CTD HOLDINGS INC Form 10-Q August 12, 2016

UNITED STAT	ES
SECURITIES A	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, 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) Identification No.)
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 August 11, 2016, the Company had outstanding 66,776,820 shares of its common stock.

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# PART I. FINANCIAL INFORMATION

## **Item 1. Financial Statements.**

# CTD HOLDINGS, INC.

## CONSOLIDATED BALANCE SHEETS

ASSETS	June 30, 2016 (Unaudited)	December 31, 2015
CURRENT ASSETS		
Cash and cash equivalents	\$2,133,725	\$1,842,233
Accounts receivable, net	81,150	55,636
Inventory	616,562	610,166
Current portion of mortgage note receivable	27,228	-
Other current assets	10,739	14,851
Total current assets	2,869,404	2,522,886
PROPERTY AND EQUIPMENT, NET	1,810,054	1,892,943
OTHER ASSETS		
Property held for sale	-	275,000
Deferred costs, net	65,342	66,424
Mortgage note receivable, less current portion	226,857	-
Total other assets	292,199	341,424
TOTAL ASSETS	\$4,971,657	\$4,757,253
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued expenses	\$434,172	\$ 257,537
Notes payable	688,734	719,737
Line of credit	000,731	34,296
Total current liabilities	1,122,906	1,011,570
STOCKHOLDERS' EQUITY		
Common stock, par value \$.0001 per share, 100,000,000 shares authorized, 66,670,347 and 58,670,347 shares issued and outstanding, respectively	6,667	5,867

Preferred stock, par value \$.0001 per share, 5,000,000 shares authorized, no shares

issued or outstanding

Additional paid-in capital

Accumulated deficit

Total stockholders' equity

10,894,782 9,015,582
(7,052,698) (5,275,766)
3,848,751 3,745,683

TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY \$4,971,657 \$4,757,253

See accompanying Notes to Consolidated Financial Statements.

## CONSOLIDATED STATEMENTS OF OPERATIONS

# (Unaudited)

	Three Months June 30,	s Ended	Six Months E. June 30,	nded
	2016	2015	2016	2015
REVENUES				
Product sales	\$384,386	\$380,340	\$697,071	\$553,538
EXPENSES				
Personnel	381,147	166,641	682,438	328,272
Cost of products sold (exclusive of amortization and depreciation, shown separately below)	56,169	57,406	93,003	79,872
Research and development	660,867	110,834	943,549	178,065
Repairs and maintenance	9,805	7,093	15,739	16,549
Professional fees	77,230	130,759	279,030	222,908
Office and other	195,459	85,042	307,315	127,787
Board of Director fees and costs	21,800	134,053	46,381	251,789
Amortization and depreciation	47,210	39,269	88,357	80,564
Freight and shipping	2,127	1,604	3,792	3,330
Loss (gain) on disposal of property and equipment	-	-	4,489	(700)
	1,451,814	732,701	2,464,093	1,288,436
LOSS FROM OPERATIONS	(1,067,428)	(352,361	) (1,767,022)	(734,898 )
OTHER INCOME (EXPENSE)				
Investment and other income	3,440	80	4,843	2,240
Interest expense	(7,173)	(7,899	) (14,753 )	(15,778)
•	(3,733)	(7,819	) (9,910 )	
LOSS BEFORE INCOME TAXES	(1,071,161)	(360,180	) (1,776,932)	(748,436 )
Provision for income taxes	-	-	-	-
NET LOSS	\$(1,071,161)	\$(360,180	) \$(1,776,932)	\$(748,436)
BASIC AND FULLY DILUTED NET LOSS PER COMMON SHARE	\$(.02)	\$(.01	) \$(.03	\$(.01)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING	60,803,680	54,455,88	2 59,737,014	54,454,132

See Accompanying Notes to Consolidated Financial Statements.

