

CTD HOLDINGS INC
Form 10-Q
August 14, 2018

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 10-Q

Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the quarterly period ended: June 30, 2018

or

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

Commission file number: 0-25466

CTD HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Florida 59-3029743
(State or other jurisdiction of (IRS Employer
incorporation or organization) Identification No.)

6714 NW 16th Street, Suite B, Gainesville, Florida 32653
(Address of principal executive offices) (Zip Code)

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

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Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes No

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

Large accelerated filer Accelerated filer
Non-accelerated filer Smaller reporting company
Emerging growth company

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act)

Yes No

As of August 14, 2018, the Company had outstanding 87,744,500 shares of its common stock.

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PART I. FINANCIAL INFORMATION**Item 1. Financial Statements.****CTD HOLDINGS, INC. AND SUBSIDIARIES****CONSOLIDATED BALANCE SHEETS**

	June 30, 2018 (Unaudited)	December 31, 2017
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$1,541,030	\$1,270,973
Accounts receivable	91,427	56,860
Inventory, net	407,586	471,221
Current portion of mortgage note receivable	35,884	35,884
Other current assets	44,823	60,846
Total current assets	2,120,750	1,895,784
FURNITURE AND EQUIPMENT, NET	22,344	25,736
OTHER ASSETS		
Mortgage note receivable, less current portion	149,369	167,128
TOTAL ASSETS	\$2,292,463	\$2,088,648
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued expenses	\$1,289,018	\$943,030
STOCKHOLDERS' EQUITY		
Common stock, par value \$.0001 per share, 500,000,000 and 100,000,000 shares authorized at June 30, 2018 and December 31, 2017, respectively, 87,239,361 and 72,999,361 shares issued and outstanding at June 30, 2018 and December 31, 2017, respectively	8,723	7,299
Preferred stock, par value \$.0001 per share, 0 and 5,000,000 shares authorized at June 30, 2018 and December 31, 2017, respectively, Series B – 50,000 shares designated,	-	2

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convertible 0 and 15,500 shares issued and outstanding at June 30, 2018 and December 31, 2017, liquidation preference \$0 and \$1,550,000 at June 30, 2018 and December 31, 2017, respectively

Additional paid-in capital	16,429,562	14,470,984
Accumulated deficit	(15,434,840)	(13,332,667)
Total stockholders' equity	1,003,445	1,145,618
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$2,292,463	\$2,088,648

See accompanying Notes to Consolidated Financial Statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
REVENUES				
Product sales	\$ 349,415	\$ 523,085	\$ 547,484	\$ 828,142
EXPENSES				
Personnel	287,776	304,836	565,343	639,365
Cost of products sold (exclusive of depreciation, shown separately below)	54,040	79,018	77,712	98,396
Research and development	844,376	526,984	1,253,574	1,170,629
Repairs and maintenance	1,271	1,203	1,271	3,995
Professional fees	297,308	302,203	531,284	426,003
Office and other	127,982	94,348	175,849	226,537
Board of Director fees and costs	27,233	39,946	43,016	76,753
Depreciation	2,526	2,252	5,026	4,460
Freight and shipping	1,643	3,150	3,525	4,611
Gain on disposal of property and equipment	-	-	-	(1,261)
	1,644,155	1,353,940	2,656,600	2,649,488
LOSS FROM OPERATIONS	(1,294,740)	(830,855)	(2,109,116)	(1,821,346)
OTHER INCOME				
Investment and other income	5,511	3,084	6,943	6,102
Total other income	5,511	3,084	6,943	6,102
LOSS BEFORE INCOME TAXES	(1,289,229)	(827,771)	(2,102,173)	(1,815,244)
Provision for income taxes	-	-	-	-
NET LOSS	\$(1,289,229)	\$(827,771)	\$(2,102,173)	\$(1,815,244)
BASIC AND FULLY DILUTED NET LOSS PER COMMON SHARE	\$(.02)	\$(.01)	\$(.03)	\$(.03)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING	78,853,583	72,879,361	75,926,472	71,098,883

See Accompanying Notes to Consolidated Financial Statements.

