**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, 2022
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

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

| Nevada | 59-3029743 |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (IRS Employer Identification No.) |
| 6714 NW 16th Street, Suite B, Gainesville, Florida | 32653 |
| (Address of principal executive offices) | (Zip Code) |

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

Securities registered pursuant to Section 12(b) of the Act:

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|---|---|---|
| Common Stock, par value $.0001 per share | CYTH | The Nasdaq Stock Market LLC |
| Warrants to purchase Common Stock | CYTHW | The Nasdaq Stock Market LLC |

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the 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 every Interactive Data File required to be submitted 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 such files). ☒ Yes ☐ No

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

| | | | |
|---|---|---|---|
| Large accelerated filer | ☐ | Accelerated filer | ☐ |
| Non-accelerated filer | ☒ | Smaller reporting company | ☒ |
| | | Emerging growth company | ☐ |

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

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

☐Yes ☒ No

As of November 10, 2022 the Company had outstanding 8,481,848 shares of its common stock.

**CYCLO THERAPEUTICS, INC.**
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## PART I. FINANCIAL INFORMATION

**Item 1. Financial Statements.**

### CYCLO THERAPEUTICS, INC. AND SUBSIDIARIES
### CONSOLIDATED BALANCE SHEETS

| | September 30, 2022 (unaudited) | December 31, 2021 |
|---|---|---|
| **ASSETS** | | |
| **CURRENT ASSETS** | | |
| Cash and cash equivalents | $ 4,290,198 | $ 16,612,711 |
| Accounts receivable, net | 394,570 | 493,113 |
| Inventory, net | 271,137 | 227,437 |
| Current portion of mortgage note receivable | - | 45,977 |
| Prepaid insurance and services | 115,889 | 42,246 |
| Prepaid clinical expenses | 3,350,002 | 2,014,851 |
| Total current assets | 8,421,796 | 19,436,335 |
| **FURNITURE AND EQUIPMENT, NET** | 60,058 | 59,583 |
| **RIGHT-TO-USE LEASE ASSET, NET** | 5,669 | 17,636 |
| **MORTGAGE NOTE RECEIVABLE, LESS CURRENT PORTION** | - | 7,279 |
| **TOTAL ASSETS** | $ 8,487,523 | $ 19,520,833 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| **CURRENT LIABILITIES** | | |
| Current portion of lease liability | $ 4,978 | $ 19,245 |
| Current portion of note payable | - | 133,712 |
| Accounts payable and accrued expenses | 2,870,085 | 3,677,979 |
| Total current liabilities | 2,875,063 | 3,830,936 |
| **LONG-TERM LIABILITIES** | | |
| Long-term note payable, less current portion | - | 18,034 |
| **Commitments and contingencies** | | |
| **STOCKHOLDERS' EQUITY** | | |
| Common stock, par value $.0001 per share, 20,000,000 shares authorized, 8,455,452 and 8,403,869 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively | 846 | 841 |
| Preferred stock, par value $.0001 per share, 5,000,000 shares authorized, 0 issued and outstanding | - | - |
| Additional paid-in capital | 64,430,566 | 64,019,513 |
| Accumulated deficit | (58,818,952) | (48,348,491) |
| Total stockholders' equity | 5,612,460 | 15,671,863 |
| **TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY** | $ 8,487,523 | $ 19,520,833 |

See accompanying Notes to Consolidated Financial Statements.

**CYCLO THERAPEUTICS, INC. AND SUBSIDIARIES**
**CONSOLIDATED STATEMENTS OF OPERATIONS**
**(Unaudited)**

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2022 | 2021 | 2022 | 2021 |
| **REVENUES** | | | | |
| Product sales | $ 452,167 | $ 403,918 | $ 1,188,957 | $ 1,000,641 |
| **EXPENSES** | | | | |
| Personnel | 887,506 | 1,668,010 | 3,075,170 | 2,769,526 |
| Cost of products sold (exclusive of direct and indirect overhead and handling costs) | 33,032 | 22,671 | 123,163 | 87,425 |
| Research and development | 2,856,160 | 1,837,720 | 5,814,595 | 7,739,379 |
| Repairs and maintenance | 2,177 | 2,425 | 10,175 | 5,738 |
| Professional fees | 611,685 | 450,490 | 1,673,582 | 1,046,979 |
| Office and other | 204,654 | 244,343 | 790,441 | 799,856 |
| Board of Director fees and costs | 98,126 | 30,708 | 314,382 | 30,708 |
| Depreciation | 5,129 | 4,207 | 14,611 | 12,620 |
| Freight and shipping | 2,198 | 2,360 | 11,819 | 5,154 |
| Total operating expenses | 4,700,667 | 4,262,934 | 11,827,938 | 12,497,385 |
| **LOSS FROM OPERATIONS** | (4,248,500) | (3,859,016) | (10,638,981) | (11,496,744) |
| **OTHER INCOME (EXPENSE)** | | | | |
| Investment and other income (expense), net | 1,620 | (1,240) | 9,996 | 2,475 |
| Gain on forgiveness of PPP loan | - | - | 158,524 | - |
| Total other income | 1,620 | (1,240) | 168,520 | 2,475 |
| **LOSS BEFORE INCOME TAXES** | (4,246,880) | (3,860,256) | (10,470,461) | (11,494,269) |
| **PROVISION FOR INCOME TAXES** | - | - | - | - |
| **NET LOSS** | $ (4,246,880) | $ (3,860,256) | $ (10,470,461) | $ (11,494,269) |
| **BASIC AND DILUTED NET LOSS PER COMMON SHARE** | $ (0.50) | $ (0.60) | $ (1.24) | $ (1.90) |
| **WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING** | 8,447,630 | 6,447,803 | 8,428,074 | 6,040,524 |

See accompanying Notes to Consolidated Financial Statements.