## CONSOLIDATED STATEMENTS OF CASH FLOWS

# (Unaudited)

	Six Months I	Ended
	June 30,	
	2016	2015
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	\$(1,776,932)	\$(748,436)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	88,357	80,564
Loss (gain) on sale of property and equipment	4,489	(700)
Increase or decrease in:		,
Accounts receivable	(25,514)	31,684
Inventory	(1,438	(26,877)
Other current assets	4,112	(16,668 )
Accounts payable and accrued expenses	176,635	(18,995)
Total adjustments	246,641	49,008
NET CASH USED IN OPERATING ACTIVITIES	(1,530,291)	(699,428)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of equipment and building improvements	(9,343	(225,175)
Proceeds from mortgage note receivable	10,915	-
Proceeds from sale of property and equipment, net of closing costs	5,510	700
NET CASH PROVIDED BY (USED IN) INVESTING ACTIVITIES	7,082	(224,475)
CASH FLOWS FROM FINANCING ACTIVITIES		
Principal payments on notes payable	(31,003	(29,562)
Payments on line of credit	(34,296	, , ,
Net proceeds from sale of common stock and warrants	1,880,000	_
NET CASH PROVIDED BY (USED IN) FINANCING ACTIVITIES	1,814,701	(29,562)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	291,492	(953,465)
CASH AND CASH EQUIVALENTS, beginning of period	1,842,233	2,380,054
CASH AND CASH EQUIVALENTS, end of period	\$2,133,725	\$1,426,589
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION Cash paid for interest	\$14,753	\$15,778

Cash paid for income taxes	\$-	\$-
SUPPLEMENTAL DISCLOSURE OF NONCASH INVESTING AND FINANCING		
Exchange of property held for sale for a mortgage note receivable	\$265,000	\$-

See Accompanying Notes to Consolidated Financial Statements.

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

**JUNE 30, 2016** 

The information presented herein as of June 30, 2016 and for the three and six months ended June 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<sup>TM</sup> 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<sup>TM</sup>.

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 six month periods ended June 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 June 30, 2016 and December 31, 2015 will be immaterial.
- (e) INVENTORY AND COST OF PRODUCTS SOLD—Inventory consists of our pharmaceutical drug Trappsol® Cyclo<sup>TM</sup>, cyclodextrin products and chemical complexes purchased for resale recorded at the lower of cost (first-in, first-out) or market. Cost of products sold includes the acquisition cost of the products sold and does not include any allocation of inbound or outbound freight charges, indirect overhead expenses, warehouse and distribution expenses, or depreciation and amortization expense.

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

**JUNE 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. No impairments were identified or recorded for the six months ended June 30, 2016 or 2015.

- (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 June 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 six months ended June 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. Four customers accounted for 86% of the accounts receivable balance at June 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.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

**JUNE 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 six months ended June 30, 2016, the Company incurred a net loss of \$1,776,932, used net cash in operations in the amount of \$1,530,291, and received net proceeds of \$1,880,000 from the sale of its securities. At June 30, 2016, the Company had a cash balance of \$2,133,725 and working capital of \$1,746,498. 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 2015-03, Interest-Imputation of Interest (Simplifying the Presentation of Debt Issuance Costs); 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.

#### (2) MORTGAGE NOTE RECEIVABLE

On January 21, 2016, we sold our 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 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 commencing March 1, 2016, with the unpaid balance due in February 2023.

#### **(3) DEBT**

We owed \$506,042 and \$516,685, at June 30, 2016 and December 31, 2015, respectively, on a mortgage note payable, collateralized by land and a building we 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 our Alachua property. The note has a voluntary prepayment penalty which was 3% of the principal repaid as of the date of this filing, and which decreases 1% on July 17 of each year. We were not in compliance with a debt coverage ratio covenant for the year ended December 31, 2015. As a result, we have reclassified the principal due in 2016 and beyond one year as current in the accompanying balance sheet.

We also owed this lender \$182,692 and \$203,052 at June 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 our equipment. There is a prepayment penalty of 2% of the outstanding balance if we voluntarily repay 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 our non-compliance with the loan covenant referred to above.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

**JUNE 30, 2016** 

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,	Year
2016	\$62,411
2017	64,982
2018	67,658
2019	70,446
2020	42,750
Thereafter	396,028
	\$704,275

#### (4) EQUITY TRANSACTIONS:

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 June 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.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
JUNE 30, 2016
(5) INCOME TAXES:
The Company reported a net loss for the three and six months ended June 30, 2016 and 2015, respectively. The Company increased its deferred tax asset valuation allowance rather than recognize an income tax benefit.
(6) SALES CONCENTRATIONS:
Sales to two major customers accounted for 64% of total sales for the six months ended June 30, 2016. Sales to one major customers accounted for 49% of total sales for the six months ended June 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.
(7) OTHER:
On January 12, 2016, the Company entered into a non-binding Letter of Intent with C.E. Rick Strattan, a significant stockholder and one of the Company's directors, to sell the Company's cyclodextrin manufacturing and distribution
business. The Letter of Intent has expired, and the parties have terminated their discussions with respect to the transactions contemplated thereby.

## 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<sup>TM</sup> 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<sup>TM</sup>.

