

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): January 4, 2024

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
<a href="#">99.1</a>	<a href="#">Investor presentation of Cognition Therapeutics, Inc.</a>
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: January 4, 2024

COGNITION THERAPEUTICS, INC.

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

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# Disease-modifying medicines for neurodegenerative disorders

*January 2024*

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# 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, and our clinical development plans, including statements regarding our clinical studies of CT1812 in animal models and any analyses of the results therefrom, 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 Securities & Exchange Commission that are available on [www.sec.gov](http://www.sec.gov). These risks are not exhaustive, and we face both known and unknown risks. 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.



## Our Mission:

Develop oral therapies to protect neurons and restore normal cellular damage responses in age-related disorders of the CNS and retina



# Cognition Therapeutics – Our Value Proposition

## Innovative Oral Therapeutics

CT1812 is designed to restore impaired cellular damage response functions, protecting neurons from damage

## Strong Clinical Pipeline

Advancing mid-to-late-stage clinical trials in multiple indications including pre-Phase 3 programs in mild-to-moderate Alzheimer's disease and DLB

## Large & Underserved Treatment Opportunities

Targeting multibillion dollar diseases; under-served markets; potential first-to-market in mild-to-moderate dementia with Lewy bodies

## Financially Disciplined

Major trials supported by extensive non-dilutive grant funding from NIH and other research funders (\$171 million)

## Experienced Management & Scientific Teams

Executive team with pharma experience; R&D staff with depth of neuroscience and development expertise

Cognition's lead product, CT1812, is an orally delivered, first-in-class, small molecule designed to restore key cellular functions that are impaired in diseases including:

Alzheimer's  
Disease

Dementia with  
Lewy Bodies

GA / Dry AMD



# CT1812 – Lead Product Candidate

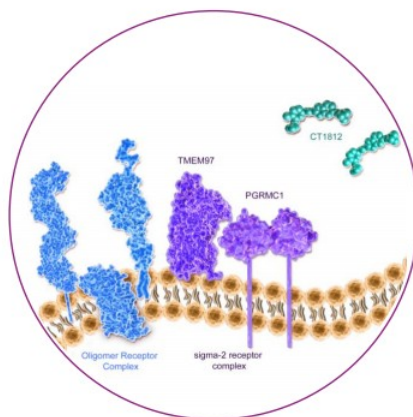
*First-in-class, orally dosed and highly brain penetrant small molecule*

## Oral, Once-daily Pill

- ✓ Oral, small molecule ligand of  $\sigma$ -2 receptor
- ✓ High degree of CNS penetration for therapeutic target engagement

## The *Right* Target

- ✓ Targeting toxic stressors: A $\beta$  and  $\alpha$ -synuclein oligomers and ROS in neurodegenerative diseases



Powerful scientific validation  
of  $\sigma$ -2 science

## Neuroprotective

- ✓ Protects neurons; restores cellular "housekeeping" processes
- ✓ Demonstrates disease-modifying impact

## Manufacturing & IP Advantages

- ✓ Scalable manufacturing from easily sourced materials
- ✓ Extensive intellectual property estate

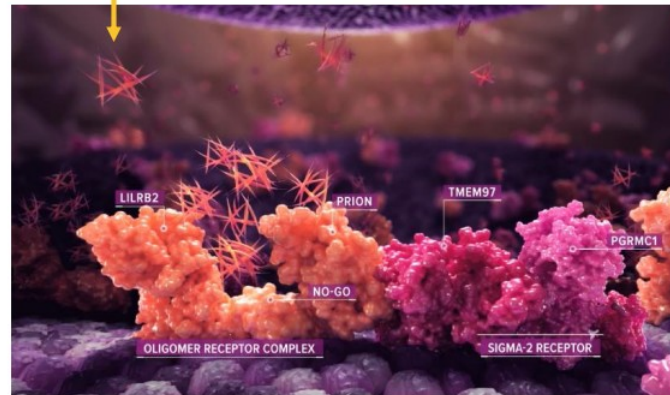
# CT1812 Protects Neurons from Toxic Stressors

*Sigma-2 ( $\sigma$ -2) complex regulates cellular damage response processes*

- Robust scientific research has demonstrated target engagement and biological effects of  $\sigma$ -2 modulation
- Backed by *in vitro* studies, *in vivo* animal models and strong preclinical program
- Science vetted through peer-reviewed publications and NIA grant process

Neurotoxic stressors include:

- A $\beta$  oligomers
- $\alpha$ -synuclein oligomers
- Reactive oxygen species (ROS)