**CYCLO THERAPEUTICS, INC. AND SUBSIDIARIES**
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**
**FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2022**
**(Unaudited)**

| | Common Stock | | Additional Paid-In Capital | Accumulated Deficit | Total Stockholders' Equity |
|---|---|---|---|---|---|
| | Shares | Par Value | | | |
| Balance, December 31, 2021 | 8,403,869 | $ 841 | $ 64,019,513 | $ (48,348,491) | $ 15,671,863 |
| Stock issued to nonemployees | 11,327 | 1 | 41,003 | - | 41,004 |
| Stock-based compensation | - | - | 106,738 | - | 106,738 |
| Net loss | - | - | - | (2,771,591) | (2,771,591) |
| Balance, March 31, 2022 | 8,415,196 | 842 | 64,167,254 | (51,120,082) | 13,048,014 |
| Stock issued to employees | 7,500 | 1 | 15,749 | - | 15,750 |
| Stock issued to nonemployees | 16,739 | 1 | 41,255 | - | 41,256 |
| Stock-based compensation | - | - | 87,012 | - | 87,012 |
| Net loss | - | - | - | (3,451,990) | (3,451,990) |
| Balance, June 30, 2022 | 8,439,435 | $ 844 | $ 64,311,270 | $ (54,572,072) | $ 9,740,042 |
| Stock issued to nonemployees | 16,017 | 2 | 30,750 | - | 30,752 |
| Stock-based compensation | - | - | 88,546 | - | 88,546 |
| Net loss | - | - | - | (4,246,880) | (4,246,880) |
| Balance, September 30, 2022 | 8,455,452 | $ 846 | $ 64,430,566 | $ (58,818,952) | $ 5,612,460 |

See accompanying Notes to Consolidated Financial Statements.

**CYCLO THERAPEUTICS, INC. AND SUBSIDIARIES**
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**
**FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2021**
**(Unaudited)**

| | Common Stock | | Additional | | Total Stockholders' |
|---|---|---|---|---|---|
| | Shares | Par Value | Paid-In Capital | Accumulated Deficit | Equity (Deficit) |
| Balance, December 31, 2020 | 4,770,761 | $ 477 | $ 44,513,841 | $ (34,061,836) | $ 10,452,482 |
| Stock issued to employees | 53,938 | 5 | 271,303 | - | 271,308 |
| Stock issued to nonemployees | 10,000 | 1 | 50,299 | - | 50,300 |
| Exercise of warrants, net | 1,522,897 | 152 | 7,583,940 | - | 7,584,092 |
| Net loss | - | - | - | (4,036,615) | (4,036,615) |
| Balance, March 31, 2021 | 6,357,596 | 635 | 52,419,383 | (38,098,451) | 14,321,567 |
| Exercise of warrants, net | 78,220 | 9 | 402,000 | - | 402,009 |
| Net loss | - | - | - | (3,597,398) | (3,597,398) |
| Balance, June 30, 2021 | 6,435,816 | 644 | 52,821,383 | (41,695,849) | (11,126,178) |
| Exercise of warrants, net | 1,000 | - | 5,000 | - | 5,000 |
| Stock issued to employees | 17,053 | 2 | 124,996 | - | 124,998 |
| Stock based compensation | - | - | 231,134 | - | 231,134 |
| Net loss | - | - | - | (3,820,256) | (3,860,256) |
| Balance, September 30, 2021 | 6,453,869 | $ 646 | $ 53,182,513 | $ (45,556,105) | $ 7,627,054 |

See accompanying Notes to Consolidated Financial Statements.

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

| | Nine Months Ended September 30, | |
|---|---|---|
| | **2022** | **2021** |
| **CASH FLOWS FROM OPERATING ACTIVITIES** | | |
| Net loss | $ (10,470,461) | $ (11,494,269) |
| | | |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 14,611 | 12,620 |
| Gain on forgiveness of PPP loan | (158,524) | - |
| Provision for doubtful accounts | (21,755) | - |
| Stock-based compensation | 282,296 | 231,134 |
| Stock issued to employees | 15,750 | 396,306 |
| Stock issued to nonemployees | 113,012 | 50,300 |
| Changes in operating assets and liabilities: | | |
| Accounts receivable, net | 120,298 | (283,847) |
| Inventory, net | (43,700) | (15,888) |
| Prepaid clinical expenses | (1,335,151) | (1,076,712) |
| Prepaid insurance and services | (73,643) | 33,991 |
| Other | - | (90) |
| Accounts payable and accrued expenses | (810,194) | (247,172) |
| Total adjustments | (1,897,000) | (899,358) |
| | | |
| **NET CASH USED IN OPERATING ACTIVITIES** | (12,367,461) | (12,393,627) |
| | | |
| **CASH FLOWS FROM INVESTING ACTIVITIES** | | |
| Purchases of furniture and equipment | (15,086) | (22,500) |
| Collections from mortgage note receivable | 53,256 | 26,988 |
| **NET CASH PROVIDED BY INVESTING ACTIVITIES** | 38,170 | 4,488 |
| | | |
| **CASH FLOWS FROM FINANCING ACTIVITIES** | | |
| Net proceeds from exercise of warrants | - | 7,991,101 |
| Payments on PPP loan | (8,159) | (6,778) |
| Refund of PPP loan payments | 14,937 | - |
| **NET CASH PROVIDED BY FINANCING ACTIVITIES** | 6,778 | 7,984,323 |
| | | |
| **NET DECREASE IN CASH AND CASH EQUIVALENTS** | (12,322,513) | (4,404,816) |
| | | |
| **CASH AND CASH EQUIVALENTS**, beginning of period | 16,612,711 | 12,846,113 |
| | | |
| **CASH AND CASH EQUIVALENTS**, end of period | $ 4,290,198 | $ 8,441,297 |

See accompanying Notes to Consolidated Financial Statements.

**CYCLO THERAPEUTICS, INC. AND SUBSIDIARIES**
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**
**(Unaudited)**

The information presented herein as of September 30, 2022 and for the three and nine months ended September 30, 2022 and 2021 is unaudited.

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

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

(a) ORGANIZATION AND OPERATIONS—The Company was incorporated in August 1990 as a Florida corporation, under the name Cyclodextrin Technologies Development, Inc. with operations beginning in July 1992. In conjunction with a restructuring in 2000, we changed our name to CTD Holdings, Inc. We changed our name to Cyclo Therapeutics, Inc. in September 2019 to better reflect our current business and on November 6, 2020, we reincorporated from the State of Florida to the State of Nevada.