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

	Six Months Ended June 30,	
	2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	\$(2,102,173)	\$(1,815,244)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	5,026	4,460
Gain on sale of property and equipment	-	(1,261)
Accrued stock compensation to employees	6,500	57,180
Accrued stock compensation to non-employees	21,450	27,960
Increase or decrease in:		
Accounts receivable	(34,567)	(11,972)
Inventory	63,635	24,247
Other current assets	16,023	10,758
Accounts payable and accrued expenses	318,038	205,792
Total adjustments	396,105	317,164
NET CASH USED IN OPERATING ACTIVITIES	(1,706,068)	(1,498,080)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of equipment	(1,634)	(4,257)
Proceeds from mortgage note receivable	17,759	17,022
Proceeds from sale of equipment	-	4,650
NET CASH PROVIDED BY INVESTING ACTIVITIES	16,125	17,415
CASH FLOWS FROM FINANCING ACTIVITIES		
Net proceeds from sale of common and preferred stock and warrants, net of issue costs	1,960,000	1,851,055
NET CASH PROVIDED BY FINANCING ACTIVITIES	1,960,000	1,851,055
NET INCREASE IN CASH AND CASH EQUIVALENTS	270,057	370,390
CASH AND CASH EQUIVALENTS, beginning of period	1,270,973	960,197
CASH AND CASH EQUIVALENTS, end of period	\$1,541,030	\$1,330,587
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION		
Cash paid for interest	\$-	\$-
Cash paid for income taxes	\$-	\$-

See Accompanying Notes to Consolidated Financial Statements.

CTD HOLDINGS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

JUNE 30, 2018

The information presented herein as of June 30, 2018 and for the three and six months ended June 30, 2018 and 2017 is unaudited.

(1) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:

The following is a summary of the more significant accounting policies of CTD Holdings, Inc. and subsidiaries (“we”, “our”, “us” or the “Company”) that affect the accompanying consolidated financial statements.

(a) ORGANIZATION AND OPERATIONS—The Company was incorporated in August 1990 as a Florida corporation, with operations beginning in July 1992. We are a biotechnology company that develops cyclodextrin-based products for the treatment of disease. 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 recently approved our Investigational New Drug application (IND) which describes our Phase I clinical plans in the U.S. for Trappsol® Cyclo™ and in January 2017 the FDA granted Fast Track designation to Trappsol® Cyclo™ for the treatment of NPC. Initial patient enrollment in the U.S. Phase I study commenced in September 2017. We have also filed Clinical Trial Applications with several European regulatory bodies, including those in the United Kingdom, Sweden, Israel and Italy, all of which have approved our applications. The first patient was dosed in our European study in July 2017.

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

(b) BASIS OF PRESENTATION—The accompanying consolidated financial statements have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation have been included.

Operating results for the three and six month periods ended June 30, 2018 are not necessarily indicative of the results that may be expected for the year ending December 31, 2018. For further information, refer to the consolidated financial statements and footnotes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2017, as filed with the Securities and Exchange Commission on April 16, 2018.

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

(d) ACCOUNTS RECEIVABLE—Accounts receivable are unsecured and non-interest bearing and are stated at the amount we expect to collect from outstanding balances. Based on our assessment of the credit history with customers having outstanding balances and current relationships with them, an allowance for uncollectible accounts was not deemed necessary at June 30, 2018 and December 31, 2017.

(e) INVENTORY AND COST OF PRODUCTS SOLD—Inventory consists of our pharmaceutical drug Trappsol® Cyclo™, cyclodextrin products and chemical complexes purchased for resale recorded at the lower of cost (first-in, first-out) or 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 \$27,500 at June 30, 2018 and December 31, 2017.

(f) EQUIPMENT—Equipment is recorded at cost, less accumulated depreciation. Depreciation on equipment is computed using primarily the straight-line method over the estimated useful lives of the assets (generally three to five years for computers, and seven to ten years for equipment and office furniture).

CTD HOLDINGS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

JUNE 30, 2018

(g) **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 our revenue recognition as the majority of our revenues continue to be recognized when the customer takes control of our product. As we did not identify any accounting changes that impacted the amount of reported revenues with respect to our 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 6, Revenues, to these condensed consolidated financial statements.

CTD HOLDINGS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

JUNE 30, 2018

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

(i) **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.

(j) **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 44,580,478 and 15,085,787 common shares were antidilutive for the three and six months ended June 30, 2018 and 2017, respectively, and have been excluded from the calculation of loss per common share.

(k) **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.