# CT1812 - Multiple Catalysts

PROGRAM	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	MILESTON
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## ALZHEIMER'S DISEASE

SHINE	MILD TO MODERATE				Topline da mid 2024
SEQUEL	MILD TO MODERATE		*completed		Data reports CTAD 202
START	EARLY				Complete pa enrollmer

## DLB

SHIMMER	MILD TO MODERATE				Topline da 2H 2024
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## DRY AMD

MAGNIFY	GEOGRAPHIC ATROPHY				Complete pa enrollmer
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# ALZHEIMER'S DISEASE



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# Alzheimer's Disease (AD) - It Impacts Every One Of Us

## 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

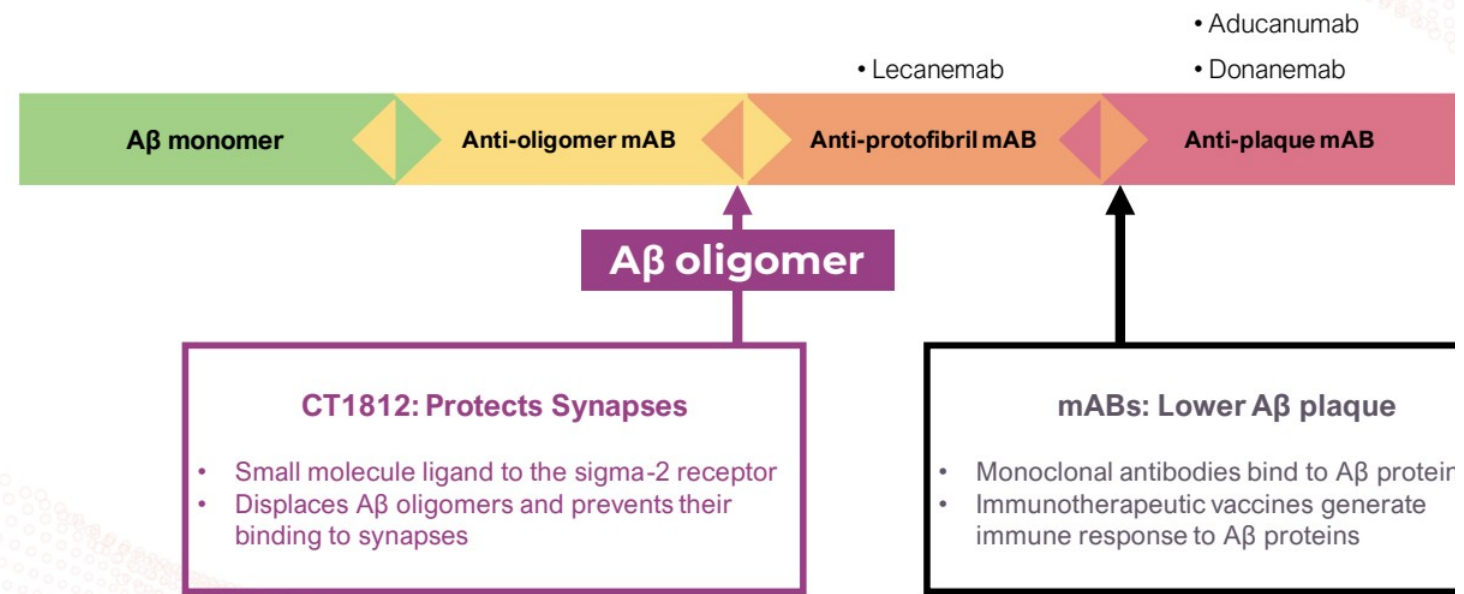
*The mismatch between demographics, economics and drug availability is unsustainable*

- Two approved mAbs, one additional drug filed for approval
  - Annual cost for therapy = \$26K - \$28K/ patient
  - Estimated \$5B cost to Medicare
- Constrained delivery systems for infused medications
  - 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



