

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): June 28, 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.

On June 28, 2023, Cognition Therapeutics, Inc. (the “Company”) issued a press release announcing topline results from its Phase 2 double-blind, single-crossover SEQUEL study (NCT04735536) of CT1812 in 16 adults with mild-to-moderate Alzheimer’s disease. The study, which was conducted in the Netherlands, met its primary endpoints for safety and tolerability and showed positive effects for CT1812-treated participants as measured via quantitative electroencephalogram. A copy of the press release is being filed as Exhibit 99.1 hereto.

Attached as Exhibit 99.2 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="#">Press Release, dated June 28, 2023</a>
<a href="#">99.2</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: June 28, 2023

COGNITION THERAPEUTICS, INC.

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



**Cognition Therapeutics Announces Positive Topline Results for CT1812 Phase 2  
SEQUEL Study for Mild-to-Moderate Alzheimer's Disease**

*Results Show Positive Treatment Effect of CT1812 on Global and Regional Brain Activity*

*Management Holding Webcast Conference Call at 8:00am ET Today*

**NEW YORK, NY, June 28, 2023** — **Cognition Therapeutics, Inc.** (NASDAQ: CGTX), a clinical-stage neuroscience company developing drugs that treat age-related degenerative disorders by regulating cellular damage response pathways, today announced topline results from its Phase 2 double-blind, single-crossover SEQUEL study (NCT04735536) of CT1812 in 16 adults with mild-to-moderate Alzheimer's disease. The study, which was conducted in the Netherlands, met its primary endpoints for safety and tolerability and showed positive effects for CT1812-treated participants as measured via quantitative electroencephalogram (qEEG).

Research suggests that overall slowing of brain activity in Alzheimer's disease can be measured by an increase in relative theta power using qEEG and other measures of brain connectivity. The SEQUEL study examined brain wave changes over 4 weeks of treatment and showed that participants treated with CT1812 experienced a numerical reduction in relative theta power compared to the period when they were on placebo. While not statistically significant, these data indicate a positive impact on underlying brain function and are supported by nominally significant and directionally positive changes in AECc and alpha power.

In addition to global measures of brain activity, this study assessed brainwave changes in frontal, central, temporal and posterior (occipital and parietal) regions. Treatment with CT1812 was associated with decreases in relative theta in each of these regions, with statistical significance in the change in relative theta in the central region.

"My colleagues and I are excited to see this favorable result, which suggests that treatment with CT1812 may be directly impacting overall brain health, as illustrated in a change in relative theta power globally and across brain regions," said Everard (Jort) Vijverberg, M.D., Ph.D., a neurologist and senior researcher at the Amsterdam University Medical Centers, and principal investigator in SEQUEL. "We look forward to continuing our work with Cognition as a clinical trial collaborator in the SHINE study, which is studying CT1812 over a six-month treatment period in 144 adults with mild-to-moderate Alzheimer's disease."

In addition to changes in theta wave patterns, an AECc analysis of the qEEG results showed that CT1812 treatment was associated with nominally statistically significantly greater connectivity between brain regions. The brain's ability to communicate and exchange information between regions is critical to cognition.

"While the study of brain connectivity is evolving, many consider this to be a highly relevant measure, as it demonstrates how well a brain network is functioning," added explained Willem de Haan, M.D. Ph.D., a neurologist and senior researcher at the Amsterdam University Medical Centers' Alzheimer Center. "The positive insights derived from this study could encourage other researchers and industry members to use qEEG as a measurement tool during clinical trials, as well as healthcare professionals monitoring disease progression and during the delivery of care."

Cognition Therapeutics, Inc.  
[www.cogrx.com](http://www.cogrx.com)

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As observed in previous studies, CT1812 was well-tolerated in the SEQUEL study with most adverse events being mild-to-moderate in severity. There were no treatment-related SAEs reported.