(l) **LIQUIDITY AND GOING CONCERN**—For the three and six months ended June 30, 2018, the Company incurred net losses of \$1,289,229 and \$2,102,173 respectively. The Company has an accumulated deficit of \$15,434,840 at June 30, 2018. Our recent losses have predominantly resulted from research and development expenses for our Trappsol® Cyclo™ product and other general operating expenses, including board advisory fees. We believe our expenses will continue to increase as we conduct clinical trials and continue to seek regulatory approval for the use of Trappsol® Cyclo™ in the treatment of NPC.

For year ended December 31, 2017, our operations used approximately \$3,062,000 in cash. This cash was provided primarily by cash on hand and net proceeds of \$3,341,000 from equity issuances. At December 31, 2017, the Company had a cash balance of approximately \$1,271,000 and current assets less current liabilities of \$953,000. At June 30, 2018, the Company had a cash balance of approximately \$1,541,000 and its current assets less current liabilities were \$832,000. In April 2018, the Company generated additional net proceeds of \$1,960,000, including the \$74,983 received in March 2018, from the sale of equity securities in a private placement. 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.

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.

We have incurred losses from operations in each of our last four 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.

CTD HOLDINGS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

JUNE 30, 2018

(m) **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, including contingencies. 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.

(n) **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, 2018 or December 31, 2017. Long-lived assets are measured at fair value on a non-recurring basis and are subject to fair value adjustments when there is evidence of impairment.

For short-term classes of our financial instruments which 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, 2018 and December 31, 2017, the carrying value of the mortgage note receivable approximates fair value.

(2) 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.

(3) EQUITY TRANSACTIONS:

The Company expensed \$13,760 and \$27,950 in employee and board member stock compensation for the three and six months ended June 30, 2018, respectively. The Company expensed \$63,640 and \$85,140 in employee and board member stock compensation for the three and six months ended June 30, 2017, respectively. The Company accrues stock compensation expense over the period earned for employees and board members.

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 Equities, LLC ("Scarsdale") acted as financial advisor to the Company in connection with the private placement and was paid a cash fee of \$50,000. We have an agreement with Scarsdale to act as our financial advisor and exclusive placement agent for which we pay a fee for investors identified by Scarsdale. N. Scott Fine, a director of the Company, was a principal of Scarsdale at the time we initially retained Scarsdale as our financial advisor, and his son is currently employed by Scarsdale, is active on our account and serves as our secretary.

In October 2017, the Company completed a private placement of 15,500 Units at a purchase price of \$100 per Unit, each Unit consisting of one share of Series B Preferred Stock, and seven-year warrants to purchase 400 shares of Common Stock at an exercise price of \$0.25 per share. Scarsdale acted as financial advisor to the Company in connection with the private placement and was paid a cash fee of \$60,000, and it and its designees were issued seven-year warrants to purchase 600 Units at an exercise price of \$100 per Unit.

CTD HOLDINGS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

JUNE 30, 2018

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 its common stock, and a seven-year warrant to purchase an additional share of common stock at an exercise price of \$0.35, for aggregate gross proceeds to the Company of \$2 million. Scarsdale Equities LLC 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.

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

As of June 30, 2018, the Company had warrants outstanding to purchase 30,440,478 shares of common stock at exercise prices of \$0.25 - \$1.00 per share that expire in various years until 2025. In addition, at June 30, 2018, there are warrants outstanding to purchase 480,000 Units sold in the Company’s May 2016 private placement at an exercise price of \$0.25 per Unit, 164,074 Units sold in the Company’s February 2017 private placement at an exercise price of \$0.35 per Unit, and 600 Units sold in the Company’s October 2017 private placement at an exercise price of \$100 per Unit.

(4) INCOME TAXES:

The Company reported a net loss for the three and six months ended June 30, 2018 and 2017, respectively. The Company increased its deferred tax asset valuation allowance rather than recognize an income tax benefit.

(5) SALES CONCENTRATIONS:

Sales to five major customers accounted for 81% of total sales for the six months ended June 30, 2018. Sales to two major customers accounted for 66% of total sales for the six months ended June 30, 2017. A loss of one of these customers could have a significant adverse effect on the Company's financial condition, results of operations and cash flows.

(6) 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(g) – Revenue Recognition for additional discussion.

