

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): August 24, 2023

Cognition Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

001-40886
(Primary Standard Industrial
Classification Code Number)

13-4365359
(I.R.S. Employer
Identification No.)

2500 Westchester Ave.
Purchase, NY
(Address of principal executive offices)

10577
(Zip Code)

Registrant's telephone number, including area code: (412) 481-2210

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of Each Class	Trading Symbol	Name of Exchange on Which Registered
Common Stock, par value \$0.001 per share	CGTX	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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. ☐

Item 7.01 Regulation FD Disclosure.

Attached as Exhibit 99.1 and furnished for purposes of Regulation FD is a presentation that Cognition Therapeutics, Inc. may use from time to time in presentations or discussions with investors, analysts, and other parties.

The information in this Item 7.01 (including Exhibit 99.1) is being furnished solely to satisfy the requirements of Regulation FD and shall not be deemed to be “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that Section, nor shall it be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

The following exhibits are being furnished herewith:

Exhibit No.	Document
99.1	Investor presentation of Cognition Therapeutics, Inc.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: August 24, 2023

COGNITION THERAPEUTICS, INC.

By: /s/ Lisa Ricciardi
Name: Lisa Ricciardi
Title: President and Chief Executive Officer



Disease-modifying medicines for neurodegenerative disorders

Perspective from a pre-Commercial Company

August 2023

Agenda for Investor Discussion

- Why we work in age-related neurodegenerative conditions
- What we are doing to prepare for Phase 3 clinical trials & commercialization
- How we fund our company

Forward-looking Statements

FORWARD-LOOKING STATEMENTS

This presentation contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. All statements contained in this presentation, other than statements of historical facts or statements that relate to present facts or current conditions, including but not limited to, statements regarding our cash, financial resources and product candidates, including CT1812, and any expected or implied benefits or results, including that initial clinical results observed with respect to CT1812 will be replicated in later trials, our clinical development plans, are forward-looking statements. These statements, including statements related to the timing and expected results of our clinical trials, involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by the forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may," "might," "will," "should," "expect," "plan," "aim," "seek," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "forecast," "potential" or "continue" or the negative of these terms or other similar expressions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition, and results of operations. These forward-looking statements speak only as of the date of this presentation and are subject to a number of risks, uncertainties and assumptions, some of which cannot be predicted or quantified and some of which are beyond our control. Factors that may cause actual results to differ materially from current expectations include, but are not limited to: competition, our ability to secure new (and retain existing) grant funding, our ability to grow and manage growth, maintain relationships with suppliers and retain our management and key employees; our ability to successfully advance our current and future product candidates through development activities, preclinical studies and clinical trials and costs related thereto; uncertainties inherent in the results of preliminary data, preclinical studies and earlier-stage clinical trials being predictive of the results of early or later-stage clinical trials; the timing, scope and likelihood of regulatory filings and approvals, including regulatory approval of our product candidates; changes in applicable laws or regulations; the possibility that we may be adversely affected by other economic, business or competitive factors, including ongoing economic uncertainty; our estimates of expenses and profitability; the evolution of the markets in which we compete; our ability to implement our strategic initiatives and continue to innovate our existing products; our ability to defend our intellectual property; the impact of the COVID-19 pandemic on our business, supply chain and labor force; and the risks and uncertainties described more fully in the "Risk Factors" section of our annual and quarterly reports filed with the SEC that are available on www.sec.gov. You should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur, and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in a dynamic industry and economy. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties that we may face. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