The **SEQUEL** study, which was supported by a grant from the National Institute on Aging (R01AG058710), was designed to assess differences in synaptic function in CT1812-treated versus placebo-treated participants using qEEG to measure changes in brain wave patterns. The sophisticated algorithms used by qEEG allow small changes in brain activity to be quantified. The changes in amplitude and frequency of wavebands over time can provide insight into the levels of activity in and between brain regions. As a fast and cost-effective method of measuring the electrical activity of the brain, qEEG may represent a non-invasive biomarker of Alzheimer's disease progression and treatment effect.

“Though an exploratory endpoint, there is substantial evidence to believe that qEEG can detect changes in both whole-brain and regional electrical patterns that are impaired in Alzheimer’s disease,” said **Anthony Caggiano, M.D., Ph.D.**, Cognition’s chief medical officer and head of R&D. “These results show CT1812’s impact on neurophysiological endpoints, which add to the growing body of evidence that we have compiled in our preclinical and clinical programs: CT1812’s target engagement observed in the SNAP study, its impact on anatomical endpoints observed in the SPARC study, and preliminary cognitive impact seen in the first cohort of patients in the SHINE study.”

**Lisa Ricciardi**, CEO of Cognition Therapeutics, added, “Each of our specialty pharmacology studies and our extensive biomarker analyses have supported the findings from our preclinical studies and provided us with important insights into the role of the  $\sigma$ -2 receptor and the potential impact of treatment with CT1812. We are increasingly optimistic about the larger patient studies that are underway in Alzheimer’s disease, as well as in dementia with Lewy bodies and dry age-related macular degeneration where we think the protective cellular role may further benefit patients.”

Ms. Ricciardi concluded, “We feel fortunate to announce positive findings from SEQUEL during this period when the community is commemorating Alzheimer’s & Brain Awareness Month. During June in particular we recognize the challenges of Alzheimer’s and other dementias that affect more than 55 million people worldwide. It gives us the opportunity to reflect and recommit to our mission to bring effective treatment to those suffering from these devastating diseases.”

Full analyses of the results from SEQUEL will be presented at an upcoming medical meeting, as will analyses of Alzheimer's canonical biomarkers and proteomics from fluid samples collected from SEQUEL participants.

**Webcast and Conference Call**

Cognition will host a conference call and webcast on June 28, 2023, at 8:00am ET to discuss these topline results. The call can be accessed by dialing (800) 715-9871 for U.S. Callers and (646) 307-1963 for international callers five minutes prior to the start of the call and providing the conference ID 7557195. A live webcast will be available on the company's website at [www.cogrx.com/events](http://www.cogrx.com/events) and will be archived for 90 days.

**About CT1812**

CT1812 is an experimental orally delivered small molecule designed to penetrate the blood-brain barrier and bind selectively to the sigma-2 ( $\sigma$ -2) receptor complex. The  $\sigma$ -2 receptor complex is involved in the regulation of key cellular processes such as membrane trafficking and autophagy that are damaged by toxic interaction with soluble beta amyloid (A $\beta$ ) oligomers, oxidative stress and other stressors. This damage to sensitive synapses can progress to a loss of synaptic function, which manifests as cognitive impairment and Alzheimer’s disease progression. CT1812 is currently in development for mild-to-moderate Alzheimer’s disease in the SHINE study (NCT03507790) and dementia with Lewy bodies in the SHIMMER study (NCT05225415).

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**About Cognition Therapeutics, Inc.**

Cognition Therapeutics, Inc. is a clinical-stage biopharmaceutical company engaged in the discovery and development of innovative, small molecule therapeutics targeting age-related degenerative disorders of the central nervous system and retina. We are currently investigating our lead candidate CT1812 in [clinical programs](#) in Alzheimer’s disease, dementia with Lewy bodies (DLB) and dry age-related macular degeneration (dry AMD). We believe CT1812 and our pipeline of investigational  $\alpha$ -2 receptor modulators can regulate pathways that are impaired in these diseases. We believe that targeting the  $\alpha$ -2 receptor with CT1812 represents a mechanism functionally distinct from other current approaches in clinical development for the treatment of degenerative diseases. More about Cognition Therapeutics and its pipeline can be found at <http://cogrx.com>.