Revenues by product are summarized as follows:

	Six Months Ended	
	June 30,	
	2018	2017
Trappsol Cyclo	\$166,596	\$314,181
Trappsol HPB	179,763	421,735
Trappsol research	117,402	70,053
Aquaplex	78,595	17,384
Other	5,128	4,789
Total revenues	\$547,484	\$828,142

Substantially all of our sales of Trappsol® Cyclo™ for the three and six months ended June 30, 2018 and June 30, 2017 were to a particular customer who exports the drug to South America. Substantially all of our Aquaplex sales are to one customer.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis provides information to explain our results of operations and financial condition. You should also read our unaudited consolidated interim financial statements and their notes included in this Form 10-Q, and our audited consolidated financial statements and their notes and other information included in our Annual Report on Form 10-K for the year ended December 31, 2017. This report may contain forward-looking statements. Forward-looking statements within this Form 10-Q are identified by words such as “believes,” “anticipates,” “expects,” “intends,” “may,” “will” “plans” and other similar expressions; however, these words are not the exclusive means of identifying such statements. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances are forward-looking statements. These forward-looking statements are subject to significant risks, uncertainties and other factors, which may cause actual results to differ materially from those expressed in, or implied by, these forward-looking statements. Except as expressly required by the federal securities laws, we undertake no obligation to publicly update or revise any forward-looking statements to reflect events, circumstances or developments occurring subsequent to the filing of this Form 10-Q with the U.S. Securities and Exchange Commission (the “SEC”) or for any other reason and you should not place undue reliance on these forward-looking statements. You should carefully review and consider the various disclosures the Company makes in this report and our other reports filed with the SEC that attempt to advise interested parties of the risks, uncertainties and other factors that may affect our business. All amounts presented herein are rounded to nearest \$1,000.

Overview

CTD Holdings, Inc. (“we” “our” “us” or “the Company”) was organized as a Florida corporation on August 9, 1990, with operations beginning in July 1992. In conjunction with a restructuring in 2000, we changed our name from Cyclodextrin Technologies Development, Inc., or CTDI, to CTD Holdings, Inc.; CTDI was then incorporated as a Florida corporation and became a wholly owned subsidiary of CTD Holdings, Inc.

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

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

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

We have also recently begun to explore the use of cyclodextrins in the treatment of Alzheimer's disease, and in January 2018, the FDA authorized a single patient IND expanded access program using Trappsol® Cyclo™ for the treatment of this disease.

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

Substantially all of our revenues are derived from the sale of cyclodextrins, including bio-pharmaceuticals containing cyclodextrins, cyclodextrin complexes, resale of cyclodextrins manufactured by others for our clients to their specifications, and our own licensed cyclodextrin products. We have trademarked certain products under our Trappsol®, Aquaplex®, and AP™-Flavor product lines. We currently sell our products directly to customers in the diagnostics, pharmaceutical, and industrial chemical industries, and to chemical supply distributors.

Trappsol® Cyclo™

At the end of 2008, we provided Trappsol® Cyclo™ to a customer for compassionate use as an Investigational New Drug to treat a set of twins in the U.S. who were diagnosed with NPC, also known as Childhood Alzheimer's. NPC is a fatal disease caused by a genetic defect that prevents proper handling of cholesterol in the body's cells. The patient's treatment with our Trappsol® Cyclo™ product proved to provide an ameliorative benefit. On May 17, 2010, the FDA granted orphan drug status to our customer for Trappsol® Cyclo™ for the treatment of NPC. To date, Trappsol® Cyclo™ has been administered to approximately 20 NPC patients in compassionate use programs around the world, including in the U.S., Brazil, and Spain. Our annual sales of Trappsol® Cyclo™ decreased to \$342,000 for 2017 from \$697,000 for 2016. Sales of Trappsol® Cyclo™ were \$167,000 and \$314,000 for the six months ended June 30, 2018 and 2017, respectively. In 2012, we began to offer 100ml vials of Trappsol® Cyclo™ in a liquid form from a contract manufacturer. In 2014, we completed validation of the Trappsol® Cyclo™ manufacturing process and submitted a Type II Drug Master File to the FDA. In 2015 we established an International Clinical Program that includes a team of experienced drug development companies and individuals. We have also obtained Orphan Drug Designation for Trappsol® Cyclo™ in both the U.S. and Europe.

