



Cyclo Therapeutics (OTCQB: CTDH)

March 2, 2020
Recent Price: \$0.17

Market Data

Fiscal Year	December
Industry	Biotech
Market Cap	\$21.2M
Shares Outstanding	121.2M
Float	70.7M
Avg. Volume (90-day)	170,460

As of March 2, 2020

Financial Data

Revenue (ttm)	\$1.0M
Gross Profit (ttm)	\$0.9M
R&D Expense (ttm)	\$4.0M
Cash (mrq)	\$4.9M
Total Assets (mrq)	\$5.9M
Debt (mrq)	\$0.0M

<http://www.cyclotherapeutics.com/>

Company Overview

Cyclo Therapeutics (CTDH) is a clinical-stage biotechnology company that develops cyclodextrin-based products for the treatment of disease. The Company's Trappsol® Cyclo™, an orphan drug designated product in the United States and Europe, is used to treat Niemann-Pick Disease Type C (NPC), a rare and fatal genetic disease, on a compassionate use basis as well as in three ongoing formal clinical trials. The Company's Scientific Advisory Board endorsed Alzheimer's Disease (AD) as the company's next drug development indication. The Company was authorized by the FDA to use Trappsol® Cyclo™ for a late-onset AD patient under a Compassionate Use Program which began intravenous dosing in May 2018.

Value Proposition

CTDH has a validated, robust manufacturing process for Trappsol® Cyclo™ that includes important trade secret steps and is proven to be scalable to commercial production. NPC clinical data are encouraging with a positive safety profile. Most patients for which data are available either stabilized or improved in disease specific features. The Phase I trial is complete; unblinding in the near term. The Company's Compassionate Use Program for AD began its second year of dosing in June 2019 after a successful annual report submission to the FDA demonstrating a positive safety profile and indications of benefit. Program costs for the AD program are 100% funded by an external organization. With a \$500M+ annual addressable market in NPC and a \$1B+ annual addressable market in AD, CTDH offers a compelling opportunity for potential upside from its current valuation.

Investment Highlights

- **Active clinical trials in Niemann Pick Disease and Alzheimer's Disease**
 - Phase II in Europe/Israel and Phase I in US; enrollment complete and dosing underway in Niemann Pick Disease Type C (NPC); enrollment also complete for Extension Protocol to NPC Phase I trial for NPC1 patients. Top line results for Phase I by Q2 2020.
 - Positive feedback from US FDA on global pivotal trial design for NPC1; meeting with EMA in Q2 2020.
 - Alzheimer's Disease (AD) moving towards Phase I/II
 - Compassionate Use Program ongoing in multiple countries for NPC
 - Granted Orphan Drug Designation (ODD) by the US FDA and European Medicines Agency; Rare Pediatric Disease and Fast Track designations in US
- **Large Market Opportunity**
 - NPC represents significant \$500M+ annual addressable market
 - AD represents \$1B+ opportunity
- **Strong management team and board**
 - Senior leadership experience at Alpharma, Pfizer, Sanofi, USP Zdrowie, Colgate-Palmolive, and Green Mountain Coffee
 - Approximately \$10M invested by insiders
 - Chief Scientific Officer, Dr. Sharon Hrynkow, appointed to the President's Council of Advisors on Science and Technology (one of first seven members)
- **Strong balance sheet**
 - Recently closed \$7.4M institutional equity financing
- **Robust Cyclodextrin portfolio & intellectual property**
 - Cyclodextrins are modifiable for multiple therapeutic areas
 - Company is leader in intravenous use of cyclodextrins
 - ODD gives market exclusivity for 7-12 years in US and EU, respectively
 - Company holds trademark, copyright, and trade secret intellectual property around the Trappsol® Cyclo™ product
- **Buy recommendation and \$1.25 price target from ThinkEquity**