**Forward-Looking Statements**

*This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. All statements contained in this press release, other than statements of historical facts or statements that relate to present facts or current conditions, including but not limited to, statements regarding our 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, are forward-looking statements. These statements, including statements relating 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 press release 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, pre-clinical 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 the 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 and are available at [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.*

Cognition Therapeutics, Inc.  
[www.cogrx.com](http://www.cogrx.com)

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## **SEQUEL (COG0202) Topline Results**

*A Pilot Electroencephalography (EEG) Study to Evaluate the Effect of CT1812 Treatment on Synaptic Activity in Subjects with Mild to Moderate Alzheimer's Disease*

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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 product candidates, including CT1812, and any expected or implied benefits or results, including that 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 our business, 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, market 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](http://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 environment. 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

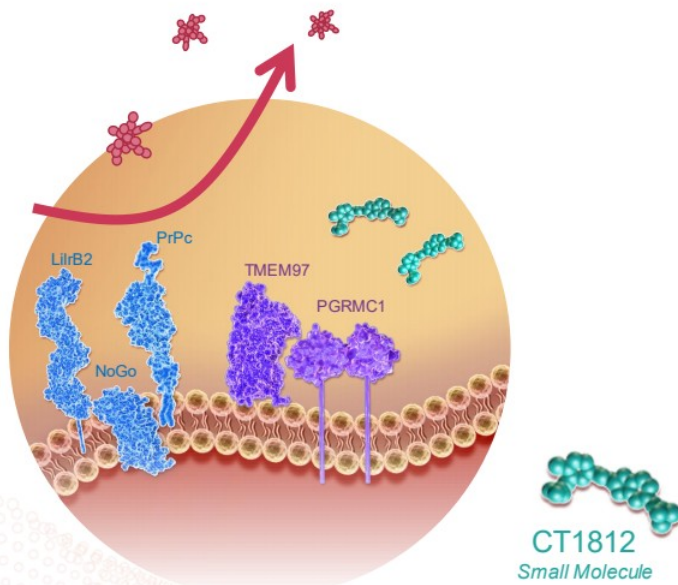
This presentation may contain trademarks, service marks, trade names and copyrights of other companies, which are the property of their respective owners. Solely for convenience, some of the trademarks, service marks and trade names referred to in this presentation may be listed without the TM, SM or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



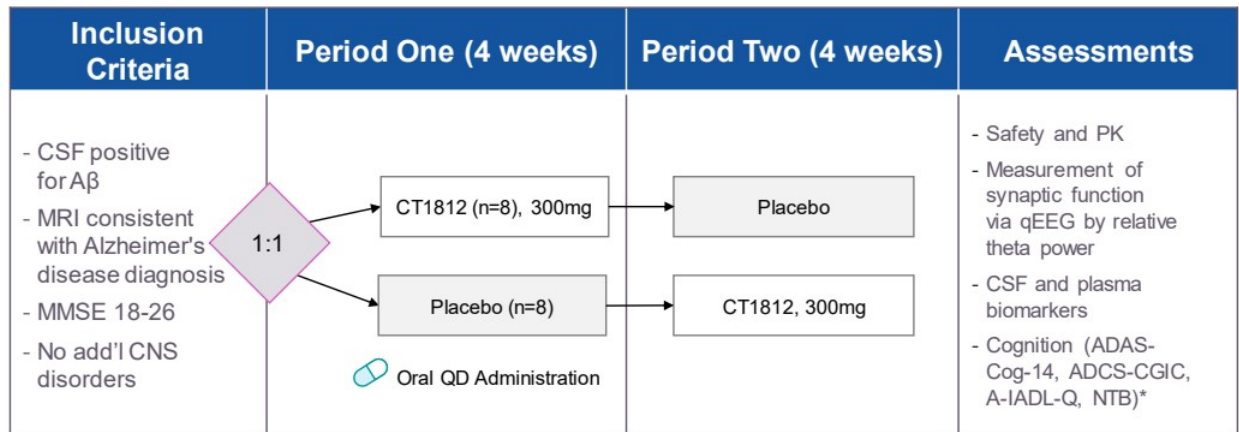
# SEQUEL Hypothesis



- Aβ oligomers impair synaptic and neuronal activity
- Will displacement of Aβ oligomers from synapses after treatment with CT1812 lead to a detectable change in EEG patterns?