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

We have also completed a Phase I/II clinical study approved by several European regulatory bodies, including those in the United Kingdom, Sweden and Italy, and in Israel. The Phase I/II study evaluated the safety, tolerability and efficacy of Trappsol® Cyclo™ through a range of clinical outcomes, including neurologic, respiratory, and measurements of cholesterol metabolism and markers of NPC. Consistent with the U.S. study, the European/Israel study administered Trappsol® Cyclo™ intravenously to NPC patients every two weeks in a double-blind, randomized trial, but differs in that the study period was for 48 weeks (24 doses). The first patient was dosed in this study in July 2017, and in March of 2021 we announced that 100% of patients who completed the trial improved or remained stable, and 89% met the efficacy outcome measure of improvement in at least two domains of the 17-domain NPC severity scale.

Additionally, in February 2020 we had a face-to-face "Type C" meeting with the FDA with respect to the initiation of our pivotal Phase III clinical trial of Trappsol® Cyclo™ based on the clinical data obtained to date. At that meeting, we also discussed with the FDA submitting a New Drug Application (NDA) under Section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for the treatment of NPC in pediatric and adult patients with Trappsol® Cyclo™. A similar request was submitted to the European Medicines Agency ("EMA") in February 2020, seeking scientific advice and protocol assistance from the EMA for proceeding with a Phase III clinical trial in Europe. In October 2020 we received a "Study May Proceed" notification from the FDA with respect to the proposed Phase III clinical trial, and in June of 2021 we commenced enrollment in TransportNPC, a pivotal Phase III study of Trappsol® Cyclo™ for the treatment of NPC.

We are also exploring the use of cyclodextrins in the treatment of Alzheimer's disease. In December of 2021, the Company received IND clearance from the FDA to proceed with a Phase II study for the treatment of Alzheimer's disease with Trappsol® Cyclo™. We expect to begin enrollment in this study during 2022.

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

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

(b) BASIS OF PRESENTATION—The consolidated financial statements include the Company and its wholly owned subsidiaries. All significant intercompany accounts and transactions have been eliminated in consolidation. The interim consolidated financial statements of the Company included in this Quarterly Report on Form 10-Q, including these notes, are unaudited. In the opinion of management, all adjustments necessary for a fair presentation of the consolidated financial statements have been included. Such adjustments are of a normal, recurring nature. The interim consolidated financial statements, and these notes, have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") and do not contain certain information included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2021. The interim consolidated financial statements should be read in conjunction with that Annual Report on Form 10-K. Results for the interim periods presented are not necessarily indicative of the results that might be expected for the entire fiscal year.

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

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

The carrying amount of accounts receivable is reduced by an allowance for credit losses that reflects management's best estimate of the amounts that will not be collected. The Company reviews each customer balance where all or a portion of the balance exceeds 90 days from the invoice date. Based on the Company's assessment of the customer's current creditworthiness, the Company estimates the portion, if any, of the balance that will not be collected, and writes off receivables as a charge to the allowance for credit losses when, in management's estimation, it is probable that the receivable is worthless. The Company estimated an allowance for doubtful accounts of $21,800 at December 31, 2021. An allowance for doubtful accounts was not deemed necessary at September 30, 2022.

(e) INVENTORY AND COST OF PRODUCTS SOLD—Inventory consists of our pharmaceutical drug Trappsol® Cyclo™, cyclodextrin products and chemical complexes purchased for resale recorded at the lower of cost (first-in, first-out) or net realizable value. Cost of products sold includes the acquisition cost of the products sold and does not include any allocation of inbound or outbound freight charges, indirect overhead expenses, warehouse and distribution expenses, or depreciation and amortization expense. The Company records a specific reserve for inventory items that are determined to be obsolete. The reserve for obsolete inventory was $52,900 at September 30, 2022 and December 31, 2021.

The Company's reserve for obsolete inventory is based on the Company's best estimates of product sales and customer demands. It is reasonably possible that the estimates used by the Company to determine its provisions for inventory write-downs will be materially different from actual write-downs. These differences could result in materially higher than expected inventory provisions and related costs, which could have a materially adverse effect on the Company's results of operations and financial condition in the near term.

(f) PREPAID CLINICAL EXPENSES—Prepaid clinical expenses consist of our pharmaceutical drug Trappsol® Cyclo™ expected to be used in our clinical trial program recorded at cost. Prepaid clinical expenses represent valid future economic benefits based on our contracts with our vendors, and will be realized in the ordinary course of business.

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

(g) MORTGAGE NOTE RECEIVABLE—The mortgage note receivable is stated at amortized value, which is the amount we expect to collect. The mortgage note receivable was paid in full as of September 30, 2022.

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

(i) REVENUE RECOGNITION—Revenues are recognized when our customer obtains control of promised goods or services in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. We recognize revenues following the five step model prescribed under Accounting Standards Codification ("ASC") Topic 606: (i) identify contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenues when (or as) we satisfy the performance obligation.

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

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

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

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

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

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

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

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

(l) RESEARCH AND DEVELOPMENT COSTS—Research and development costs are expensed as incurred. Research and development expense primarily consists of product development, third-party contractors, salaries and materials.

(m) INCOME TAXES—Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective income tax bases. Deferred tax assets and liabilities are measured using enacted rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. In addition, tax benefits related to positions considered uncertain are recognized only when it is more likely than not the position will be sustained upon examination by the tax authorities. Such tax positions shall initially and subsequently be measured as the largest amount of tax benefit that has a greater than 50% likelihood of being realized upon ultimate settlement with the tax authority assuming full knowledge of the position and relevant facts. As of September 30, 2022 and December 31, 2021, the Company has recorded a full valuation allowance against its deferred tax assets.

(n) NET LOSS PER COMMON SHARE— Basic and fully diluted net loss per common share is computed using a simple weighted average of common shares outstanding during the periods presented, as outstanding warrants to purchase 2,045,846 common shares were antidilutive for the three and nine months ended September 30, 2022 and 2,048,186 common shares were antidilutive for the three and nine months ended September 30, 2021. Additionally, outstanding options to purchase 425,646 shares of common stock were antidilutive for the three and nine months ended September 30, 2022 and outstanding options to purchase 222,700 shares of common stock were antidulitve for the three and nine months ended September 30, 2021.

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

The Company periodically issues stock options under its 2021 Equity Incentive Plan. The Company uses the Black-Scholes valuation method to estimate the fair value of stock options at grant date. Compensation expense is recognized on the straight-line basis over the requisite service period, which is generally the vesting period.

