (the "Underwriter's Warrants") will contain a cashless exercise feature. Each Underwriter's Warrant is exercisable for one share of common stock on a cash or cashless basis at an exercise price of 110% of the price of each unit sold in the offering. The Underwriter's Warrants will be subject to a lock-up for 180 days from the commencement of sales of this offering in accordance with FINRA Rule 5110(e) and will be non-exercisable for six (6) months after the effective date (the "Effective Date") of the registration statement of which this Prospectus forms a part of this offering, and will expire five (5) years from the commencement of sales of this offering. The Underwriter's Warrants will contain provisions for one demand registration of the shares underlying the Underwriter's Warrants at the Company's expense and one registration of the Underwriter's Warrants at the Representative's expense for a period of five (5) years from the commencement of sales of this offering, and unlimited piggyback registration rights for a period of five (5) years from the commencement of sales of this offering at the Company's expense.

The number of Underwriter's Warrants outstanding, and the exercise price of those securities, will be adjusted proportionately, as permitted by FINRA Rule 5110(g)(8)(E).

Discounts and Commissions; Expenses

The following table shows the public offering price, underwriting discount and proceeds, before expenses, to us. The information assumes either no exercise or full exercise by the Representative of the over-allotment option.

	Per Share(1)	Total Without Over-Allotment Option	Total With Full Over-Allotment Option
Public offering price	$	$	$
Underwriting discount (8%)	$	$	$
Proceeds, before expenses, to us	$	$	$

(1) The fees shown do not include the warrant to purchase shares of common stock issuable to the underwriters at closing.

The underwriters propose to offer the shares offered by us to the public at the public offering price per share set forth on the cover of this prospectus. In addition, the underwriters may offer some of the shares to other securities dealers at such price less a concession of $ per shares. After the initial offering, the public offering price and concession to dealers may be changed.

We have paid an expense deposit of $25,000 to the Representative, which will be applied against the accountable expenses that will be paid by us to the Representative in connection with this offering.

We have also agreed to reimburse the Representative for reasonable out-of-pocket expenses not to exceed $125,000. We estimate that total expenses payable by us in connection with this offering, other than the underwriting discount, will be approximately $.

Lock-Up Agreements

We and each of our officers, directors, affiliates and certain existing stockholders aggregating at least 10.0% of our outstanding shares have agreed, subject to certain exceptions, not to offer, issue, sell, contract to sell, encumber, grant any option for the sale of or otherwise dispose of any shares of our common stock or other securities convertible into or exercisable or exchangeable for shares of our common stock for a period of six (6) months after this offering is completed without the prior written consent of Maxim.

Maxim may in its sole discretion and at any time without notice release some or all of the shares subject to lock-up agreements prior to the expiration of the lock-up period. When determining whether or not to release shares from the lock-up agreements, the Representative will consider, among other factors, the security holder's reasons for requesting the release, the number of shares for which the release is being requested and market conditions at the time.

Right of First Refusal

We have granted Maxim a right of first refusal, for a period of thirteen (13) months from the commencement of sales of this offering, to act as sole and exclusive investment banker, book-runner, financial advisor, underwriter and/or placement agent, at the Maxim's sole and exclusive discretion, for each and every future public and private equity and debt offering, including all equity linked financings (each, a "Subject Transaction"), during such thirteen (13) month period, of the Company, or any successor to or subsidiary of the Company, on terms and conditions customary to the Maxim for such Subject Transactions.

Indemnification

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, and to contribute to payments that the underwriters may be required to make for these liabilities.

OTCQB and Nasdaq Capital Market

Our common stock is presently quoted on the OTCQB marketplace under the symbol "CTDH". We have applied to have our common stock and warrants listed on The Nasdaq Capital Market under the symbols "CYTH" and "CYTHW" respectively. No assurance can be given that our application will be approved. Trading Quotes of securities on an over-the-counter marketplace may not be indicative of the market price of those securities on a national securities exchange. There is no established public trading market for the warrants. No assurance can be given that a trading market will develop for the warrants.

Price Stabilization, Short Positions, and Penalty Bids

In connection with this offering, the underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of our common stock. Specifically, the underwriters may over-allot in connection with this offering by selling more shares and warrants than are set forth on the cover page of this prospectus. This creates a short position in our common stock for its own account. The short position may be either a covered short position or a naked short position. In a covered short position, the number of shares common stock or warrants over-allotted by the underwriters is not greater than the number of shares of common stock or warrants that they may purchase in the over-allotment option. In a naked short position, the number of shares of common stock or warrants involved is greater than the number of shares common stock or warrants in the over-allotment option. To close out a short position, the underwriters may elect to exercise all or part of the over-allotment option. The underwriters may also elect to stabilize the price of our common stock or reduce any short position by bidding for, and purchasing, common stock in the open market. Since the warrants will not be listed and are not expected to trade, the underwriters cannot purchase the warrants in the open market and, as a result, the underwriters cannot and will not enter into naked short positions.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter or dealer repays selling concessions allowed to it for distributing a security in this offering because the underwriter repurchases that security in stabilizing or short covering transactions.

Finally, the underwriters may bid for, and purchase, shares of our common stock in market making transactions, including "passive" market making transactions as described below.

These activities may stabilize or maintain the market price of our common stock at a price that is higher than the price that might otherwise exist in the absence of these activities. The underwriters are not required to engage in these activities, and may discontinue any of these activities at any time without notice. These transactions may be effected on Nasdaq, in the over-the-counter market, or otherwise.

In connection with this offering, the underwriters and selling group members, if any, or their affiliates may engage in passive market making transactions in our common stock immediately prior to the commencement of sales in this offering, in accordance with Rule 103 of Regulation M under the Exchange Act. Rule 103 generally provides that:

- a passive market maker may not effect transactions or display bids for our common stock in excess of the highest independent bid price by persons who are not passive market makers;
- net purchases by a passive market maker on each day are generally limited to 30% of the passive market maker's average daily trading volume in our common stock during a specified two-month prior period or 200 shares, whichever is greater, and must be discontinued when that limit is reached; and
- passive market making bids must be identified as such.

Electronic Distribution

A prospectus in electronic format may be made available on a website maintained by the representatives of the underwriters and may also be made available on a website maintained by other underwriters. The underwriters may agree to allocate a number of shares to underwriters for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives of the underwriters to underwriters that may make Internet distributions on the same basis as other allocations. In connection with the offering, the underwriters or syndicate members may distribute prospectuses electronically. No forms of electronic prospectus other than prospectuses that are printable as Adobe® PDF will be used in connection with this offering.

The underwriters have informed us that they do not expect to confirm sales of shares and warrants offered by this prospectus to accounts over which they exercise discretionary authority.

Other than the prospectus in electronic format, the information on any underwriter's website and any information contained in any other website maintained by an underwriter is not part of the prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or any underwriter in its capacity as underwriter and should not be relied upon by investors.

Certain Relationships

Certain of the underwriters and their affiliates may provide, from time to time, investment banking and financial advisory services to us in the ordinary course of business, for which they may receive customary fees and commissions.

Notice to Prospective Investors in Canada

This prospectus constitutes an "exempt offering document" as defined in and for the purposes of applicable Canadian securities laws. No prospectus has been filed with any securities commission or similar regulatory authority in Canada in connection with the offer and sale of the shares. No securities commission or similar regulatory authority in Canada has reviewed or in any way passed upon this prospectus or on the merits of the shares and any representation to the contrary is an offence.

Canadian investors are advised that this prospectus has been prepared in reliance on section 3A.3 of National Instrument 33-105 Underwriting Conflicts ("NI 33-105"). Pursuant to section 3A.3 of NI 33-105, this prospectus is exempt from the requirement that the Company and the underwriter(s) provide Canadian investors with certain conflicts of interest disclosure pertaining to "connected issuer" and/or "related issuer" relationships that may exist between the Company and the underwriter(s) as would otherwise be required pursuant to subsection 2.1(1) of NI 33-105.

Resale Restrictions

The offer and sale of the shares in Canada is being made on a private placement basis only and is exempt from the requirement that the Company prepares and files a prospectus under applicable Canadian securities laws. Any resale of shares acquired by a Canadian investor in this offering must be made in accordance with applicable Canadian securities laws, which may vary depending on the relevant jurisdiction, and which may require resales to be made in accordance with Canadian prospectus requirements, pursuant to a statutory exemption from the prospectus requirements, in a transaction exempt from the prospectus requirements or otherwise under a discretionary exemption from the prospectus requirements granted by the applicable local Canadian securities regulatory authority. These resale restrictions may under certain circumstances apply to resales of the shares outside of Canada.

Representations of Purchasers

Each Canadian investor who purchases shares will be deemed to have represented to the Company, the underwriters and to each dealer from whom a purchase confirmation is received, as applicable, that the investor is (i) purchasing as principal, or is deemed to be purchasing as principal in accordance with applicable Canadian securities laws, for investment only and not with a view to resale or redistribution; (ii) an "accredited investor" as such term is defined in section 1.1 of National Instrument 45-106 *Prospectus Exemptions* or, in Ontario, as such term is defined in section 73.3(1) of the *Securities Act* (Ontario); and (iii) is a "permitted client" as such term is defined in section 1.1 of National Instrument 31-103 *Registration Requirements, Exemptions and Ongoing Registrant Obligations*.

Taxation and Eligibility for Investment

Any discussion of taxation and related matters contained in this prospectus does not purport to be a comprehensive description of all of the tax considerations that may be relevant to a Canadian investor when deciding to purchase the shares and, in particular, does not address any Canadian tax considerations. No representation or warranty is hereby made as to the tax consequences to a resident, or deemed resident, of Canada of an investment in the shares or with respect to the eligibility of the shares for investment by such investor under relevant Canadian federal and provincial legislation and regulations.

Rights of Action for Damages or Rescission

Securities legislation in certain of the Canadian jurisdictions provides certain purchasers of securities pursuant to an offering memorandum (such as this prospectus), including where the distribution involves an "eligible foreign security" as such term is defined in Ontario Securities Commission Rule 45-501 *Ontario Prospectus and Registration Exemptions* and in Multilateral Instrument 45-107 *Listing Representation and Statutory Rights of Action Disclosure Exemptions*, as applicable, with a remedy for damages or rescission, or both, in addition to any other rights they may have at law, where the offering memorandum, or other offering document that constitutes an offering memorandum, and any amendment thereto, contains a "misrepresentation" as defined under applicable Canadian securities laws. These remedies, or notice with respect to these remedies, must be exercised or delivered, as the case may be, by the purchaser within the time limits prescribed under, and are subject to limitations and defenses under, applicable Canadian securities legislation. In addition, these remedies are in addition to and without derogation from any other right or remedy available at law to the investor.

