

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): September 12, 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 8.01 Other Events.

Attached as Exhibit 99.1 is a presentation that the Company may use from time to time in presentations or discussions with investors, analysts, and other parties.

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: September 12, 2023

COGNITION THERAPEUTICS, INC.

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



Disease-modifying medicines for neurodegenerative disorders

September 2023

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 of 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 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 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. 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," "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 will affect our 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 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, 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; the timing, scope and likelihood of 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, 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. These forward-looking statements are 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 predicted. 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 be 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 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 our own 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 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. 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.

Alzheimer's Disease (AD) – It impacts every one of

The people

- 2021 ~ 6.5M Americans
- 2060 ~ 12.7M Americans

The Cost

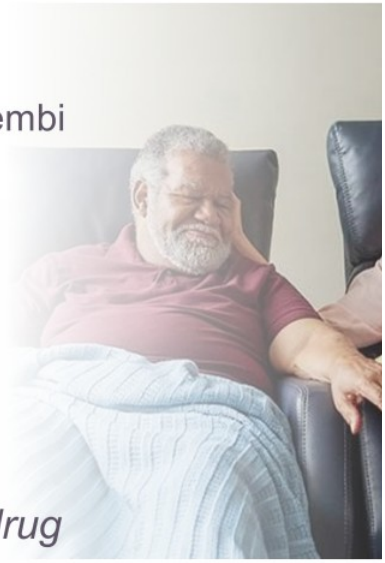
- 2020 – Estimated 11M family members/unpaid caregivers provided 15.3B hours of care at a value of ~\$257B*
- 2050 – Anticipated caregiving costs ~ \$1.1 trillion (in 2019 dollars) **

* <https://pubmed.ncbi.nlm.nih.gov/33756057/> ** <https://www.brightfocus.org/alzheimers/article/alzheimers-disease-facts-figures>



AD – Finally breakthroughs & the realities of constraints

- 2 approved mAbs, 1 additional drug filed for approval
 - Annual cost for therapy = \$26K - \$28K/ patient
 - Estimated \$5B cost to Medicare for 216K patients on Legembi
- Diagnostics & treatment considerations
 - 3,600 Infusion centers in the US
 - 2,500 PET scanners in the US performing 2M scans/year
 - 11,900 MRI systems in the US
- *The mismatch between demographics, economics and drug availability is unsustainable*