(p) FAIR VALUE MEASUREMENTS AND DISCLOSURES—The Fair Value Measurements and Disclosures topic of the Accounting Standards Codification ("ASC") requires companies to determine fair value based on the price that would be received to sell the asset or paid to transfer the liability to a market participant. The Fair Value Measurements and Disclosures topic emphasizes that fair value is a market-based measurement, not an entity-specific measurement.

The guidance requires that assets and liabilities carried at fair value be classified and disclosed in one of the following categories:

- Level 1: Quoted market prices in active markets for identical assets or liabilities.
- Level 2: Observable market-based inputs or unobservable inputs that are corroborated by market data.
- Level 3: Unobservable inputs that are not corroborated by market data.

We have no assets or liabilities that are required to have their fair value measured on a recurring basis at September 30, 2022 and December 31, 2021. Long-lived assets are measured at fair value on a non-recurring basis and are subject to fair value adjustments when there is evidence of impairment.

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

For short-term classes of our financial instruments, which include cash, accounts receivable and accounts payable, and which are not reported at fair value, the carrying amounts approximate fair value due to their short-term nature. The fair value of the mortgage note receivable is estimated based on the present value of the underlying cash flows discounted at current rates. At September 30, 2022 the mortgage note receivable was paid in full. At December 31, 2021, the carrying value of the mortgage note receivable approximated fair value.

(q) USE OF ESTIMATES—The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions, including regarding contingencies, that affect the amounts reported in the consolidated financial statements and accompanying notes. The Company's most significant estimates relate to inventory obsolescence, stock-based compensation and warrant liability valuation. 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.

(r) RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS—In June 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2016-13, "Financial Instruments – Credit Losses" (Topic 326), which provides guidance on how an entity should measure credit losses on financial instruments. The ASU is effective for smaller reporting company's for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. The Company does not expect this ASU to have a material impact on its consolidated financial statements. The Company does not believe that any other recently issued, but not yet effective, accounting standards would have a material effect on the consolidated financial statements.

(s) WARRANTS—The Company accounts for its warrants as either equity-classified or liability-classified instruments based on an assessment of the specific terms of the warrants considering the authoritative guidance in ASC 480, "Distinguishing Liabilities from Equity" ("ASC 480") and ASC 815, "Derivatives and Hedging" ("ASC 815"). The assessment considers whether the warrants meet the definition of a liability pursuant to ASC 480, and meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to the Company's own common stock and satisfy additional conditions for equity classification. Warrants that are liability-classified are measured at fair value at each reporting date in accordance with the guidance in ASC 820, "Fair Value Measurement," with any subsequent changes in fair value recognized in the statement of operations in the period of change. The fair value of liability classified warrants was not material at September 30, 2022 and December 31, 2021.

(t) LIQUIDITY AND GOING CONCERN—For the three and nine months ended September 30, 2022, the Company incurred net losses of approximately $4,247,000 and $10,470,000, respectively. The Company has an accumulated deficit of approximately $58,819,000 at September 30, 2022. Our recent losses have predominantly resulted from research and development expenses for our Trappsol® Cyclo™ product and other general operating expenses, including personnel expenses and board advisory fees. We believe our expenses will continue to increase as we continue to conduct clinical trials and seek regulatory approval for the use of Trappsol® Cyclo™ in the treatment of NPC and Alzheimer's disease.

For the nine months ended September 30, 2022, the Company's operations used approximately $12,367,000 in cash, and at September 30, 2022, the Company had a cash balance of approximately $4,290,000 and current assets less current liabilities of approximately $ 5,547,000. We will need to raise additional capital through the sale of our securities, the issuance of debt, the sale or licensing of existing assets or assets in development or from non-dilutive funding mechanism from time to time for the foreseeable future to fund the development of our drug product candidates through clinical development, manufacturing and commercialization. Our ability to obtain such additional capital will likely be subject to various factors, including our overall business performance and market conditions. If we cannot raise the additional funds required for our anticipated operations, we may be required to reduce the scope of or eliminate our research and development programs, delay our clinical trials and the ability to seek regulatory approvals, downsize our general and administrative infrastructure, or seek alternative measures to avoid insolvency. If we raise additional funds through future offerings of shares of our Common Stock or other securities, such offerings would cause dilution of current stockholders' percentage ownership in the Company, which could be substantial. Future offerings also could have a material and adverse effect on the price of our Common Stock.

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

Our consolidated financial statements for the three and nine months ended September 30, 2022 were prepared on the basis of a going concern, which contemplates that we will be able to realize assets and discharge liabilities in the normal course of business. Our ability to continue as a going concern is dependent upon the availability of equity financing as noted above. These factors raise substantial doubt about our ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of these uncertainties.

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

**(2) REVENUES:**

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

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

Revenues by product are summarized as follows:

| | Three Months Ended September 30 | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | **2022** | **2021** | **2022** | **2021** |
| Trappsol® Cyclo™ | $ 270 | $ 90 | $ 970 | $ 2,020 |
| Trappsol® HPB | 337,474 | 285,648 | 759,079 | 542,748 |
| Trappsol® Fine Chemical | 113,124 | 115,628 | 421,448 | 424,976 |
| Aquaplex® | - | 228 | 816 | 23,220 |
| Other | 1,299 | 2,324 | 6,644 | 7,677 |
| Total revenues | $ 452,167 | $ 403,918 | $ 1,188,957 | $ 1,000,641 |

Substantially all of our sales of Trappsol® Cyclo™ for the three and nine months ended September 30, 2022 and 2021 were to a single customer who exports the drug to South America. Substantially all of our Aquaplex® sales for the three and nine months ended September 30, 2022 and 2021 were to one customer.

**(3) MAJOR CUSTOMERS AND SUPPLIERS:**

Our revenues are derived primarily from chemical supply and pharmaceutical companies located primarily in the United States. For the three months ended September 30, 2022, two customers accounted for 86% of total revenues. For the nine months ended September 30, 2022, three major customers accounted for 67% of total revenues. For the three months ended September 30, 2021, five major customers accounted for 86% of total revenues. For the nine months ended September 30, 2021, four major customers accounted for 65% of total revenues.