Resale of Cyclodextrin and Cyclodextrin Complexes

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

We acquire our products principally from outside the United States, including from Wacker Biosolutions, a division of Wacker Chemie AG (Germany), with a production facility located in Adrian, Michigan and Hangzhou Pharma and Chem Co. (China), Quian Hui (China), and Cyclodextrin Research & Development Laboratory (Hungary), but are

gradually finding satisfactory supply sources in the United States. While we enjoy lower supply prices from outside the United States, changes in shipping costs and currency exchange rates are making domestic sources more competitively priced. We make patent information about cyclodextrins available to our customers. We also offer our customers our knowledge of the properties and potential new uses of cyclodextrins and complexes.

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

Liquidity and Capital Resources

Our cash increased to \$1,541,030 as of June 30, 2018, compared to \$1,270,973 as of December 31, 2017. Our current assets less current liabilities were \$832,000 as of June 30, 2018, compared to \$953,000 at December 31, 2017. We used \$1,706,000 in operations for the six months ended June 30, 2018, compared to \$1,498,000 for the same period in 2017.

In April 2018, we generated additional net proceeds of \$1,960,000 from the sale of our equity securities in a private placement.

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

We will need to raise additional capital to support our ongoing operations and continue our clinical trials. While we presently lack sufficient cash to meet our anticipated operating costs and capital expenditure requirements through August 2019, we expect to continue to raise additional capital through the sale of our securities from time to time for the foreseeable future to fund the development of our drug product candidates through clinical development, manufacturing and commercialization. Our ability to obtain such additional capital will likely be subject to various factors, including our overall business performance and market conditions. Our need for additional capital as described above raises substantial doubt about our ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of these uncertainties.

We have no off-balance sheet arrangements at June 30, 2018.

Results of Operations - Three and Six Months Ended June 30, 2018 Compared to Three and Six Months Ended June 30, 2017

We reported a net loss of \$(1,289,000) and \$(2,102,000) for the three and six months ended June 30, 2018, respectively, compared to a net loss of \$(828,000) and \$(1,815,000) for the three and six months ended June 30, 2017, respectively.

Total revenues for the three month period ended June 30, 2018 decreased 33% to \$349,000 compared to \$523,000 for the same period in 2017. Total revenues for the six month period ended June 30, 2018 decreased 34% to \$547,000 compared to \$828,000 for the same period in 2017.

Our change in the mix of our product sales for the three and six months ended June 30, 2018 and 2017 is as follows:

Trappsol® Cyclo

Our sales of Trappsol® Cyclo™ decreased by 47% for the three month period ended June 30, 2018, to \$152,000 from \$287,000 for the three month period ended June 30, 2017. Our sales of Trappsol® Cyclo™ decreased by 47% for the six month period ended June 30, 2018, to \$167,000 from \$314,000 for the six month period ended June 30, 2017. Our sales to a particular customer who exports Trappsol® Cyclo™ to South America were \$152,000 (100% of total sales of Trappsol® Cyclo™) for the three months ended June 30, 2018, compared to \$287,000 (100% of total sales of Trappsol® Cyclo™) for the three months ended June 30, 2017; and our sales to that same customer were \$167,000 (100% of total sales of Trappsol® Cyclo™) for the six month period ended June 30, 2018, compared to \$287,000 (91% of total sales of Trappsol® Cyclo™) for the six month period ended June 30, 2017. Our annual 2017 sales to this customer were \$287,000 (84% of total 2017 sales of Trappsol® Cyclo™). This product is designated as an orphan drug; the population of patients is small and while we expect our future sales to increase, the timing of sales will be unpredictable and our ability to market the drug for use other than research is severely constrained by regulatory restrictions in the applicable jurisdictions.

Trappsol® HPB

Our sales of Trappsol® HPB decreased by 42% for the three month period ended June 30, 2018, to \$105,000 from \$182,000 for the three months ended June 30, 2017. Our sales of Trappsol® HPB decreased by 57% for the six month period ended June 30, 2018, to \$180,000 from \$422,000 for the six month period ended June 30, 2017.

Trappsol® other products

Our sales of other Trappsol® products increased by 10% for the three month period ended June 30, 2018, to \$56,000 from \$51,000 for the three month period ended June 30, 2017. Our sales of other Trappsol® products increased by 67% for the six month period ended June 30, 2018, to \$117,000 from \$70,000 for the six month period ended June 30, 2017.

Aquaplex®

Our sales of Aquaplex® for the three month period ended June 30, 2018 were \$49,000 compared to negligible sales for the three month period ended June 30, 2017. Our sales of Aquaplex® were \$79,000 for the six month period ended June 30, 2018 compared to \$17,000 for the six month period ended June 30, 2017.