# SEQUEL (COG0202): Single-site qEEG Study in 16 Adults with Mild-to-moderate Alzheimer's Disease

Two-group cross-over design



<https://clinicaltrials.gov/ct2/show/NCT04735536>

# Study Design

**Design:** Two-group cross-over study in 16 adults with mild-to-moderate AD

**Single site:** VUmc Alzheimer's Center, Amsterdam

**Primary objectives:**

- Assess safety, tolerability, PK of CT1812 following repeated dosing for 28 days
- Evaluate efficacy of CT1812 in restoring synaptic function through quantitative EEG as measured by:
  - Global relative theta power (primary endpoint)
  - Global alpha AECC, global relative alpha power, global relative beta power – key pre-specified exploratory endpoint
  - Additional pre-specified EEG exploratory endpoints

**Exploratory objectives:**

- Cognitive measures: impact of CT1812 on cognitive and global functioning, as measured by the following:
  - ADAS-Cog-14, ADCS-CGIC, A-IADL-Q
  - Neuropsychological test battery (NTB), Controlled Word Association Test (COWAT), Trail Making Test (TMT) Parts A & B, and Wechsler Memory Digit Span (VMDS)
  - Exploratory – biomarkers – pending

## Topline Data Overview

- Disposition and demographics
- Safety and tolerability
- Topline EEG findings



 **COGNITION**  
Therapeutics

# COG0202 Disposition and Demographics

## Disposition

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- 34 subjects screened; 16 randomized
- 15 completed the study
  - No subjects discontinued due to AEs
  - One patient discontinued after treatment period 1 due to withdrawal of consent (death in the family)
- n=14 for placebo period (one participant missed visit 7); n=16 for CT1812 period

## Demographics

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- Mean Age: 66.4 years
- 50% Female
- 100% White, non-Hispanic
- Baseline cognitive measures:
  - Mean MMSE: 21.1
  - ADAS-Cog14: 30.2
  - Amsterdam IADL: 52.6
- ApoE genotypes:
  - 31.3% ApoE e3/e3
  - 37.5% ApoE e3/e4
  - 31.3% ApoE e4/e4
- Time since diagnosis: 1.14 years



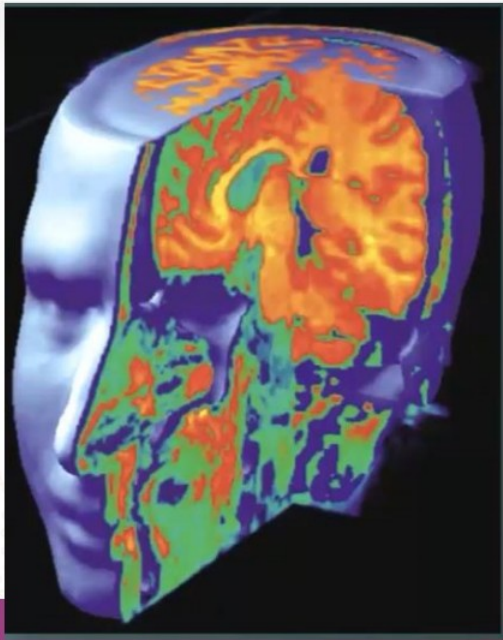
# COG0202 SEQUEL: Safety and Tolerability

*Safety and tolerability profile consistent with previous studies*

- CT1812 was well-tolerated
  - All AEs were mild and moderate
  - No Severe AEs, No SAEs, No AEs leading to death or discontinuation
- TEAEs:
  - Occurred in 11 participants in the CT1812 period and 6 participants in the placebo period
  - 6 TEAEs were categorized as related to study drug (3 in CT1812 period and 3 in placebo period)
- Most common AEs by MedDRA system organ class:
  - GI: nausea, diarrhea
  - Injury & procedural complications: procedural headache
- Consistent with previous studies – 1 participant with mild (2X ULN) elevated liver enzymes