Substantially all inventory purchases were from three vendors in 2022 and 2021. These vendors are located primarily outside the United States.

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

For the nine months ended September 30, 2022, the product mix of our revenues consisted of 98% basic natural and chemically modified cyclodextrins and 2% cyclodextrin complexes. For the three months ended September 30, 2022 the product mix of our revenues consisted entirely of basic natural and chemically modified cyclodextrins. For the nine months ended September 30, 2021, the product mix of our revenues consisted of 98% basic natural and chemically modified cyclodextrins and 2% cyclodextrin complexes. For the three months ended September 30, 2021, the product mix of our revenues consisted entirely of basic natural and chemically modified cyclodextrins.

**(4) MORTGAGE NOTE RECEIVABLE:**

On January 21, 2016, we sold our real property located in High Springs, Florida, to an unrelated party. Pursuant to the terms of the sale, at the closing, the buyer paid $10,000 in cash, less selling costs and settlement charges, and delivered to us a promissory note in the principal amount of $ 265,000, and a mortgage in our favor securing the buyer's obligations under the promissory note. The promissory note provides for monthly payments of $3,653, including principal and interest at 4.25%, over a seven-year period that commenced March 1, 2016, with the unpaid balance due in February 2023. In August 2022, the buyer paid the remaining balance in full.

**(5) NOTE PAYABLE:**

On May 4, 2020, the Company's wholly owned subsidiary, Cyclodextrin Technologies Development, Inc., borrowed $ 158,524 from BBVA USA under the Paycheck Protection Program (PPP) which was established under the Coronavirus Aid, Relief and Economic Security Act ("CARES Act"). The loan matured on May 4, 2022 and bore interest at a rate of 1% per annum, payable monthly commencing on September 5, 2021. Under the Paycheck Protection Program, because the loan was used to fund certain qualifying expenses as described in the CARES Act, the full amount of the loan, including accrued interest was forgiven in March 2022. As a result, the balance forgiven is presented separately as gain on the forgiveness of PPP loan in the accompanying consolidated statement of operations.

**(6) EQUITY TRANSACTIONS:**

On June 24, 2021, following the approval of the Company's stockholders at its annual meeting, the Company's Articles of Incorporation were amended to increase the number of authorized shares of common stock from 10,000,000 to 20,000,000.

The Company did not issue shares to employees in the three months ended September 30, 2022, and issued 7,500 shares with a value of $15,750 to an employee in the nine months ended September 30, 2022. The Company expensed $15,570 in employee stock compensation for the nine months ended September 30, 2022. The Company did not expense any employee stock compensation for the three months ended September 30, 2021, and expensed $125,000 in employee stock compensation for the nine months ended September 30, 2021.

The Company issued 5,000 shares with a value of $10,500 to a member of the scientific advisory board in the nine months ended September 30, 2022. The Company expensed $10,500 in board stock compensation for the nine months ended September 30, 2022. During the three months ended September 30, 2022, and three and nine months ended September 30, 2021, the Company did not issue shares to any members of the scientific advisory board.

**(6) EQUITY TRANSACTIONS: (CONTINUED)**

The Company accrues stock compensation expense over the period earned for employees and board members. Stock compensation expense for board members is included in "Board of Directors fees and costs" on our consolidated statement of operations, and stock compensation expense for officers and employees that are not board members is included in "Personnel" on our consolidated statement of operations. In the three and nine months ended September 30, 2022, the Company issued 16,017 and 39,083 shares to board members with a value of $ 30,752 and $102,512, respectively, at the time of issuance. Compensation expense for the 11,327 shares issued to board members with a value of $ 41,004 at the time of issuance had been accrued as of December 31, 2021.

In January 2021, the Company issued 10,000 shares of common stock with a value of $ 50,300 to a consultant for services. In January 2021, the Company issued 53,938 shares of common stock with a value of $ 271,308 to employees for compensation that had been accrued as of December 31, 2020.

During 2021, warrants to purchase an aggregate of 1,599,204 shares of common stock were exercised, resulting in gross proceeds to the Company of $7,991,101.

In March 2021, warrants to purchase an aggregate of 9,436 shares of common stock were exercised on a cashless basis, resulting in the issuance of 2,913 shares of common stock.

On November 19, 2021 the Company sold 1,950,000 shares of common stock in a public offering underwritten by Maxim, at a price to the public of $ 6.00 per share, resulting in gross proceeds of $11,700,000, before deducting underwriting discounts and commissions of seven percent (7%), and expenses. The total expenses of this offering were approximately $927,000, which included Maxim's expenses relating to the offering.

As of September 30, 2022, the Company had warrants outstanding to purchase 2,045,846 shares of common stock at exercise prices of $ 5.00 - $65.00 per share that expire at various dates through 2027. In addition, there are currently outstanding seven-year warrants to purchase (i) 4,800 Units sold in our May 2016 private placement at an exercise price of $ 25.00 per Unit, (ii) 1,641 Units sold in our February 2017 private placement at an exercise price of $35.00 per Unit, and (iii) 2,400 Units sold in our October 2017 private placement at an exercise price of $ 25.00 per Unit. The exercise in full of these warrants to purchase units (including exercise of the warrants underlying these warrants) would result in the issuance of 17,681 additional shares of our common stock at an aggregate exercise price of $474,852.

**(7) INCOME TAXES:**

The Company reported a net loss for the three and nine months ended September 30, 2022 and 2021, respectively. The Company increased its deferred tax asset valuation allowance rather than recognize an income tax benefit.

**(8) EQUITY INCENTIVE PLAN:**

On August 29, 2019, the Company's stockholders approved the Company's 2019 Omnibus Equity Incentive Plan at a special meeting of stockholders (the "Incentive Plan"). The Incentive Plan provides for the issuance of up to 68,437 shares of common stock pursuant to the grant of shares of common stock, stock options or other awards, to employees, officers or directors of, and consultants to, the Company and its subsidiaries. Options granted under the Incentive Plan may either be intended to qualify as incentive stock options under the Internal Revenue Code of 1986, or may be non-qualified options, and are exercisable over periods not exceeding ten years from date of grant. As of September 30, 2022, we had awarded 68,437 shares of common stock as awards under the Incentive Plan, with no shares of common stock remaining available for future awards under the Incentive Plan.