Language of Documents

Upon receipt of this document, each Canadian investor hereby confirms that it has expressly requested that all documents evidencing or relating in any way to the sale of the securities described herein (including for greater certainty any purchase confirmation or any notice) be drawn up in the English language only. *Par la réception de ce document, chaque investisseur canadien confirme par les présentes qu'il a expressément exigé que tous les documents faisant foi ou se rapportant de quelque manière que ce soit à la vente des valeurs mobilières décrites aux présentes (incluant, pour plus de certitude, toute confirmation d'achat ou tout avis) soient rédigés en anglais seulement.*

Transfer Agent and Registrar

The transfer agent and registrar for our common stock and warrant agent is vStock Transfer LLC, at 18 Lafayette Place, Woodmere, NY 11598. The transfer agent's telephone number is (212) 828-8436.

LEGAL MATTERS

Selected legal matters with respect to the validity of the securities offered by this prospectus will be passed upon for us by Fox Rothschild LLP, 101 Park Avenue, New York, NY 10178.

EXPERTS

The audited consolidated balance sheets at December 31, 2019 and 2018 and the audited consolidated statements of operations, stockholders' equity and cash flows for the years ended December 31, 2019 and 2018 have been audited by WithumSmith+Brown, PC, our independent registered public accounting firm. We have included these financial statements in this registration statement in reliance upon the reports of such firm given their authority as experts in accounting and auditing.

ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the SEC. You should rely only on the information provided in this prospectus. We have not authorized anyone to provide you with information different from that contained in this prospectus. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of Common Stock. Applicable SEC rules may require us to update this prospectus in the future.

WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and current reports, proxy statements and other information with the SEC. You may read and copy any report, statement or other information that we file with the SEC at the SEC Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. You may obtain further information on the operation of the Public Reference room by calling the SEC at 1-800-SEC-0330. Our SEC filings are also available to the public at the SEC's website at www.sec.gov, as well as our website at www.ctd-holdings.com. Information contained on our website does not constitute a part of this prospectus.

This prospectus is part of a registration statement that we filed with the SEC. This prospectus and any accompanying prospectus supplement do not contain all of the information included in the registration statement, and certain statements contained in this prospectus and any accompanying prospectus supplement about the provisions or contents of any contract, agreement or any other document referred to herein are not necessarily complete. For each of these contracts, agreements or documents filed as an exhibit to the registration statement, we refer you to the actual exhibit for a more complete description of the matters involved. In addition, we have omitted certain parts of the registration statement in accordance with the rules and regulations of the SEC. To obtain all of the information that we filed with the SEC in connection herewith, we refer you to the registration statement, including its exhibits and schedules. You should assume that the information contained in this prospectus and any accompanying prospectus supplement is accurate only as of the date appearing on the front of the prospectus or prospectus supplement, as applicable.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

CYCLO THERAPEUTICS, INC. AND SUBSIDIARIES
CONSOLIDATED FINANCIAL STATEMENTS

Table of Contents

CYCLO THERAPEUTICS, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	June 30, 2020 (Unaudited)	December 31, 2019
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 1,008,355	$ 2,783,719
Accounts receivable	161,233	143,429
Inventory, net	216,609	242,630
Current portion of mortgage note receivable	39,061	39,061
Prepaid insurance and services	71,151	137,069
Prepaid clinical expenses	591,676	612,161
Total current assets	2,088,085	3,958,069
FURNITURE AND EQUIPMENT, NET	60,437	13,546
RIGHT-TO-USE LEASE ASSET, NET	42,515	51,017
MORTGAGE NOTE RECEIVABLE, LESS CURRENT PORTION	71,264	90,596
TOTAL ASSETS	$ 2,262,301	$ 4,113,228
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES		
Current portion of lease liability	$ 16,968	$ 16,385
Current portion of long-term debt	60,879	-
Accounts payable and accrued expenses	3,979,395	3,124,735
Total current liabilities	4,057,242	3,141,120
LONG-TERM LIABILITIES		
Long-term lease liability, less current portion	27,453	36,126
Long-term debt, less current portion	97,645	-
Total long-term liabilities	125,098	36,126
STOCKHOLDERS' EQUITY (DEFICIT)		
Common stock, par value $.0001 per share, 500,000,000 shares authorized, 141,671,462 and 121,564,990 shares issued and outstanding, at June 30, 2020 and December 31, 2019	14,155	12,155
Preferred stock, par value $.0001 per share, 5,000,000 shares authorized	-	-
Additional paid-in capital	28,012,423	26,044,060
Accumulated deficit	(29,946,617)	(25,120,233)
Total stockholders' equity (deficit)	(1,920,039)	935,982
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)	$ 2,262,301	$ 4,113,228

See accompanying Notes to Consolidated Financial Statements

CYCLO THERAPEUTICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	**2019**	**2020**	**2019**
REVENUES				
Product sales	$ 209,594	$ 273,095	$ 535,328	$ 493,921
EXPENSES				
Personnel	433,628	311,077	903,333	721,076
Cost of products sold (exclusive of direct and indirect overhead and handling costs)	12,947	16,309	39,380	36,859
Research and development	1,713,435	786,811	3,773,041	2,129,574
Repairs and maintenance	1,311	1,299	3,113	2,983
Professional fees	143,427	246,276	362,963	461,251
Office and other	79,823	247,495	258,185	350,137
Board of Director fees and costs	21,367	31,611	28,716	64,696
Depreciation	3,118	1,485	6,236	2,969
Freight and shipping	1,169	1,016	3,032	2,450
Bad debt expense	1,272	-	1,272	-
Total operating expenses	2,411,497	1,643,379	5,379,271	3,771,995
LOSS FROM OPERATIONS	(2,201,903)	(1,370,284)	(4,843,943)	(3,278,074)
OTHER INCOME				
Investment and other income	9,511	2,273	17,559	5,897
LOSS BEFORE INCOME TAXES	(2,192,392)	(1,368,011)	(4,826,384)	(3,272,177)
PROVISION FOR INCOME TAXES	-	-	-	-
NET LOSS	$ (2,192,392)	$ (1,368,011)	$ (4,826,384)	$ (3,272,177)
BASIC AND DILUTED NET LOSS PER COMMON SHARE	$ (.02)	$ (.01)	$ (.04)	$ (.03)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING	136,676,101	101,013,435	129,120,546	95,886,380

See Accompanying Notes to Consolidated Financial Statements.

CYCLO THERAPEUTICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2020
(Unaudited)

	Common Stock		Additional		Total Stockholders'
	Shares	Par Value	Paid-In Capital	Accumulated Deficit	Equity (Deficit)
Balance, December 31, 2019	121,564,990	$ 12,155	$ 26,044,060	$ (25,120,233)	$ 935,982
Net loss	-	-	-	(2,633,992)	(2,633,992)
Balance, March 31, 2020	121,564,990	12,155	26,044,060	(27,754,225)	(1,698,010)
Sale of common stock, net of issuance fees	20,000,000	2,000	1,968,363	-	1,970,363
Net loss	-	-	-	(2,192,392)	(2,192,392)
Balance, June 30, 2020	141,564,990	$ 14,155	$ 28,012,423	$ (29,946,617)	$ (1,920,039)

See accompanying Notes to Consolidated Financial Statements.

CYCLO THERAPEUTICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2019
(Unaudited)

	Common Stock		Additional Paid-In Capital	Subscription Receivable	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par Value				
Balance, December 31, 2018	90,759,324	$ 9,075	$ 18,701,211	$ (130,062)	$ (17,587,700)	$ 992,524
Collection of subscription receivable	-	-	-	130,062	-	130,062
Net loss	-	-	-	-	(1,904,166)	(1,904,166)
Balance, March 31, 2019	90,759,324	9,075	18,701,211	-	(19,491,866)	(781,580)
Sale of common stock, net of issuance fees	29,770,000	2,977	6,986,623	-	-	6,989,600
Net loss	-	-	-	-	(1,368,011)	(1,368,011)
Balance, June 30, 2019	120,529,324	$ 12,052	$ 25,687,834	$ -	$ (20,859,877)	$ 4,840,009

See accompanying Notes to Consolidated Financial Statements.

CYCLO THERAPEUTICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)

	Six Months Ended June 30,	
	2020	**2019**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (4,826,384)	$ (3,272,177)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	6,236	2,969
Accrued stock compensation to employees	4,810	13,100
Accrued stock compensation to non-employees	9,250	54,830
Increase or decrease in:		
Accounts receivable	(17,804)	(74,066)
Inventory	26,021	18,947
Prepaid clinical expenses	20,485	(178,200)
Prepaid insurance and services	65,918	(10,304)
Other	412	864
Accounts payable and accrued expenses	840,600	697,370
Total adjustments	955,928	525,510
NET CASH USED IN OPERATING ACTIVITIES	(3,870,456)	(2,746,667)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of furniture and equipment	(53,127)	(1,324)
Proceeds from mortgage note receivable	19,332	18,530
NET CASH PROVIDED BY (USED IN) INVESTING ACTIVITIES	(33,795)	17,206
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from PPP loan	158,524	-
Collection of stock subscription receivable	-	130,062
Net proceeds from sale of common and preferred stock and warrants, net of issue costs	1,970,363	6,989,600
NET CASH PROVIDED BY FINANCING ACTIVITIES	2,128,887	7,119,662
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(1,775,364)	4,390,201
CASH AND CASH EQUIVALENTS, beginning of period	2,783,719	2,217,412
CASH AND CASH EQUIVALENTS, end of period	$ 1,008,355	$ 6,607,613
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION		
Cash paid for interest	$ -	$ -
Cash paid for income taxes	$ -	$ -
NON-CASH INVESTING AND FINANCING ACTIVITIES		
Capitalization of right-to-use asset and lease liability	$ -	$ 60,383

See accompanying Notes to Consolidated Financial Statements.

The information presented herein as of June 30, 2020 and for the six months ended June 30, 2020 and 2019 is unaudited.

(1) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:

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

(a) ORGANIZATION AND OPERATIONS— The Company was incorporated in August 1990 as a Florida corporation, under the name Cyclodextrin Technologies Development, Inc. with operations beginning in July 1992. In conjunction with a restructuring in 2000, we changed our name to CTD Holdings, Inc. We changed our name to Cyclo Therapeutics, Inc. in September 2019 to better reflect our current business. We are a clinical stage biotechnology company that develops cyclodextrin-based products for the treatment of disease. We have filed a Type II Drug Master File with the U.S. Food and Drug Administration ("FDA") for our lead drug candidate, Trappsol® Cyclo™ as a treatment for Niemann-Pick Type C disease ("NPC"), a rare and fatal cholesterol metabolism disease that impacts the brain, lungs, liver, spleen, and other organs. The FDA approved our Investigational New Drug application (IND) which describes our Phase I clinical plans in the U.S. for Trappsol® Cyclo™ and in January 2017 the FDA granted Fast Track designation to Trappsol® Cyclo™ for the treatment of NPC. Initial patient enrollment in the U.S. Phase I study commenced in September 2017. Enrollment in this study was completed in October 2019, and in May 2020 the Company announced Top Line data showing a favorable safety and tolerability profile for Trappsol® Cyclo™ in this study.