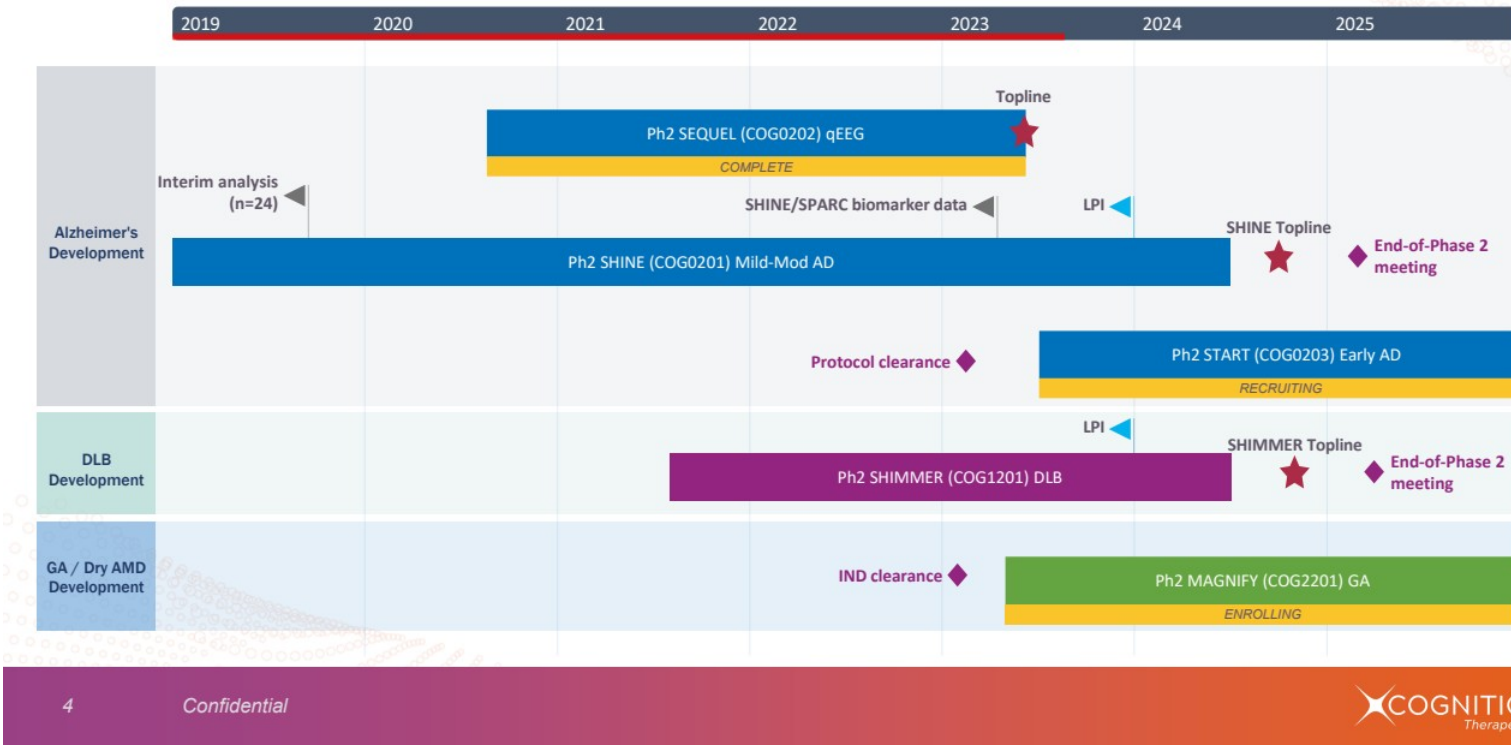
TRADEMARKS

This presentation may contain trademarks, service marks, trade names and copyrights of other companies, which are the property of their respective owners. Solely for convenience, some of the trademarks, service marks, trade names and copyrights referred to in this presentation may be listed without the TM, SM © or ® symbols, but we will assert, to the fullest extent under applicable law, the rights of the applicable owners, if any, to these trademarks, service marks, trade names and copyrights.

MARKET & INDUSTRY DATA

Projections, estimates, industry data and information contained in this presentation, including the size of and growth in key end markets, are based on information from third-party sources and management estimates. Although we believe that these third party-sources are reliable, we cannot guarantee the accuracy or completeness of these sources. Our management's estimates are derived from third-party sources, publicly available information, our knowledge of our industry and assumptions based on such information and knowledge. Our management's estimates have not been verified by any independent source. All of the projections, estimates, market data and industry information used in this presentation involve a number of assumptions and limitations, and you are cautioned not to give undue weight to such information. In addition, projections, estimates and assumptions relating to us and our industry's future performance are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including, but not limited to, those described above, that could cause future performance to differ materially from our expressed projections, estimates and assumptions or those provided by third parties.