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. Subsequent to the three-month period ended June 30, 2016, we listed for sale our real property located in Alachua, Florida. In the event we are able to complete the sale of this property, we expect to repay our secured loans and terminate our cyclodextrin manufacturing and distribution business. 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<sup>TM</sup>-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<sup>TM</sup>

At the end of 2008, we provided Trappsol® Cyclo<sup>TM</sup> 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<sup>TM</sup> product proved to provide an ameliorative benefit. On May 17, 2010, the FDA granted orphan drug status to our customer for Trappsol® Cyclo<sup>TM</sup> for the treatment of NPC. To date, Trappsol® Cyclo<sup>TM</sup> 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<sup>TM</sup> decreased to \$352,000 for 2015 from \$901,000 for 2014. Sales of Trappsol® Cyclo<sup>TM</sup> were \$380,000 and \$386,000 for the three and six months ended June 30, 2016, respectively. In 2012, we began to offer 100ml vials of Trappsol® Cyclo<sup>TM</sup> in a liquid form from a contract manufacturer. In 2014, we completed validation of the Trappsol® Cyclo<sup>TM</sup> 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<sup>TM</sup> in both the U.S. and Europe.

Most recently, we filed our IND for Trappsol® Cyclo™ as a treatment for NPC with the FDA, as well as a Clinical Trial Application with the United Kingdom's Medicines and Healthcare Products Regulatory Agency,. Following approval of the IND, we expect to conduct a U.S. clinical study in which we will provide Trappsol® Cyclo™ intravenously to NPC patients two years of age and older in order to track biochemical markers of cholesterol metabolism and to measure effects on neurologic, lung and liver symptoms.

#### 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 increased to \$2,134,000 as of June 30, 2016, compared to \$1,842,000 as of December 31, 2015, primarily as a result of the private placement we completed in June 2016 which resulted in net proceeds to us of \$1,880,000. Our working capital was \$1,746,000 as of June 30, 2016, compared to \$1,511,000 at December 31, 2015. All of our debt has been classified as current at both June 30, 2016 and December 31, 2015 due to our non-compliance with a loan covenant as described below. We owed \$506,042 at June 30, 2016 on a secured mortgage note and \$182,692 under an equipment loan, with a bank that has a debt service covenant. We were not in compliance with this debt service coverage covenant for the year ended December 31, 2015. 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.

Subsequent to June 30, 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 and terminate our cyclodextrin manufacturing and distribution business. Our strategy going forward is to focus on biopharmaceutical opportunities in healthcare where we believe cyclodextrin applications have maximum value.

The Company presently believes that it has sufficient cash to meet its anticipated operating costs and capital expenditure requirements for at least the next twelve months. Additional capital will 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 the 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<sup>TM</sup> orphan drug product, including implementation of our International Clinical Program and U.S. clinical trials and designs, and other general corporate purposes.

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

Results of Operations - Three and Six Months Ended June 30, 2016 Compared to Three and Six Months Ended June 30, 2016

We reported a net loss of \$(1,071,000) and \$(1,777,000) for the three and six months ended June 30, 2016, respectively, compared to a net loss of \$(360,000) and \$(748,000) for the three and six months ended June 30, 2015, respectively.

Total revenues for the three month period ended June 30, 2016 increased 10% to \$384,000 compared to \$380,000 for the same period in 2015. Total revenues for the six month period ended June 30, 2016 increased 26% to \$697,000

compared to \$554,000 for the same period in 2015.

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

#### Trappsol® Cyclo

Our sales of Trappsol® Cyclo<sup>TM</sup> were relatively unchanged for the three month period ended June 30, 2016, at \$241,000, compared to \$240,000 for the three month period ended June 30, 2015. Our sales of Trappsol® Cyclo<sup>TM</sup> increased by 25% for the six month period ended June 30, 2016, to \$386,000 from \$310,000 for the six month period ended June 30, 2015. Our sales to a particular customer who exports Trappsol® Cyclo<sup>TM</sup> to South America were \$231,000 (96% of total sales of Trappsol® Cyclo<sup>TM</sup>) for the three months ended June 30, 2016, compared to \$213,000 (89% of total sales of Trappsol® Cyclo<sup>TM</sup>) for the three months ended June 30, 2015; and our sales to that same customer who exports Trappsol® Cyclo<sup>TM</sup> to South America were \$365,000 (95% of total sales of Trappsol® Cyclo<sup>TM</sup>) for the six month period ended June 30, 2016, compared to \$270,000 (87% of total sales of Trappsol® Cyclo<sup>TM</sup>) for the six month period ended June 30, 2015. Our 2015 sales to this customer were \$296,000 (84% of total 2015 sales of Trappsol® Cyclo<sup>TM</sup>). 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 9% for the three month period ended June 30, 2016, to \$90,000 from \$83,000 for the three months ended June 30, 2015. Our sales of Trappsol® HPB increased by 49% for the six month period ended June 30, 2016, to \$228,000 from \$153,000 for the six month period ended June 30, 2015.

