OTCQB: CTDH

Cyclo Therapeutics, Inc.

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Some of the information in this report relates to future events or future business and financial performance. Such statements constitute forward-looking information within the meaning of the Private Securities Litigation Act of 1995. Such statements can be only predictions and the actual events or results may differ from those discussed due to, among other things, the risks described in the public filings and other publications of Cyclo Therapeutics, Inc. Forward-looking statements are identified by words such as “anticipates”, “projects”, “expects”, “plans”, “intends”, “believes”, “estimates”, “target”, and other similar expressions that indicate trends and future events.

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Covid-19

All of us have been affected by the Covid-19 pandemic. The pandemic has caused a delay in some of our patients' dosing and we are working with health professionals and regulators to help these patients in any way we can.

We have communicated with our vendors as to how we can help each other and work in the current environment.

We will communicate with stakeholders through the filing of our 10K.

We as a Company will do our part globally to help and work with the world to enable us to navigate through and continue to move forward our Clinical Trials to help the NPC community; they are depending on us.

All of us need to protect each other and carry on; this team is dedicated to that end.

Company Overview

Cyclo Therapeutics, Inc. a clinical-stage biotechnology company, is developing cyclodextrin-based drugs for the treatment of disease.

- Corporate headquarters in Gainesville, FL
- Founded in 1990 as a cyclodextrin-distribution company
- Game changer: Dr. Benny Liu showed in 2006 that one version of cyclodextrins, **hydroxypropyl beta cyclodextrins, can release cholesterol from cells** in animal models of Niemann-Pick Disease Type C (NPC). NPC is a rare inherited neurodegenerative disease that affects infants, children and adults. It is caused by an accumulation of lipids in the liver, brain and spleen.
- This discovery led directly to Cyclo Therapeutics providing cyclodextrins to NPC families for use in compassionate programs. Dr. Hastings was first to administer our product to NPC patients, route of administration was Intravenous.
- This led directly to ground-breaking work of other physicians in the US, Brazil and other countries, and ultimately to our decision to develop our version of hydroxypropyl beta cyclodextrin, Trappsol® Cyclo™, as a treatment for Niemann-Pick Disease Type C1.

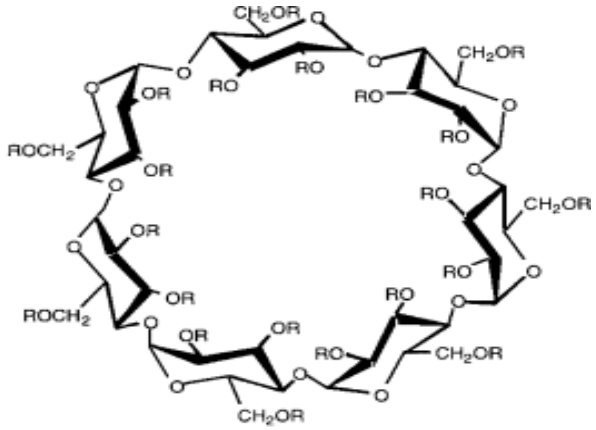
Management Team & Board of Directors

N. Scott Fine	Chairman & CEO
Sharon H. Hrynkow, PhD	Chief Scientific Officer
Jeffrey L. Tate, PhD	COO, CQO, Director
Michael Lisjak	Global Head of Regulatory Affairs
Joshua M. Fine	Chief Financial Officer
C.E. “Rick” Strattan	Director & Founder
Markus Sieger	Lead Director
William S. Shanahan	Director
F. Patrick Ostronic	Director
Randall Toig, MD	Director

Investment Highlights

Trappsol® Cyclo™ Clinical programs in Niemann Pick Disease and Alzheimer's Disease	• Phase I in U.S. – Completed, Top Line Results May 2020 • Phase II in Europe/Israel – Fully enrolled, Interim analysis May 2020 • NPC1 and AD, Compassionate Use Program ongoing in multiple countries • Granted Orphan Drug Designation (ODD) by the U.S. Food and Drug Administration and European Medicines Agency; Rare Pediatric Disease Designation (U.S.) and Fast Track designation (U.S.)
Large Market Opportunity	• Alzheimer's Disease moving towards Phase I/II • NPC represents significant $500mm+ annual addressable market • Alzheimer's Disease $1 Billion+ Opportunity
Strong Management Team & Board	y $10 million inv polpharma, GREEN MOUNTAIN COFFEE, SANOFI, USP Zdrowie, COLGATE-PALMOLIVE, Pfizer
Robust Cyclodextrin Portfolio & IP	• Cyclodextrins are modifiable for multiple therapeutic areas • Company is leader in intravenous use of cyclodextrins • Orphan Drug Designation gives market exclusivity for 7- 12 years, US and EU, respectively • The company holds trademark, copyright and trade secret intellectual property around the Trappsol® Cyclo™ product.