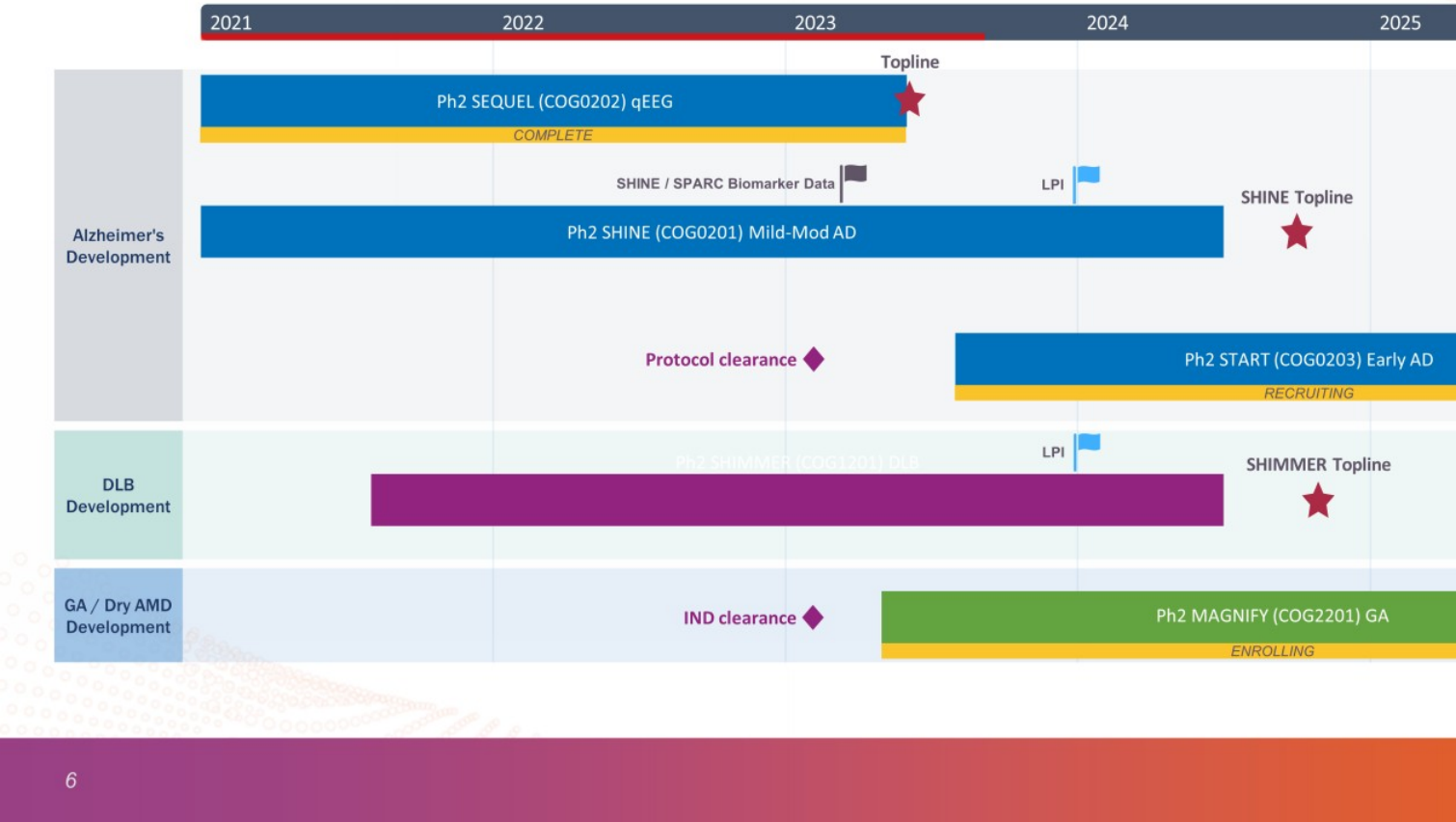


* <https://hitconsultant.net/2022/12/14/report-the-state-of-cancer-centers-2022/>

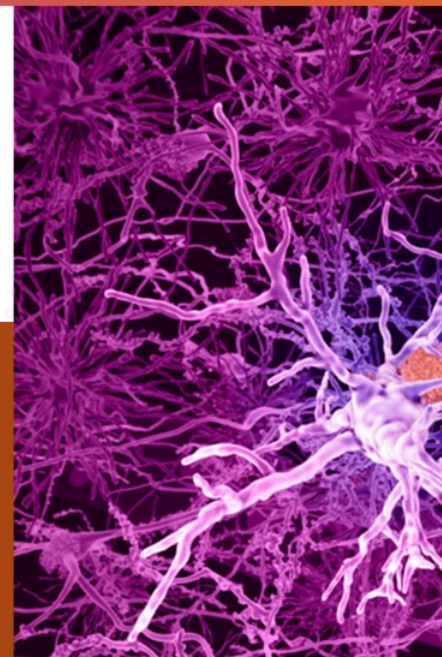
Cognition Therapeutics – Our Company

- **Why we do what we do:** Neurodegenerative diseases, particularly Alzheimer disease, impacts every one of us.
- **How we address neurodegenerative diseases:** We identify neurodegenerative targets and treatments. NIH and Advocacy groups help us cost-effectively develop clinical candidates.
- **What we offer:** CT1812 is a potential oral therapy for Alzheimer's disease and Dementia with Lewy Bodies. We are evaluating clinical, regulatory and biomarker programs to assess speed to market
- **Changing the paradigm:** Oral drug for the treatment of dry AMD; proven ability to get to the back of the eye

CGTX Near-term Catalysts



Our approach to neurodegenerative diseases



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CT1812 Protects Neurons from Toxic Stress

