

CTD HOLDINGS INC
Form 10-Q
November 10, 2016

**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: September 30, 2016

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 incorporation or organization)	(IRS Employer Identification No.)

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14120 N.W. 126th Terrace, Alachua, Florida 32615
(Address of principal executive offices) (Zip Code)

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

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, or a smaller reporting company. See the definitions of 'large accelerated filer,' 'accelerated filer,' and 'smaller reporting company' in Rule 12b-2 of the Exchange Act.

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

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

Yes No

As of November 10, 2016, the Company had outstanding 66,952,529 shares of its common stock.

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

	September 30, 2016 (Unaudited)	December 31, 2015
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$1,270,046	\$1,842,233
Accounts receivable, net	124,234	55,636
Inventory	595,366	610,166
Current portion of mortgage note receivable	27,228	-
Other current assets	1,678	14,851
Total current assets	2,018,552	2,522,886
 PROPERTY AND EQUIPMENT, NET	 33,691	 1,892,943
 OTHER ASSETS		
Property held for sale	963,115	275,000
Mortgage note receivable, less current portion	218,569	-
Total other assets	1,181,684	275,000
 TOTAL ASSETS	 \$3,233,927	 \$4,690,829
 LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued expenses	\$267,716	\$257,537
Notes payable	608,232	653,313
Line of credit	-	34,296
Total current liabilities	875,948	945,146
 STOCKHOLDERS' EQUITY		
Common stock, par value \$.0001 per share, 100,000,000 shares authorized, 66,952,529 and 58,670,347 shares issued and outstanding, respectively	6,695	5,867
Preferred stock, par value \$.0001 per share, 5,000,000 shares authorized, no shares issued or outstanding	-	-

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Additional paid-in capital	11,018,915	9,015,582
Accumulated deficit	(8,667,631)	(5,275,766)
Total stockholders' equity	2,357,979	3,745,683
 TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	 \$3,233,927	 \$ 4,690,829

See accompanying Notes to Consolidated Financial Statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
REVENUES				
Product sales	\$278,196	\$234,660	\$975,267	\$788,198
EXPENSES				
Personnel	327,858	222,922	1,010,296	551,194
Cost of products sold (exclusive of amortization and depreciation, shown separately below)	30,893	25,219	123,896	105,091
Research and development	311,351	221,362	1,254,900	399,427
Repairs and maintenance	3,334	7,144	19,073	23,693
Professional fees	175,616	101,097	454,646	324,005
Office and other	171,425	85,005	478,740	212,792
Board of Director fees and costs	53,195	140,068	99,576	391,857
Amortization and depreciation	3,789	44,426	92,146	124,990
Freight and shipping	1,465	2,599	5,257	5,929
Loss (gain) on disposal of property and equipment	-	-	4,489	(700)
Impairment on assets held for sale	810,000	125,000	810,000	125,000
	1,888,926	974,842	4,353,019	2,263,278
LOSS FROM OPERATIONS	(1,610,730)	(740,182)	(3,377,752)	(1,475,080)
OTHER INCOME (EXPENSE)				
Investment and other income	2,766	375	7,609	2,615
Interest expense	(6,969)	(7,749)	(21,722)	(23,527)
	(4,203)	(7,374)	(14,113)	(20,912)
LOSS BEFORE INCOME TAXES	(1,614,933)	(747,556)	(3,391,865)	(1,495,992)
Provision for income taxes	-	-	-	-
NET LOSS	\$(1,614,933)	\$(747,556)	\$(3,391,865)	\$(1,495,992)
BASIC AND FULLY DILUTED NET LOSS PER COMMON SHARE	\$(.02)	\$(.01)	\$(.05)	\$(.03)
	66,889,822	57,262,835	62,121,283	55,390,366

WEIGHTED AVERAGE NUMBER OF COMMON
SHARES OUTSTANDING

See Accompanying Notes to Consolidated Financial Statements.