Trappsol® Cyclo™



β-Cyclodextrin, R=H
HPβCD, R=$OCH_2CH(CH_3)OH$ or H

This schematic represents interaction of cylinder shaped cyclodextrins and cholesterol in a 1:1 or 1:2 ratio

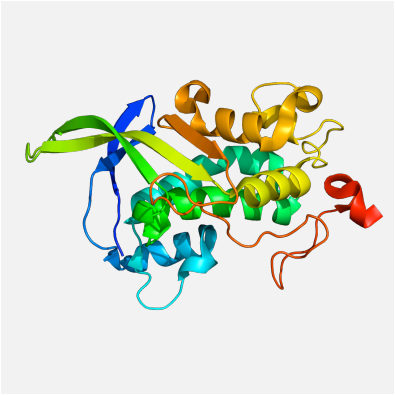
Figure is courtesy of David Begley, Kings College

- Trappsol® Cyclo™ is Cyclo Therapeutics' proprietary formulation of hydroxypropyl beta cyclodextrin.
- HPβCD is a ring of 7 pyranose form glucose molecules, modified by adding hydroxypropyl groups, to enhance solubility. Cholesterol and other poorly water soluble molecules can be complexed in the central cavity of an HPβCD molecule.
- HPβCD is widely used as excipient in products including Sporanox® (a broad-spectrum anti-fungal), eye drops, and mouthwash.

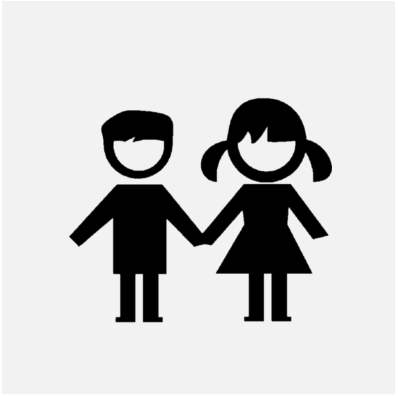
Niemann-Pick Disease Type C: Overview

An autosomal recessive lysosomal storage disease

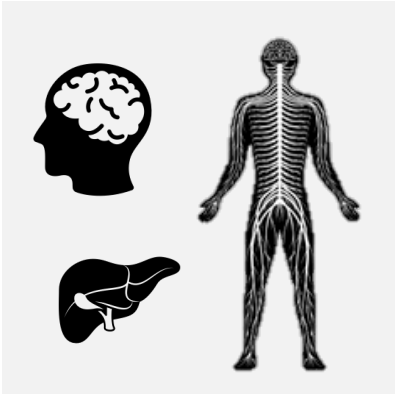
1/80,000 - 1/120,000
Live Birth Incidences



The disease is associated with accumulation of cholesterol in late endosomes and lysosomes due to **loss of normal function of the NPC protein** (NPC1 in 95% of cases, NPC2 in 5% of cases).



NPC is highly variable, presenting **usually in young children**, who often do not survive into adulthood, and also has a later onset presentation which leads to longer term disability. The disease is difficult to diagnose and, therefore, under-diagnosed.



NPC damage can be **found in the brain, liver, and other body tissues**. Depending on severity of the disease, cognitive impairment, movement disorders, swallowing, lung, liver and other normal functions are affected.

Niemann-Pick Disease Type C: Market Potential

Existing NPC Cases	Number of live births	Incidence	New Cases / Year	Annual Diagnosis Rate	Patient Penetration	Treatable Cases/Year	Annual IV Orphan Drug Price (Avg.)
3,000*	137,000,000	**1/100,000	1,370	25%	50%	171	$404,737***

- Addressable market approaching $500mm
- Diagnostic capacity is improving – numbers of patients seeking treatment will increase

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* Extrapolation from BMC Neurol. Dec 15,15(1):257) and other assumptions **Wassif, C et al. Genet Med. 2016 January ; 18 (1):41-48***LifeSci Capital., “Analysis of Orphan Drug Market”. Feb 4, 2016,

Compassionate Use/Expanded Access with Intravenous Trappsol® Cyclo™

- Cyclo Therapeutics' expanded access program in NPC began in 2009 with US and Brazilian patients being the first to use Trappsol® Cyclo™ intravenously, later intrathecal added in some cases. Physicians in Europe later joined the program. Some patients now nearing the 10 year mark.

- Cyclo Therapeutics gathered safety and efficacy data from 20 NPC patients in 2014 – 2015 and used these data to launch formal clinical trials for Trappsol® Cyclo™.

- We learned from Intravenous expanded access programs: Favorable safety profile allowed physicians to continue to use the drug for many years; individual patients benefited by **reduction in liver size; restoration of language skills; resolution of interstitial lung disease; improvement in fine and gross motor skills, improvement in quality of life**.

