



Athira Pharma Reports Second Quarter 2024 Financial Results and Pipeline and Business Updates

August 1, 2024

Topline data from completed Phase 2/3 LIFT-AD clinical trial of fosgonimeton as a potential treatment for mild-to-moderate Alzheimer's disease targeted for September 2024

Phase 2/3 LIFT-AD data to be presented in an oral presentation at CTAD in October 2024

Phase 1 clinical trial of ATH-1105 underway for the potential treatment of amyotrophic lateral sclerosis (ALS)

BOTHELL, Wash., Aug. 01, 2024 (GLOBE NEWSWIRE) -- **Athira Pharma, Inc.** (NASDAQ: ATHA), a late clinical-stage biopharmaceutical company focused on developing small molecules to restore neuronal health and slow neurodegeneration, today reported financial results for the quarter ended June 30, 2024, and provided recent pipeline and business updates.

"We are excited to be fast approaching the topline data readout from our Phase 2/3 LIFT-AD clinical trial by the end of the third quarter, as we believe it will further support fosgonimeton's potential as a first-in-class therapy for mild-to-moderate Alzheimer's disease patients," said Mark Litton, Ph.D., President and Chief Executive Officer of Athira. "We were delighted to present preclinical data at the recent Alzheimer's Association International Conference that showed fosgonimeton attenuated amyloid- β -induced autophagic impairments in primary cortical neurons, which may have important implications regarding the mitigation of pTau pathology and neurodegeneration observed in our preclinical models. These results suggest that fosgonimeton may have beneficial impacts on key indicators of protein pathology (pTau) and the associated neurodegeneration in Alzheimer's disease. Plasma biomarkers of Alzheimer's disease pathology, including Amyloid- β and pTau, will be evaluated in our LIFT-AD trial in addition to our primary endpoint combining measures of cognition and function."

Clinical Development & Pipeline Programs

Athira's drug development pipeline includes potential first-in-class (fosgonimeton) and next-generation (ATH-1105 and ATH-1020) small molecule drug candidates designed to promote the neurotrophic hepatocyte growth factor (HGF) system, which activates neuroprotective, neurotrophic and anti-inflammatory pathways in the central nervous system. Athira's drug candidates have distinct properties, which the Company believes may be applicable to a broad range of neurodegenerative diseases.

Fosgonimeton (ATH-1017) – A potentially first-in-class, once daily, subcutaneously administered drug candidate initially targeted for the potential treatment of Alzheimer's disease.

LIFT-AD Phase 2/3 clinical trial of fosgonimeton in mild-to-moderate Alzheimer's disease ([NCT04488419](#))

- Athira is targeting to release topline data from LIFT-AD in the third quarter of 2024 and plans to present the fuller dataset in an oral presentation at the 17th Annual Clinical Trials on Alzheimer's Disease (CTAD) taking place October 29-November 1, 2024, in Madrid, Spain.
- In July 2024, Athira announced the completion of dosing for the last patient enrolled in the LIFT-AD study.
- The LIFT-AD study is investigating the effects of fosgonimeton 40 mg compared with placebo in a primary analysis population of approximately 315 mild-to-moderate AD patients who are not receiving background therapy. The primary endpoint is the Global Statistical Test (GST), a combination of results of measures of cognition (ADAS-Cog11) and function (ADCS-ADL23), which Athira believes is a comprehensive measure of overall disease burden. Other secondary and exploratory endpoints include changes in plasma biomarkers of neurodegeneration, protein pathology, and neuroinflammation.

Open Label Extension (OLEX) fosgonimeton trial ([NCT04886063](#))

- Eligible participants who complete the Company's LIFT-AD or ACT-AD clinical trials and elect to participate in the ongoing OLEX are able to receive up to 48 months of open-label treatment.
- Notably, 85% of eligible participants who completed either study elected to enroll in OLEX.
- Currently, more than 70 patients are continuing fosgonimeton treatment beyond 18 months, with nearly 50 patients continuing fosgonimeton treatment beyond 24 months, reflecting an unexpected long-term participation rate in a progressive mild-to-moderate Alzheimer's disease population.
- Athira believes the OLEX will provide insights into fosgonimeton's long-term effects for potentially over four years of investigational treatment.