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

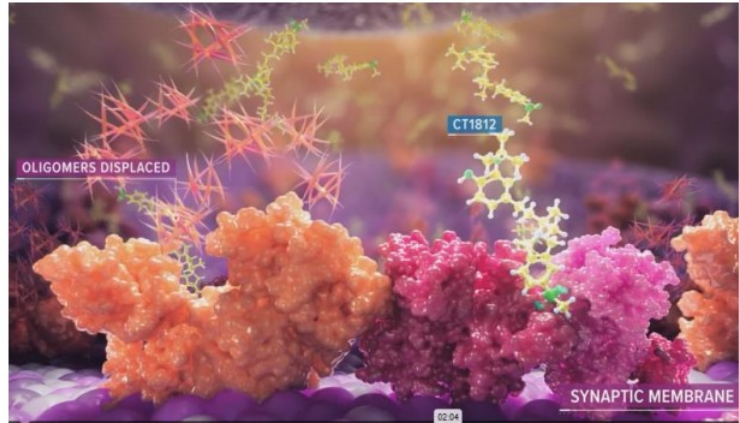
# CT1812: A Novel Approach Within the Established Amyloid Cascade



# CT1812 - Unique Mechanism of Action for Treating AD



Age-related build-up of stressors including Aβ oligomers drive Alzheimer's disease





Aβ oligomers bind to synapses and interfere with cellular functions such as autophagy, leading to neuronal loss


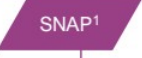
CT1812 binds at  $\sigma$ -2, resulting in displacement of oligomers

# What We Have Learned From Clinical Trials to Date



## Endpoint of Interest:

 Preliminary cognitive improvement 





 Target engagement 



 Anatomical effect 



 Neurophysiology 



## Result:

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

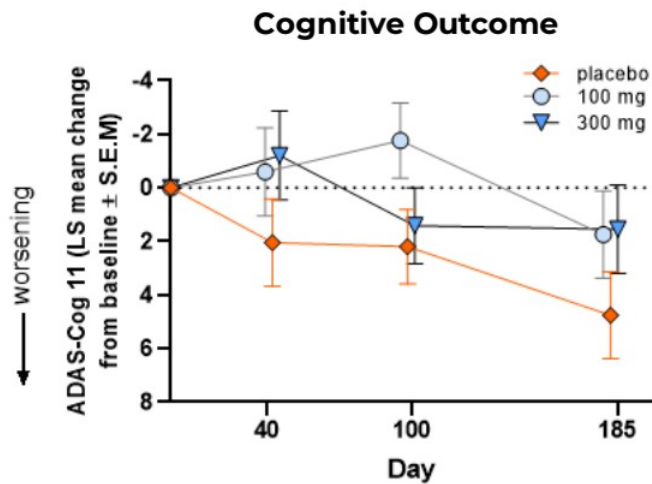
Demonstrated displacement of amyloid oligomers from synapses

Demonstrated effect on slowing brain atrophy

Brain wave patterns normalized across multiple measures

1. AD/PD™ 2022
2. LaBarbera, et al. *Transl Neurodegener* 2023
3. SPARC results submitted for publication
4. CTAD 2023 SEQUEL imaging results presented

# Preliminary Clinical Evidence of Cognitive Benefit



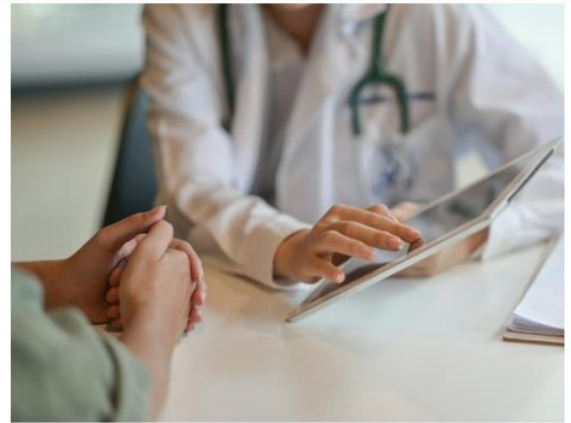
## SHINE Interim Analysis (n=24)

- 3-point difference (ADAS-COG 11) between treated and untreated participants at Day 185
- Clinically meaningful magnitude of change
- Trend towards slower cognitive decline in CT1812-treated vs placebo-treated participants

SHINE COG0201 Study (NCT03507790) funded by NIA grant R01AG058660



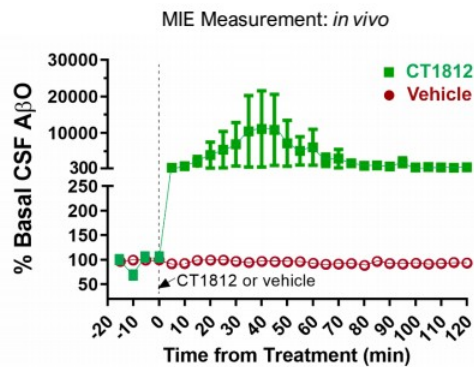
- A total of 153 adults with mild-to-moderate Alzheimer's disease were enrolled
  - Exceeded target of 144
- Randomized to receive placebo or CT1812 (100mg or 300mg) for 6 months
- Last-patient / last-visit therefore expected in May 2024



