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

November 7, 2024

Expects to complete healthy volunteer Phase 1 clinical study of ATH-1105 by year end and begin dosing ALS patients in 2025

BOTHELL, Wash., Nov. 07, 2024 (GLOBE NEWSWIRE) -- **Athira Pharma, Inc.** (NASDAQ: ATHA), a clinical-stage biopharmaceutical company focused on developing small molecules to restore neuronal health and slow neurodegeneration, today reported financial results for the quarter ended September 30, 2024, and provided recent pipeline and business updates.

“We are pleased to be continuing the advancement of ATH-1105 as a potential treatment for ALS. This novel, oral, next-generation HGF-modulating drug candidate has improved blood-brain-barrier penetration and pharmacokinetic properties. Specifically, preclinically ATH-1105 has shown a consistent ability in various ALS models to reduce plasma neurofilament light chain (NfL) levels, a key marker of ALS disease progression, and to improve motor and nerve function, enhance neuronal survival, and improve biomarkers of inflammation and neurodegeneration,“ said Mark Litton, Ph.D., President and Chief Executive Officer of Athira. “We continue to progress ATH-1105 in the ongoing Phase 1 study in healthy volunteers, which is targeted to complete by year end, and look forward to dosing ALS patients in 2025.”

Clinical Development & Pipeline Programs

Athira’s drug development pipeline includes potential first-in-class and next-generation novel 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.

ATH-1105 – A next-generation, novel, orally administered, small molecule drug candidate in development for the potential treatment of amyotrophic lateral sclerosis (ALS) and other neurodegenerative diseases.

- Athira is conducting a first-in-human Phase 1 (NCT 06432647) double-blind, placebo-controlled trial that is enrolling up to 80 healthy volunteers to evaluate single and multiple oral ascending doses of ATH-1105. The study is evaluating the safety and tolerability of ATH-1105 and includes measurements of pharmacokinetic outcomes.
- In June 2024, Athira completed the first cohort of healthy volunteers in its ongoing, dose escalation Phase 1 trial.
- Athira expects to complete the Phase 1 study by year-end 2024 and plans to begin dosing ALS patients in 2025.
- ATH-1105’s potential is supported by a growing body of preclinical evidence demonstrating improvements in 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).

Fosgonimeton (ATH-1017) – A once daily, subcutaneously administered drug candidate initially targeted for the potential treatment of Alzheimer’s disease

- In September 2024, Athira announced topline results from the LIFT-AD Phase 2/3 clinical trial of fosgonimeton in mild-to-moderate Alzheimer’s disease. The study did not meet its primary or key secondary endpoints, but biomarker and subgroup data were directionally consistent with the broad neuroprotective mechanism of action.

Plans to Explore Strategic Alternatives

- Following Athira’s receipt of the topline results of LIFT-AD, the company made the determination to explore strategic alternatives focused on maximizing stockholder value. As part of that effort, Athira has paused further development of fosgonimeton while continuing our ongoing development of ATH-1105 and are exploring partnering options. Athira has engaged Cantor Fitzgerald & Co. to act as an advisor in the process to explore strategic alternatives.

Financial Results

- **Cash Position.** Cash, cash equivalents and investments were $68.9 million as of September 30, 2024, compared to $147.4 million as of December 31, 2023. Net cash used in operations was $71.2 million for the nine months ended September 30, 2024, compared to $74.5 million for the nine months ended September 30, 2023.

- **Research and Development (R&D) Expenses.** R&D expenses were $17.9 million for the quarter ended September 30, 2024, compared to $27.2 million for the quarter ended September 30, 2023.
- **General and Administrative (G&A) Expenses.** G&A expenses were $7.6 million for the quarter ended September 30, 2024, compared to $7.8 million for the quarter ended September 30, 2023.
- **Legal Expense.** Legal expense of $4.1 million was accrued during the quarter ended September 30, 2024, in connection with the United States Department of Justice investigative demand.
- **Net Loss.** Net loss was $28.7 million, or $0.75 per share, for the quarter ended September 30, 2024, compared to a net loss of $33.0 million, or $0.87 per share, for the quarter ended September 30, 2023.

About Athira Pharma, Inc.
Athira Pharma, Inc., headquartered in the Seattle, Washington area, is a 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 amyotrophic lateral sclerosis, Alzheimer's disease, 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; Athira's ability to advance its drug candidates into later stages of development; and Athira's plans and expectations regarding Athira's exploration of strategic alternatives. 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; 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; risks related to Athira's exploration of strategic alternatives; 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)

	September 30, 2024	December 31, 2023
	(unaudited)	
Assets		
Cash and cash equivalents	$ 68,856	$ 90,584
Short-term investments	—	56,835
Other short-term assets	13,146	7,310
Other long-term assets	4,244	5,516
Total assets	$ 86,264	$ 160,245
Liabilities and stockholders' equity		
Current liabilities	$ 27,751	$ 28,840
Long-term liabilities	912	1,217
Total liabilities	28,663	30,057
Stockholders' equity	57,583	130,188
Total liabilities and stockholders' equity	$ 86,246	$ 160,245

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

	Three Months Ended September 30,	
	2024	**2023**
Operating expenses:		
Research and development	$ 17,922	$ 27,202
General and administrative	7,572	7,840
Legal expense	4,127	—
Total operating expenses	29,621	35,042
Loss from operations	(29,621)	(35,042)
Other income, net	880	2,072
Net loss	$ (28,741)	$ (32,970)
Unrealized gain on available-for-sale securities	41	261
Comprehensive loss attributable to common stockholders	$ (28,700)	$ (32,709)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.75)	$ (0.87)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	38,517,602	38,054,583