ATH-1105 – A next-generation, orally administered, small molecule drug candidate in development for the potential treatment of ALS.

- Athira is currently conducting a first-in-human, dose escalation Phase 1 clinical trial evaluating safety, tolerability and pharmacokinetics of ATH-1105 in up to 80 healthy volunteers.

- Athira announced the completion of the first cohort of healthy volunteers in June 2024, and the Company expects trial completion by year-end 2024.
- ATH-1105's potential is supported by a growing body of preclinical evidence demonstrating statistically significant improvements on nerve and motor function, biomarkers of inflammation and neurodegeneration, and survival in various models of ALS.
- These data have been presented at a variety of key scientific and medical meetings including the American Association of Neurology (AAN), the Alzheimer's Association International Congress (AAIC), the Northeast Amyotrophic Lateral Sclerosis Consortium® (NEALS), and the Motor Neurone Disease Association (MNDA).

Recent Presentations and Publications

- In July 2024, Athira presented preclinical data in poster presentations at the Alzheimer's Association International Conference (AAIC) 2024. One highlighted fosgonimeton's ability to potentially address autophagic impairment in AD, which may have important implications regarding the attenuation of pTau pathology. In the presentation titled, "Fosgonimeton attenuates amyloid- β -induced autophagic impairments in primary cortical neurons," study authors concluded that the data "demonstrate the ability of fosgonimeton to potentially address autophagic impairment in Alzheimer's disease, which may lead to the reduction of pTau pathology with treatment." The other presentation titled "Neuroprotective effects of fosgonimeton and amyloid- β -targeting monoclonal antibodies against amyloid- β toxicity in primary neuron culture" highlighted research that demonstrated the neuroprotective ability of fosgonimeton, alone or in combination with lecanemab, against amyloid- β -mediated toxicity in primary neurons. Athira's scientific presentations can be accessed on the Athira website here: [Medical Affairs – Athira Pharma](#).
- In June 2024, Athira hosted a Key Opinion Leader webinar event focused on the LIFT-AD trial endpoint of GST. The event featured presentations from Suzanne Hendrix, Ph.D., Founder and CEO of Pentara Corporation, and Anton P. Porsteinsson, M.D., Director of the University of Rochester Alzheimer's Disease Care, Research, and Education Program (AD-CARE). A replay of the event can be accessed [here](#).

Financial Results

- **Cash Position.** Cash, cash equivalents and investments were \$91.8 million as of June 30, 2024, compared to \$147.4 million as of December 31, 2023. Net cash used in operations was \$48.1 million for the six months ended June 30, 2024, compared to \$50.5 million for the six months ended June 30, 2023.
- **Research and Development (R&D) Expenses.** R&D expenses were \$22.2 million for the quarter ended June 30, 2024, compared to \$21.6 million for the quarter ended June 30, 2023. The increase was driven primarily by an increase in ATH-1105 program costs associated with the Phase 1 clinical trial, which commenced in the second quarter of 2024. This increase was partially offset by decreases in fosgonimeton program costs, preclinical programs and other direct costs, and personnel-related expenses.
- **General and Administrative (G&A) Expenses.** G&A expenses were \$5.9 million for the quarter ended June 30, 2024, compared to \$10.0 million for the quarter ended June 30, 2023. The decrease was driven by decreases in legal costs, business development expenses, professional services expenses, and other general corporate expenses.
- **Net Loss.** Net loss was \$26.9 million, or \$0.70 per share, for the quarter ended June 30, 2024, compared to a net loss of \$29.6 million, or \$0.78 per share, for the quarter ended June 30, 2023.

About Athira Pharma, Inc.

