



DIVISION OF
CORPORATION FINANCE

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

November 5, 2024

Joshua M. Fine
Chief Financial Officer
Cyclo Therapeutics, Inc.
6714 NW 16th Street, Suite B
Gainesville, Florida 32653

Re: Cyclo Therapeutics, Inc.
Form 10-K for Fiscal Year Ended December 31, 2023
File No. 001-39780

Dear Joshua M. Fine:

We have reviewed your filing and have the following comments.

Please respond to this letter within ten business days by providing the requested information or advise us as soon as possible when you will respond. If you do not believe a comment applies to your facts and circumstances, please tell us why in your response.

After reviewing your response to this letter, we may have additional comments.

Form 10-K for Fiscal Year Ended December 31, 2023

Item 1. Business

Overview, page 1

1. Please revise your disclosure regarding Cyclo's business to remove or revise all statements implying safety or efficacy, as the company's product candidates have not yet received regulatory approval. Examples of such statements include, but are not limited to, the following:
 - "...to date, our clinical studies have preliminarily demonstrated that Trappsol Cyclo is safe and efficacious in the treatment of NPC over a range of dose groups."
 - "Preliminary data from our completed clinical studies suggest that Trappsol Cyclo clears toxic deposits of cholesterol and other lipids from cells, has a consistent pharmacokinetic profile peripherally, and 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 patient also exhibited signs of improvement with less volatility and shorter latency in word-finding."

- "Initial patient enrollment in the U.S. Phase I study commenced in September 2017, and in May 2020 Cyclo announced Top Line data showing a favorable safety and tolerability profile for Trappsol Cyclo in this study."

Safety and efficacy conclusions are within the sole authority of the FDA or equivalent foreign regulators. Please remove or revise these statements to instead present the objective data observed in your clinical trials.

2. We note that you announced top line data in May 2020 from your Phase I study in the U.S. We also note that you completed a Phase I/II study in the United Kingdom, Sweden and Israel under the purview of the EMA, and that in October 2020 you were notified by the FDA that you could proceed with a proposed Phase III clinical trial in the U.S. Please revise your disclosure to clarify whether you conducted a Phase II study in the U.S. or whether you relied on data obtained from your Phase I/II trial abroad to support the commencement of your Phase III trial. In the event you did conduct a Phase II trial in the U.S., please revise your disclosure in relation to clinical studies to include information regarding the trial, including, but not limited to, the number of participants, demographic information, and the resulting data including endpoints and p-values.

Competition, page 8

3. You state that you believe there is a perceived barrier to entry into the cyclodextrin industry because of the lack of general experience with cyclodextrins. Please reconcile this statement with your disclosure on page 19 that "[i]n Japan, at least twelve pharmaceutical preparations are now marketed which contain cyclodextrins; there are also multiple products in Europe and the United States."

Management's Discussion and Analysis of Financial Condition and Results of Operations
Year Ended December 31, 2023 Compared to Year Ended December 31, 2022, page 35

4. Please expand your disclosure to discuss the reasons why your revenue from the sales of Trappsol HPB and other Trappsol products decreased 24% and 18%, respectively, from fiscal year 2022 to fiscal year 2023.

Controls and Procedures, page 40

5. We note you concluded that your disclosure controls and procedures were effective as of December 31, 2023. Considering the material weakness identified in your Management's Report on Internal Control over Financial Reporting, under this heading, please tell us how you have reached this conclusion in light of the guidance in SEC Release No. 33-8238, Final Rule: Management's Report on Internal Control Over Financial Reporting and Certification of Disclosure in Exchange Act Periodic Reports, which states that disclosure controls and procedures will include those components of internal control over financial reporting that provide reasonable assurances that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles. In addition, we note that you continue to represent that disclosure controls and procedures are effective in your subsequent interim filings on Form 10-Q, with no changes described in your internal control over financial reporting. Please

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tell us how you are able to support your conclusion of effective disclosure controls and procedures as of March 31, 2024 and June 30, 2024.

6. We note you have disclosed the conclusion of the effectiveness of your disclosure controls and procedures as of the end of the period covered by your report, as required by Item 307 of Regulation S-K. However, you are also required to disclose the conclusion of the effectiveness of your internal control over financial reporting as of the end of your fiscal period in your Management's Report on Internal Control over Financial Reporting, in accordance with Item 308(a)(3) of Regulation S-K. Please revise your disclosure accordingly.

We remind you that the company and its management are responsible for the accuracy and adequacy of their disclosures, notwithstanding any review, comments, action or absence of action by the staff.

Please contact Tracie Mariner at 202-551-3744 or Daniel Gordon at 202-551-3486 if you have questions regarding comments on the financial statements and related matters. Please contact Tamika Sheppard at 202-551-8346 or Laura Crotty at 202-551-7614 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Alison Newman