Multiple Near-term Catalysts



Cognition Therapeutics – Our Company

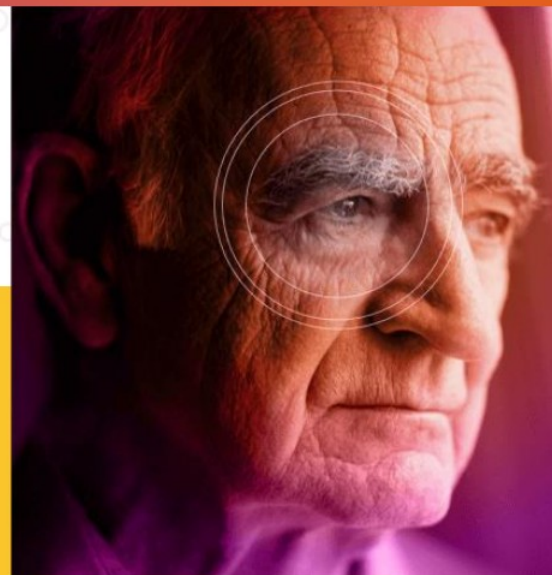
- **The Why:** Our science shows we can impact intractable conditions. Our senior team is driven to treat Alzheimer's disease and mitigate fear. Commercial executives have developed programs with pharma interest in mind.
- **The What:** Our Pittsburgh Labs were formed *to identify* specific neurodegeneration targets. The result is an oral candidate, a well-defined clinical target, and clinical & regulatory programs underpinned by a biomarker strategy.
- **The How:** Strong community support from Alzheimer's disease specialists, funding entities including the NIA and MJFF, and investors has enabled our research and clinical operations.

A Pipeline in a Pill – lead candidate CT1812

Innovative and familiar

- Within the amyloid hypothesis, oligomers are a pathogenic form produced early in disease
- Innovation lies in blocking toxic oligomer binding and displacing bound oligomers
 - High degree of blood brain barrier penetration, thus reaches its target
 - Disease-modifying impact on synapses
- Potential breakthrough efficiency: treating Alzheimer's disease with an oral drug, minimizing imaging requirements and associated side effects
- Familiar small molecule chemistry and receptor targeting
- Manufactured from easily sourced materials