- Based on these findings, Cyclo Therapeutics published most extensive set of case studies on expanded access use of HPβCDs to treat NPC children and young adults, October 2019, in peer-reviewed journal Orphanet J. Rare Diseases 2019, 14:228. Hastings, Vieira, Lui… and Hrynkow.

    - No safety issues, drug was well-tolerated, easy to administer.

    - Moderately affected NPC patients treated with HPβCD showed slowing of disease progression.

    - "Neurologic and neurocognitive benefits were seen in most patients with intravenous alone, independent of the administration of IT administration."

In Sept. 2019, FDA approved a single IND program for a pediatric NPC patient with neurologic symptoms to receive intravenous Trappsol® Cyclo™

Trappsol® Cyclo™ Phase I Study to Evaluate Safety and Impact On Biomarkers of NPC Disease

United States

Randomization 6:6 Between Dose Groups

Trappsol® Cyclo™: Bi-weekly 8 hour intravenous treatment for a period of 14 weeks

RANDOMIZE (N=12)

Dose Group 1	Dose Group 2
1500 mg/kg	**2500 mg/kg**

Primary Endpoint	• Plasma levels of Trappsol® Cyclo™
Secondary Endpoint	• Markers of Cholesterol metabolism/synthesis • CSF Levels of Trappsol® Cyclo™ • hepatic and splenic morphology • global impression of disease
Exploratory Endpoint	• CSF biomarkers of NPC Disease

- Niemann-Pick Disease Type C1
  - Confirmed diagnosis of NPC1
  - NIH NPC Severity Score <30 and with no more then 4 individual domains with a score of > 3
  - Age range: 18 years upwards
- Single site in the U.S.
  - UCSF Benioff Children's Hospital Oakland
  - Emmes is supporting the study with site management and monitoring
- Trial Timeline
  - First patient enrollment: Q'3 17
  - First patient dosed Q'3 17
  - Last patient enrolled Q'4 19
  - Top Line data expected Q'2 20

Cyclo Therapeutics, Inc.

Trappsol® Cyclo™
Phase I/II Study to Evaluate Safety and Efficacy

Europe

Randomization 4:4:4 Between Dose Groups

Trappsol® Cyclo™: Bi-weekly 8 hour intravenous treatment for a period of 48 weeks

RANDOMIZE (N=12)

Dose Group 1	Dose Group 2	Dose Group 3
1500 mg/kg	**2000 mg/kg**	**2500 mg/kg**

Primary Endpoint	• Plasma levels of Trappsol® Cyclo™
Secondary Endpoint	• Markers of Cholesterol metabolism/synthesis • CSF Levels of Trappsol® Cyclo™ • Clinical Outcomes (motor Skills, cognition, eye movements, liver morphology et al) • global impression of disease
Exploratory Endpoint	• CSF biomarkers of NPC Disease

- Niemann-Pick Disease Type C1
  - Confirmed diagnosis of NPC1
  - NIH NPC Severity Score <30 and with no more then 4 individual domains with a score of > 3
  - Age range: 2 years upwards
- Total Sites: 5-6 in 4 Countries
  - UK, Sweden, Italy, Israel
  - Aptus/Synteract is supporting the trial with site management and monitoring
- Trial Timeline
  - First patient enrollment: Q'2 17
  - First patient dosed Q'3 17
  - Last patient enrolled Q'1 20
  - Interim analysis expected Q'2 20

Cyclo Therapeutics, Inc.

Initial Data from U.S. and E.U./Israel trials

- Safety data show positive profile.
- Trappsol® Cyclo™ releases cholesterol from cells of NPC patients, allowing for cells to normalize.
- Trappsol® Cyclo™ crosses the blood-brain-barrier following intravenous administration.
- One marker for NPC disease severity, lysosphingomyelin-509, shows a downward trend with successive administration of intravenous Trappsol® Cyclo™. Another biomarker of neurodegeneration, tau, trends downward in the cerebrospinal fluid. This tells us that as Trappsol® Cyclo™ clears cholesterol from cells and there are downstream effects on markers of NPC disease severity.
- Clinical efficacy data are limited but encouraging. Disease specific features, including fine motor, gait, and cognition improve in some subjects. Most patients for which data are available either stabilized or improved in disease specific features.