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

	Nine Months Ended September 30,	
	2016	2015
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	\$(3,391,865)	\$(1,495,992)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	92,146	124,990
Loss (gain) on sale of property and equipment	4,489	(700)
Impairment on assets held for sale	810,000	125,000
Stock compensation to employees	57,114	-
Stock compensation to non-employees	44,106	-
Increase or decrease in:		
Accounts receivable	(68,598)	(33,279)
Inventory	19,758	(63,941)
Other current assets	13,173	(8,183)
Accounts payable and accrued expenses	33,120	185,541
Total adjustments	1,005,308	329,428
NET CASH USED IN OPERATING ACTIVITIES	(2,386,557)	(1,166,564)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of equipment and building improvements	(9,343)	(337,884)
Proceeds from mortgage note receivable	19,203	-
Proceeds from sale of property and equipment, net of closing costs	5,510	700
NET CASH PROVIDED BY (USED IN) INVESTING ACTIVITIES	15,370	(337,184)
CASH FLOWS FROM FINANCING ACTIVITIES		
Principal payments on notes payable	(46,704)	(44,484)
Payments on line of credit	(34,296)	-
Net proceeds from sale of common stock and warrants	1,880,000	1,910,595
NET CASH PROVIDED BY FINANCING ACTIVITIES	1,799,000	1,866,111
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(572,187)	362,363
CASH AND CASH EQUIVALENTS, beginning of period	1,842,233	2,380,054
CASH AND CASH EQUIVALENTS, end of period	\$1,270,046	\$2,742,417

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SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION

Cash paid for interest	\$21,722	\$23,527
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Cash paid for income taxes	\$-	\$-
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SUPPLEMENTAL DISCLOSURE OF NONCASH INVESTING AND FINANCING

Exchange of property held for sale for a mortgage note receivable	\$265,000	\$-
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See Accompanying Notes to Consolidated Financial Statements.

CTD HOLDINGS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

SEPTEMBER 30, 2016

The information presented herein as of September 30, 2016 and for the three and nine months ended September 30, 2016 and 2015 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 (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”), and recently filed an Investigational New Drug application (IND) with the FDA which describes our Phase I clinical plans in the US. The Company has also filed a Clinical Trial Application with the United Kingdom's Medicines and Healthcare Products Regulatory Agency, and launched an International Clinical Program for Trappsol® Cyclo™.

While 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, 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 nine-month periods ended September 30, 2016 are not necessarily indicative of the results that may be expected for the year ending December 31, 2016. 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, 2015, as filed with the Securities and Exchange Commission on March 30, 2016.

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

(d) ACCOUNTS RECEIVABLE—Accounts receivable are unsecured and non-interest bearing and stated at the amount we expect to collect from outstanding balances. Based on our assessment of the credit history with customers having outstanding balances and current relationships with them, we have concluded that losses on balances outstanding at September 30, 2016 and December 31, 2015 will be immaterial.

(e) INVENTORY AND COST OF PRODUCTS SOLD—Inventory consists of our pharmaceutical drug Trappsol® Cyclo™, cyclodextrin products and chemical complexes purchased for resale recorded at the lower of cost (first-in, first-out) or net realizable. 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.

CTD HOLDINGS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

SEPTEMBER 30, 2016

(f) **PROPERTY AND EQUIPMENT**—Property and equipment are recorded at cost. Depreciation on property and equipment is computed using primarily the straight-line method over the estimated useful lives of the assets (generally three to five years for computers and vehicles, seven to ten years for machinery and furniture, fifteen years for certain land improvements, and forty years for buildings and building improvements). We periodically review our long-lived assets to determine if the carrying value of assets may not be recoverable. If an impairment is identified, we recognize a loss for the difference between the carrying amount and the estimated fair value of the asset (see Note 2).

(g) **REVENUE RECOGNITION**—We recognize revenue from product sales, royalties, and drying services rendered when the following four revenue recognition criteria are met: persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the selling price is fixed or determinable, and collectability is reasonably assured. Product sales and shipping revenues, net of any discounts or return allowances, are recorded when the products are shipped and title passes to customers. Sales to customers are made pursuant to a sales contract that provides for transfer of both title and risk of loss upon our delivery to the carrier. Return allowances, which reduce product revenue, have been historically infrequent, and are recorded when they become known. Amounts received in advance are deferred and recognized as revenue when all four revenue recognition criteria have been met. There is no deferred revenue at September 30, 2016 and December 31, 2015.