On June 24, 2021, the Company's stockholders approved the Company's 2021 Equity Incentive Plan at its annual meeting of stockholders (the "2021 Plan"). The 2021 Plan provides for the issuance of up to 3,000,000 shares of common stock pursuant to the grant of shares of common stock, stock options or other awards, to employees, officers or directors of, and consultants to, the Company and its subsidiaries. Options granted under the 2021 Plan may either be intended to qualify as incentive stock options under the Internal Revenue Code of 1986, or may be non-qualified options, and are exercisable over periods not exceeding ten years from date of grant. As of September 30, 2022, we had awarded 68,636 shares of common stock and granted options to purchase 425,646 shares of common stock under the 2021 Plan, with 2,505,718 shares of common stock remaining available for future awards.

**(8) EQUITY INCENTIVE PLAN: (CONTINUED)**

During the three months ended September 30, 2022, the Company did not grant any options. During the nine months ended September 30, 2022, the Company granted options to purchase 226,746 shares of common stock at exercise prices of $ 2.10 to $3.39 per share to employees. Under the option agreements, the options vest either immediately or in equal quarterly installments over four years, and have a 10-year term. The options granted during the nine months ended September 30, 2022 were valued using the Black Scholes option pricing model using the following assumptions: i) expected term of 5.00 to 6.25 years; (ii) risk free interest rate of 1.83% to 2.76%; (iii) expected volatility of 90.5% to 92.3%; and (iv) dividend yield of 0.0%. The weighted-average grant date fair value of the options issued by the Company during the nine months ended September 30, 2022 ranged from $1.60 to $2.47 per share.

**(9) NET LOSS PER SHARE:**

The following table sets forth the computation of basic and diluted net loss per common share.

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2022 | 2021 | 2022 | 2021 |
| Numerator | | | | |
| Net loss | $ (4,246,880) | $ (3,860,256) | $ (10,470,461) | $ (11,494,269) |
| Denominator | | | | |
| Weighted-average common shares outstanding, basic and diluted | 8,447,630 | 6,447,803 | 8,428,074 | 6,040,524 |
| Net loss per share, basic and diluted | $ (0.50) | $ (0.60) | $ (1.24) | $ (1.90) |

The Company reported a net loss for the three and nine months ended September 30, 2022 and 2021, therefore, the basic and diluted net loss per share are the same in the respective periods because of the inclusion of potential common shares would have an anti-dilutive effect. Potential shares of common stock that are excluded from the computation of diluted weighted-average shares outstanding are as follows:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2022 | 2021 | 2022 | 2021 |
| Stock options | 425,646 | 222,700 | 425,646 | 222,700 |
| Warrants | 2,045,846 | 2,048,186 | 2,045,846 | 2,048,186 |

**(10) SUBSEQUENT EVENTS:**

The Company has evaluated subsequent events through the date these interim consolidated financial statements were issued and filed with the Securities and Exchange Commission, and has determined that there were no such events that warrant disclosure or recognition in the consolidated financial statements.

**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, 2021. This report may contain forward-looking statements. Forward-looking statements within this Form 10-Q are identified by words such as "believes," "anticipates," "expects," "intends," "may," "will" "plans" and other similar expressions; however, these words are not the exclusive means of identifying such statements. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances are forward-looking statements. These forward-looking statements are subject to significant risks, uncertainties and other factors, which may cause actual results to differ materially from those expressed in, or implied by, these forward-looking statements. Except as expressly required by the federal securities laws, we undertake no obligation to publicly update or revise any forward-looking statements to reflect events, circumstances or developments occurring subsequent to the filing of this Form 10-Q with the U.S. Securities and Exchange Commission (the "SEC") or for any other reason and you should not place undue reliance on these forward-looking statements. You should carefully review and consider the various disclosures the Company makes in this report and our other reports filed with the SEC that attempt to advise interested parties of the risks, uncertainties and other factors that may affect our business. All amounts presented herein are rounded to nearest $1,000.*

**Overview**

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

We have also completed a Phase I/II clinical study approved by several European regulatory bodies, including those in the United Kingdom, Sweden and Italy, and in Israel. The Phase I/II study evaluated the safety, tolerability and efficacy of Trappsol® Cyclo™ through a range of clinical outcomes, including neurologic, respiratory, and measurements of cholesterol metabolism and markers of NPC. Consistent with the U.S. study, the European/Israel study administered Trappsol® Cyclo™ intravenously to NPC patients every two weeks in a double-blind, randomized trial, but differs in that the study period was for 48 weeks (24 doses). The first patient was dosed in this study in July 2017, and in March of 2021 we announced that 100% of patients who completed the trial improved or remained stable, and 89% met the efficacy outcome measure of improvement in at least two domains of the 17-domain NPC severity scale.

Additionally, in February 2020 we had a face-to-face "Type C" meeting with the FDA with respect to the initiation of our pivotal Phase III clinical trial of Trappsol® Cyclo™ based on the clinical data obtained to date. At that meeting, we also discussed with the FDA submitting a New Drug Application (NDA) under Section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for the treatment of NPC in pediatric and adult patients with Trappsol® Cyclo™. A similar request was submitted to the European Medicines Agency ("EMA") in February 2020, seeking scientific advice and protocol assistance from the EMA for proceeding with a Phase III clinical trial in Europe. In October 2020 we received a "Study May Proceed" notification from the FDA with respect to the proposed Phase III clinical trial, and in June of 2021 we commenced enrollment in TransportNPC, a pivotal Phase II study of Trappsol® Cyclo™ for the treatment of NPC.

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

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

We are also exploring the use of cyclodextrins in the treatment of Alzheimer's disease. In January 2018, the FDA authorized a single patient IND expanded access program using Trappsol® Cyclo™ for the treatment of Alzheimer's disease. After 18 months of treatment in this geriatric patient with late-onset disease, the disease was stabilized and the drug was well tolerated. The patient also exhibited signs of improvement with less volatility and shorter latency in word-finding. We prepared a synopsis for an early stage protocol using Trappsol® Cyclo™ intravenously to treat Alzheimer's disease that was presented to the FDA in January of 2021. We received feedback from the FDA on this synopsis in April 2021 and incorporated the feedback into an IND for a Phase II study for the treatment of Alzheimer's disease with of Trappsol® Cyclo™ that we submitted to the FDA in November 2021. In December of 2021, we received IND clearance from the FDA, allowing us to proceed with our Phase II study of Trappsol® Cyclo™ for the treatment of Alzheimer's disease. We expect to begin enrollment in this study during 2022.

