Cognition Therapeutics Reports Financial Results for the Second Quarter 2024 and Provides Business and Clinical Update

Aug 8, 2024 |

- Proof-of-Concept Phase 2 SHINE Trial Demonstrates ~40% Mean Improvement in ADAS-Cog 11 vs Placebo and Consistent Positive Changes Across Multiple Cognitive and Functional Measures -

- On Track to Report Topline Results from SHIMMER Study in Mild-to-Moderate DLB by YE 2024 -

- Company to Host Investor Conference Call at 8:30 a.m. -

PURCHASE, N.Y., Aug. 08, 2024 (GLOBE NEWSWIRE) -- **Cognition Therapeutics, Inc. (Nasdaq: CGTX),** a clinical stage company developing product candidates that treat neurodegenerative disorders, (the "Company" or "Cognition"), today reported financial results for the second quarter ended June 30, 2024, and provided a business update.

"We announced favorable results from the Phase 2 'SHINE' Study that provided proof-of-concept that CT1812 has potential to slow the progression of mild-to-moderate Alzheimer's disease after just six months of treatment," said Lisa Ricciardi, Cognition's president and CEO. "In terms of next steps, we are looking forward to reading out results from our 'SHIMMER' study in mild-to-moderate dementia with Lewy bodies by year-end 2024 and are now planning the next phase of development in our Alzheimer's disease program."

Business and Corporate Highlights

- Phase 2 proof-of-concept SHINE study (NCT03507790) of CT1812 in 153 participants with mild-to-moderate Alzheimer's disease demonstrated consistent positive changes slowing cognitive decline, a biomarker signal of neuroprotection, and a favorable safety and tolerability profile
    - Participants treated with once daily oral CT1812 (pooled 100 and 300mg) experienced a 39% slowing of decline compared to placebo-treated as measured with ADAS-Cog 11*
    - Consistent trends favoring CT1812 were observed in other cognitive measures: ADAS-Cog 13, cognitive composite, MMSE; and in functional measures: ADCS-ADL and ADCS-CGIC
    - A significant reduction in neurofilament light chain (NfL), a biomarker of neurodegeneration, in participants treated with 300mg CT1812 compared to placebo
    - No discontinuations due to AEs in the 100mg CT1812 group; all elevated liver enzymes occurring in the 300 mg dose group; serious adverse events (SAE) similar in placebo and treated arms
    - Results presented at the 2024 Alzheimer's Association International Conference (AAIC)
- Investor webcast held to discuss SHINE results, an archive of which is available here.
- Published three manuscripts that demonstrate CT1812 impact on pathways related to amyloid biology, synapse and neuroinflammation, hallmarks of Alzheimer's disease pathology:
    - Proteomic analyses from the first cohort of the Phase 2 COG0201 'SHINE' study (SHINE-A) in the journal, *Neurobiology of Disease*
    - Clinical findings from the Phase 1b COG0105 'SPARC' study in *Alzheimer's Research & Therapy* and the Phase 2 COG0202 'SEQUEL' study in *The Journal of Prevention of Alzheimer's Disease*
- Continued progress in Phase 2 START study (NCT05531656) of CT1812 in early Alzheimer's disease
- Continued enrollment in Phase 2 MAGNIFY study (NCT05893537) of CT1812 in geographic atrophy secondary to dry age-related macular degeneration

Second Quarter 2024 Financial Results

Cash and cash equivalents as of June 30, 2024 were approximately $28.5 million and total grant funds remaining from the NIA were $57.3 million. The Company estimates that it has sufficient cash to fund operations and capital expenditures into the second quarter of 2025.

Research and development expenses were $11.6 million for the second quarter ended June 30, 2024, compared to $8.5 million for the comparable period in 2023. The increase was primarily related to higher costs associated with advancing our clinical programs, including Phase 2 trial activities with contract research organizations and personnel cost.

General and administrative expenses were $3.1 million for the second quarter ended June 30, 2024, compared to $3.3 million for the comparable period in 2023. The decrease was primarily related to lower professional services.

The Company reported a net loss of $7.0 million, or $(0.18) per basic and diluted share for the second quarter ended June 30, 2024, compared to a net loss of $4.7 million, or $(0.16) per basic and diluted share for the same period in 2023.

Conference Call

Date / Time	August 8, 2024 at 8:30am ET / 5:30am PT
Telephone Access:	US/Canada Participant Toll-Free Dial-in Number: (800) 715-9871 US/Canada Participant International Dial-In Number: (646) 307-1963 Conference ID Number: 3702003
Webcast Access:	The audio webcast with live Q&A will be accessible at https://edge.media-server.com/mmc/p/3napeebe or via the Investor Relations section of Cognition's website. An archive of the webcast and presentation will be available for 90 days beginning at approximately 10:30 a.m. ET on August 8, 2024.

** CT1812 did not achieve statistical significance on ADAS-Cog 11, the first of the ordered secondary efficacy endpoints, in the pooled 100mg and 300mg dose group compared to placebo*

About Cognition Therapeutics:
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, are forward-looking statements. These statements, including statements relating to 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 late trials and our clinical development plans, including statements regarding our clinical studies of CT1812 and any analyses of the results therefrom, the timing and expected results of our clinical trials, upcoming presentations on our clinical trials, and cash runway, 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: 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; 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; 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 impacts of ongoing global and regional conflicts; the impact of the 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.

Cognition Therapeutics, Inc.
Unaudited Selected Financial Data

(in thousands, except share and per share data amounts)	Three Months Ended June 30,		Six Months Ended June 30,	
Consolidated Statements of Operations Data:	**2024**	**2023**	**2024**	**2023**
Operating Expenses:				
Research and development	$ 11,577	$ 8,497	$ 22,130	$ 13,927
General and administrative	3,101	3,320	6,650	6,863
Total operating expenses	14,678	11,817	28,780	20,790
Loss from operations	(14,678)	(11,817)	(28,780)	(20,790)
Other income (expense):				
Grant income	7,311	6,925	12,223	10,351
Other income (expense), net	333	172	577	(443)

Interest expense	(7)	(6)	(17)	(16)
Loss on currency translation from liquidation of subsidiary	—	—	(195)	—
Total other income, net	7,637	7,091	12,588	9,892
Net loss	$ (7,041)	$ (4,726)	$ (16,192)	$ (10,898)
Foreign currency translation adjustment, including reclassifications	—	(1)	195	3
Total comprehensive loss	$ (7,041)	$ (4,727)	$ (15,997)	$ (10,895)
Net loss per share:				
Basic	$ (0.18)	$ (0.16)	$ (0.44)	$ (0.37)
Diluted	$ (0.18)	$ (0.16)	$ (0.44)	$ (0.37)
Weighted-average common shares outstanding:				
Basic	40,062,954	29,614,822	36,899,112	29,356,144
Diluted	40,062,954	29,614,822	36,899,112	29,356,144

	As of	
(in thousands)	**June 30, 2024**	**December 31, 2023**
Consolidated Balance Sheet Data:		
Cash and cash equivalents	$ 28,533	$ 29,922
Total assets	34,369	35,163
Total liabilities	11,360	10,689
Accumulated deficit	(157,381)	(141,189)
Total stockholders' equity	23,009	24,474

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