We also filed Clinical Trial Applications with several European regulatory bodies, including those in the United Kingdom, Sweden and Italy, and in Israel, all of which have approved our applications. The first patient was dosed in this study in July 2017, and in February 2020, the Company announced completion of enrollment of 12 patients in this study. In May of 2020 the Company announced interim results of this study showing a favorable safety and tolerability profile for Trappsol® Cyclo™ as well as encouraging signals in efficacy for all dose groups (1500 mg/kg, 2000 mg/kg and 2500 mg/kg) evaluated in this study. Additionally, in February 2020 the Company had a face-to-face "Type C" meeting with the FDA with respect to the initiation of a Phase III clinical trial of Trappsol® Cyclo™ based on the clinical data obtained to date.

In addition, we are exploring the use of cyclodextrins in the treatment of Alzheimer's disease, and in October 2019 entered into an agreement with a Contract Research Organization to conduct a clinical trial to evaluate the safety and efficacy of Trappsol® Cyclo™ for the treatment of this disease.

We also sell cyclodextrins and related products to the pharmaceutical, nutritional, and other industries, primarily for use in diagnostics and specialty drugs. However, our core business has transitioned to a biotechnology company primarily focused on the development of cyclodextrin-based biopharmaceuticals for the treatment of disease from a business 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. The interim consolidated financial statements of the Company included in this Quarterly Report on Form 10-Q, including these notes, are unaudited. In the opinion of management, all adjustments necessary for a fair presentation of the consolidated financial statements have been included. Such adjustments are of a normal, recurring nature. The consolidated financial statements, and these notes, have been prepared in accordance with GAAP and do not contain certain information included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2019. The consolidated financial statements should be read in conjunction with that Annual Report on Form 10-K. Results for the interim periods presented are not necessarily indicative of the results that might be expected for the entire fiscal year.

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

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

The carrying amount of accounts receivable are reduced by an allowance for credit losses that reflects management's best estimate of the amounts that will not be collected. The Company reviews each customer balance where all or a portion of the balance exceeds 90 days from the invoice date. Based on the Company's assessment of the customer's current creditworthiness, the Company estimates the portion, if any, of the balance that will not be collected, and writes off receivables as a charge to the allowance for credit losses when, in management's estimation, it is probable that the receivable is worthless. Based on management's assessment of the credit history with customers having outstanding balances and current relationships with them, an allowance for doubtful accounts was not deemed necessary at June 30, 2020 and December 31, 2019.

(e) INVENTORY AND COST OF PRODUCTS SOLD—Inventory consists of our pharmaceutical drug Trappsol® Cyclo™, cyclodextrin products and chemical complexes purchased for resale recorded at the lower of cost (first-in, first-out) or net realizable value. Cost of products sold includes the acquisition cost of the products sold and does not include any allocation of outbound freight charges, indirect overhead expenses, warehouse and distribution expenses, or depreciation and amortization expense. The Company records a specific reserve for inventory items that are determined to be obsolete. The reserve for obsolete inventory was $52,922 at June 30, 2020 and December 31, 2019, respectively. The Company's reserve for obsolete inventory is based on the Company's best estimates of product sales and customer demands. It is reasonably possible that the estimates used by the Company to determine its provisions for inventory write-downs will be materially different from actual write-downs. These differences could result in materially higher than expected inventory provisions and related costs, which could have a materially adverse effect on the Company's results of operations and financial condition in the near term.

(f) PREPAID CLINICAL EXPENSES—Prepaid clinical expenses consist of our pharmaceutical drug Trappsol® Cyclo™ expected to be used in our clinical trial program recorded at cost.

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

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

(i) REVENUE RECOGNITION—Under the revenue standards of ASC 606, revenues are recognized when our customer obtains control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. We recognize revenues following the five step model prescribed under ASU No. 2014-09: (i) identify contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenues when (or as) we satisfy the performance obligation.

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

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

Reserves for Discounts and Allowances

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

Product revenue reserves, which are classified as a reduction in product revenues, are generally characterized in the following categories: discounts, contractual adjustments and returns. These reserves are based on estimates of the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable (if the amount is payable to our customer) or a liability (if the amount is payable to a party other than our customer). Our estimates of reserves established for variable consideration typically utilize the most likely method and reflect our historical experience, current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns. The transaction price, which includes variable consideration reflecting the impact of discounts and allowances, may be subject to constraint and is included in the net sales price only to the extent that it is probable that a significant reversal of the amount of the cumulative revenues recognized will not occur in a future period. Actual amounts may ultimately differ from our estimates. If actual results vary, we adjust these estimates, which could have an effect on earnings in the period of adjustment. For additional information on our revenues, please read Note 2, Revenues, to these consolidated financial statements.

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

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

(l) RESEARCH AND DEVELOPMENT COSTS—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 65,311,724 common shares were antidilutive for the three and six months ended June 30, 2020 and 2019.

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

(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 June 30, 2020 or December 31, 2019. Long-lived assets are measured at fair value on a non-recurring basis and are subject to fair value adjustments when there is evidence of impairment.

For short-term classes of our financial instruments, which include cash, accounts receivable and accounts payable, and which are not reported at fair value, the carrying amounts approximate fair value due to their short-term nature. The fair value of the mortgage note receivable is estimated based on the present value of the underlying cash flows discounted at current rates. At June 30, 2020 and December 31, 2019, the carrying value of the mortgage note receivable approximates fair value.

(q) LIQUIDITY AND GOING CONCERN—For the six months ended June 30, 2020 and the year ended December 31, 2019, the Company incurred net losses of $4,826,000 and $7,533,000, respectively. The Company has an accumulated deficit of approximately $29,946,000 at June 30, 2020. Our recent losses have predominantly resulted from research and development expenses for our Trappsol® Cyclo™ product and other general operating expenses, including personnel expenses and board advisory fees. We believe our expenses will continue to increase as we conduct clinical trials and continue to seek regulatory approval for the use of Trappsol® Cyclo™ in the treatment of NPC.

For the six months ended June 30, 2020, our operations used approximately $3,870,000 in cash. This cash was provided primarily by cash on hand and a private placement of our securities. At June 30, 2020, the Company had a cash balance of approximately $1,008,000 and current liabilities exceeded current assets by $1,969,000. We will need additional capital to maintain our operations, continue our research and development programs, conduct clinical trials, seek regulatory approvals and manufacture and market our products.

The Company has incurred losses from operations in each of the last six years. We will need to raise additional capital through the sale of our securities from time to time for the foreseeable future to fund the development of our drug product candidates through clinical development, manufacturing and commercialization. Our ability to obtain such additional capital will likely be subject to various factors, including our overall business performance and market conditions. If we cannot raise the additional funds required for our anticipated operations, we may be required to reduce the scope of or eliminate our research and development programs, delay our clinical trials and the ability to seek regulatory approvals, downsize our general and administrative infrastructure, or seek alternative measures to avoid insolvency. If we raise additional funds through future offerings of shares of our Common Stock or other securities, such offerings would cause dilution of current stockholders' percentage ownership in the Company, which could be substantial. Future offerings also could have a material and adverse effect on the price of our Common Stock.

Our consolidated financial statements for the three and six months ended June 30, 2020 and year ended December 31, 2019 were prepared on the basis of a going concern which contemplates that we will be able to realize assets and discharge liabilities in the normal course of business. We have incurred losses from operations in each of our last five fiscal years. Our ability to continue as a going concern is dependent upon the availability of equity financing as noted above. We will need to raise additional capital to support our ongoing operations and continue our clinical trials. These factors raise substantial doubt about our ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of these uncertainties.

(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, including regarding contingencies, that affect the amounts reported in the consolidated financial statements and accompanying notes.

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

In December 2019, the FASB issued ASU 2019-12, *Simplifying the Accounting for Income Taxes.* The amendments in ASU 2019-12 simplify the accounting for income taxes by removing certain exceptions to the general principles and clarifying a handful of narrow issues within the broad topic of income tax accounting. The amendments in ASU 2019-12 are effective for years beginning after December 15, 2020. The Company does not expect this ASU to have a material impact on its consolidated financial statements.

(t) UNCERTAINTY— The recent outbreak of the COVID-19 coronavirus is impacting worldwide economic activity. COVID-19 poses the risk that we or our employees, CROs, suppliers, manufacturers and other partners may be prevented from conducting business activities for an indefinite period of time, including due to the spread of the disease or shutdowns that may be requested or mandated by governmental authorities. While it is not possible at this time to estimate the full impact that COVID-19 could have on our business, the continued spread of COVID-19 could disrupt our clinical trials, supply chain and the manufacture or shipment of our cyclodextrin products, and other related activities, which could have a material adverse effect on our business, financial condition and results of operations. While we have not yet experienced any disruptions in our business or other negative consequences relating to COVID-19, the extent to which the COVID-19 pandemic impacts our results will depend on future developments that are highly uncertain and cannot be predicted. See also Note 9.

(2) REVENUES:

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

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

Revenues by product are summarized as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Trappsol® Cyclo™	$ -	$ -	$ 30,096	$ 25,971
Trappsol® HPB	151,188	135,878	366,150	206,746
Trappsol® Fine Chemical	55,631	39,100	133,740	104,952
Aquaplex®	928	97,130	928	149,690
Other	1,847	987	4,414	6,562
Total revenues	$ 209,594	$ 273,095	$ 535,328	$ 493,921

Substantially all of our sales of Trappsol® Cyclo™ for the six months ended June 30, 2020 and year ended December 31, 2019 were to a single customer who exports the drug to South America. All of our Aquaplex® sales for the six months ended June 30, 2020 and year ended December 31, 2019 were to three customers.

(3) MAJOR CUSTOMERS AND SUPPLIERS:

Our revenues are derived primarily from chemical supply and pharmaceutical companies located primarily in the United States. For the six months ended June 30, 2020 two major customers accounted for 60% of total revenues. For the six months ended June 30, 2019, four major customers accounted for 65% of total revenues.

Substantially all inventory purchases were from three vendors in 2020 and 2019. These vendors are located primarily outside the United States.