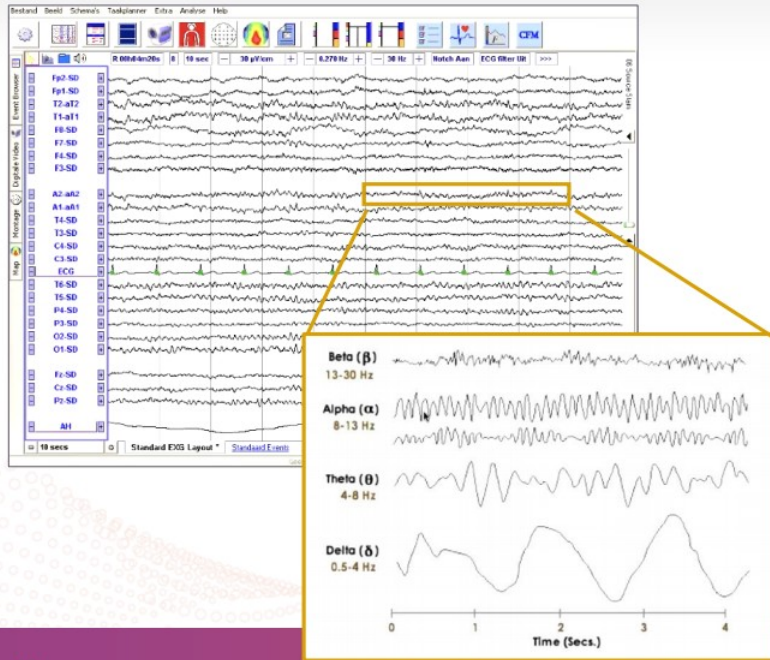
# Biomarkers of Disease

## *Introducing quantitative EEG*



- Amyloid burden can be measured by PET
- Canonical biomarkers assessed via serum and blood
- Anatomic changes can be measured by vMR
- Cognition and executive function can be measured with ADAS-Cog and other scales
- Neurophysiology / quantitative EEG:
  - Global and regional brain activity
  - Regional connectivity

# Brain Waves – a Brief Primer



- An EEG reading compares electrical activity between electrodes on the scalp
- Fast waves in the alpha and beta frequencies dominate healthy EEG patterns
- Alzheimer's disease is associated with slower waves – a theta or delta pattern
- The dominance of one wave pattern over another is referred to as "relative power"