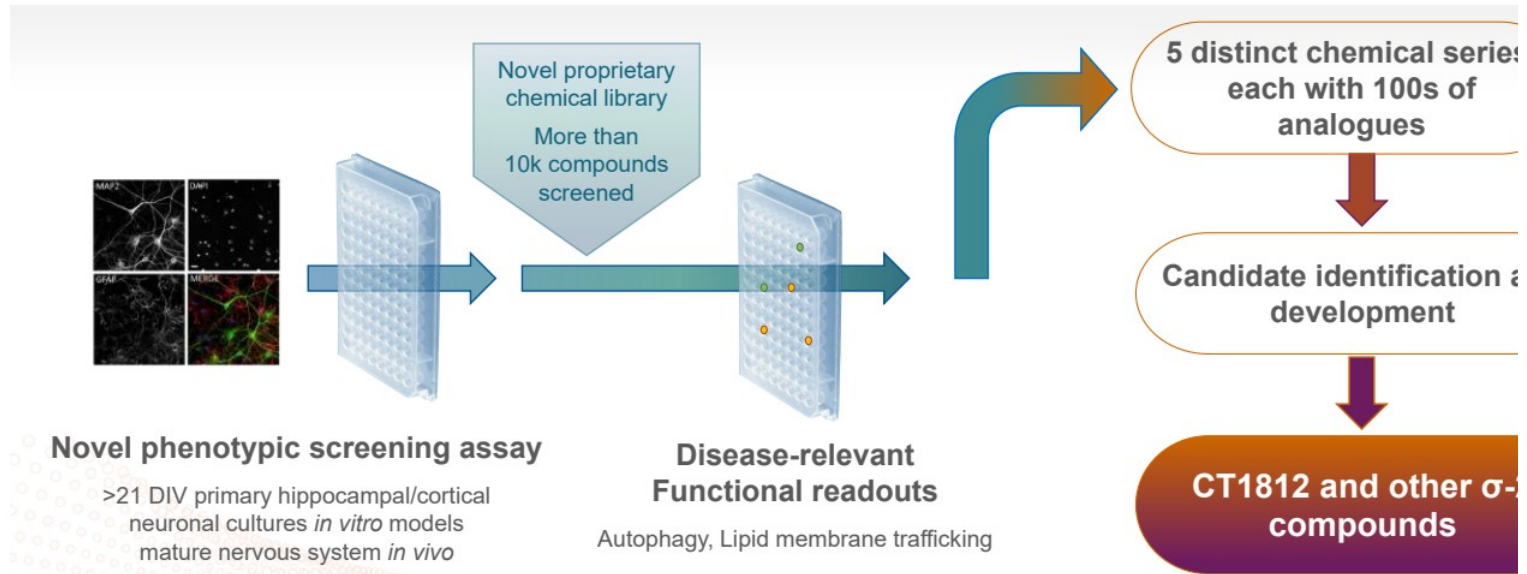
The Why: **Our Science**



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The Founding Scientists' Goal was to Identify Protective Mechanisms for Neuronal Damage in AD

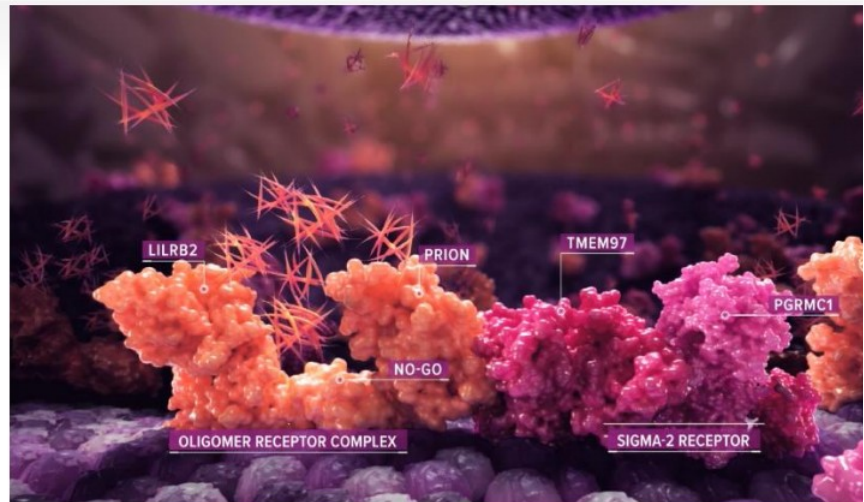
Platform-enabled product company built on novel library & screening assay



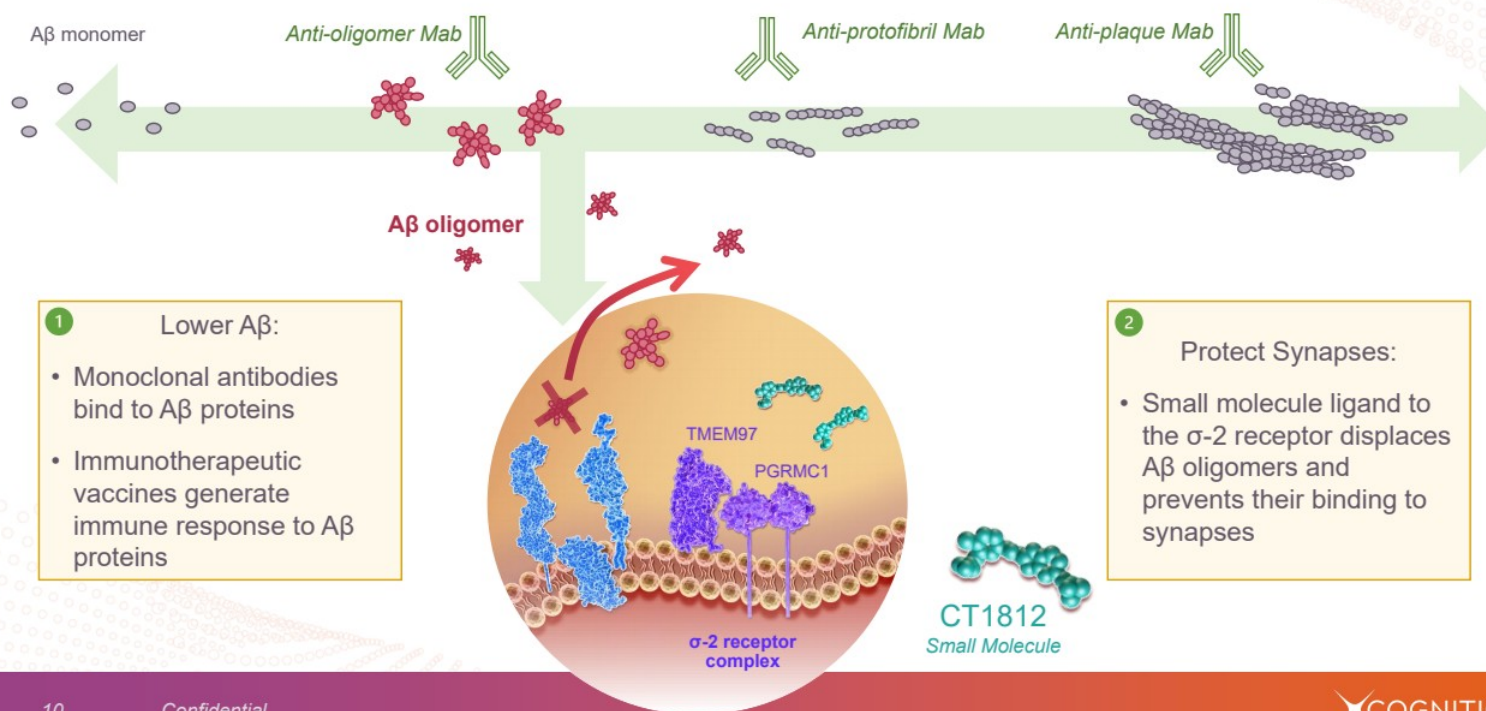
CT1812 Operates at a Cellular Level to Protect Neurons and Processes Impaired in Neurodegenerative Disease

