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): **March 15, 2023**

Cognition Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-40886**	**13-4365359**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification No.)

2500 Westchester Avenue **Purchase, NY**	**10577**
(Address of principal executive offices)	(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 March 15, 2023, Cognition Therapeutics, Inc. (the "Company") issued a press release announcing the Company received clearance of its Investigational New Drug application from the U.S. Food and Drug Administration for its oral drug candidate, CT1812, in patients with geographic atrophy ("GA") secondary to dry age-related macular degeneration ("dry AMD"). The Company now plans to initiate the Phase 2 MAGNIFY trial of CT1812 in 2023, in individuals with dry AMD who have measurable GA. A copy of the press release is being filed as Exhibit 99.1 hereto.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Document
99.1	Press Release, dated March 15, 2023
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.

COGNITION THERAPEUTICS, INC.

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

Date: March 15, 2023

Exhibit 99.1

Cognition Therapeutics Announces Development Plans for Oral CT1812 in Geographic Atrophy Secondary to Dry AMD

NEW YORK, NY, March 15, 2023 — Cognition Therapeutics, Inc. (NASDAQ: CGTX) announced that its Investigational New Drug (IND) application for investigation of CT1812 for geographic atrophy (GA) secondary to dry age-related macular degeneration (dry AMD) has been cleared by the U.S. Food and Drug Administration (FDA). Cognition plans to initiate the Phase 2 MAGNIFY trial of its oral drug candidate, CT1812 in 2023 in individuals with dry AMD who have measurable GA.

“We enjoyed a collaborative dialogue with the ophthalmology division of the FDA during our pre-IND meeting and are excited to assess the potential of CT1812 to impact GA and slow the decline in visual acuity in people with dry AMD,” said Anthony Caggiano, M.D., Ph.D., Cognition’s chief medical officer and head of R&D. “We believe that CT1812's oral systemic delivery combined with its potential to protect the retinal pigment epithelium (RPE) from damage in both the affected and fellow eyes, may represent significant advantage to the millions of people with dry AMD who are at risk for permanent vision loss.”

The MAGNIFY study (COG2201) is a randomized, placebo-controlled phase 2 trial expected to enroll approximately 246 people who have been diagnosed with dry AMD with measurable GA. Over the treatment period, change in GA lesion size and best-corrected visual acuity, as well as other measures of safety and efficacy will be assessed to determine if treatment can slow vision loss.

“Expansion of our pipeline programs into GA is an excellent example of how we are leveraging our scientific expertise to tackle some of the most challenging diseases,” added Lisa Ricciardi, president and CEO of Cognition. “Looking ahead, I’m excited by our continued clinical progress as we advance CT1812 through ongoing studies and now into this new indication.”

About CT1812
CT1812 is an experimental orally delivered small molecule designed to penetrate the blood-brain and blood-retina barriers and bind selectively to the sigma-2 (σ-2) receptor complex. The σ-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 (Aβ) oligomers, oxidative stress and other stressors. Such damage to sensitive cells in the central nervous system (CNS) such as neurons and RPE cells can progress to a loss of function. In dry AMD, this can result in a loss of visual acuity and eventual vision loss.

Early proof-of-concept studies with CT1812 indicate a role of σ-2 receptor modulators in rescuing sensitive RPE cells from damage by stressors such as pathogenic proteins and oxidative stress, thus preserving this crucial component of the macula.

In addition to Cognitions’ new Phase 2 MAGNIFY clinical trial, CT1812 is being studied in three ongoing Phase 2 clinical trials: the SEQUEL study, which recently concluded enrollment of adults with mild-to-moderate Alzheimer’s disease; the SHINE study in individuals with mild-to-moderate Alzheimer’s disease; and the SHIMMER study in individuals with dementia with Lewy bodies. CT1812 has not been approved by the U.S. FDA or other regulatory agency.

About Geographic Atrophy Secondary to Dry AMD
Dry AMD, one of two forms of AMD, is common among people over 50 and is caused by a degeneration and thinning of the macula, the part of the retina responsible for central vision. The gradual loss of central vision associated with dry AMD can present limitations in reading and driving. As the disease progresses in severity into geographic atrophy, which affects approximately 5 million people worldwide and 1 million in the United States, degeneration of retinal pigment epithelial cells can result in permanent vision loss.

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 σ-2 receptor modulators can regulate pathways that are impaired in these diseases. We believe that targeting the σ-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 https://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, our clinical development plans, including statements regarding our expected timing of the Phase 2 MAGNIFY trial, are forward-looking statements. These statements 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. These and other risks and uncertainties are described more fully in the "Risk Factors" section of our most recent filings with the Securities and Exchange Commission and are available at www.sec.gov. 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 and pre-clinical studies being predictive of the results of 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 ongoing COVID-19 pandemic on our business, supply chain and labor force; and the risks and uncertainties described in the "Risk Factors" section of our annual and quarterly reports filed the Securities Exchange Commission. 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.

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