We filed an international patent application in October 2019 under the Patent Cooperation Treaty directed to the treatment of Alzheimer's disease with cyclodextrins, and we are pursuing national and regional stage applications based on this international application. The terms of any patents resulting from these national or regional stage applications would be expected to expire in 2039 if all the requisite maintenance fees are paid.

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

**Results of Operations - Three and Nine Months Ended September 30, 2022 Compared to Three and Nine Months Ended September 30, 2021**

We reported net losses of approximately $4,247,000 and $10,470,000 for the three and nine months ended September 30, 2022, compared to net losses of approximately $3,860,000 and $11,494,000 for the three and nine months ended September 30, 2021.

Total revenues for the three month period ended September 30, 2022 increased 12% to approximately $452,000 compared to approximately $404,000 for the same period in 2021. Total revenues for the nine month period ended September 30, 2022 increased 19% to approximately $1,189,000 compared to approximately $1,000,000 for the same period in 2021. Our change in the mix of our product sales for the three and nine months ended September 30, 2022 and 2021 is as follows:

Trappsol® Cyclo HPBCDs

First and second-generation formulations of Trappsol® Cyclo™ HPBCD (in liquid and powder form) have been sold to a single customer who exports to Brazil for compassionate use in NPC patients. We sold $270 and $90 of Trappsol® Cyclo™ for the three month periods ended September 30, 2022 and 2021, respectively. We sold $970 and $2,020 for the nine month periods ended September 30, 2022 and 2021, respectively. This product is designated as an orphan drug; the population of patients who use the product on a compassionate basis is small.

Trappsol® HPB

Our sales of Trappsol® HPB increased by 18% for the three month period ended September 30, 2022, to approximately $337,000 from approximately $286,000 for the three months ended September 30, 2021. Our sales of Trappsol® HPB increased by 40% for the nine month period ended September 30, 2022, to approximately $759,000 from approximately $543,000 for the nine months ended September 30, 2021.

Trappsol® other products

Our sales of other Trappsol® other products decreased by 3% for the three month period ended September 30, 2022, to approximately $113,000 from approximately $116,000 for the three months ended September 30, 2021. Our sales of other Trappsol® other products decreased by 1% for the nine months ended September 30, 2022 to approximately $421,000 from approximately $425,000.

Aquaplex®

We did not sell any Aquaplex® for the three month period ended September 30, 2022, as compared to sales of Aquaplex® for the three months ended September 30, 2021 of $228. Our sales of Aquaplex® for the nine month period ended September 30, 2022 were approximately $800, as compared to sales of Aquaplex® for the nine months ended September 30, 2021 of approximately $23,000.

The largest customers for our legacy fine chemical business continue to follow historical product ordering trends by placing periodic large orders that represent a significant share of our annual sales volume. During the nine months ended September 30, 2022, our three largest customers accounted for 67% of our sales; the largest accounted for 40% of sales. During the nine months ended September 30, 2021, our four largest customers accounted for 65% of our sales; the largest accounted for 21% 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 three month period ended September 30, 2022 increased 43% to approximately $33,000 from approximately $23,000 for the same period in 2021. Our cost of products sold (excluding any allocation of direct and indirect overhead and handling costs) for the nine month period ended September 30, 2022 increased 41% to approximately $123,000 from approximately $87,000 for the same period in 2021. Our cost of products sold (excluding any allocation of direct and indirect overhead and handling costs) as a percentage of sales was 10% for the nine months ended September 30, 2022 and 9% for the nine months ended September 30, 2021. 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 2021, or the first nine months of 2022.

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

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

Personnel expenses decreased by 47%, to approximately $888,000 for the three months ended September 30, 2022 from approximately $1,668,000 for the three months ended September 30, 2021. Personnel expenses increased by 11%, to approximately $3,075,000 for the nine months ended September 30, 2022 from approximately $2,770,000 for the nine months ended September 30, 2021. The overall increase in personnel expense in the recent nine-month period is due to the hiring of a Chief Medical Officer and other personnel between September 2021 and June 2022 and the accrual of bonuses during such period as a result of the achievement of targets for such bonuses approved by our Board of Directors. The decrease in personnel expense in the recent three-month period is due to employee bonuses being accrued monthly in 2022, whereas nine months of the 2021 employee bonus was reflected in the three months ended September 2021. We expect to maintain our level of employees and related costs in the near term.

Research and development expenses increased 55% to approximately $2,856,000 for the three months ended September 30, 2022, from approximately $1,838,000 for the three months ended September 30, 2021. Research and development expenses decreased 25% to approximately $5,815,000 for the nine months ended September 30, 2022, from approximately $7,739,000 for the nine months ended September 30, 2021. Research and development expenses as a percentage of our total operating expenses decreased to 49% for the nine months ended September 30, 2022 from 58% for the nine months ended September 30, 2021. The changes in research and development expenses relate to the timing of startup costs in our clinical programs in various periods.

Professional fees increased 36% to approximately $612,000 for the three months ended September 30, 2022, compared to approximately $450,000 for the three months ended September 30, 2021. Professional fees increased 60% to approximately $1,674,000 for the nine months ended September 30, 2022, compared to approximately $1,047,000 for the nine months ended September 30, 2021. Professional fees may continue to increase in the future due to new initiatives in raising capital and the continuation of product development.

Office and other expenses decreased 16% to approximately $205,000 for the three months ended September 30, 2022, compared to approximately $244,000 for the three months ended September 30, 2021. Office and other expenses decreased 1% to approximately $790,000 for the nine months ended September 30, 2022, compared to approximately $800,000 for the nine months ended September 30, 2021.

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 or nine months ended September 30, 2022, and 2021, respectively.

**Liquidity and Capital Resources**

Our cash decreased to approximately $4,290,000 as of September 30, 2022, compared to approximately $16,613,000 as of December 31, 2021. Our current assets less current liabilities were approximately $5,547,000 as of September 30, 2022, compared to approximately $15,605,000 at December 31, 2021. Cash used in operations was approximately $12,367,000 for the nine months ended September 30, 2022, compared to approximately $12,394,000 for the same period in 2021.