# Evidence of Target Engagement



SNAP (n=3) mirrored preclinical

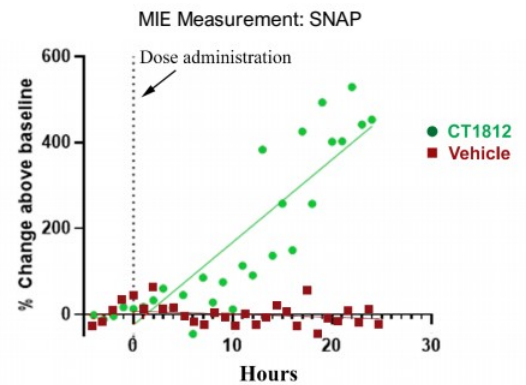


NOTE: Microimmuno-electrodes coated with oligomer-specific antibody detect soluble Aβ in transgenic hAPP/PS1 mice

Izzo et al. Preclinical and clinical biomarker studies of CT1812: A novel approach to Alzheimer's disease modification. *Alzheimer's Dement.* 2021 Aug; 17(8):1365-1382

Oligomer Displacement in Mice

Replicates in Alzheimer's Patients

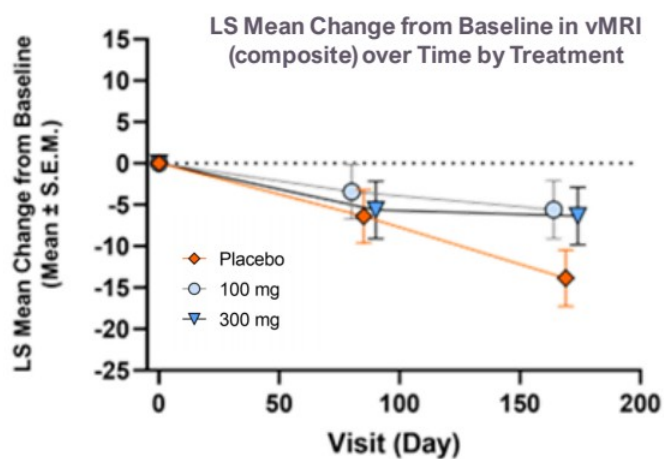


LaBarbera et al. A phase 1b randomized clinical trial of CT1812 to measure Aβ oligomer displacement in Alzheimer's disease using an indwelling CSF catheter. *Transl Neurodegener* 2023, 12(24)

# CT1812 Treatment Associated with Reduced Brain Atrophy



SPARC Results: AAIC 2022



MRI Brain Volume (cm <sup>3</sup> ) 6-mo change from baseline			
	CT1812 (Pooled)	Placebo	P-value vs placebo
Hippocampus	-0.09 (0.08)	-0.40 (0.11)	0.0412
Prefrontal Cortex	-0.41 (0.95)	-4.80 (1.37)	0.0125
Pericentral Cortex	0.07 (0.53)	-2.90 (0.77)	0.0032

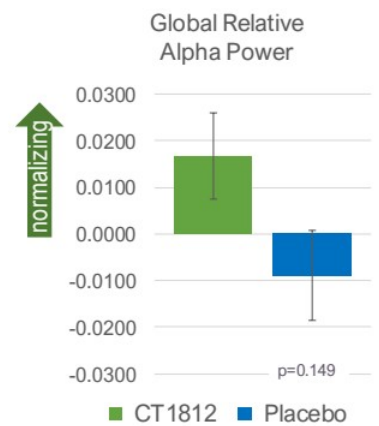
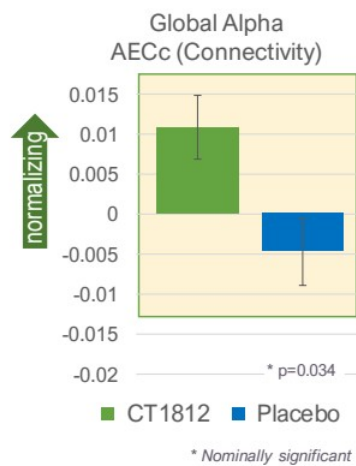
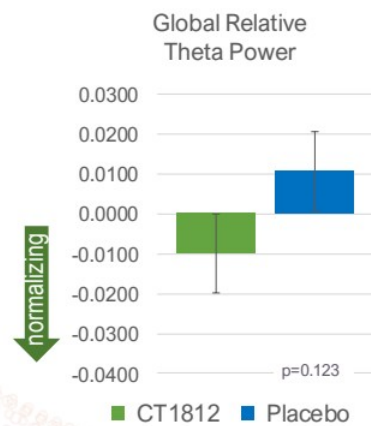
PIs Christopher H. van Dyck, M.D. at the Yale Alzheimer's Disease Research Unit and Richard E. Carson, Ph.D. at the Yale PET Center  
SPARC COG0105 study partially funded by NIA grant R01AG057553