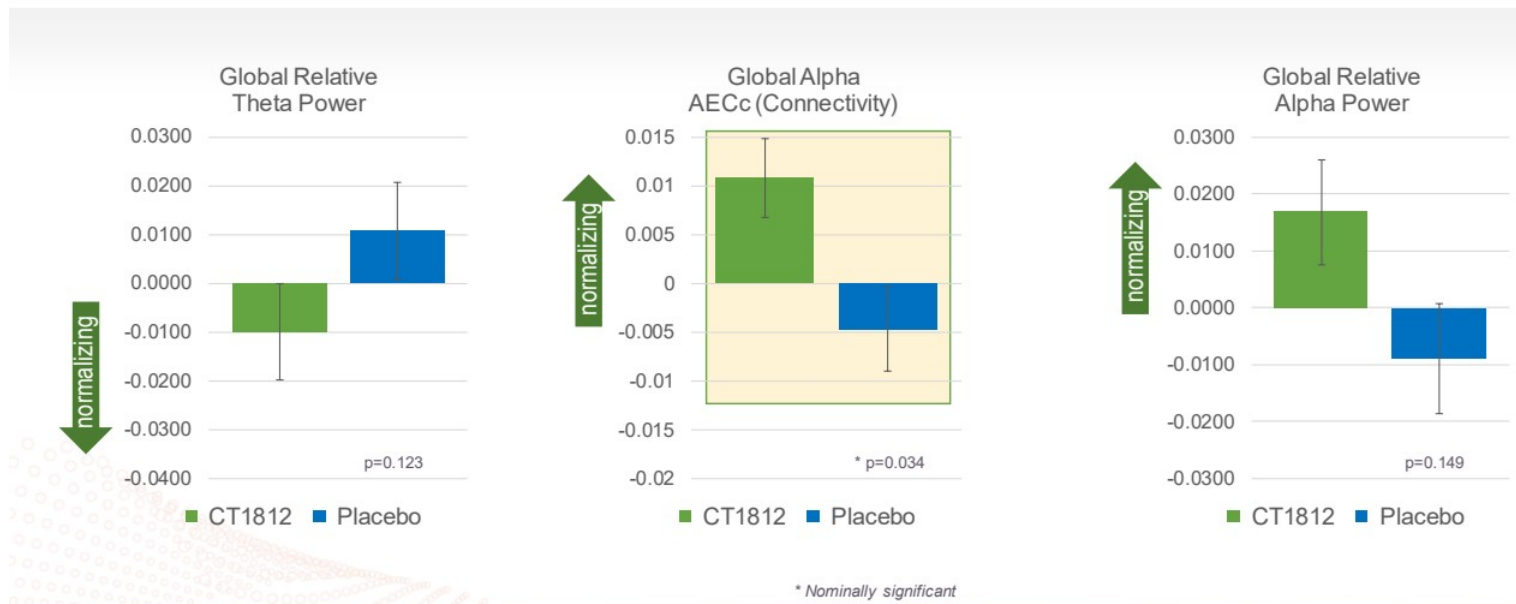


# SEQUEL: Topline EEG Data

- ✓ Assess safety, tolerability, PK of CT1812 following repeated dosing for 28 days
- Evaluate efficacy of CT1812 in restoring synaptic function through quantitative EEG as measured in rank order:
  - Global relative theta power (primary endpoint)
  - Global alpha AECC, global relative alpha power, global relative beta power – key pre-specified exploratory endpoints
  - Additional pre-specified EEG exploratory endpoints

# SEQUEL Topline Results

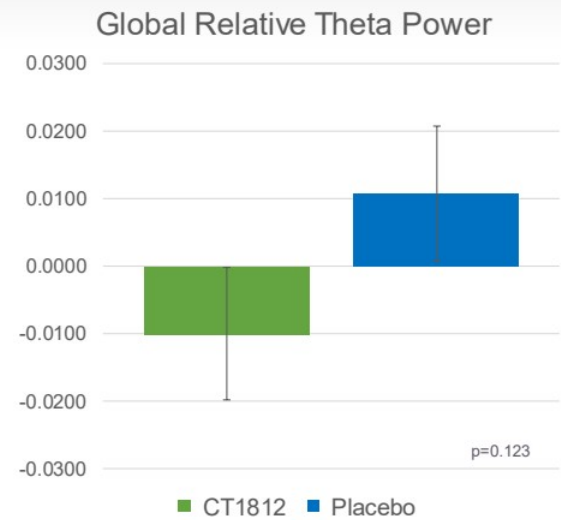
*Positive trends in first three ranked outcomes measures*



# SEQUEL Topline Results

*Positive trends in brain activity - reduced global & regional theta power - following 4 wks of treatment*

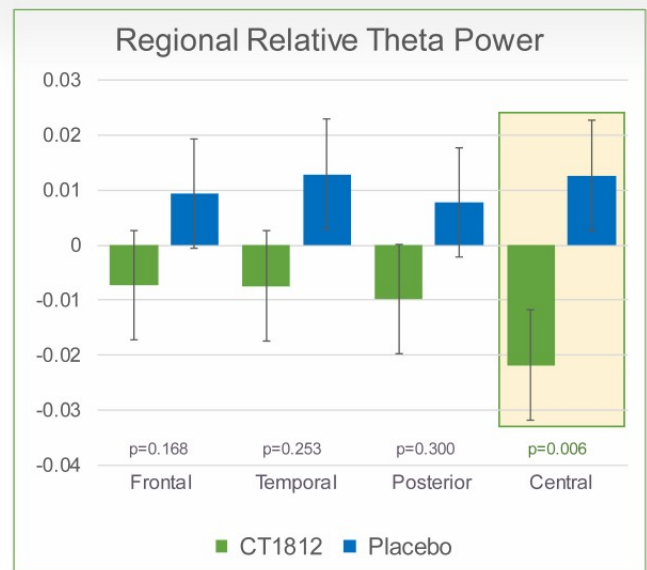
- CT1812 treatment was associated with a reduction in global relative theta power