#### Trappsol® other products

Our sales of other Trappsol® products decreased by 19% for the three month period ended June 30, 2016, to \$25,000 from \$31,000 for the three month period ended June 30, 2015. Our sales of other Trappsol® products decreased by 26% for the six month period ended June 30, 2016, to \$40,000 from \$54,000 for the six month period ended June 30, 2015.

#### <u>Aquaplex®</u>

Our sales of Aquaplex® were \$21,000 for the three month period ended June 30, 2016 compared to \$23,000 for the three month period ended June 30, 2015. Our sales of Aquaplex® were \$21,000 for the six month period ended June 30, 2016 compared to \$31,000 for the six month period ended June 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 six months ended June 30, 2016, our three largest customers accounted for 73% of our sales; the largest accounted for 54% of sales. During the six months ended June 30, 2015, our three largest customers accounted for 65% of our sales; the largest accounted for 49% of sales. Historically, our usual smaller sales of HPB occur more frequently throughout the year compared to our large sales that we receive periodically. The timing of when we receive and are able to complete these two kinds of sales has a significant effect on our quarterly revenues and operating results and makes period to period comparisons difficult.

Our cost of products sold (excluding any allocation of direct and indirect overhead and handling costs) for the six month period ended June 30, 2016 was 15% (\$93,000) compared to 14% (\$80,000) 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 15% (\$56,000) for the three months ended June 30, 2016 compared to 15% (\$57,000) 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 six 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 \$381,000 for the three months ended June 30, 2016 from \$167,000 for the three months ended June 30, 2015. Personnel expenses increased to \$682,000 for the six months ended June 30, 2016 from \$328,000 for the six months ended June 30, 2015. The increase in personnel expense is due to an increase in the

number of employees and employee healthcare benefits. We expect personnel costs to continue to increase in 2016 as the result of additional employees and our International Clinical Program product development activities.

Research and development expenses increased to \$661,000 for the three months ended June 30, 2016, from \$111,000 for the three months ended June 30, 2015. Research and development expenses increased to \$944,000 for the six months ended June 30, 2016, from \$178,000 for the six months ended June 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<sup>TM</sup> in the treatment of NPC.

Repairs and maintenance expenses increased to \$10,000 for the three months ended June 30, 2016 from \$7,000 for the three months ended June 30, 2015. Repairs and maintenance expenses increased to \$16,000 for the six months ended June 30, 2016 from \$17,000 for the six months ended June 30, 2015.

Professional fees decreased to \$77,000 for the three months ended June 30, 2016, compared to \$131,000 for the three months ended June 30, 2015. Professional fees increased to \$279,000 for the six months ended June 30, 2016, compared to \$223,000 for the six months ended June 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 \$195,000 for the three months ended June 30, 2016 compared to \$85,000 for the three months ended June 30, 2015. Office and other expenses increased to \$307,000 for the six months ended June 30, 2016 compared to \$128,000 for the six months ended June 30, 2015.

Board of Directors fees and costs decreased to \$22,000 for the three months ended June 30, 2016, compared to
\$134,000 for the three months ended June 30, 2015. Board of Directors fee and costs decreased to \$46,000 for the six
months ended June 30, 2016, compared to \$252,000 for the six months ended June 30, 2015.

Amortization and depreciation was \$47,000 for the three months ended June 30, 2016, compared to \$39,000 for the three months ended June 30, 2015. Amortization and depreciation was \$88,000 for the six months ended June 30, 2016, compared to \$81,000 for the six months ended June 30, 2015.

Freight and shipping was \$2,000 for the three months ended June 30, 2016 and 2015, respectively. Freight and shipping was \$4,000 for the six months ended June 30, 2016, compared to \$3,000 for the six months ended June 30, 2015.

Interest expense was \$7,000 for the three months ended June 30, 2016, compared to \$8,000 for the six months ended June 30, 2015. Interest expense was \$15,000 for the six months ended June 30, 2016, compared to \$16,000 for the six months ended June 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 six months ended June 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: August 12, 2016 By:/s/ N. Scott Fine

N. Scott Fine

Chief Executive Officer

(principal executive, financial and accounting officer)