σ -2 is a druggable receptor target

- Robust scientific legacy has defined biological effects of σ -2 modulation, resulting in new molecules
- Behavioral data from *in vivo* animal models and *in vitro* studies
- CT1812 is in multiple Phase 2 clinical trials
- Science vetted through peer-reviewed publications and peer-reviewed NIA grant process



CT1812: A Novel Approach Within the Established Amyloid Cascade



Our MoA Video: <https://vimeo.com/800999561>



AMYLOID BETA (β)

The What: **Our Target Product** **Profile and Trials**



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Recent Breakthroughs include:

- ✓ Conditional approval for Aduhelm,
- ✓ Full approval for Leqembi
- ✓ BLA filing of donenamab

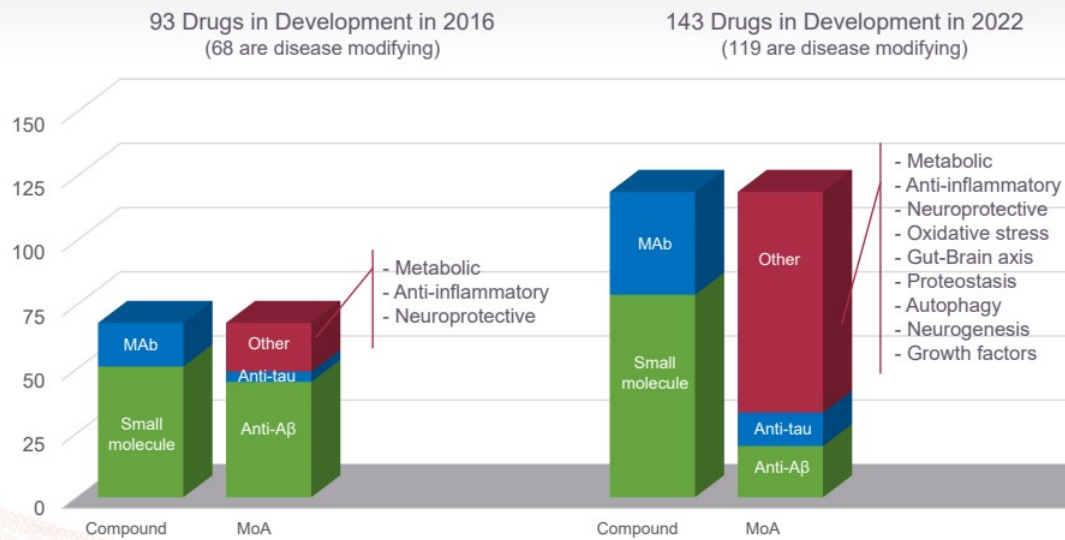


The Evolving AD Market Needs Oral Therapy

- Labeled for initiation of use only in early and mild Alzheimer's patients
- CMS coverage is evolving along with considerations for total cost burden
 - Therapy
 - Monitoring requirements / imaging