Athira Pharma, Inc., headquartered in the Seattle, Washington area, is a late clinical-stage biopharmaceutical company focused on developing small molecules to restore neuronal health and slow neurodegeneration. Athira aims to alter the course of neurological diseases by advancing its pipeline of drug candidates that modulate the neurotrophic HGF system. For more information, visit www.athira.com. You can also follow Athira on [Facebook](#), [LinkedIn](#), [X](#) (formerly known as Twitter) and [Instagram](#).

Forward-Looking Statements

This communication contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. These forward-looking statements are not based on historical fact and include statements regarding: Athira's drug candidates as potential treatments for Alzheimer's disease, Parkinson's disease, dementia with Lewy bodies, amyotrophic lateral sclerosis and other neurodegenerative diseases; future development plans; the anticipated reporting of data; the potential learnings from preclinical studies and other nonclinical data and their ability to inform and improve future clinical development plans; expectations regarding the potential efficacy and commercial potential of Athira's drug candidates; and Athira's ability to advance its drug candidates into later stages of development. Forward-looking statements generally include statements that are predictive in nature and depend upon or refer to future events or conditions, and include words such as "may," "will," "should," "on track," "would," "expect," "plan," "believe," "intend," "pursue," "continue," "suggest," "potential," "target," and similar expressions. Any forward-looking statements are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to, the data from preclinical and clinical trials may not support the safety, efficacy and tolerability of Athira's drug candidates; development of drug candidates may cease or be delayed; regulatory authorities could object to protocols, amendments and other submissions; future potential regulatory milestones for drug candidates, including those related to current and planned clinical studies, may be insufficient to support regulatory submissions or approval; the anticipated timing of the topline data from the LIFT-AD trial may be delayed; whether Athira's trials are sufficiently powered to meet the planned

endpoints; Athira may not be able to recruit sufficient patients for its clinical trials; the outcome of legal proceedings that have been or may in the future be instituted against Athira, its directors and officers; possible negative interactions of Athira's drug candidates with other treatments; Athira's assumptions regarding its financial condition and the sufficiency of its cash, cash equivalents and investments to fund its planned operations may be incorrect; adverse conditions in the general domestic and global economic markets; the impact of competition; the impact of expanded drug candidate development and clinical activities on operating expenses; the impact of new or changing laws and regulations; as well as the other risks detailed in Athira's filings with the Securities and Exchange Commission from time to time. These forward-looking statements speak only as of the date hereof and Athira undertakes no obligation to update forward-looking statements. Athira may not actually achieve the plans, intentions, or expectations disclosed in its forward-looking statements, and you should not place undue reliance on the forward-looking statements.

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Athira Pharma, Inc. Condensed Consolidated Balance Sheets (Amounts in thousands)

	June 30, 2024 (unaudited)	December 31, 2023
Assets		
Cash and cash equivalents	\$ 73,828	\$ 90,584
Short-term investments	17,941	56,835
Other short-term assets	6,562	7,310
Other long-term assets	12,922	5,516
Total assets	<u>\$ 111,253</u>	<u>\$ 160,245</u>
Liabilities and stockholders' equity		
Current liabilities	\$ 26,902	\$ 28,840
Long-term liabilities	1,016	1,217
Total liabilities	27,918	30,057
Stockholders' equity	83,335	130,188
Total liabilities and stockholders' equity	<u>\$ 111,253</u>	<u>\$ 160,245</u>

Athira Pharma, Inc. Condensed Consolidated Statements of Operations and Comprehensive Loss (Amounts in thousands, except share and per share amounts) (Unaudited)

	Three Months Ended June 30, 2024	2023
Operating expenses:		
Research and development	\$ 22,154	\$ 21,615
General and administrative	5,874	10,025
Total operating expenses	28,028	31,640
Loss from operations	(28,028)	(31,640)
Other income, net	1,169	2,043
Net loss	<u>\$ (26,859)</u>	<u>\$ (29,597)</u>
Unrealized gain on available-for-sale securities	99	90
Comprehensive loss attributable to common stockholders	<u>\$ (26,760)</u>	<u>\$ (29,507)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.70)</u>	<u>\$ (0.78)</u>
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	38,379,733	37,999,578