(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 9,057,500 and 577,500 common shares were antidilutive for the three and nine months ended September 30, 2016 and

2015, 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) CONCENTRATIONS OF CREDIT RISK—Significant concentrations of credit risk for all financial instruments owned by the Company are as follows:

(i) DEMAND AND CERTIFICATE OF 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.

(ii) ACCOUNTS RECEIVABLE—Our accounts receivable consist of amounts due primarily from chemical supply and pharmaceutical companies located primarily in the United States. Three customers accounted for 94% of the accounts receivable balance at September 30, 2016. Five customers accounted for 89% of the accounts receivable balance at December 31, 2015. We have no policy requiring collateral or other security to support our accounts receivable.

CTD HOLDINGS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

SEPTEMBER 30, 2016

(m) **LIQUIDITY**—For the year ended December 31, 2015, the Company incurred a net loss of approximately \$2,551,000 and used net cash in operations in the amount of approximately \$1,989,000. For the nine months ended September 30, 2016, the Company incurred a net loss of \$3,391,865, used net cash in operations in the amount of \$2,386,557, and received net proceeds of \$1,880,000 from the sale of its securities. At September 30, 2016, the Company had a cash balance of \$1,270,046, current assets of \$2,018,552 and current liabilities of \$875,948. The Company seeks to raise capital from time to time through the sale of its common stock and other securities. In the event that the Company cannot raise sufficient capital when required, management may have to reduce expenditures related to its operations.

(n) **USE OF ESTIMATES**—The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Although management bases its estimates on historical experience and assumptions that are believed to be reasonable under the circumstances, actual results could significantly differ from these estimates.

(o) **NEW ACCOUNTING PRONOUNCEMENTS**—The Financial Accounting Standards Board (FASB) has issued various Accounting Standards Updates (ASUs), including ASU 2014-09, Revenue from Contracts with Customers, as subsequently amended; ASU 2014-15, Presentation of Financial Statements-Going Concern; ASU 2015-17, Income Taxes; and ASU 2016-02, Leases, which are effective in future fiscal years. We do not expect the adoption of these standards to have a material effect on our financial position or results of operations. The Company adopted ASU 2015-03, Interest-Imputation of Interest (Simplifying the Presentation of Debt Issuance Costs), and reclassified net deferred financing costs of \$64,801 from noncurrent assets as a reduction of the associated notes payable balance as of September 30, 2016. This change reduced noncurrent assets and liabilities by \$64,801. There was no change in the net loss for the periods presented as a result of this reclassification. The Company also reclassified certain items on the December 31, 2015 balance sheet to be consistent with the current presentation.

(2) ASSETS HELD FOR SALE

The Company has offered for sale its office and manufacturing facility in Alachua, Florida, which includes its pulse dryer. Accordingly, these assets have been reclassified as assets held for sale in the accompanying balance sheet as of September 30, 2016. As a result, an impairment loss of \$810,000 has been identified and recognized in the three and

nine months ended September 30, 2016. The impairment loss is equal to the difference between the former carrying amount and the current estimated market value of \$963,000 for these assets. For the three and nine months ended September 30, 2015, the Company determined the fair value of its High Springs property was less than its carrying value and therefore recorded an impairment loss of \$125,000 to adjust the carrying value to \$275,000. The High Springs property was sold in January 2016 (see Note 3 below).

(3) MORTGAGE NOTE RECEIVABLE

On January 21, 2016, the Company sold its real property located in High Springs, Florida to an unrelated party. This property was previously classified on our balance sheet as property held for sale, with a carrying value of \$275,000. Pursuant to the terms of the sale, at the closing, the buyer paid \$10,000 in cash, less selling costs and settlement charges, and delivered to the Company a promissory note in the principal amount of \$265,000, and a mortgage in our favor securing the buyer's obligations under the promissory note. The promissory note provides for monthly payments of \$3,653, including principal and interest at 4.25%, over a seven-year period commencing March 1, 2016, with the unpaid balance due in February 2023. Scheduled debt principal collections on this mortgage for the next five years and thereafter are as follows:

Year Ending	
December 31, Principal	
2016	\$46,431
2017	34,393
2018	35,884
2019	37,439
2020	39,061
Thereafter	71,792
	\$265,000

CTD HOLDINGS, INC.**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****SEPTEMBER 30, 2016****(4) FAIR VALUES OF FINANCIAL INVESTMENTS**