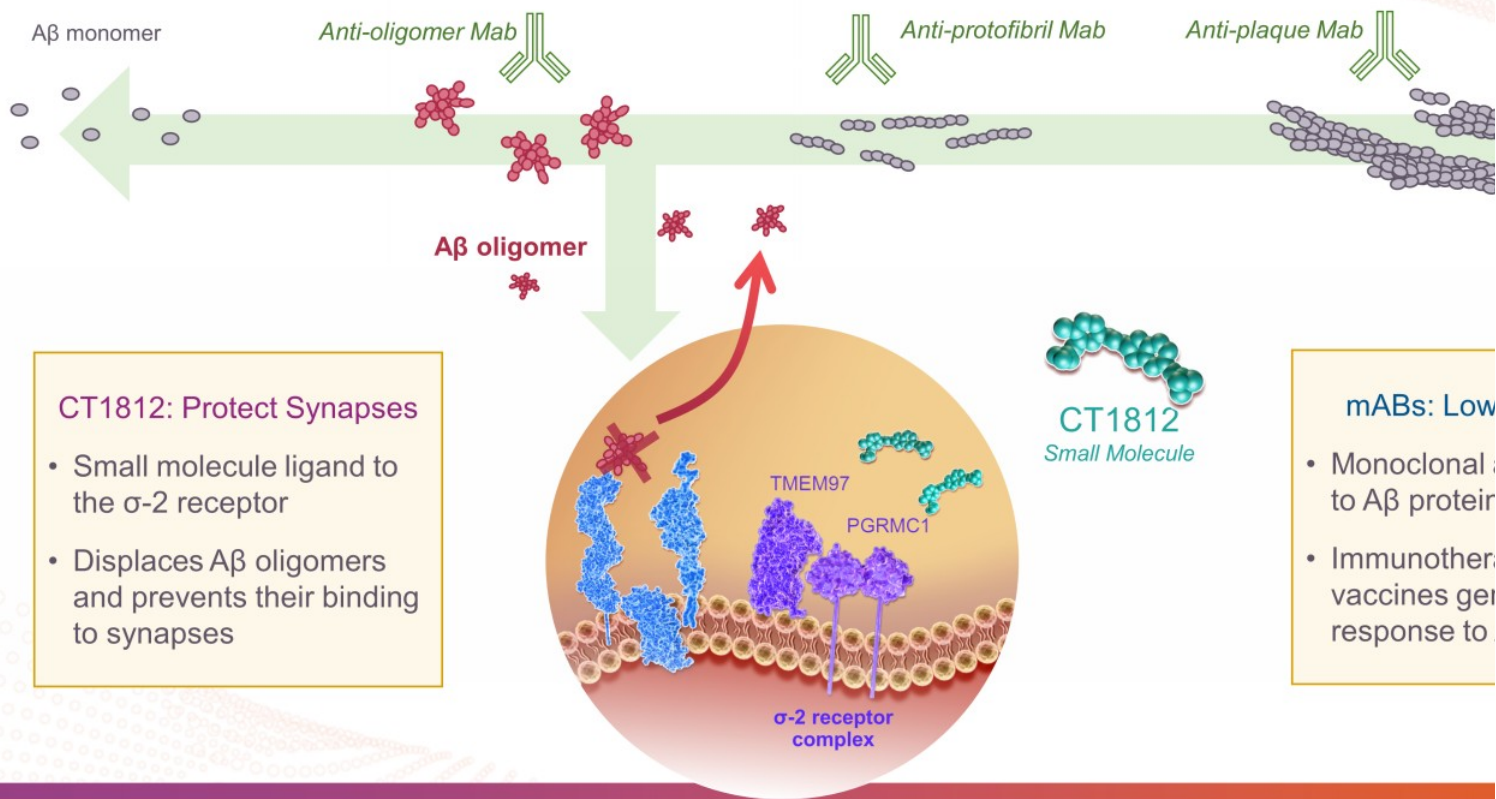
Innovative mechanism of action within the established amyloid cascade

- Oral, small molecule ligand of sigma-2 (σ -2) receptor
 - High degree of blood brain barrier penetration, reaches therapeutic target
- Targets oligomers, a pathogenic form of amyloid plaques produced early in AD
- Blocks toxic oligomer binding, displaces bound oligomers -protecting synapse
 - Demonstrated disease-modifying impact on synapses
- Scalable manufacturing from easily sourced materials, well protected IP



*Represents potential breakthrough:
Treat Alzheimer's disease with a once daily oral drug,
minimize imaging requirements and associated side effects*