# CT1812 Normalizes qEEG Measures of Synaptic Function and Connectivity

Positive trends in first three ranked outcomes measures



SEQUEL Results: CTAD 202



# **START** Expanding CT1812 Experience into Early Disease

- Early / mild Alzheimer disease
- Recruitment ongoing
  - 540 target enrollment
  - Permitting participants to be enrolled who are receiving lecanemab infusions
  - Placebo or CT1812 (100mg or 200mg) 50+ sites expected to be activated
- Treatment period: 18 month
- Conducted in collaboration with ACTC\*
  - Project director: Christopher van Dyck, MD, Yale Alzheimer's Disease Research Unit director
  - \$81M grant\* from the National Institute of Aging of the National Institutes of Health

\*(R01AG0652



# Dementia with Lewy Bodies



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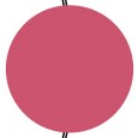
- Mild-to-moderate DLB (including patients with Alzheimer's co-pathology)
- Enrollment ongoing
  - Target n=120
  - Oral QD placebo or CT1812 (100mg or 300mg)
- Treatment period: 6 months
  - Topline expected 2H 2024
- Conducted in collaboration with LBDA & University of Miami
  - Principal investigator: James E. Galvin, MD, MPH
  - \$30M NIA grant\* from the National Institute of Aging

\*(R01AG0716

# CT1812 has the Potential to be a Single Oral Medication to Treat Alzheimer's Disease and DLB



Only therapeutic that targets A $\beta$  oligomers and  $\alpha$ -synuclein oligomers



Appx 50% of DLB patients have both A $\beta$  and  $\alpha$ -synuclein oligomers present



By regulating cellular damage response functions through the  $\sigma$ -2 complex, CT1812 shown to protect neurons from both pathogenic oligomers

# Geographic Atrophy Secondary to Dry AMD



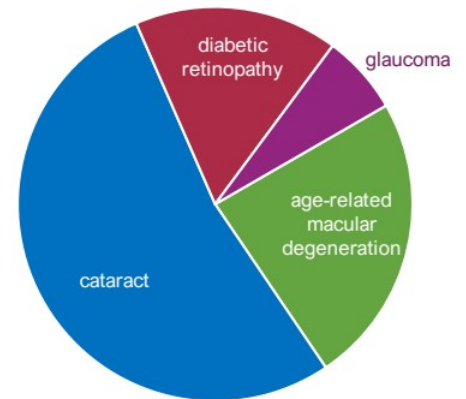
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# Dry Age-related Macular Degeneration (AMD)

*Large projected market with no FDA-approved therapies*

- Total AMD drug market: \$9B<sup>1</sup> (approximately \$6B for dry form<sup>2</sup>)
- Dry AMD Phase 2 planned (subject to discussion with FDA)
  - Genetic link in dry AMD to  $\sigma$ -2 receptor
  - Novel mechanism of action
  - Proof-of-concept preclinical support
  - Proteomics from Alzheimer's disease clinical trial patient data

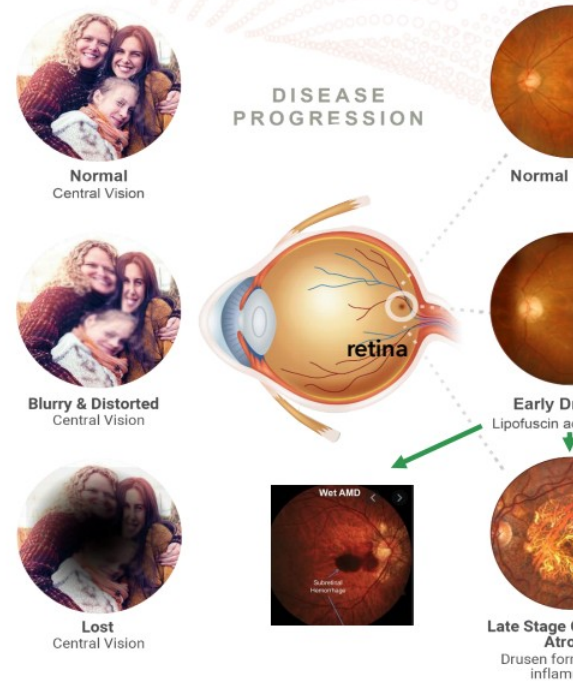
Diseases Leading to Blindness  
US Prevalence