The carrying amounts of cash and cash equivalents, accounts receivable, accounts payable and accrued expenses approximate fair value because of the short maturity of those instruments. The Company accounts for the fair value of financial investments in accordance with FASB ASC No. 820 “Fair Value Measurements” (ASC No. 820). ASC No. 820 defines fair value as the price that would be received upon the sale of an asset or paid to transfer a liability (i.e. exit price) in an orderly transaction between market participants at the measurement date. ASC No. 820 requires disclosures that categorize assets and liabilities measured at fair value into one of three different levels depending on the assumptions (i.e. inputs) used in the valuation. Financial assets and liabilities are classified in their entirety based on the lowest level of input significant to the fair value measurement. The ASC No. 820 fair value hierarchy is defined as follows:

Level 1—Valuations are based on unadjusted quoted prices in active markets for identical assets or liabilities.

Level 2—Valuations are based on quoted prices for similar assets or liabilities in active markets, or quoted prices in markets that are not active for which significant inputs are observable, either directly or indirectly.

Level 3—Valuations are based on prices or valuation techniques that require inputs that are both unobservable and significant to the overall fair value measurement. Inputs reflect management’s best estimate of what market participants would use in valuing the asset or liability at the measurement date.

The following table represents the Company’s financial assets and liabilities which are carried at fair value at September 30, 2016.

	Level 1	Level 2	Level 3
Non-recurring fair value instrument	\$ -	\$ -	\$245,797

The level 3 non-recurring fair value investment represents a mortgage note receivable (see Note 2). The carrying amount of the mortgage note receivable approximates fair value because the stated interest rate approximates current market interest rates.

(5) DEBT

The Company owed \$500,667 and \$516,685, at September 30, 2016 and December 31, 2015, respectively, on a mortgage note payable, collateralized by land and a building acquired in September 2010. Monthly payments of \$3,506, including principal and interest at 3.99%, are due, with a final balloon payment of approximately \$350,000 due in July 2023. The note is secured by a mortgage on the Company's Alachua property. The note has a voluntary prepayment penalty which was 2% of the principal repaid as of the date of this filing in the event of a refinancing, and which decreases 1% on July 17 of each year. The Company was not in compliance with a debt coverage ratio covenant for the year ended December 31, 2015. As a result, the principal due in 2016 and beyond one year has been reclassified as current in the accompanying balance sheet.

The Company also owed this lender \$172,366 and \$203,052 at September 30, 2016 and December 31, 2015, respectively, under an equipment loan related to the installation of a pulse dryer and related building renovations. Monthly payments of \$4,051, including principal and interest at 3.99%, are due through and including July 2020. The note is collateralized by all of the Company's equipment. There is a prepayment penalty of 2% of the outstanding balance if the Company voluntarily repays the loan prior to July 17, 2018. Principal due under this loan has also been reclassified as current in the accompanying balance sheet due to the Company's non-compliance with the loan covenant referred to above.

Notes payable has been reduced by capitalized deferred financing costs of \$64,801 and \$66,424 at September 30, 2016 and December 31, 2015, respectively.

Scheduled debt obligations on both loans for the next five years and thereafter are as follows, assuming the bank does not call the loans due to the debt covenant non-compliance:

Year Ending December 31,	
2016	\$62,411
2017	64,982
2018	67,658
2019	67,709
2020	24,940
Thereafter	385,333
	\$673,033

CTD HOLDINGS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

SEPTEMBER 30, 2016

(6) EQUITY TRANSACTIONS:

The Company expensed \$30,460 and \$101,220 in stock compensation for the three and nine months ended September 30, 2016. The Company did not have any stock compensation expense for the three and nine months ended September 30, 2015. The Company accrues stock compensation expense over the period earned for employees and board members. The Company issued 264,000 shares of common stock due to an employee and board member on July 22, 2016.

On January 21, 2015, the Company awarded 35,000 shares of common stock to a consultant for past services. The Company accrued and expensed \$16,520 for this award in 2014.

On July 10, 2015, the Company entered into a Securities Purchase Agreement under which it issued 2.6 million shares of its common stock in a private placement, at a purchase price of \$0.50 per share, for aggregate gross proceeds to the Company of \$1.3 million. Scarsdale Equities LLC ("Scarsdale") acted as financial advisor to the Company in connection with the private placement and was paid a cash fee in an amount equal to 6% of the gross proceeds of the private placement and it and its designees were issued seven-year warrants to purchase 156,000 shares of common stock at an exercise price of \$0.50 per share.