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

For the six months ended June 30, 2020, the product mix of our revenues consisted of 6% biopharmaceutical and 94% basic natural and chemically modified cyclodextrins. For the six months ended June 30, 2019 the product mix of our revenues consisted of 6% biopharmaceuticals, 63% basic natural and chemically modified cyclodextrins, and 30% cyclodextrin complexes.

(4) MORTGAGE NOTE RECEIVABLE

On January 21, 2016, we sold our real property located in High Springs, Florida to an unrelated party. Pursuant to the terms of the sale, at the closing, the buyer paid $10,000 in cash, less selling costs and settlement charges, and delivered to us 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.

(5) EQUITY TRANSACTIONS:

The Company expensed $6,840 and $14,060 in employee and board member stock compensation for the three and six months ended June 30, 2020. The Company expensed $36,540 and $67,930 in employee and board member stock compensation for the three and six months ended June 30, 2019. These shares were valued using quoted market values. The Company accrues stock compensation expense over the period earned for employees and board members. Stock compensation expense for board members is included in "Board of Directors fees and costs" on our statement of operations, and stock compensation expense for officers and employees that are not board members is included in "Personnel" on our statement of operations.

On May 31, 2019, the Company completed a private placement of its securities to a group of accredited investors that included several directors of the Company and members of management. Investors in the private placement purchased a total of 29,770,000 units at a price per unit of $0.25, each unit consisting of one share of common stock and one warrant to purchase a share of common stock, resulting in gross proceeds to the Company of $7,442,500, before deducting placement agent fees and offering expenses of $452,900 resulting in net cash proceeds of $6,989,600. The warrants are exercisable immediately upon issuance at an exercise price of $0.30 per share and expire on the 66th month anniversary of the issuance date. The Company paid a cash fee to its placement agent of $452,900 and issued warrants to the placement agent and its designees to purchase an aggregate of 1,359,000 shares of common stock with the same terms as the warrants issued to the investors. The Company filed a registration statement with the Securities and Exchange Commission to register the resale of the outstanding common stock and the shares of common stock underlying the warrants and the warrants issued to the placement agent, which was declared effective on July 12, 2019. In addition, the Company's directors and officers entered into Lock-Up Agreements at the closing under which they have agreed not to sell any of their securities of the Company until the earliest of (i) 270 days after the effective date of the Registration Statement, (ii) 365 days after the closing, and (iii) 120 days after the listing of Company's common stock on a national securities exchange.

Pursuant to terms of the Placement Agency Agreement between the Company and ThinkEquity, a division of Fordham Financial Management, Inc. ("ThinkEquity"), entered into in connection with Company's May 2019 private placement (the "May Placement"), the Company paid ThinkEquity (i) a cash fee in the amount of $29,637, representing 8% of the gross proceeds in the Private Placement received from investors that were first introduced to the Company by ThinkEquity in connection with the May Placement, and (ii) a warrant to purchase 222,282 shares of Common Stock, representing 6% of the shares of Common Stock purchased by such investors in the Private Placement, at an exercise price of $0.11 per share (110% of the price per share paid by investors in the Private Placement).

On April 24, 2020, the Company completed a private placement of common stock to a group of accredited investors that included several directors of the Company and members of management (the "Private Placement"). Investors in the Private Placement purchased a total of 20 million shares of common stock at a price of $0.10 per share, resulting in gross proceeds to the Company of $2,000,000.

As of June 30, 2020, the Company had warrants outstanding to purchase 63,543,576 shares of common stock at exercise prices of $0.11 - $1.00 per share that expire at various dates through 2025. In addition, there are seven-year warrants outstanding at June 30, 2020 to purchase 480,000 Units sold in our May 2016 private placement at an exercise price of $0.25 per Unit, 164,074 Units sold in our February 2017 private placement at an exercise price of $0.35 per Unit, and 600 Units sold in our October 2017 private placement at an exercise price of $100 per Unit.

(6) INCOME TAXES:

The Company reported a net loss for the three and six months ended June 30, 2020 and 2019, respectively. The Company increased its deferred tax asset valuation allowance rather than recognize an income tax benefit.

(7) EQUITY INCENTIVE PLAN:

On August 29, 2019, the Company's stockholders approved the Company's 2019 Omnibus Equity Incentive Plan at a special meeting of stockholders (the "Incentive Plan"). The Incentive Plan provides for the issuance of up to 6,843,750 shares of common stock pursuant to the grant of shares of common stock, stock options or other awards, to employees, officers or directors of, and consultants to, the Company and its subsidiaries. Options granted under the Incentive Plan may either be intended to qualify as incentive stock options under the Internal Revenue Code of 1986, or may be non-qualified options, and are exercisable over periods not exceeding ten years from date of grant. As of June 30, 2020, we had awarded 450,000 shares of common stock as awards under the Incentive Plan, with 6,393,750 shares of common stock remaining available for future awards under the Incentive Plan.

(8) LEASES:

The Company adopted ASU 2016-02 "*Leases* (Topic 842)" along with related clarifications and improvements effective at the beginning of fiscal 2019, using the modified retrospective transition method. Comparative information has not been restated and continues to be reported under the accounting standards in effect for those periods, as the Company has elected the package of practical expedients permitted under the transition guidance, which among other things, allows us to carryforward our prior lease classifications under ASC 840, "Leases."

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

The Company has elected the package of practical expedients permitted under the transition guidance, which among other things, allows us to carryforward our prior lease classifications under ASC 840, "Leases."

Adoption of Topic 842 did not have a material impact on our annual operating results or cash flows. Operating lease expense is recognized on a straight-line basis over the lease term and is included in operating costs or General and administrative expense. Variable lease payments are expensed as incurred.

The Company determines if an arrangement is or contains a lease at contract inception and recognizes a right-of-use asset and a lease liability at the lease commencement date. Leases with an initial term of 12 months or less but greater than one month are not recorded on the balance sheet for select asset classes. The lease liability is measured at the present value of future lease payments as of the lease commencement date, or the opening balance sheet date for leases existing at adoption of Topic 842. The right-of-use asset recognized is based on the lease liability adjusted for prepaid and deferred rent and unamortized lease incentives.

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

The Company has one office lease, which is as an operating lease and included in the right-of-use asset, current portion of lease liability, and long-term lease liability captions on the Company's consolidated balance sheet.

Operating lease assets are recorded net of accumulated amortization of $25,507 as of June 30, 2020. Lease expense for lease payments are recognized on a straight-line basis over the lease term. Lease expense for the six months ended June 30, 2020 and 2019 was $8,929 and $11,376.

(9) NOTE PAYABLE:

On May 4, 2020, the Company's wholly-owned subsidiary Cyclodextrin Technologies Development, Inc., borrowed $158,524 from BBVA USA under the Paycheck Protection Program which was established under the Coronavirus Aid, Relief and Economic Security Act ("CARES Act"). The loan matures on May 4, 2022 and bears interest at a rate of 1% per annum, payable monthly commencing on December 4, 2020. Under the Paycheck Protection Program, the loan may be partially or wholly forgiven if the loan is used to fund certain qualifying expenses as described in the CARES Act. The Company intends to use all of the loan proceeds for qualifying expenses and to apply for forgiveness of the loan in accordance with the terms of the CARES Act. Maturities of this note payable over the term of this note and in the aggregate are as follows:

Year Ending December 31,	Amount
2020	$ 7,994
2021	$ 106,035
2022	$ 44,495
Total	$ 158,524

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Cyclo Therapeutics, Inc., formerly known as CTD Holdings, Inc., and subsidiaries (the "Company") as of December 31, 2019 and 2018, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2019, and the related notes (collectively referred to as the "financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2019, in conformity with accounting principles generally accepted in the United States of America.

Substantial Doubt Regarding Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has suffered recurring losses from operations and has a significant accumulated deficit. In addition, the Company continues to experience negative cash flows from operations. These factors raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The accompanying consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion.

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

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

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements.

Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Adoption of New Accounting Standard

As discussed in Note 1 to the consolidated financial statements, the Company changed its method of accounting for leases in 2019 due to the adoption of ASU 2016-02, Leases (Topic 842).

/s/ WithumSmith+Brown, PC

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

Orlando, Florida

March 30, 2020

CYCLO THERAPEUTICS, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	December 31,	
	2019	**2018**
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 2,783,719	$ 2,217,412
Accounts receivable	143,429	80,044
Inventory, net	242,630	416,531
Current portion of mortgage note receivable	39,061	37,439
Prepaid insurance and services	137,069	18,185
Prepaid clinical expenses	612,161	-
Total current assets	3,958,069	2,769,611
FURNITURE AND EQUIPMENT, NET	13,546	18,571
RIGHT-TO-USE LEASE ASSET, NET	51,017	-
MORTGAGE NOTE RECEIVABLE, LESS CURRENT PORTION	90,596	129,674
TOTAL ASSETS	$ 4,113,228	$ 2,917,856
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Current portion of lease liability	$ 16,385	$ -
Accounts payable and accrued expenses	3,124,735	1,925,332
Total current liabilities	3,141,120	1,925,332
LONG-TERM LEASE LIABILITY	36,126	-
STOCKHOLDERS' EQUITY		
Common stock, par value $.0001 per share, 500,000,000 shares authorized, 121,564,990 and 90,759,324 shares issued and outstanding at December 31, 2019 and 2018, respectively	12,155	9,075
Preferred stock, par value $.001 per share, 5,000,000 shares authorized, 0 outstanding	-	-
Additional paid-in capital	26,044,060	18,701,211
Stock subscription receivable	-	(130,062)
Accumulated deficit	(25,120,233)	(17,587,700)
Total stockholders' equity	935,982	992,524
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 4,113,228	$ 2,917,856

See accompanying Notes to Consolidated Financial Statements.

CYCLO THERAPEUTICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31,	
	2019	**2018**
REVENUES		
Product sales	$ 1,007,198	$ 1,011,477
EXPENSES		
Personnel	1,906,438	1,171,941
Cost of products sold (exclusive of direct and indirect overhead and handling costs)	75,493	105,026
Research and development	4,869,160	2,711,275
Repairs and maintenance	8,295	3,821
Professional fees	571,937	808,770
Office and other	845,624	354,102
Board of Directors fees and costs	109,473	95,431
Depreciation	5,681	10,124
Freight and shipping	5,885	5,643
Inventory write down	153,772	12,150
Total operating expenses	8,551,758	5,278,283
LOSS FROM OPERATIONS	(7,544,560)	(4,266,806)
OTHER INCOME		
Investment and other income	12,027	11,773
LOSS BEFORE INCOME TAXES	(7,532,533)	(4,255,033)
PROVISION FOR INCOME TAXES	-	-
NET LOSS	$ (7,532,533)	$ (4,255,033)
BASIC AND FULLY DILUTED NET LOSS PER COMMON SHARE	$ (0.07)	$ (0.05)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING	108,191,753	81,756,839

See accompanying Notes to Consolidated Financial Statements.