Alzheimer's Research Continues to Expand

New mechanisms being developed



Our goal: Develop and Launch A Commercially Successful AD Drug

Addresses Patient Care and Caregiver Needs and Economic Burden of Treatment

- Routine diagnostic examinations
- Once-daily oral therapy
- Modest side effect profile
- No imaging requirements; reduced associated economics
- Limited potential for ARIA
- Minimized caregiver burden of administration and monitoring requirements
- Strong intellectual property position on key parameters of drug & treatment

Considerations for Potential Pharma Partners

- Clinical trial design consistent with established regulatory endpoints
- FDA interactions supportive of trial plans
- Strong intellectual property including filings and issued patents
- Commercial product profile with competitive differentiation
- Well considered pricing strategy

"Conversations"

Our development efforts include patient, caregiver and KOL input

<https://cogrx.com/conversations/>



Episode 1: Dementia with Lewy Bodies

Featuring:

- James Galvin, MD, MPH, Univ of Miami Miller School of Medicine



Episode 2: Amyloid Lowering Key Insights from Recent Data

Featuring:

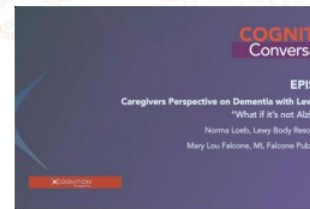
- Christopher H. van Dyck, MD, Yale University School of Medicine
- Anton P. Porsteinsson, MD, Univ of Rochester School of Medicine and Dentistry



Episode 3: What if it's not Alzheimer's? The Caregiver's Perspective on Lewy Body Dementia

Featuring:

- Norma Loeb, Lewy Body Dementia Resource Center
- Mary Lou Falcone, caregiver



Episode 4: Insights for the HCP Recognizing Dementia w Lewy Bodies

Featuring:

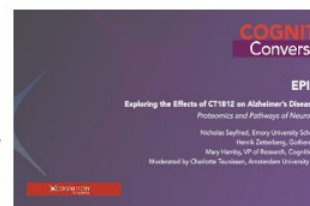
- Brendan Kelley, MD, Univ of Texas SW
- Sarah B. Berman, MD, PhD, Univ of PGH
- James Leverenz, MD, Cleveland Clinic Lou Ruvo Center for Brain Health
- David Shprecher, DO, Banner Sun Health Research Institute



Episode 5: Proteomics & Pathways of Neurodegeneration

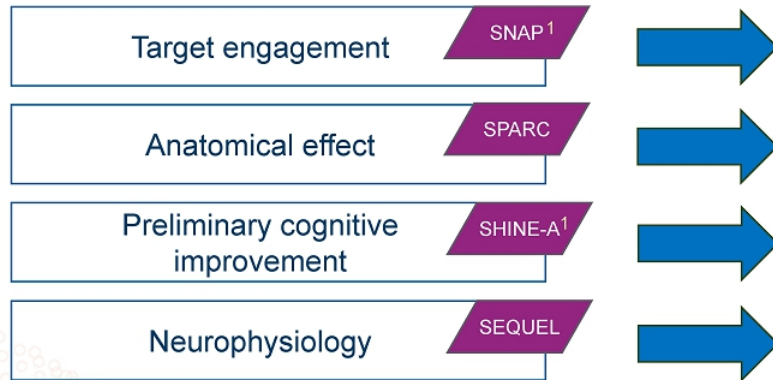
Featuring:

- Charlotte Teunissen, PhD, Amsterdam University Medical Center
- Nicholas Seyfried, PhD, Emory University School of Medicine
- Henrik Zetterberg, MD, PhD, Gothenburg University



What We Have Learned From Clinical Trials to Date

Endpoint of Interest:



Results:

CT1812 engages target for neuroprotection

Demonstrated effect on slowing brain atrophy

Demonstrated 3+ point difference in cognition measured by ADAS-COG at Day 185

Brain wave patterns move toward normalization across multiple measures

1. AD/PD™ 2022 & LaBarbera, et al. *Transl Neurodegener* 2023

Our Biomarker Strategy: Measure Impact on Synapse Health, Neuroinflammation and Amyloid Biology