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

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

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

As of September 30, 2016, the Company had warrants outstanding to purchase 8,577,500 shares of common stock at exercise prices of \$0.25 - \$1.00 per share that expire in years 2021 through 2023. The Company also had warrants outstanding to purchase 480,000 Units, which expire in 2023. Each Unit consists of one share of its common stock, and a seven-year warrant to purchase an additional share of common stock at an exercise price of \$0.25

(7) INCOME TAXES:

The Company reported a net loss for the three and nine months ended September 30, 2016 and 2015, respectively. The Company increased its deferred tax asset valuation allowance rather than recognize an income tax benefit.

(8) SALES CONCENTRATIONS:

Sales to two major customers accounted for 52% of total sales for the nine months ended September 30, 2016. Sales to one major customer accounted for 34% of total sales for the nine months ended September 30, 2015. 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.

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, 2015. 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.

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 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”), and recently filed an Investigational New Drug application (“IND”) with the FDA which describes our Phase I clinical plans for a randomized, double blind, parallel group study at a single clinical site in the US. We have also filed a Clinical Trial Application with the United Kingdom's Medicines and Healthcare Products Regulatory Agency, and launched an International Clinical Program for Trappsol® Cyclo™.

While 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, 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. On August 5, 2016, we listed for sale our real property (which includes our pulse dryer) located in Alachua, Florida. In the event we are able to complete the sale of this property, we expect to repay our secured loans. Although we expect to continue to operate our cyclodextrin distribution business following such sale, our strategy going forward is to focus on biopharmaceutical opportunities in healthcare where we believe cyclodextrin applications have maximum value.

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 \$352,000 for 2015 from \$901,000 for 2014. Sales of Trappsol® Cyclo™ were \$21,000 and \$401,000 for the three and nine months ended September 30, 2016, 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.

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

Resale of Cyclodextrin and Cyclodextrin Complexes

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

We acquire our products principally from outside the United States, including from Wacker Biosolutions, a division of Wacker Chemie AG (Germany), with a production facility located in Adrian, Michigan and Hangzhou Pharma and Chem Co. (China), Quian Hui (China), and Cyclodextrin Research & Development Laboratory (Hungary), but are gradually finding satisfactory supply sources in the United States. We make patent information about cyclodextrins available to our customers. We also offer our customers our knowledge of the properties and potential new uses of cyclodextrins and complexes.

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

Liquidity and Capital Resources

Our cash decreased to \$1,270,000 as of September 30, 2016, compared to \$1,842,000 as of December 31, 2015. Our current assets and current liabilities were \$2,018,552 and \$875,948, respectively, as of September 30, 2016, compared to current assets of \$2,522,886 and current liabilities of \$945,146 at December 31, 2015. All of our term debt is classified as current at both September 30, 2016 and December 31, 2015 due to our non-compliance with a loan covenant as described below. We owed \$500,667 at September 30, 2016 on a secured mortgage note and \$172,366 under an equipment loan, with a bank that has a debt service covenant. We are not in compliance with this debt service coverage covenant. If we are unable to have the debt covenant modified, or we are unable to refinance the indebtedness, we may be required to use our cash on hand to repay the indebtedness, which will have a material adverse effect on our financial condition by diverting cash intended for use in our development of a clinical trial program or for other business development efforts.

On August 5, 2016, the Company listed for sale its real property located in Alachua, Florida. In the event we are able to complete the sale of this property on terms acceptable to us, we expect to repay our secured loans in full.

The Company presently believes that it will require additional cash to meet its anticipated operating costs and capital expenditure requirements for the next twelve months, including, without limitation, to commence and continue its approved U.S. and U.K. clinical trials. To date, the Company has been able to generate sufficient cash to fund its drug development activities from private offerings of its equity securities, together with cash generated from operations and asset sales. While we expect to continue to be successful in obtaining additional funds to meet our cash requirements, no assurance can be given that adequate additional funding will be available to us on acceptable terms, if at all. Additional capital will also be required in the future to develop 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 the results of our clinical trials, our progress in obtaining regulatory approval for our drug candidates and market conditions.