# Why Dry AMD?

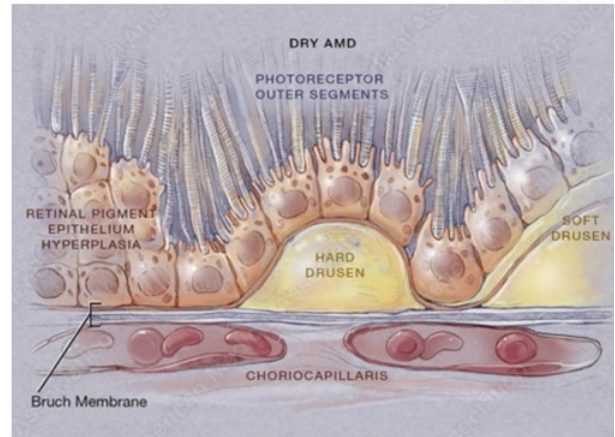
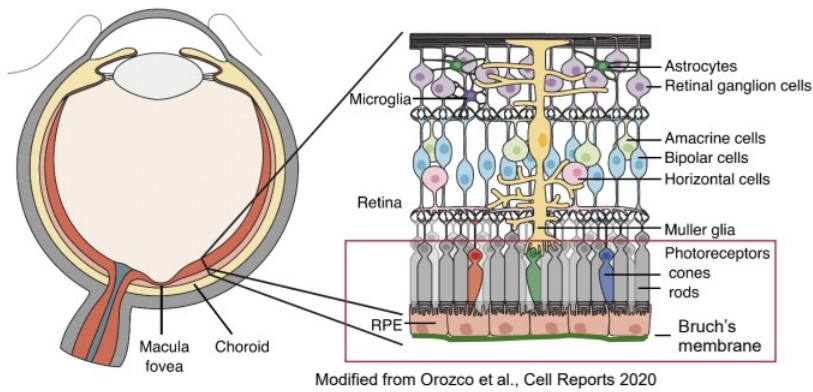
- Significant unmet medical need:
  - AMD is a leading cause of blindness
  - Approximately 11.2 M people are afflicted in U.S. alone
- Patients suffer a loss of central vision due to deterioration of the macula, causing blurry vision making daily activities (reading, driving, watching TV, walking up/downs stairs) difficult or impossible
- Two types of late-stage AMD
  - wet AMD – most severe form, but less prevalent and treatments exist
  - advanced dry AMD or geographic atrophy (GA) – approximately 90% of all cases are dry AMD
- There are no approved therapies for dry AMD
  - Many therapies tested are invasive



<http://www.scienceofamd.org/learn>

Modified from <https://www.linbioscience.com/Pipeline>

# Cellular and Molecular Pathogenesis of Dry AMD



American Medical Association. JAMA. 2011; 305(15):1577-1584;  
<http://www.alison-burke.com/works-cellsmols.html>

- In early dry AMD, drusen (i.e., deposits of lipids and some proteins) accumulates and causes a thickening of the Bruch's membrane, disrupting the cytoarchitecture of the retinal pigment epithelium (RPE)
- Subsequently and progressively, this impacts the health and functions of RPE cells and photoreceptors by impairing transport, and through oxidative stress and inflammation, leading to RPE cell and photoreceptor cell death

# CT1812- Oral Agent for the Treatment of Dry AMD

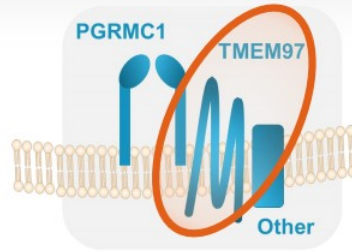
## Reasons to Believe

### Genetic Evidence

- Genetic Mutation (SNP) in TMEM97-VTN locus confers decreased risk of dry AMD
  - Further study will determine if and how SNP affects TMEM97 expression or function