We borrowed approximately $158,000 under the Paycheck Protection Program in May 2020. The full amount of the loan plus accrued interest was forgiven in March 2022 because the loan was used to fund certain qualifying expenses as described in the CARES Act.

The Company has continued to realize losses from operations. However, as a result of our recent public offerings, we believe we will have sufficient cash to meet our anticipated operating costs and capital expenditure requirements for at least the next 12 months. We will need to raise additional capital in the future to support our ongoing operations and continue our clinical trials. We expect to continue to raise additional capital through the sale of our securities from time to time for the foreseeable future to fund the development of our drug product candidates through clinical development, manufacturing and commercialization. Our ability to obtain such additional capital will likely be subject to various factors, including our overall business performance and market conditions. There can be no guarantee that the Company will be successful in its ability to raise capital to fund future operational and development initiatives.

Our consolidated financial statements for the nine months ended September 30, 2022 and the year ended December 31, 2021 were prepared on the basis of a going concern, which contemplates that we will be able to realize assets and discharge liabilities in the normal course of business. Our ability to continue as a going concern is dependent upon the availability of equity financing as noted above.

At December 31, 2021, we had approximately $37,510,000 in net state and federal operating loss carryforwards expiring from 2022 through 2037, including $29,000,000 that will not expire, that can be used to offset our current and future taxable net income and reduce our income tax liabilities. We have provided a 100% valuation allowance on our deferred tax asset based on our expected future expenses related to our clinical trials and other development initiatives.

We had no off-balance sheet arrangements as of September 30, 2022.

**Critical Accounting Policies and Estimates**

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S. The preparation of these financial statements requires us to make judgments, estimates, and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as the reported revenue and expenses during the reporting periods. We continually evaluate our judgments, estimates and assumptions. We base our estimates on the terms of underlying agreements, our expected course of development, historical experience and other factors we believe are reasonable based on the circumstances, the results of which form our management's basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

There were no significant changes to our critical accounting policies during the quarter ended September 30, 2022. For information about critical accounting policies, see the discussion of critical accounting policies in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021.

**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 report (the "Evaluation Date"). Based on such evaluation, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures were effective as of September 30, 2022.

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 our Annual Report on Form 10-K for our year ended December 31, 2021 that we filed with the Securities and Exchange Commission on March 11, 2022. Readers are urged to carefully review our risk factors because they may cause our results to differ from the "forward-looking" statements made in this report. Additional risks not presently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business, financial condition and results of operations. We do not undertake to update any of the "forward-looking" statements or to announce the results of any revisions to these "forward-looking" statements except as required by law.

**Item 6. Exhibits.**

| EXHIBIT NO. | DESCRIPTION |
|---|---|
| 3.1 | Articles of Incorporation of Cyclo Therapeutics, Inc., a Nevada corporation (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 10, 2020). |
| 3.2 | Certificate of Amendment to Articles of Incorporation of Cyclo Therapeutics, Inc., filed June 24, 2021 (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on June 24, 2021). |
| 3.3 | Bylaws of Cyclo Therapeutics, Inc., a Nevada corporation (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 10, 2020). |
| 31.1 | Rule 13a-14(a)/15d-14a(a) Certification of Chief Executive Officer |
| 31.2 | Rule 13a-14(a)/15d-14a(a) Certification of Chief Financial Officer |
| 32.1 | Section 1350 Certification of Chief Executive Officer |
| 32.2 | Section 1350 Certification of Chief Financial Officer |
| 101.INS | Inline XBRL Instance Document |
| 101.SCH | Inline XBRL Taxonomy Extension Schema Document |
| 101.CAL | Inline XBRL Taxonomy Extension Calculation Linkbase Document |
| 101.DEF | Inline XBRL Taxonomy Extension Definition Linkbase Document |
| 101.LAB | Inline XBRL Taxonomy Extension Label Linkbase Document |
| 101.PRE | Inline XBRL Taxonomy Extension Presentation Linkbase Document |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL and contained in Exhibit 101) |

**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.

**CYCLO THERAPEUTICS, INC.**

Date: November 10, 2022

By: */s/ N. Scott Fine*
N. Scott Fine
Chief Executive Officer
(principal executive officer)

Date: November 10, 2022

By: */s/ Joshua M. Fine*
Joshua M. Fine
Chief Financial Officer
(principal financial and accounting officer)

**EXHIBIT 31.1**

**CERTIFICATION PURSUANT TO RULE 13a-14(a)/15d-14(a)**
**OF THE SECURITIES EXCHANGE ACT OF 1934**

I, N. Scott Fine, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Cyclo Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 10, 2022

By: */s/ N. Scott Fine*
N. Scott Fine
Chief Executive Officer
(principal executive officer)

**EXHIBIT 31.2**

**CERTIFICATION PURSUANT TO RULE 13a-14(a)/15d-14(a)**
**OF THE SECURITIES EXCHANGE ACT OF 1934**

I, Joshua M. Fine, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Cyclo Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 10, 2022

By: */s/ Joshua M. Fine*
Joshua M. Fine
Chief Financial Officer
(principal financial and accounting officer)

**EXHIBIT 32.1**

**CERTIFICATION PURSUANT TO**
**18 U.S.C. SECTION 1350,**
**AS ADOPTED PURSUANT TO**
**SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with this Quarterly Report on Form 10-Q of Cyclo Therapeutics, Inc. (the "Company") for the fiscal quarter ended September 30, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, N. Scott Fine, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 10, 2022

/s/ *N. Scott Fine*
N. Scott Fine
Chief Executive Officer
(principal executive, financial and accounting officer)

**EXHIBIT 32.2**

**CERTIFICATION PURSUANT TO**
**18 U.S.C. SECTION 1350,**
**AS ADOPTED PURSUANT TO**
**SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with this Quarterly Report on Form 10-Q of Cyclo Therapeutics, Inc. (the "Company") for the fiscal quarter ended September 30, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Joshua M. Fine, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 10, 2022

/s/ *Joshua M. Fine*
Joshua M. Fine
Chief Financial Officer
(principal financial and accounting officer)