CYCLO THERAPEUTICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
YEARS ENDED DECEMBER 31, 2019 AND 2018

	Common Stock		Preferred Stock Series B		Additional Paid-In Capital	Subscription Receivable	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par Value	Units	Par Value				
Balance, December 31, 2017	72,999,361	$ 7,299	15,500	$ 2	$ 14,470,984	$ -	$ (13,332,667)	$ 1,145,618
Sale of preferred stock units, net of issuance fees	-	-	20,100	2	1,959,998	-	-	1,960,000
Conversion of preferred stock units to common stock	14,240,000	1,424	(35,600)	(4)	(1,420)	-	-	-
Sale of common stock, net of issuance fees	3,519,963	352	-	-	2,271,649	(130,062)	-	2,141,939
Net loss	-	-	-	-	-		(4,255,033)	(4,255,033)
Balance, December 31, 2018	90,759,324	9,075	-	-	18,701,211	(130,062)	(17,587,700)	992,524
Collection of subscription receivable	-	-	-	-	-	130,062	-	130,062
Sale of common stock, net of issuance fees	29,770,000	2,977	-	-	6,986,623	-	-	6,989,600
Stock-based compensation	1,035,666	103	-	-	356,226	-	-	356,329
Net loss	-	-	-	-	-	-	(7,532,533)	(7,532,533)
Balance, December 31, 2019	121,564,990	$ 12,155	-	$ -	$ 26,044,060	$ -	$ (25,120,233)	$ 935,982

See accompanying Notes to Consolidated Financial Statements.

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

	Year Ended December 31,	
	2019	**2018**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (7,532,533)	$ (4,255,033)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	5,681	10,124
Accrued stock compensation to employees	19,340	19,400
Accrued stock compensation to nonemployees	61,030	64,020
Issuance of stock-based compensation	356,329	-
Inventory valuation allowance	13,265	12,150
Increase or decrease in:		
Accounts receivable	(63,385)	(23,184)
Inventory	160,636	42,540
Prepaid clinical expenses	(612,161)	-
Prepaid insurance and services	(118,884)	42,661
Other	2,162	-
Accounts payable and accrued expenses	1,119,033	898,882
Total adjustments	943,046	1,066,593
NET CASH USED IN OPERATING ACTIVITIES	(6,589,487)	(3,188,440)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of furniture and equipment	(1,324)	(2,959)
Proceeds from mortgage note receivable	37,456	35,899
NET CASH PROVIDED BY INVESTING ACTIVITIES	36,132	32,940
CASH FLOWS FROM FINANCING ACTIVITIES		
Collection of stock subscription receivable	130,062	-
Proceeds from sale of common stock, preferred stock and warrants, net of issuance costs	6,989,600	4,101,939
NET CASH PROVIDED BY FINANCING ACTIVITIES	7,119,662	4,101,939
NET INCREASE IN CASH AND CASH EQUIVALENTS	566,307	946,439
CASH AND CASH EQUIVALENTS, beginning of year	2,217,412	1,270,973
CASH AND CASH EQUIVALENTS, end of year	$ 2,783,719	$ 2,217,412
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION		
Cash paid for interest	$ -	$ -
Cash paid for income taxes	$ -	$ -
NONCASH INVESTING AND FINANCING ACTIVITIES		
Capitalization of right-to-use asset and lease liability	$ 68,022	$ -
Common stock issued in exchange for a subscription receivable	$ -	$ 130,062
Conversion of preferred stock into common stock	$ -	$ 1,424

See accompanying Notes to Consolidated Financial Statements.

(1) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:

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

(a) ORGANIZATION AND OPERATIONS—The Company was incorporated in August 1990 as a Florida corporation, under the name Cyclodextrin Technologies Development, Inc. with operations beginning in July 1992. In conjunction with a restructuring in 2000, we changed our name to CTD Holdings, Inc. We changed our name to Cyclo Therapeutics, Inc. in September 2019 to better reflect our current business. We are a clinical stage biotechnology company that develops cyclodextrin-based products for the treatment of disease. We have filed a Type II Drug Master File with the U.S. Food and Drug Administration ("FDA") for our lead drug candidate, Trappsol® Cyclo™ as a treatment for Niemann-Pick Type C disease ("NPC"), a rare and fatal cholesterol metabolism disease that impacts the brain, lungs, liver, spleen, and other organs. The FDA approved our Investigational New Drug application (IND) which describes our Phase I clinical plans in the U.S. for Trappsol® Cyclo™ and in January 2017 the FDA granted Fast Track designation to Trappsol® Cyclo™ for the treatment of NPC. Initial patient enrollment in the U.S. Phase I study commenced in September 2017. Enrollment in this study was completed in October 2019, with initial results expected in the second quarter of 2020. We have also filed Clinical Trial Applications with several European regulatory bodies, including those in the United Kingdom, Sweden and Italy, and in Israel, all of which have approved our applications. The first patient was dosed in this study in July 2017, and in February 2020, the Company announced completion of enrollment of 12 patients in this study. More recently, we began exploring the use of cyclodextrins in the treatment of Alzheimer's disease, and in October 2019 entered into an agreement with a Contract Research Organization to conduct a clinical trial to evaluate the safety and efficacy of Trappsol® Cyclo™ for the treatment of this disease.

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

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

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

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

The carrying amount of accounts receivable are reduced by an allowance for credit losses that reflects management's best estimate of the amounts that will not be collected. The Company reviews each customer balance where all or a portion of the balance exceeds 90 days from the invoice date. Based on the Company's assessment of the customer's current creditworthiness, the Company estimates the portion, if any, of the balance that will not be collected, and writes off receivables as a charge to the allowance for credit losses when, in management's estimation, it is probable that the receivable is worthless. Based on management's assessment of the credit history with customers having outstanding balances and current relationships with them, an allowance for doubtful accounts was not deemed necessary at December 31, 2019 and 2018.

(e) INVENTORY AND COST OF PRODUCTS SOLD—Inventory consists of our pharmaceutical drug Trappsol® Cyclo™, cyclodextrin products and chemical complexes purchased for resale recorded at the lower of cost (first-in, first-out) or net realizable value. Cost of products sold includes the acquisition cost of the products sold and does not include any allocation of inbound or outbound freight charges, indirect overhead expenses, warehouse and distribution expenses, or depreciation and amortization expense. The Company records a specific reserve for inventory items that are determined to be obsolete. The reserve for obsolete inventory was $52,900 and $39,700 at December 31, 2019 and 2018, respectively. The Company's reserve for obsolete inventory is based on the Company's best estimates of product sales and customer demands. It is reasonably possible that the estimates used by the Company to determine its provisions for inventory write-downs will be material different from actual write-downs. These differences could result in materially higher than expected inventory provisions and related costs, which could have a materially adverse effect on the Company's results of operations and financial condition in the near term.

(f) PREPAID CLINICAL EXPENSES—Prepaid clinical expenses consist of our pharmaceutical drug Trappsol® Cyclo™ expected to be used in our clinical trial program recorded at cost.

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

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

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

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

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

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

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

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

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

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

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

(l) RESEARCH AND DEVELOPMENT COSTS—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.

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

(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 convertible preferred stock and outstanding warrants to purchase 63,321,294 and 32,192,294 common shares were antidilutive for 2019 and 2018, 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.

(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, 2019 or 2018. Long-lived assets are measured at fair value on a non-recurring basis and are subject to fair value adjustments when there is evidence of impairment.

For short-term classes of our financial instruments, which include cash, accounts receivable and accounts payable, and which are not reported at fair value, the carrying amounts approximate fair value due to their short-term nature. The fair value of the mortgage note receivable is estimated based on the present value of the underlying cash flows discounted at current rates. At December 31, 2019 and 2018, the carrying value of the mortgage note receivable approximates fair value.

(q) LIQUIDITY AND GOING CONCERN—For the years ended December 31, 2019 and 2018, the Company incurred net losses of $7,533,000 and $4,255,000, respectively. The Company has an accumulated deficit of approximately $25,120,000 at December 31, 2019. Our recent losses have predominantly resulted from research and development expenses for our Trappsol® Cyclo™ product and other general operating expenses, including personnel expenses and board advisory fees. We believe our expenses will continue to increase as we conduct clinical trials and continue to seek regulatory approval for the use of Trappsol® Cyclo™ in the treatment of NPC.

For year ended December 31, 2019, our operations used approximately $6,589,000 in cash. This cash was provided primarily by cash on hand and net proceeds of $7,120,000 from equity issuances. At December 31, 2019, the Company had a cash balance of $2,784,000 and current assets less current liabilities of $817,000. We will need additional capital to maintain our operations, continue our research and development programs, conduct clinical trials, seek regulatory approvals and manufacture and market our products.

The Company has incurred losses from operations in each of the last six years. We will need to raise additional capital through the sale of our securities from time to time for the foreseeable future to fund the development of our drug product candidates through clinical development, manufacturing and commercialization. Our ability to obtain such additional capital will likely be subject to various factors, including our overall business performance and market conditions. If we cannot raise the additional funds required for our anticipated operations, we may be required to reduce the scope of or eliminate our research and development programs, delay our clinical trials and the ability to seek regulatory approvals, downsize our general and administrative infrastructure, or seek alternative measures to avoid insolvency. If we raise additional funds through future offerings of shares of our Common Stock or other securities, such offerings would cause dilution of current stockholders' percentage ownership in the Company, which could be substantial. Future offerings also could have a material and adverse effect on the price of our Common Stock.

Our consolidated financial statements for the years ended December 31, 2019 and 2018 were prepared on the basis of a going concern which contemplates that we will be able to realize assets and discharge liabilities in the normal course of business. We have incurred losses from operations in each of our last five fiscal years. Our ability to continue as a going concern is dependent upon the availability of equity financing as noted above. We will need to raise additional capital to support our ongoing operations and continue our clinical trials. These factors raise substantial doubt about our ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of these uncertainties.
(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. The Company's most significant estimate relates to inventory obsolescence. 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) RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS—In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842), which requires that lessees recognize assets and liabilities for leases with lease terms greater than 12 months in the statement of financial position. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. This update also requires improved disclosures to help users of financial statements better understand the amount, timing and uncertainty of cash flows arising from leases. The update became effective for fiscal years beginning after December 15, 2018, including interim reporting periods within that reporting period. The Company adopted Topic 842 as of January 1, 2019. See Note 7.