Our largest customers 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, 2018, our five largest customers accounted for 81% of our sales; the largest accounted for 31% of sales. During the six months ended June 30, 2017, our two largest customers accounted for 66% of our sales; the largest accounted for 34% 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) as a percentage of sales for the six month period ended June 30, 2018 was 14% (\$78,000) compared to 12% (\$98,000) for the same period in 2017. Our cost of products sold (excluding any allocation of direct and indirect overhead and handling costs) as a percentage of sales was 15% (\$54,000) for the three months ended June 30, 2018 compared to 15% (\$79,000) for the same period in 2017. 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 2017 or the first six months of 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 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. We have four employees who provide receiving, inspection, warehousing and shipping operations for us. The cost of these employees, and our other employees, are included in personnel expense. Our other costs of warehousing and shipping functions are included in office and other expense.

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

Personnel expenses decreased 6% to \$288,000 for the three months ended June 30, 2018 from \$305,000 for the three months ended June 30, 2017. Personnel expenses decreased 12% to \$565,000 for the six months ended June 30, 2018 from \$639,000 for the six months ended June 30, 2017. The decrease in personnel expense is due to a decrease in the number of employees and related benefits. We expect to maintain our level of employees and related costs in the near term.

Research and development expenses increased to \$844,000 for the three months ended June 30, 2018, from \$527,000 for the three months ended June 30, 2017. Research and development expenses increased to \$1,254,000 for the six months ended June 30, 2018, from \$1,171,000 for the six months ended June 30, 2017. Research and development expenses as a percentage of our total operating expenses increased to 48% for the six months ended June 30, 2018 from 44% for the six months ended June 30, 2017. 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.

Professional fees decreased 2% to \$297,000 for the three months ended June 30, 2018, compared to \$302,000 for the three months ended June 30, 2017. Professional fees increased 25% to \$531,000 for the six months ended June 30, 2018, compared to \$426,000 for the six months ended June 30, 2017. The increase from 2017 is due to our lawsuit against the National Institute of Health and legal expenses incurred in connection with our intellectual property. Professional fees may further increase due to new initiatives in raising capital and the continuation of product development.

Office and other expenses increased 36% to \$128,000 for the three months ended June 30, 2018 compared to \$94,000 for the three months ended June 30, 2017. Office and other expenses decreased 22% to \$176,000 for the six months ended June 30, 2018 compared to \$227,000 for the six months ended June 30, 2017. 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 \$27,000 for the three months ended June 30, 2018, compared to \$40,000 for the three months ended June 30, 2017. Board of Directors fee and costs decreased to \$43,000 for the six months ended June 30, 2018, compared to \$77,000 for the six months ended June 30, 2017. Board of Directors fees and costs include fees paid to our non-employee directors and scientific advisory board members, reimbursement of expenses of our board members, and related expenses.

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 three and six months ended June 30, 2018, and 2017, respectively.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Not applicable.

Item 4. Controls and Procedures.

a. Evaluation of Disclosure Controls and Procedures.

Our management, with the participation of our principal executive and principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) as of the end of the period covered by this quarterly report (the "Evaluation Date"). Based on such evaluation, our principal executive and principal financial officer has concluded that, as of the Evaluation Date, our disclosure controls and procedures are effective.

b. Changes in Internal Control.

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

PART II. OTHER INFORMATION**Item 1A. Risk Factors.**

We have identified no additional risk factors other than those included in Part I, Item 1A of our Form 10-K for the fiscal year ended December 31, 2017. Readers are urged to carefully review our risk factors because they may cause our results to differ from the "forward-looking" statements made in this report. Additional risks not presently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business, financial condition and results of operations. We do not undertake to update any of the "forward-looking" statements or to announce the results of any revisions to these "forward-looking" statements except as required by law.

Item 6. Exhibits.**EXHIBIT NO. DESCRIPTION**

3.1	<u>Amended and Restated Articles of Incorporation filed June 29, 2018</u>
31.1	<u>Rule 13a-14(a)/15d-14a(a) Certifications</u>
32.1	<u>Section 1350 Certifications</u>
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

SIGNATURES

Pursuant to the requirements of the Exchange Act, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

CTD HOLDINGS, INC.

Date: August 14, 2018 By: */s/ N. Scott Fine*
N. Scott Fine
Chief Executive Officer
(principal executive, financial and accounting officer)