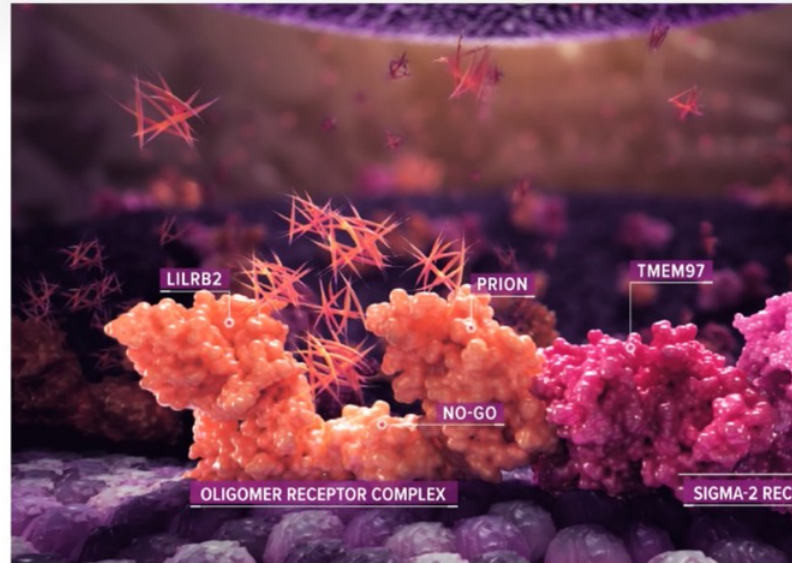
CT1812: A Novel Approach Within the Established Amyloid



CT1812 Designed to Protect Neurons and Processes Impaired by Neurodegenerative Disease

σ -2 is a druggable receptor target

- Robust scientific research has demonstrated target engagement and biological effects of σ -2 modulation
- Backed by *in vitro* studies, behavioral data from *in vivo* animal models and strong preclinical program
- Now in multiple Phase 2 trials
- Science vetted through peer-reviewed publications and peer-reviewed NIA grant process

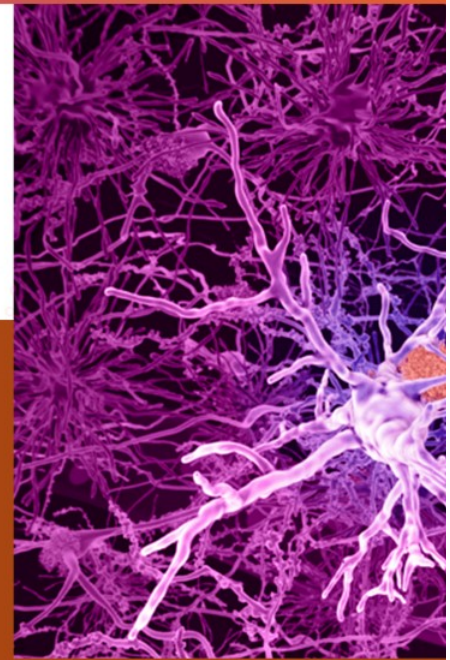


Our MoA Video: <https://vimeo.com/800999561>



AMYLOID BETA (β)

Our Trials and Target Product Profile



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What We Have Learned From Clinical Trials to

Endpoint of Interest:

Target engagement	SNAP ¹
Anatomical effect	SPARC ²
Preliminary cognitive improvement	SHINE-A ¹
Neurophysiology	SEQUEL ³

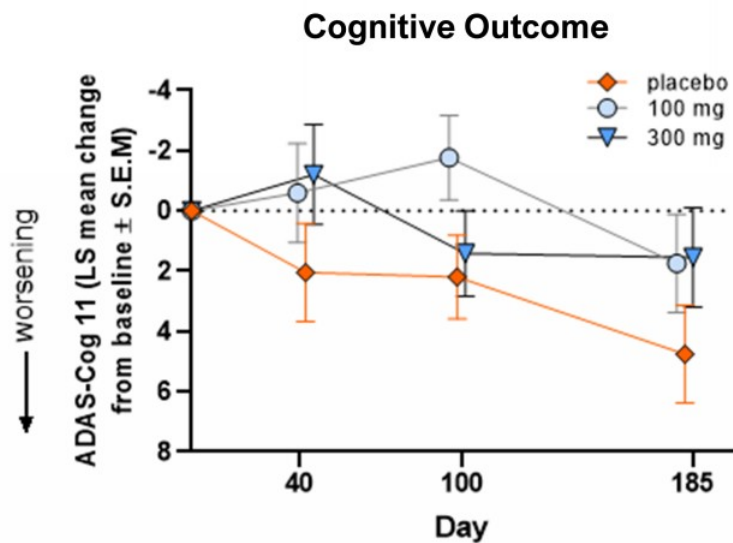
Result:

→	CT1812 demonstrated target enga
→	Demonstrated effect on slowing br
→	Demonstrated 3+ point difference measured by ADAS-COG ay Day
→	Brain wave patterns normalized ac multiple measures

1. AD/PD™ 2022 & LaBarbera, et al. Transl Neurodegener 2023
2. SPARC results submitted for publication
3. Abstract of SEQUEL imaging results submitted for upcoming presentation

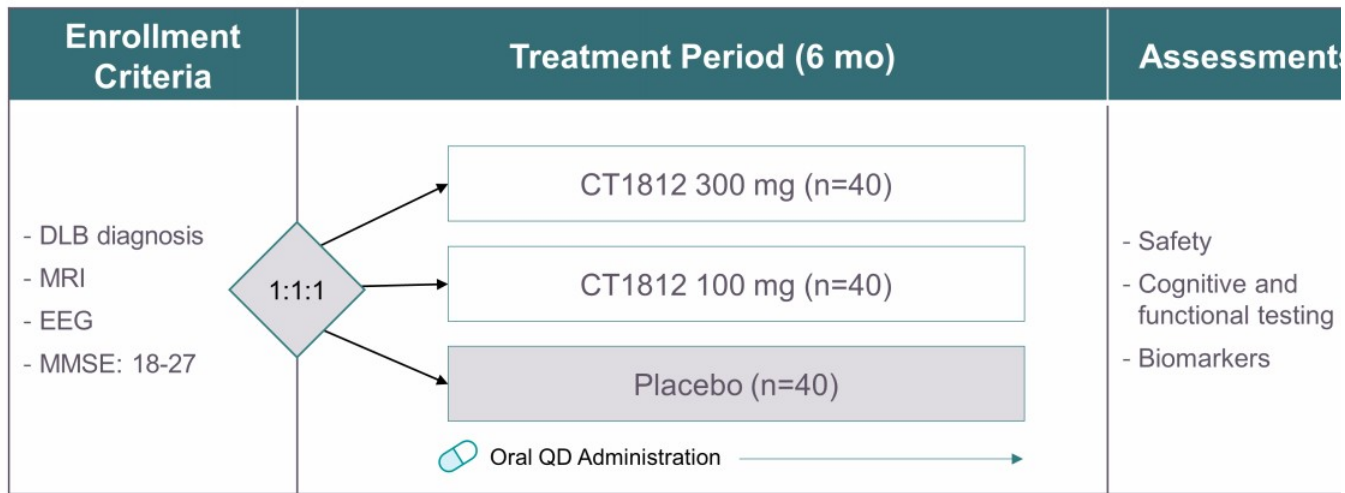


Clinical Evidence of Cognitive Benefit



- SHINE interim analysis (n=2) promising evidence:
 - 3-point difference (ADAS-COG) between treated and untreated at Day 185
 - Clinically meaningful magnitude
 - Trend towards slower cognitive decline in CT1812-treated vs placebo-treated participants