On January 21, 2016, we closed on the sale of our real property located in High Springs, Florida, which had been previously classified on our balance sheet as property held for sale, with a carrying value of \$275,000. Pursuant to the terms of the sale, at the closing, the buyer paid us \$10,000 in cash, less selling costs and settlement charges, and we received 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 commencing March 1, 2016.

We plan to use our available cash primarily for the development of our Trappsol® Cyclo™ orphan drug product, including implementation of our U.S. and international clinical trials and designs, and other general corporate purposes.

We have no off-balance sheet arrangements at September 30, 2016.

Results of Operations - Three and Nine Months Ended September 30, 2016 Compared to Three and Nine Months Ended September 30, 2015

We reported a net loss of \$(1,615,000) and \$(3,392,000) for the three and nine months ended September 30, 2016, respectively, compared to a net loss of \$(748,000) and \$(1,496,000) for the three and nine months ended September 30, 2015, respectively.

Total revenues for the three-month period ended September 30, 2016 increased 18% to \$278,000 compared to \$235,000 for the same period in 2015. Total revenues for the nine-month period ended September 30, 2016 increased 24% to \$975,000 compared to \$788,000 for the same period in 2015.

Our change in the mix of our product sales for the three and nine months ended September 30, 2016 and 2015 is as follows:

Trappsol® Cyclo

Our sales of Trappsol® Cyclo™ increased 11% for the three-month period ended September 30, 2016, to \$21,000, from \$19,000 for the three-month period ended September 30, 2015. Our sales of Trappsol® Cyclo™ increased by 22% for the nine-month period ended September 30, 2016, to \$401,000 from \$329,000 for the nine-month period ended September 30, 2015. Our sales to a particular customer who exports Trappsol® Cyclo™ to South America were \$21,000 (100% of total sales of Trappsol® Cyclo™) for the three months ended September 30, 2016, compared to no sales for the three months ended September 30, 2015; and our sales to that same customer who exports Trappsol® Cyclo™ to South America were \$386,000 (96% of total sales of Trappsol® Cyclo™) for the nine-month period ended September 30, 2016, compared to \$270,000 (82% of total sales of Trappsol® Cyclo™) for the nine-month period ended September 30, 2015. Our 2015 sales to this customer were \$296,000 (84% of total 2015 sales of Trappsol® Cyclo™). This product is designated as an orphan drug; the population of patients is small and while we expect our future sales to increase, the timing of sales will be unpredictable and our ability to market the drug for use other than research is severely constrained by regulatory restrictions in the applicable jurisdictions.

Trappsol® HPB

Our sales of Trappsol® HPB increased by 31% for the three-month period ended September 30, 2016, to \$163,000 from \$124,000 for the three months ended September 30, 2015. Our sales of Trappsol® HPB increased by 43% for the nine-month period ended September 30, 2016, to \$397,000 from \$278,000 for the nine-month period ended September 30, 2015.

Trappsol® other products

Our sales of other Trappsol® products decreased by 36% for the three-month period ended September 30, 2016, to \$35,000 from \$55,000 for the three-month period ended September 30, 2015. Our sales of other Trappsol® products decreased by 32% for the nine-month period ended September 30, 2016, to \$74,000 from \$109,000 for the nine-month period ended September 30, 2015.

Aquaplex®

Our sales of Aquaplex® were \$57,000 for the three-month period ended September 30, 2016 compared to \$32,000 for the three-month period ended September 30, 2015. Our sales of Aquaplex® were \$78,000 for the nine-month period ended September 30, 2016 compared to \$63,000 for the nine-month period ended September 30, 2015.

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 nine months ended September 30, 2016, our two largest customers accounted for 52% of our sales; the largest accounted for 41% of sales. During the nine months ended September 30, 2015, our three largest customers accounted for 50% 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) for the nine-month period ended September 30, 2016 was 13% (\$124,000) compared to 13% (\$105,000) for the same period in 2015. Our cost of products sold (excluding any allocation of direct and indirect overhead and handling costs) as a percentage of sales was 11% (\$31,000) for the three months ended September 30, 2016 compared to 11% (\$25,000) for the same period in 2015. 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 2015 or 2014, or the first nine months of 2016.