### Biology

- Knocking down TMEM97 rescues retinal pigment epithelial (RPE) cells from death by oxidative stress
  - Supports role of TMEM97 in dry AMD
- Literature supports role of  $\sigma$ -2 in relevant processes: autophagy, vesicle trafficking, lipid metabolism, cellular stress



### Proteomic Studies

- Proteomics from Alzheimer's trials in patients given CT1812 showed differential movement in proteins known to be involved in dry AMD

# Human Genetics Points to a Role for TMEM97 in dry AM

GWAS identified a SNP in TMEM97-VTN locus that confers decreased risk of dry AMD

## Locus identified in several independent and large-scale GWAS

Table 4. Results for 34 AMD risk variants reported in the latest case-control study conducted by the International AMD Genomics Consortium

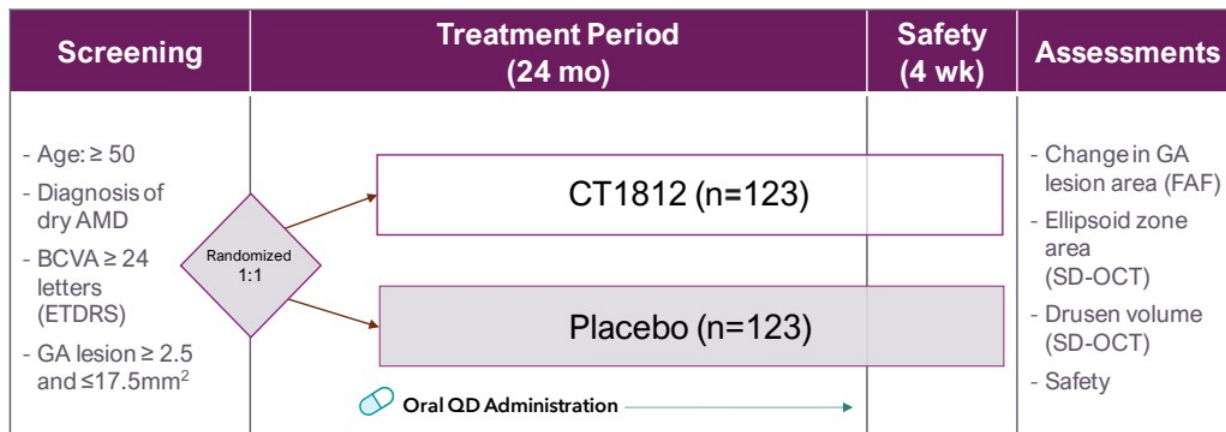
SNP	Chr	Position	Major/ minor allele	MAF	Gene	With BL severity		Without BL severity		Fritsche <i>et al.</i> case-control results	
						HR	P-value	HR	P-value	OR	P-value
Known SNPs identified in consortium case-control studies											
rs11080055	17	26 649 724	C/A	0.48	TMEM97-VTN	0.89	0.0267	0.97	0.5847	0.91	1.0 × 10 <sup>-4</sup>
rs6565597	17	79 526 821	C/T	0.38	NPLOC4-TSPAN10	1.03	0.5769	1.06	0.2877	1.13	1.5 × 10 <sup>-3</sup>
rs67538026	19	1 031 438	C/T	0.45	CNN2	0.90	0.0475	0.90	0.0684	0.9	2.6 × 10 <sup>-3</sup>
rs142450006	20	44 614 991	TTTTTC/T	0.13	MMP9	0.77	0.0021	0.77	0.0029	0.85	2.4 × 10 <sup>-3</sup>
rs201459901	20	56 653 724	T/TA	0.06	C20orf85	1.07	0.4688	0.96	0.7440	0.76	3.1 × 10 <sup>-3</sup>

Further study will be needed to determine if and how this single nucleotide polymorphism (SNP) affects TMEM97 expression or function

Yan et al. Human Molecular Genetics



COG2201 – NCT NCT05893537





# Summary



Evidence supports targeting  $\sigma$ -2 receptor for dry AMD as a promising therapeutic approach



The ability to target the  $\sigma$ -2 receptor with an oral small molecule approach would enable a competitive advantage by providing a non-invasive therapy for dry AMD to patients



Plans to advance CT1812 into a Phase 2 study for dry AMD are under way, pending discussion with Food and Drug Administration



Preclinical PoC studies in progress will further elucidate the mechanism(s) by which  $\sigma$ -2 modulators ameliorate various disease biologies in dry AMD, and inform upon the appropriate patient selection, time of intervention, and clinical outcome measures to enable a successful clinical trial design