Milestones – Niemann Pick trials

- Engaged with Worldwide Clinical Trials as CRO for Global pivotal program
- Scientific Advice meeting with FDA on Feb 27, 2020 was positive and confirmed our ability to move toward a Phase III trial
- Safety Review Committee confirms positive safety profile from Phase I data (March 2020)
- Phase I trial – Completed enrollment, Top Line results anticipated May 2020.
- Phase I/II trial – Completed enrollment, Interim analysis anticipated May 2020.
  - Unblinded data will be used to correlate dose and efficacy
- Scientific Advice on pivotal program from EMA anticipated May 2020
- Global pivotal trial protocol anticipated to be submitted in Q'3 2020 to FDA and Q'4 2020 Globally
- First Patient In anticipated for late Q'3 2020

Links between NPC and Alzheimer's Disease

NPC and Alzheimer's Disease share common features:

- Neurofibrillary tangles, tau, amyloid beta plaques in brains of NPC and AD patients
- Hypercholesterolemia is a risk factor for AD
- Lysosomal dysfunction found in both NPC and AD
- Increased cellular cholesterol increases the association of an enzyme, secretase, with the precursor protein to amyloid beta (APP), leading to increased levels of amyloid beta
- Cognitive decline

Cell and Animal models for AD studies using HPBCDs show:

- HPβCDs added to cells that over-express the precursor protein APP lowers amyloid beta
- HPβCDs given subcutaneously to a mouse that over-expresses APP:
  - reduces amyloid beta by reducing cleavage of APP;
  - improves memory as shown in a standard water maze test;
  - reduces microgliosis;
  - up-regulates genes involved in cholesterol transport and amyloid beta clearance

    (as well as NPC1)

Reference: J. Yao, et al. Neuroprotection by cyclodextrin in cell and mouse models of Alzheimer disease. J. Exp. Med. 2012, V. 209 (13): 2501-2513

Alzheimer's Disease Compassionate Use Program

- Individual IND authorized by FDA to use Trappsol® Cyclo™ in late-onset Alzheimer's patient, first geriatric patient to receive Trappsol® Cyclo™
  - Intravenous Dosing of Alzheimer's patient on a Monthly basis began in 2018
- PI is award-winning, highly recognized Alzheimer's expert, Diana Kerwin, MD
- Program costs funded 100% by external organization with Cyclo providing clinical manuals and other clinical materials, validation methodologies for biomarker analyses, and expert input on protocol design
- FDA accepted annual report in 2019 which described favorable safety profile, stabilization of disease and improvements in behavior (less volatility and improved word-finding ability).
- After 18 months the patient voluntarily withdrew, not for safety reasons.

Highlights of our Alzheimer's clinical trial

- Worldwide Clinical Trials selected to lead development and execution of our AD program
- Synopsis of Phase II dose-finding in preparation along with the investigator brochure and site feasibility.
- Worldwide has a long list of potential sites and PIs, academic and private centers.

IP & Patent Protection

- The Company has a validated, robust manufacturing process for Trappsol® Cyclo™ that includes important trade secret steps and is proven to be scalable to commercial production.
- Trappsol® Cyclo™ has stability monitoring data to support a 48 month expiration date and will soon be able to support 60 months.
  - This includes in-use stability data for 48 hours following dispensing
- The Company holds valuable registered trademarks and copyrights including the Trappsol® Cyclo™ brand name
- Type II Drug Master File (DMF) for Drug Product
- Cyclo Therapeutics, Inc. filed a patent, “Methods for Treating Alzheimer’s Disease”, with US Patent and Trademark Office (Oct 2018); amended application based on 1-year data (Aug 2019); and filed International Application/Patent Cooperation Treaty (Oct 2019)
  - The filing describes dosing regimens and routes of administration of hydroxypropyl beta cyclodextrins for the treatment of Alzheimer’s Disease.
- Orphan Drug Designation for NPC allows market exclusivity for 7 and 12 years in the US and EU, respectively.

Scientific Advisory Board

Rita Colwell, PhD	Co-Chair	Distinguished Professor, U. of Maryland, former Director National Science Foundation
Sharon Hrynkow, PhD	Co-Chair	Cyclo Therapeutics' CSO & SVPMA, Neuroscientist
M. Flint Beal, MD		Professor of Neurology and Neuroscience, Weill Cornell Medical College
Caroline Hastings, MD		Fellowship Director, Pediatric Hematologist/Oncologist, UCSF Benioff Children's Hospital Oakland
Benny Liu, MD		Gastroenterologist, Alameda Health System and UCSF Benioff Children's Hospital Oakland

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Trappsol® Cyclo™

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- Alzheimer's Disease $1 Billion+ Opportunity

Strong Management Team & Board

y $10 million inv

polpharma · GREEN MOUNTAIN COFFEE · SANOFI · USP Zdrowie · COLGATE-PALMOLIVE · Pfizer

Robust Cyclodextrin Portfolio & IP

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- Company is leader in intravenous use of cyclodextrins
- Orphan Drug Designation gives market exclusivity for 7- 12 years, US and EU, respectively
- The company holds trademark, copyright and trade secret intellectual property around the Trappsol® Cyclo™ product.

Thank You

Cyclo Therapeutics, Inc.