# SEQUEL Topline Results

*Positive trends in brain activity - reduced regional theta power - following 4 wks of treatment*

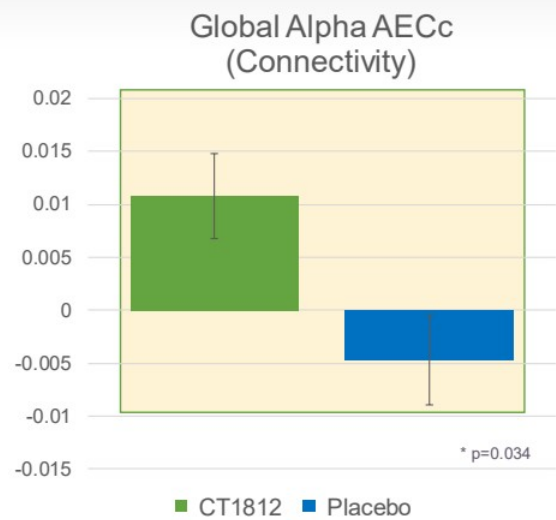
- Decreases in relative theta power were also observed in specific brain regions: frontal, temporal, posterior (parietal and occipital), and central
  - Statistical significance was only achieved in the central region ( $p < 0.006$ )



# SEQUEL Topline Results

*Positive trends in brain activity - increased connectivity - observed following 4 wks of treatment*

- In addition, an analysis of the qEEG results showed that CT1812 treatment was associated with greater connectivity between brain regions
  - This suggests that the brain's ability to communicate and exchange information between regions can be rescued by CT1812

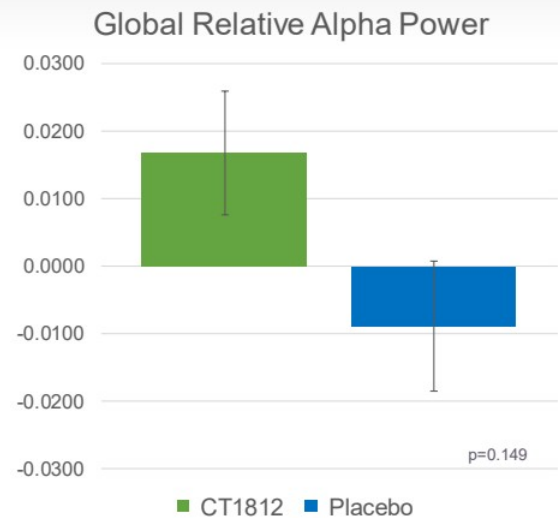


\* Nominally significant

# SEQUEL Topline Results

*Positive trends in brain activity - increased alpha power - observed following 4 wks of treatment*

- Increases in relative power in the alpha band were observed globally
  - Fast alpha waves are considered to be part of the normal background rhythm of a healthy brain
  - In Alzheimer's, alpha waves lose their dominance and are gradually replaced by slower-oscillating, lower-amplitude theta and delta waves