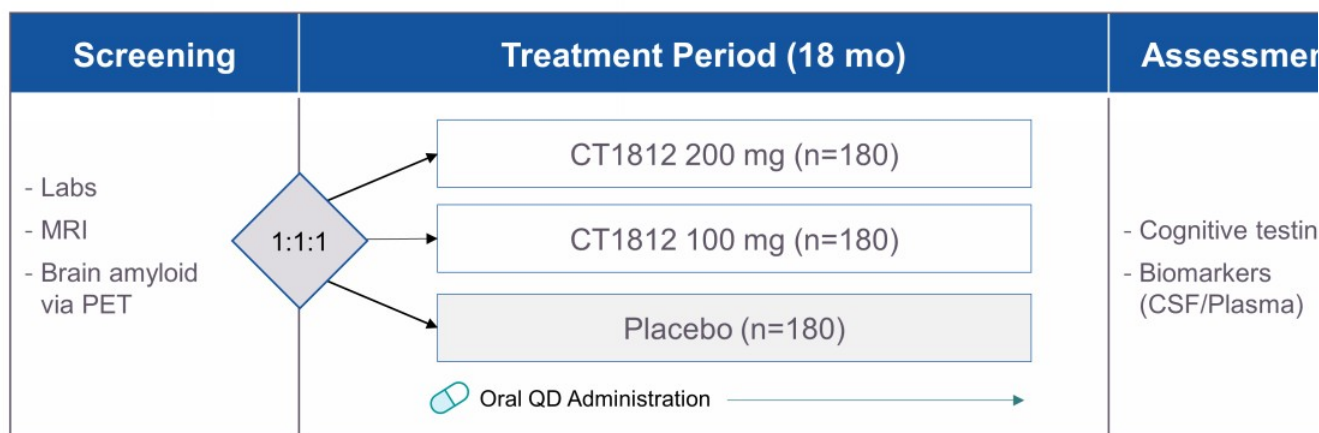
SHINE COG0201 Study (NCT03507790) funded by NIA grant R01AG058660



Principal investigator: James E. Galvin, MD, MPH, professor of neurology and director of the Comprehensive Center for Brain Health
SHIMMER COG1201 study (NCT05225415) partially funded by \$30M NIA grant R01AG071643

Phase 2 Efficacy Study in 540 Adults with *Early Alzheimer's Disease*

Conducted in collaboration with Alzheimer's Clinical Trials Consortium



START COG0203 study (NCT05531656) partially funded by \$81M NIA grant R01AG065248
ACTC funded by NIA grant U24AG057437



First study to collect data on combination use of CT1812 and antibody drug

Our Goal: Develop & Launch Commercially Successful Dementia Di to the Realities of US Healthcare System, Patients and Families

Addresses patient care and caregiver needs and economic burden of treatment

CT1812 – Target profile

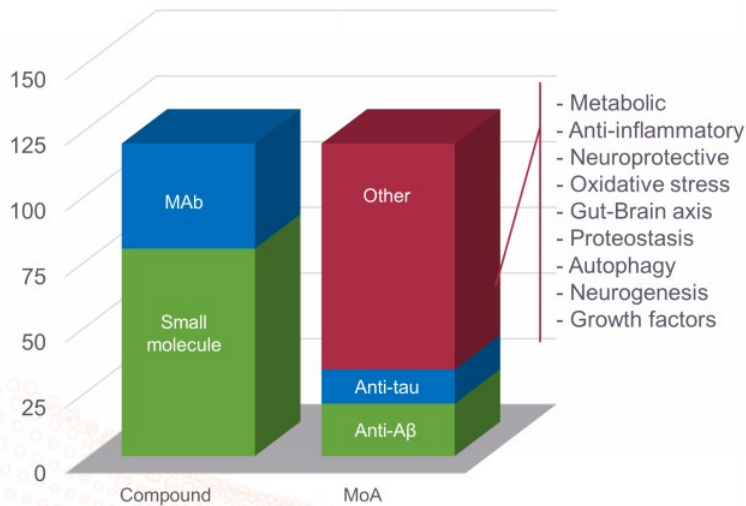


- Once-daily oral therapy
- Slows cognitive and functional decline in early/MCI and mild-to-moderate AD including Dementia with Lewy Bodies
- Well tolerated, modest side effect profile for use in aging population
 - Limited potential for ARIA
- Minimal caregiver burden and costs
 - Routine diagnostics and monitoring requirements
 - No imaging requirements; reduced associated economics

New Mechanisms Being Developed, Creating Poter Market for Combination Use

Successful drugs will address gaps in the market

143 Drugs in Development in 2022
(119 are disease modifying)



Gaps in development-stage ca

- Breadth of Indication: AD spect early, MCI, mild and moderate /
- Limited diagnostic exclusions
- Comparable efficacy as measu COG or CDR-SB
- No requirement for PET surveil
- No ARIA or infusion safety cons
- Convenience QD dosing, limite