✓ Completed:

- *Unbiased* analyses of plasma and CSF samples from:
 - Phase 1/2
 - SHINE Cohort A
 - SPARC
 - SHINE A / SPARC pooled
 - SEQUEL
- Identified candidate biomarkers of CT1812 target engagement


☐ Next steps:

- Analyze SHINE and SHIMMER clinical data to determine correlation of biomarkers with cognitive outcomes
- Evaluate prospective study to assess predetermined biomarkers

Phase 2 Program Informs Phase 3 & Regulatory Strategy

Phase 3 program supported by clinical data to date and validation of mechanism

- Estimating enrollment of 700-1,500 participants each in two studies
 - Global enrollment
 - Randomized 2:1 to CT1812 or placebo
 - Phase 2 results inform duration of treatment
- Stratification with concomitant therapy
- Initiate HEOR (health economics, outcomes research) and pricing research



The How: **Support for Research and Clinical Trials**



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Long History of Financial Support, Competitively Won From NIA Partners

Funding Org	Year	Project	Amount
National Institute on Aging (NIH)	2016	COG0101 Ph1b first-in-patient trial for CT1812	\$2,410,669
National Institute on Aging (NIH)	2016	COG0102 Ph1b/2a Clinical Trial for CT1812	\$2,410,669
National Institute on Aging (NIH)	2017	COG0104 Ph1 SNAP Study: CSF Catheter	\$2,527,271
National Institute on Aging (NIH)	2017	COG0105 Ph1 SPARC Study: SV2a PET	\$4,795,774
National Institute on Aging (NIH)	2018	COG0201 Ph2 SHINE Study	\$16,848,329
National Institute on Aging (NIH)	2019	COG0202 Ph2 SEQUEL Study: qEEG	\$3,300,642
National Institute on Aging (NIH)	2020	COG0203 Ph2 Study with ACTC	\$80,974,766
National Institute on Aging (NIH)	2021	COG0108 Study: hAME	\$1,642,783
National Institute on Aging (NIH)	2021	COG0201 Ph2 SHINE Amendment	\$13,634,548
National Institute on Aging (NIH)	2021	COG1201: Study: DLB	\$29,498,048
National Institute on Aging (NIH)	2022	COG0202 Ph2 SEQUEL Supplement	\$2,144,409
NIH and others	2010-2018	Ten Preclinical Programs	\$10,359,971
			\$170,547,879

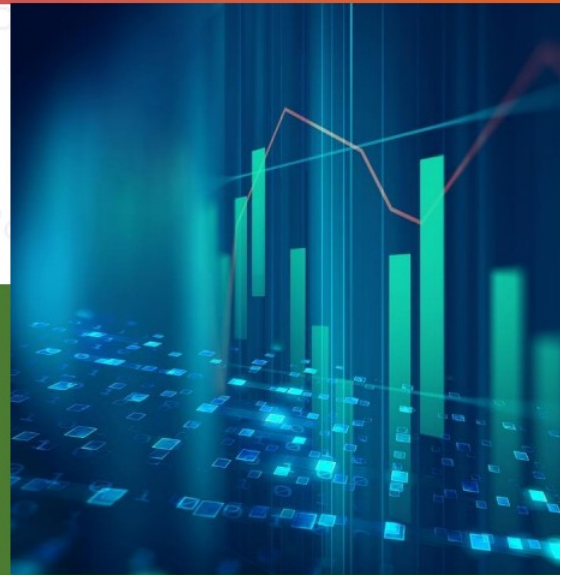
Financial Position

Financials as of June 30, 2023

- Cash and Cash Equivalents: \$37.2 million
- Expected cash runway through third quarter of 2024

Grant funding for CT1812 studies as of June 30, 2023

- Preclinical through Phase 2: appx \$171.0 million
 - Approximate funding used: (\$89.2 million)
 - Remaining grant funding: **\$81.8 million**



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Next Steps: Preparations for Phase 3 & Commercialization

- Develop protocol for prospective biomarker study
- Complete dementia trials: mild-moderate Alzheimer's and DLB
- Progress START study in early Alzheimer's disease
- Advance MAGNIFY study in dry AMD
- Initiate research on IRA & pricing impact
- Conduct KOL panels on product profile
- Ascertain Initial support for pharma engagement



Thank You

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