# Conclusions

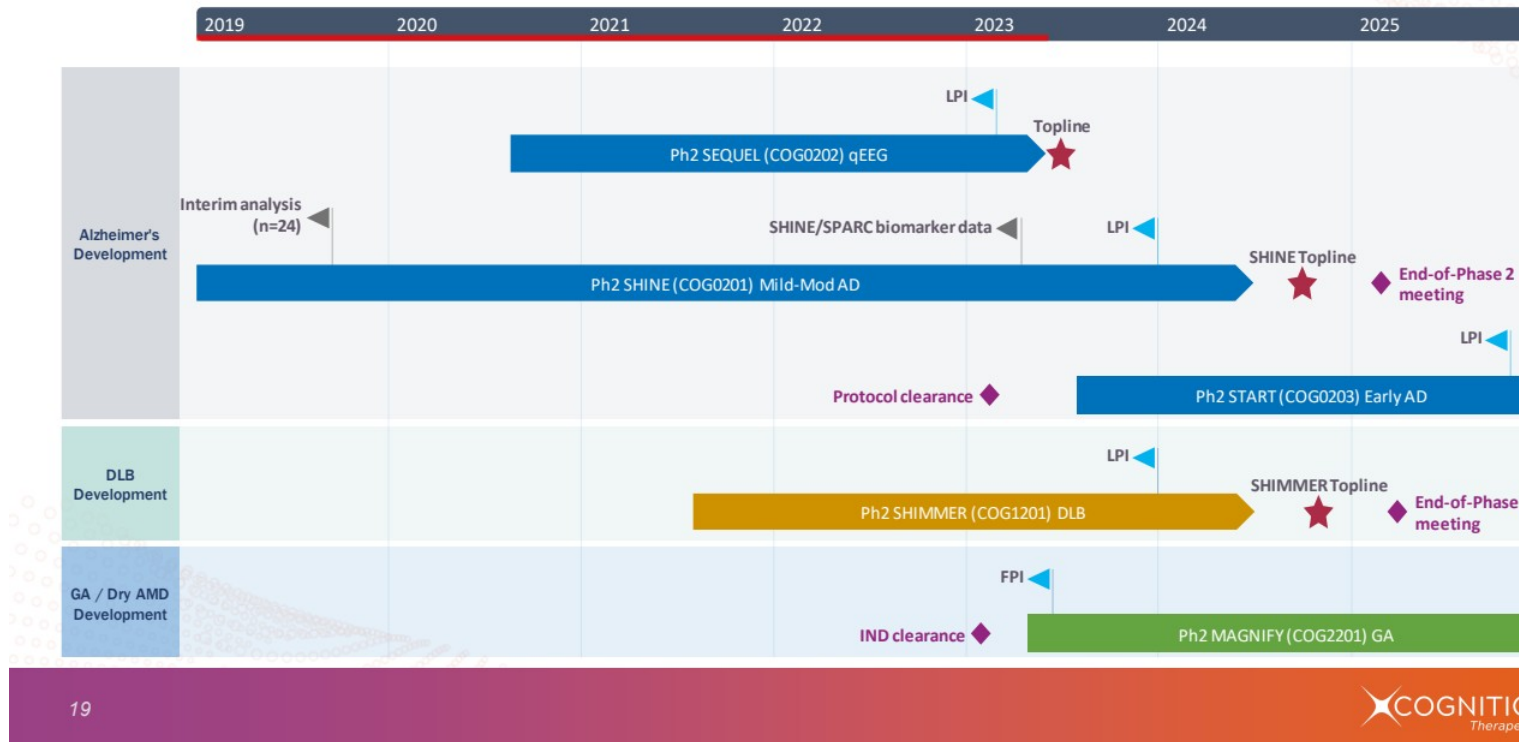
- CT1812 was well tolerated in this 28-day study
  - All AEs were mild to moderate
  - There were no serious or severe AEs
  - No AEs led to study discontinuation or death
- Strong trends on pre-specified qEEG measures
  - Consistent trend across all qEEG measures
  - Nominally significant treatment differences including global alpha AECc and central relative theta power
- In conclusion, CT1812 has demonstrated an impact on brain activity in mild-to-moderate Alzheimer's patients

# Evidence of CT1812 Impact on Alzheimer's Disease

- Studies to date provide evidence of:
  - Target engagement (SNAP)
  - Anatomical effect (SPARC)
  - Preliminary cognitive improvement (SHINE cohort A)
  - Neurophysiology (SEQUEL)
- Supportive biomarker evidence of biological effect
- Fully funded proof-of-concept studies ongoing:
  - Early Alzheimer's disease
  - Mild-to-moderate Alzheimer's disease
  - Dementia with Lewy bodies



# Multiple Near-term Catalysts Expected





## Thank You

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 **COGNITION**  
Therapeutics