# Clinical, Market & Financial Outlook



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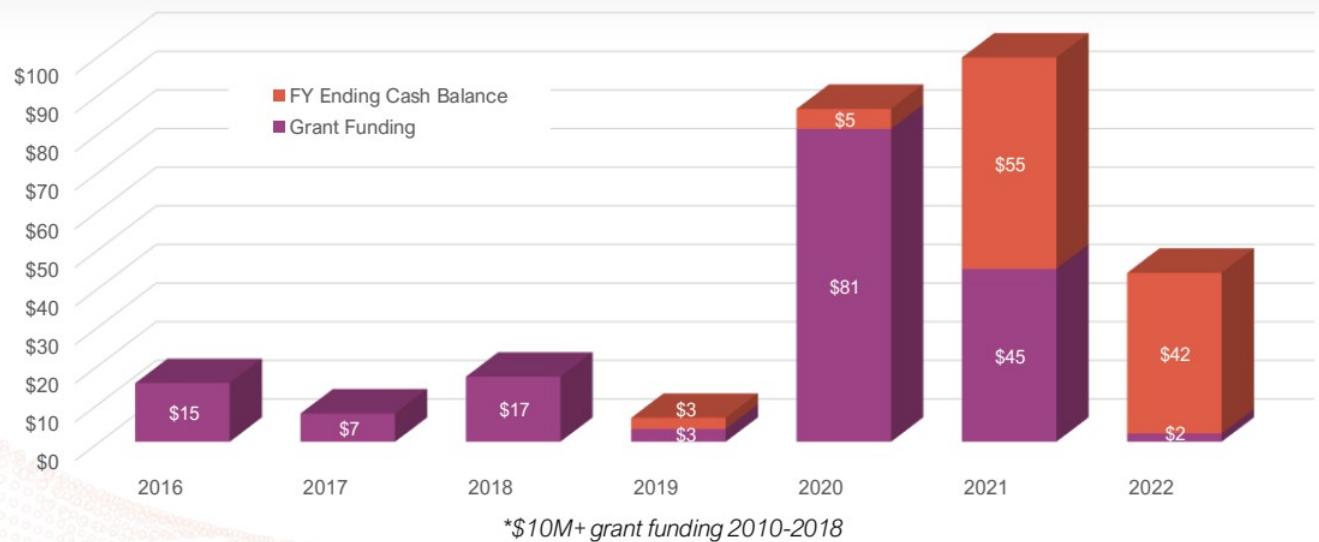
# New Mechanisms Being Developed, Creating Potential Market for Combination Use

Successful drugs will address gaps in the market

- Breadth of Indications: multiple stages of Alzheimer's (early, MCI, mild, moderate) as well as DLB
- Limited diagnostic exclusions
- Comparable efficacy as measured by ADAS-COG or CDR-SB
- No requirement for PET surveillance
- No ARIA or infusion safety considerations
- Convenience QD dosing, limited monitoring

# Grant Funding Has Provided Substantial Support

*Full Grant Awards by year of Award, significantly support operations*



# Near-Term Catalysts, Phase 3 Prep & Commercialization

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



## Clinical Programs

- SHINE (Mild-to-Moderate AD)
  - Report topline data in mid 2024
- START (Early AD)
  - Next milestone: complete enrollment
- SHIMMER (DLB)
  - Next milestone: complete enrollment
  - Report topline data in 2H 2024
- MAGNIFY (Dry AMD)
  - Next milestone: complete enrollment



## Phase 3 & Commercial Prep

- Advance discussions with FDA
  - End-of-Phase 2 meeting
  - Phase 3 trial protocol
- Conduct KOL panels on dementia product profile for Phase 3 development
- Initiate research on IRA & pricing impact
- Continue pharma engagement



# Financial Position

## Financials as of September 30, 2023

- Cash and Cash Equivalents: \$33 million
- Expected cash runway through November 2024

## Grant funding for CT1812 studies as of Sep 30, 2023

- Preclinical through Phase 2: appx \$171.0 million
  - Approximate funding used: (\$96.7 million)
  - Remaining grant funding: **\$74.3 million**





## Thank You

Lisa Ricciardi  
President & CEO  
[lricciardi@cogrx.com](mailto:lricciardi@cogrx.com)

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Tony Caggiano, MD, PhD  
CMO and Head of R&D  
[acaggiano@cogrx.com](mailto:acaggiano@cogrx.com)

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John Doyle  
Chief Financial Officer  
[jdoyle@cogrx.com](mailto:jdoyle@cogrx.com)

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