In December 2019, the FASB issued ASU 2019-12, *Simplifying the Accounting for Income Taxes.* The amendments in ASU 2019-12 simplify the accounting for income taxes by removing certain exceptions to the general principles and clarifying a handful of narrow issues within the broad topic of income tax accounting. The amendments in ASU 2019-12 are effective for years beginning after December 15, 2020. The Company does not expect this ASU to have a material impact on its consolidated financial statements.

(2) REVENUES:

The Company operates in one business segment, which primarily focuses on the development and commercialization of innovative cyclodextrin-based products for the treatment of people with serious and life threatening rare diseases and medical conditions. The Company considers there to be revenue concentration risks for regions where net product revenues exceed 10% of consolidated net product revenues. The concentration of the Company's net product revenues within the regions below may have a material adverse effect on the Company's revenues and results of operations if sales in the respective regions experience difficulties. The Company adopted the requirements of ASC 606 on January 1, 2018 using the modified retrospective method. See Note 1(i) – Revenue Recognition for additional discussion.

Revenues by product are summarized as follows:

	Year Ended December 31,	
	2019	**2018**
Trappsol® Cyclo™	$ 103,596	$ 166,596
Trappsol® HPB	481,379	484,101
Trappsol® Fine Chemical	265,947	233,910
Aquaplex®	149,878	116,806
Other	6,398	10,064
Total revenues	$ 1,007,198	$ 1,011,477

Substantially all of our sales of Trappsol® Cyclo™ for the years ended December 31, 2019 and 2018 were to a single customer who exports the drug to South America. Substantially all of our Aquaplex® sales are to one customer.

(3) MAJOR CUSTOMERS AND SUPPLIERS:

Our revenues are derived primarily from chemical supply and pharmaceutical companies located primarily in the United States. In 2019, four major customers accounted for 70% of total revenues. Accounts receivable balances for these major customers represent 95% of total accounts receivable at December 31, 2019. In 2018, four major customers accounted for 57% of total revenues. Accounts receivable balances for these major customers represent 31% of total accounts receivable at December 31, 2018.

Substantially all inventory purchases were from three vendors in 2019 and 2018. These vendors are located primarily outside the United States.

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

For the year ended December 31, 2019, the product mix of our revenues consisted of 10% biopharmaceuticals, 75% basic natural and chemically modified cyclodextrins, and 15% cyclodextrin complexes. For the year ended December 31, 2018, the product mix of our revenues consisted of 17% biopharmaceuticals, 71% basic natural and chemically modified cyclodextrins, and 12% cyclodextrin complexes.

(4) MORTGAGE NOTE RECEIVABLE:

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

Year Ending December 31,	Principal
2020	$ 39,061
2021	40,754
2022	42,520
2023	7,322
	$ 129,657

(5) CONCENTRATIONS OF CREDIT RISK:

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

DEMAND DEPOSITS—We maintain bank accounts in Federal credit unions and other financial institutions, which are insured up to the Federal Deposit Insurance Corporation limits. The bank accounts may exceed federally insured levels; however, we have not experienced any losses in such accounts.

(6) FURNITURE AND EQUIPMENT:

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

	2019	2018
Machinery and equipment	$ 16,524	$ 16,089
Office furniture	49,490	52,820
	66,014	68,909
Less: accumulated depreciation	52,468	50,338
Furniture and equipment, net	$ 13,546	$ 18,571

(7) LEASES:

The Company adopted ASU 2016-02 "*Leases* (Topic 842)" along with related clarifications and improvements effective at the beginning of fiscal 2019, using the modified retrospective transition method. There was no cumulative-effect adjustment to the Company's consolidated balance sheet as of December 31, 2018. Comparative information has not been restated and continues to be reported under the accounting standards in effect for those periods, as the Company has elected the package of practical expedients permitted under the transition guidance, which among other things, allows us to carryforward our prior lease classifications under ASC 840, "Leases."

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

The Company has elected the package of practical expedients permitted under the transition guidance, which among other things, allows us to carryforward our prior lease classifications under ASC 840, "Leases."

Adoption of Topic 842 did not have a material impact on our annual operating results or cash flows. Operating lease expense is recognized on a straight-line basis over the lease term and is included in operating costs or General and administrative expense. Variable lease payments are expensed as incurred.

The effects of the changes made to the Company's consolidated balance sheet as of December 31, 2018 for the adoption of Topic 842 is as follows:

The Company determines if an arrangement is or contains a lease at contract inception and recognizes a right-of-use asset and a lease liability at the lease commencement date. Leases with an initial term of 12 months or less but greater than one month are not recorded on the balance sheet for select asset classes. The lease liability is measured at the present value of future lease payments as of the lease commencement date, or the opening balance sheet date for leases existing at adoption of Topic 842. The right-of-use asset recognized is based on the lease liability adjusted for prepaid and deferred rent and unamortized lease incentives.

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

The Company has one office lease, which is as an operating lease and included in the right-of-use asset, current portion of lease liability, and long-term lease liability captions on the Company's consolidated balance sheet.
Operating lease assets are recorded net of accumulated amortization of $17,006 as of December 31, 2019. Lease expense for lease payments are recognized on a straight-line basis over the lease term. Lease expense for the years ended December 31, 2019 and 2018 was $17,006 and $22,249, respectively.

The following is a maturity analysis of the annual undiscounted cash flows of the operating lease liabilities as of December 31, 2019:

Year ending December 31,	Amounts
2020	$ 19,170
2021	19,170
2022	19,170
2023	1,598
2024	-
Total	$ 59,108

(8) EQUITY TRANSACTIONS:

The Company expensed $168,120 and $83,420 in employee and board member stock compensation in 2019 and 2018, respectively. These shares were valued using quoted market values. The Company accrues stock compensation expense over the period earned for employees and board members. Stock compensation expense for board members is included in "Board of Directors fees and costs" on our statement of operations, and stock compensation expense for officers and employees that are not board members is included in "Personnel" on our statement of operations. In 2019, the Company issued 450,000 shares of Common Stock to employees as a bonus with a value of $87,750, and issued 241,666 shares as a bonus to advisory board members with a value of $109,908. In addition, the Company issued 344,000 shares of Common Stock in 2019 to board members and officers with a value of $158,670 at the time of issuance, with respect to which compensation expense had been accrued with respect to 172,000 of such shares in 2018 and 172,000 of such shares in 2017. In 2018, the Company did not issue shares of Common Stock for compensation.

In April 2014, we entered into a one-year agreement with Scarsdale Equities, LLC ("Scarsdale"), which was subsequently extended, to act as our financial advisor and exclusive placement agent. Under the agreement, Scarsdale is entitled to a fee with respect to each private placement of debt or equity securities of the Company in an amount equal to 6% of the proceeds of such financing raised by Scarsdale, and a seven-year warrant to purchase 6% of the securities issued as a part of such financing raised by Scarsdale, with an exercise price equal to 100% of the offering price of the securities sold during the term of the agreement. The foregoing compensation terms were modified for private placements effected in 2017, resulting in the compensation described in more detail below. The agreement also provides for payment of the above fees for any financing within one year of the expiration of the term, with investors identified by Scarsdale during the term. N. Scott Fine, the Company's Chief Executive Officer and Chairman of the Board, was a principal of Scarsdale at the time we initially retained Scarsdale as our financial adviser, and his son, Joshua M. Fine, was employed by Scarsdale at the time of its initial engagement by us and active on our account until his appointment as our Chief Financial Officer in June 2019.

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

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

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

On May 31, 2019, the Company completed a private placement of its securities to a group of accredited investors that included several directors of the Company and members of management. Investors in the private placement purchased a total of 29,770,000 units at a price per unit of $0.25, each unit consisting of one share of common stock and one warrant to purchase a share of common stock, resulting in gross proceeds to the Company of $7,442,500, before deducting placement agent fees and offering expenses of $452,900 resulting in cash proceeds of $6,989,600. The warrants are exercisable immediately upon issuance at an exercise price of $0.30 per share and expire on the 66th month anniversary of the issuance date. The Company paid a cash fee to its placement agent of $452,900 and issued warrants to the placement agent and its designees to purchase an aggregate of 1,359,000 shares of common stock with the same terms as the warrants issued to the investors. The Company filed a registration statement with the Securities and Exchange Commission to register the resale of the outstanding common stock and the shares of common stock underlying the warrants and the warrants issued to the placement agent, which was declared effective on July 12, 2019. In addition, the Company's directors and officers entered into Lock-Up Agreements at the closing under which they have agreed not to sell any of their securities of the Company until the earliest of (i) 270 days after the effective date of the Registration Statement, (ii) 365 days after the closing, and (iii) 120 days after the listing of Company's common stock on a national securities exchange.

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

Warrants outstanding, December 31, 2017	20,632,331
Issued	11,559,963
Exercised	-
Expired	-
Warrants outstanding, December 31, 2018	32,192,294
Issued	31,129,000
Exercised	-
Expired	-
Warrants outstanding, December 31, 2019	63,321,294

The following table presents the number of Common Stock warrants outstanding, their exercise price, and expiration dates at December 31, 2019:

Warrants Issued	Exercise Price	Expiration Date
240,000	$ 0.25	April 2021
103,500	$ 1.00	July 2021
156,000	$ 0.50	July 2022
78,000	$ 0.50	August 2022
8,100,000	$ 0.25	June 2023
5,754,831	$ 0.35	February 2024
6,200,000	$ 0.25	October 2024
31,129,000	$ 0.30	November 2024
8,040,000	$ 0.25	April 2025
3,519,963	$ 0.65	December 2025
63,321,294		

In addition, there are seven-year warrants outstanding at December 31, 2019 to purchase 480,000 Units sold in our May 2016 private placement at an exercise price of $0.25 per Unit, 164,074 Units sold in our February 2017 private placement at an exercise price of $0.35 per Unit, and 600 Units sold in our October 2017 private placement at an exercise price of $100 per Unit.

(9) PREFERRED STOCK:

The Company's Articles of Incorporation provide for 5,000,000 shares of "blank check" preferred stock. At December 31, 2019 and 2018, no shares of preferred stock were outstanding or designated.

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

(10) INCOME TAXES:

If all of our net operating loss carryforwards and temporary deductible differences were used, we would realize a net deferred tax asset of approximately $8,881,000 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, 2019, we have determined it is more likely than not that we will not realize our temporary deductible differences and net operating loss carryforwards, and have provided a 100% valuation allowance on our net deferred tax asset.

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

We have available at December 31, 2019, unused federal and state net operating loss carryforwards totaling approximately $18,335,000 that may be applied against future taxable income.