Our gross margins may not be comparable to those of other entities, since some entities include all the costs related to their distribution network in cost of goods sold. Our cost of goods sold includes only the cost of products sold and does not include any allocation of inbound or outbound freight charges, indirect overhead expenses, warehouse and distribution expenses, or depreciation and amortization expense. We have six 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 had and will continue to 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.

Personnel expenses increased to \$328,000 for the three months ended September 30, 2016 from \$223,000 for the three months ended September 30, 2015. Personnel expenses increased to \$1,010,000 for the nine months ended September 30, 2016 from \$551,000 for the nine months ended September 30, 2015. The increase in personnel expense is due to an increase in the number of employees and employee benefits. We expect personnel costs to continue to increase in

2016 as the result of additional employees and our International Clinical Program product development activities.

Research and development expenses increased to \$311,000 for the three months ended September 30, 2016, from \$221,000 for the three months ended September 30, 2015. Research and development expenses increased to \$1,255,000 for the nine months ended September 30, 2016, from \$399,000 for the nine months ended September 30, 2015. The increase in research and development expense is due to the International Clinical Program. We expect research and development costs to increase in 2016 as we continue to seek regulatory approval for the use of Trappsol® Cyclo™ in the treatment of NPC.

Repairs and maintenance expenses decreased to \$3,000 for the three months ended September 30, 2016 from \$7,000 for the three months ended September 30, 2015. Repairs and maintenance expenses decreased to \$19,000 for the nine months ended September 30, 2016 from \$24,000 for the nine months ended September 30, 2015.

Professional fees increased to \$176,000 for the three months ended September 30, 2016, compared to \$101,000 for the three months ended September 30, 2015. Professional fees increased to \$455,000 for the nine months ended September 30, 2016, compared to \$324,000 for the nine months ended September 30, 2015. Professional fees may further increase due to new initiatives in raising capital or compliance for developing new products.

Office and other expenses increased to \$171,000 for the three months ended September 30, 2016 compared to \$85,000 for the three months ended September 30, 2015. Office and other expenses increased to \$479,000 for the nine months ended September 30, 2016 compared to \$213,000 for the nine months ended September 30, 2015.

Board of Directors fees and costs decreased to \$53,000 for the three months ended September 30, 2016, compared to \$140,000 for the three months ended September 30, 2015. Board of Directors fee and costs decreased to \$100,000 for the nine months ended September 30, 2016, compared to \$392,000 for the nine months ended September 30, 2015.

Amortization and depreciation was \$4,000 for the three months ended September 30, 2016, compared to \$44,000 for the three months ended September 30, 2015. Amortization and depreciation was \$92,000 for the nine months ended September 30, 2016, compared to \$125,000 for the nine months ended September 30, 2015.

Freight and shipping was \$1,000 for the three months ended September 30, 2016, compared to \$3,000 for the three months ended September 30, 2015. Freight and shipping was \$5,000 for the nine months ended September 30, 2016, compared to \$6,000 for the nine months ended September 30, 2015.

Interest expense was \$7,000 for the three months ended September 30, 2016, compared to \$8,000 for the three months ended September 30, 2015. Interest expense was \$22,000 for the nine months ended September 30, 2016, compared to \$24,000 for the nine months ended September 30, 2015.

We recorded a \$810,000 impairment loss on our office and pulse dryer for the three and nine months ended September 30, 2016. We recorded a \$125,000 impairment loss on our High Springs property (which was subsequently sold) for the three and nine months ended September 30, 2015.

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 nine months ended September 30, 2016, and 2015, 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, 2015. 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

31.1 Rule 13a-14(a)/15d-14a(a) Certifications

32.1 Section 1350 Certifications

101.INS XBRL Instance Document

101.SCH XBRL Taxonomy Extension Schema Document

101.CAL XBRL Taxonomy Extension Calculation Linkbase Document

101.DEF XBRL Taxonomy Extension Definition Linkbase Document

101.LAB XBRL Taxonomy Extension Label Linkbase Document

101.PRE XBRL Taxonomy Extension Presentation Linkbase Document

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: November 10, 2016 By: */s/ N. Scott Fine*
N. Scott Fine
Chief Executive Officer
(principal executive, financial and accounting officer)