Getting to Goal: Phase 2 Program Informs Phase 3 & Regulatory

Robust SNAP, SHINE, SPARC and SEQUEL data to drive program design

Preliminary Phase 3 Considerations

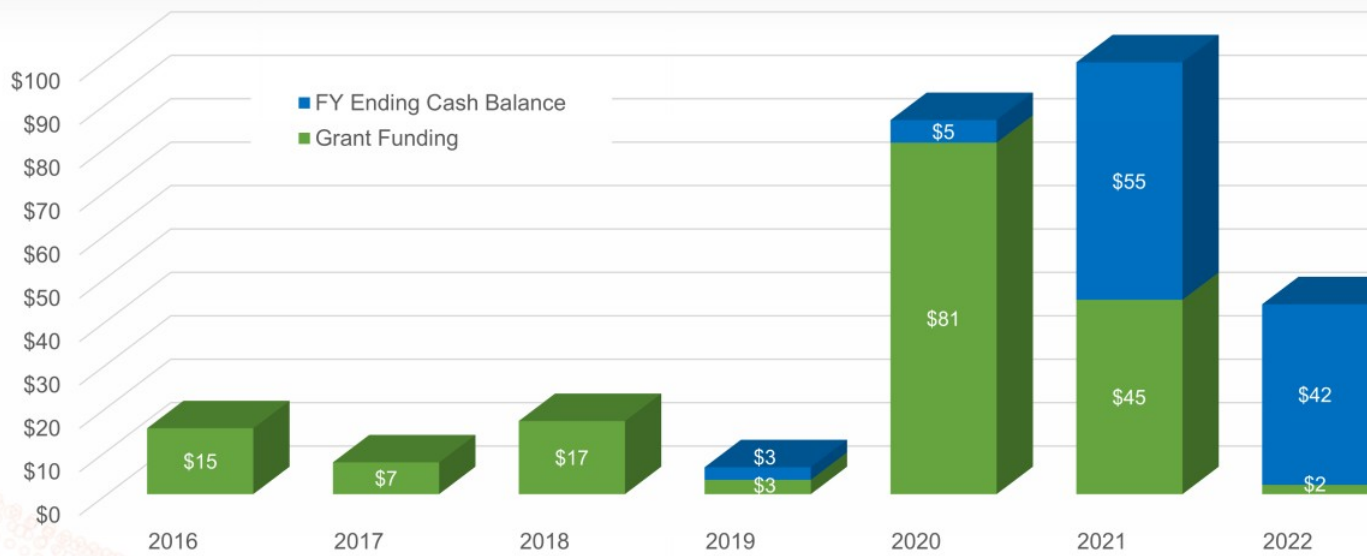
- Enrollment appx 700 - 1,500 / study
- Global enrollment
 - Randomized 2:1 to CT1812 or placebo
 - Phase 2 results inform duration
- Stratification with concomitant therapy
- Initiate health economics and outcomes research, pricing research and IRA considerations

Preliminary Biomarker Strategy Considerations

- Baseline - unbiased analyses of plasma/
 - Phase 1/2
 - SHINE Cohort A
 - SPARC
 - SHINE A / SPARC pooled
 - SEQUEL
- Identified biomarkers of CT1812 target engagement
- Analyzed SHINE, SHIMMER clinical data for correlation of biomarkers with cognitive outcomes
- Now, evaluate prospective study to assess predetermined biomarkers measuring impact on synapse health, neuroinflammation and neurodegeneration

Grant Funding Has Provided Substantial Sup

Full Grant Awards by year of Award, significantly support operations



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**



Next Steps: Preparations for Phase 3 & Commercialization

- Complete dementia trials: mild-moderate Alzheimer's and DLB
- Progress START study in early Alzheimer's disease
- Conduct KOL panels on dementia product profile for Phase 3 development
- Advance MAGNIFY study in dry AMD
- Initiate research on IRA & pricing impact
- Continue pharma engagement

Mild-to-moderate dementia trials to read out in mid 2024



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Tony Caggia
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