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

Year Ending December 31,	Amount
2020	$ 174,000
2021	71,000
2024	66,000
2028	7,000
2030	160,000
2031	73,000
2032	48,000
2034	727,000
2035	1,969,000
2036	2,867,000
2037	2,481,000
Indefinite	9,692,000
Total	$ 18,335,000

A change in ownership pursuant to Section 382 of the Internal Revenue Code occurred during 2014. As a result, net operating losses in existence as of the date of the ownership change are subject to an annual Section 382 limitation. At December 31, 2019, the amount of net operating losses subject to an annual Section 382 limitation has not been determined.

The Company has expenses that qualify for the Orphan Drug Credit. The Orphan Drug Credit may be used to offset any current tax liabilities. Unused credits may be carried forward for 20 years. If the credit has not been used by the end of the 20 year carryforward period, it can be deducted as an expense for federal income tax purposes. The cumulative unused credit carryforward was $4,292,000 at December 31, 2019.

For 2019, we did not recognize a benefit or provision for income taxes. The net deferred tax asset before the valuation allowance increased $2,645,000 from 2018 to 2019, which is primarily the result of an additional net operating loss for 2019. We increased our valuation allowance to offset this increase in our deferred tax asset.

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

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

	2019	2018
Deferred tax assets:		
Net operating loss carryforwards	$ 4,496,000	$ 3,017,000
Tax credits	4,292,000	3,085,000
Impairment allowances	13,000	10,000
Stock-based compensation	20,000	64,000
Other	62,000	62,000
Less valuation allowance	(8,881,000)	(6,235,000)
Deferred tax asset, net of valuation	2,000	3,000
Deferred tax liabilities:		
Property and equipment	(2,000)	(3,000)
Deferred tax liabilities	(2,000)	(3,000)
Net tax assets	$ -	$ -

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

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The Company's net tax asset as of December 31, 2018 was determined based on the current enacted federal tax rate of 34% prior to the passage of the Act. As a result of the reduction in the corporate income tax rate to 21% from 34% under the Act, the Company revalued its net deferred tax assets and liabilities as of January 1, 2018. The impact of the reduction of the income tax rate was a reduction of deferred tax asset and the corresponding valuation allowance of approximately $768,000. Effective January 1, 2019, the Florida corporate state income tax rate was reduced from 5.5% to 4.458%. The impact of this rate reduction was a reduction in the Company's deferred tax asset and the corresponding valuation allowance of approximately $102,000.

The differences between the effective income tax rate reflected in the benefit (provision) for income taxes and the amounts, which would be determined by applying federal statutory income tax rate of 21% at December 31, 2019 and 2018, is summarized as follows:

	2019	2018
Tax benefit (expense) at Federal statutory rate	$ 1,582,000	$ 894,000
Effect of State taxes	265,000	185,000
Effect of tax rate change	(102,000)	-
Tax credits	1,217,000	676,000
Nondeductible expenses	(317,000)	(180,000)
Valuation allowance – deferred tax assets	(2,645,000)	(1,575,000)
Total tax benefit (provision)	$ -	$ -

The Company files income tax returns in the U.S. Federal jurisdiction, and in the State of Florida. The Company is no longer subject to U.S. Federal or state income tax examinations by tax authorities for years before 2016.

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.

(11) 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 2019 and 2018, the Company elected to match the employee's contribution, not to exceed 4% of compensation. The Company's 401(k) contributions were $29,410 and $24,765 for 2019 and 2018, respectively.

(12) EQUITY INCENTIVE PLAN:

On August 29, 2019, the Company's stockholders approved the Company's 2019 Omnibus Equity Incentive Plan at a special meeting of stockholders (the "Incentive Plan"). The Incentive Plan provides for the issuance of up to 6,843,750 shares of common stock pursuant to the grant of shares of common stock, stock options or other awards, to employees, officers or directors of, and consultants to, the Company and its subsidiaries. Options granted under the Incentive Plan may either be intended to qualify as incentive stock options under the Internal Revenue Code of 1986, or may be non-qualified options, and are exercisable over periods not exceeding ten years from date of grant. As of December 31, 2019, we had awarded 450,000 shares of common stock as awards under the Incentive Plan, with 6,393,750 shares of common stock remaining available for future awards under the Incentive Plan.

(13) COMMITMENTS AND CONTINGENCIES:

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

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

(14) RELATED PARTY TRANSACTIONS:

As discussed in Note 7 above, N. Scott Fine, our Chief Executive Officer and Chairman of the Board, was a principal of Scarsdale at the time we initially retained Scarsdale as our financial adviser, and his son, Joshua M. Fine, was employed by Scarsdale at the time of its initial engagement by us and active on our account until his appointment as our Chief Financial Officer in June 2019.

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

In June 2019, we engaged Joshua M. Fine, the son of our Chief Executive Officer, to serve as our Chief Financial Officer. Mr. Fine receives an annual salary of $125,000. In addition, he was awarded a stock bonus of 50,000 shares in September 2019.

During 2017, Rebecca A. Fine, the daughter of our Chief Executive Officer, provided executive assistant services at the rate of $5,000 per month. From January through May 2019, she provided these services at the rate of $5,800 per month. In June 2019, Ms. Fine was employed by us as a full-time employee serving as an executive assistant with an annual salary of $69,600. Ms. Fine also received a stock bonus of 25,000 shares in September 2019.

Kevin J. Strattan, the son of C.E. Rick Strattan, has been employed by us since 2008, and since 2014 has been our Vice President, Finance – Compensation. His annual salary increased from $100,000 to $107,200 in October 2018. In addition, he received cash bonuses of $10,000 and $12,500 in 2018 and 2019, respectively. Mr. Strattan also received a stock bonus of 50,000 shares in September 2019.

Corey E. Strattan, the daughter-in-law of C.E. Rick Strattan, has been employed by us since 2011 as a documentation specialist and logistics coordinator. Her annual salary increased from $72,000 in 2018, to $78,000 in 2019. In addition, she received a cash bonus of $5,000 in 2018. Ms. Strattan also received a stock bonus of 25,000 shares in September 2019.

UNITS, EACH UNIT COMPRISED OF

ONE SHARE OF COMMON STOCK AND ONE WARRANT
TO PURCHASE ONE SHARE OF COMMON STOCK

P R O S P E C T U S

Sole Book Running Manager

Maxim Group LLC

September [__], 2020

PART II
INFORMATION NOT REQUIRED IN PROSPECTUS

ITEM 13. OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION

The following table sets forth the costs and expenses incurred by us in connection with the sale of the Common Stock being registered by this registration statement. All amounts shown are estimates, except for the Securities and Exchange Commission ("SEC") registration fee.

SEC registration fee	$	2,748.78
Accounting fees and expenses	$	*
Legal fees and expenses	$	*
Miscellaneous expenses	$	*
Total	$	*

* To be completed by amendment.

ITEM 14. INDEMNIFICATION OF DIRECTORS AND OFFICERS

Nevada law provides that a Nevada corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative, other than an action by or in the right of the corporation (i.e., a "non-derivative proceeding"), by reason of the fact that he or she is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses, including attorneys' fees, judgments, fines and amounts paid in settlement actually and reasonably incurred by him in connection with the action, suit or proceeding if he or she:

- Is not liable under Section 78.138 of the Nevada Revised Statutes for breach of his or her fiduciary duties to the corporation; or
- Acted in good faith and in a manner which he or she reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful.

In addition, a Nevada corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the corporation to procure a judgment in its favor (i.e., a "derivative proceeding"), by reason of the fact that he or she is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against expenses, including amounts paid in settlement and attorneys' fees actually and reasonably incurred by him or her in connection with the defense or settlement of the action or suit if he:

- Is not liable under Section 78.138 of the Nevada Revised Statutes for breach of his or her fiduciary duties to the corporation; or
- Acted in good faith and in a manner which he or she reasonably believed to be in or not opposed to the best interests of the corporation.

Under Nevada law, indemnification may not be made for any claim, issue or matter as to which such a person has been adjudged by a court of competent jurisdiction, after exhaustion of all appeals therefrom, to be liable to the corporation or for amounts paid in settlement to the corporation, unless and only to the extent that the court in which the action or suit was brought or other court of competent jurisdiction determines upon application that in view of all the circumstances of the case, the person is fairly and reasonably entitled to indemnity for such expenses as the court deems proper.

To the extent that a director, officer, employee or agent of a corporation has been successful on the merits or otherwise in defense of any non-derivative proceeding or any derivative proceeding, or in defense of any claim, issue or matter therein, the corporation is obligated to indemnify him or her against expenses, including attorneys' fees, actually and reasonably incurred in connection with the defense.

Further, Nevada law permits a Nevada corporation to purchase and maintain insurance or to make other financial arrangements on behalf of any person who is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise for any liability asserted against him or her and liability and expenses incurred by him or her in his or her capacity as a director, officer, employee or agent, or arising out of his or her status as such, whether or not the corporation has the authority to indemnify him or her against such liability and expenses.

Our bylaws provide that, the Company shall, to the fullest extent permitted by the laws of the State of Nevada, indemnify any person who is or was a director or officer of the Company or any predecessor of the Company or is or was serving at the Company's request as a director, officer, employee or agent of another corporation, partnership, joint venture, trust, or other entity (each such person, an "Indemnitee") against expenses, including attorneys' fees, judgments, fines, and amounts paid in settlement, actually and reasonably incurred by the Indemnitee in connection with any threatened, pending, or completed action, suit, or proceeding, whether civil, criminal, administrative, or investigative, other than a proceeding by or in the right of the Company, to which the Indemnitee is, was, or is threatened to be made a party by reason of being an Indemnitee, if the Indemnitee either: (a) did not breach, through intentional misconduct, fraud, or a knowing violation of law, the Indemnitee's fiduciary duties as a director or officer to act in good faith and in the interests of the Company; or (b) acted in good faith and in a manner the Indemnitee reasonably believed to be in or not opposed to the best interests of the Company and, with respect to any criminal action or proceeding, had no reasonable cause to believe the Indemnitee's conduct was unlawful.

Additionally, our bylaws provide that the Company shall, to the fullest extent permitted by the laws of the State of Nevada, indemnify any Indemnitee against expenses, including attorneys' fees and amounts paid in settlement, actually and reasonably incurred by the Indemnitee in connection with any threatened, pending, or completed suit or action by or in the right of the Corporation to which the Indemnitee is, was, or is threatened to be made a party by reason of being an Indemnitee, if the Indemnitee either: (a) did not breach, through intentional misconduct, fraud, or a knowing violation of law, the Indemnitee's fiduciary duties as a director or officer to act in good faith and in the interests of the Company; or (b) acted in good faith and in a manner the Indemnitee reasonably believed to be in or not opposed to the best interests of the Company.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Company pursuant to the foregoing provisions, or otherwise, we have been advised that in the opinion of the SEC this indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

ITEM 15. RECENT SALES OF UNREGISTERED SECURITIES

Over the past three years, we have issued and sold the following securities without registration under the Securities Act:

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

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

In 2017, the Company issued 292,000 shares of Common Stock to eight board members, the Company's secretary, and to employees as a bonus, for services to the Company.

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

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

On May 31, 2019, the Company completed a private placement (the "May 2019 Private Placement") of "Units" to a group of accredited investors that included several directors and members of management, pursuant to a Securities Purchase Agreement (the "Purchase Agreement"), dated as of May 30, 2019. Investors in the May 2019 Private Placement purchased a total of 29,770,000 Units at a price per unit of $0.25, each unit consisting of one share of Common Stock (the "Shares") and one warrant to purchase a share of Common Stock (the "Investor Warrants"), resulting in gross proceeds to us of $7,442,500, before deducting placement agent fees and offering expenses. The Investor Warrants are exercisable immediately upon issuance at an exercise price of $0.30 per share and expire on the 66-month anniversary of the issuance date. The May 2019 Private Placement was effected pursuant to Section 4(a)(2) of the Securities Act of 1933, as amended and Rule 506(b) promulgated thereunder. ThinkEquity, a division of Fordham Financial Management, Inc. ("ThinkEquity"), acted as sole placement agent for the offering pursuant to a Placement Agency Agreement dated as of May 30, 2019. Pursuant to terms of the Placement Agency Agreement, the Company paid a cash fee to ThinkEquity in the amount of $453,000 and issued warrants (the "Placement Agent Warrants") to ThinkEquity and its designees to purchase an aggregate of 1,359,000 shares of Common Stock, with the same terms as the Investor Warrants issued to the Investors. Pursuant to the Purchase Agreement, the Company entered into a Registration Rights Agreement (the "Registration Rights Agreement") with the investors in the May 2019 Private Placement, pursuant to which we has agreed to file the registration statement which includes this prospectus (the "Registration Statement") with the Securities and Exchange Commission to register the resale of the Shares and shares of Common Stock underlying the Investor Warrants and the Placement Agent Warrants.

On April 24, 2020, the Company completed a private placement of common stock to a group of accredited investors that included several directors of the Company and members of management (the "April 2020 Private Placement"). Investors in the April 2020 Private Placement purchased a total of 20 million shares of common stock at a price of $0.10 per share, resulting in gross proceeds to the Company of $2,000,000. The Company did not utilize a financial adviser or placement agent in connection with the April 2020 Private Placement. However, pursuant to terms of the Placement Agency Agreement with ThinkEquity, the Company paid ThinkEquity (i) a cash fee in the amount of $29,637, representing 8% of the gross proceeds in the April 2020 Private Placement received from investors that were first introduced to the Company by ThinkEquity in connection with the May 2019 Private Placement, and (ii) a warrant to purchase 22,228 shares of Common Stock, representing 6% of the shares of Common Stock purchased by such investors in the April 2020 Private Placement, at an exercise price of $0.11 per share (110% of the price per share paid by investors in the April 2020 Private Placement).

On August 27, 2020, the Company completed a private placement of common stock to a group of accredited investors that included several directors of the Company and members of management (the "August 2020 Private Placement"). Investors in the August 2020 Private Placement purchased a total of 28,311,140 "Units" at a price of $0.10 per Unit, resulting in gross proceeds to the Company of $2,831,114. Each Unit consisted of one share of Common Stock and a seven-year warrant ("Warrant") to purchase one share of Common Stock at an exercise price of $0.15 per share.

All of the foregoing securities were issued in private placement transactions exempt from the registration requirements of the Securities Act pursuant to Section 4(a)(2) of the Securities Act directly by us without engaging in any advertising or general solicitation of any kind.

ITEM 16. EXHIBITS

The following exhibits are filed as part of this registration statement:

Exhibits		
1.1**		Form of Underwriting Agreement
2.1		Form of Agreement and Plan of Merger, dated October __, 2020, by and between Cyclo Therapeutics, Inc., a Florida corporation and Cyclo Therapeutics, Inc., a Nevada corporation (incorporated by reference to Exhibit A to the Company's Proxy Statement on Schedule 14A filed September 15, 2020).
3.1		Amended and Restated Articles of Incorporation filed June 29, 2018 (incorporated by reference to the Company's Form 10-Q filed with the Securities and Exchange Commission on August 14, 2018).
3.2		By-Laws (incorporated by reference to the Company's Form 10-SB filed with the Securities and Exchange Commission on February 1, 1994).

3.3	Form of Articles of Incorporation of the Company to be effective upon the Company's reincorporation in the State of Nevada upon completion of this offering (incorporated by reference to Exhibit B to the Company's Proxy Statement on Schedule 14A filed September 15, 2020).
3.4	Form of By-Laws of the Company to be effective upon the Company's reincorporation in the State of Nevada upon completion of this offering (incorporated by reference to Exhibit C to the Company's Proxy Statement on Schedule 14A filed September 15, 2020).
4.1	Form of Warrant issued to investors in private placements conducted in 2016, 2017 and 2018 (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed June 8, 2016).
4.2	Form of Warrant, dated May 31, 2019, issued by CTD Holdings, Inc. to investors and ThinkEquity, a division of Fordham Financial Management, Inc., and its designees (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed June 4, 2019).
4.4	Form of Warrant, dated August 27, 2020, issued by Cyclo Therapeutics, Inc. to investors in a private placement conducted in August 2020 (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed September 2, 2020).
4.5**	Form of Representative's Warrant.
5.1**	Opinion of Fox Rothschild LLP
10.1	Conversion Agreement dated as of February 19, 2014 between CTD Holdings, Inc. and C.E. Rick Strattan (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed February 20, 2014).
10.2	Voting Commitment Letter dated as of February 19, 2014 between CTD Holdings, Inc. and C.E. Rick Strattan (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K filed February 20, 2014).
10.3	Securities Purchase and Collaboration Agreement dated as of April 9, 2014 between CTD Holdings, Inc. and Novit, L.P. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed April 15, 2014).
10.4†	Employment Agreement between the Company and N. Scott Fine, dated as of September 14, 2015 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed October 16, 2015).
10.5†	Amendment to Employment Agreement between the Company and N. Scott Fine, dated as of November 7, 2017 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed November 8, 2017).
10.6	Promissory Note in the original principal amount of $265,000, dated January 21, 2016, by Crit, Inc. DBA Commercial Gates & Electric, in favor of CTD Holdings, Inc. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed January 27, 2016).
10.7	Mortgage, dated January 21, 2016, by Crit, Inc. DBA Commercial Gates & Electric, in favor of CTD Holdings, Inc. (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed January 27, 2016).
10.8	Commercial Contract between Alchem Laboratories Corporation and Nanosonic Products Inc., entered into September 6, 2016 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed December 20, 2016).
10.9	Form of Securities Purchase Agreement between CTD Holdings, Inc. and investors in the October 2017 private placement (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed October 20, 2017).
10.10†	Employment Agreement between the Company and Dr. Sharon H. Hrynkow, dated as of September 14, 2015 (incorporated by reference to Exhibit 10.10 to the Company's Annual Report on Form 10-K filed March 15, 2019).
10.11†	Amendment to Employment Agreement between the Company and Dr. Sharon H. Hrynkow, dated as of November 8, 2017 (incorporated by reference to Exhibit 10.11 to the Company's Annual Report on Form 10-K filed March 15, 2019).
10.12	Securities Purchase Agreement, dated as of May 30, 2019, between CTD Holdings, Inc. and purchasers party thereto (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed June 4, 2019)
10.13	Placement Agency Agreement, dated as of May 30, 2019, between CTD Holdings, Inc. and ThinkEquity, a division of Fordham Financial Management, Inc. (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed June 4, 2019).
10.14	Registration Rights Agreement, dated as of May 30, 2019, between CTD Holdings, Inc. and purchasers party thereto (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed June 4, 2019).
10.15†	2019 Omnibus Equity Incentive Plan (incorporated by reference to Appendix B to the Company's Proxy Statement on Schedule 14A filed July 19, 2019).
10.16	Promissory Note, dated May 4, 2020, by Cyclodextrin Technologies Development, Inc., a wholly-owned subsidiary of the Company, in favor of BBVA USA (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed May 6, 2020).
21.1	Subsidiaries (incorporated by reference to Exhibit 21.1 to the Company's Annual Report on Form 10-K filed April 16, 2018).
23.1*	Consent of WithumSmith+Brown, PC.
23.2	Consent of Fox Rothschild LLP (included in Exhibit 5.1)
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.
** To be filed by amendment.
† Management contract or compensatory plan or arrangement.

ITEM 17. UNDERTAKINGS

(a) The undersigned registrant hereby undertakes:

(1) to file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) to include any prospectus required by Section 10(a)(3) of the Securities Act;

(ii) to reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and

(iii) to include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

(2) that, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

(3) to remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) that, for the purpose of determining liability under the Securities Act to any purchaser, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

(b) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, on September 29, 2020.

CYCLO THERAPEUTICS, INC.

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

KNOW ALL PERSONS BY THESE PRESENTS, that each individual whose signature appears below constitutes and appoints N. Scott Fine, with full authority to act without the others, his true and lawful attorney-in-fact and agent with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to this registration statement, and to file the same, with all exhibits thereto, and all documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agents full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities and on the dates indicated:

Signature	Title	Date
/s/ N. Scott Fine N Scott Fine	Chief Executive Officer, Director	September 29, 2020
/s/ Joshua M. Fine Joshua M. Fine	Chief Financial Officer	September 29, 2020
/s/ C.E. Rick Strattan C.E. Rick Strattan	Director	September 29, 2020
/s/ Jeffrey L. Tate Jeffrey L. Tate	Chief Operating Officer, Director	September 29, 2020
/s/ Randall M. Toig Randall M. Toig	Director	September 29, 2020
/s/ William S. Shanahan William S. Shanahan	Director	September 29, 2020
/s/ F. Patrick Ostronic F. Patrick Ostronic	Director	September 29, 2020
/s/ Markus W. Sieger Markus W. Sieger	Director	September 29, 2020

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the use in this Registration Statement on Form S-1 of our report dated March 30, 2020 relating to the December 31, 2019 and 2018 consolidated financial statements which appear in Cyclo Therapeutics Inc.'s Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 on Form 10-K for the year ended December 31, 2019.

We also consent to the reference to us under the caption "Experts" in this Registration Statement.

/s/ WithumSmith+Brown, PC
Orlando, FL

September 29, 2020