Athira Pharma Reports Full Year 2023 Financial Results and Pipeline and Business Updates

February 22, 2024

Enrollment completed in Phase 2/3 LIFT-AD clinical trial of fosgonimeton as a potential treatment for mild-to-moderate Alzheimer's disease; topline data expected in second half of 2024

On track to initiate first-in-human studies of ATH-1105 for the treatment of amyotrophic lateral sclerosis in first half of 2024

Strong balance sheet to support innovative pipeline through key inflection points

BOTHELL, Wash., Feb. 22, 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 year ended December 31, 2023, and reviewed recent pipeline and business updates.

"We've made important progress in our pursuit to advance potential new treatment options for neurodegenerative diseases. Importantly, in January, we announced completing enrollment in our Phase 2/3 LIFT-AD clinical trial, which is evaluating fosgonimeton in approximately 315 patients with mild-to-moderate Alzheimer's disease," stated Mark Litton, Ph.D., President and Chief Executive Officer of Athira. "We are encouraged by results shown to date, which we believe support fosgonimeton's potential to deliver a first-in-class therapy to Alzheimer's disease patients and expect to report topline data from LIFT-AD in the second half of 2024. Additionally, we are excited to advance ATH-1105 for the potential treatment of ALS and remain on-track to initiate the first-in-human study in the first half of 2024. We ended 2023 with a strong balance sheet that we believe will support the ongoing advancement of our pipeline, including fosgonimeton and ATH-1105, through key inflection points."

Recent Highlights

Pipeline

- In February 2024, the Company announced publication of research highlighting the neuroprotective and anti-inflammatory effects of ATH-1105 in preclinical models of amyotrophic lateral sclerosis (ALS) in the peer-reviewed journal, *Frontiers in Neuroscience.* The original research article is titled: "ATH-1105, a small-molecule positive modulator of the neurotrophic HGF system, is neuroprotective, preserves neuromotor function, and extends survival in preclinical models of ALS."
- In January 2024, the Company completed enrollment in the Phase 2/3 LIFT-AD clinical trial of fosgonimeton as a potential treatment for mild-to-moderate Alzheimer's disease (AD). The Phase 2/3 LIFT-AD clinical trial enrolled approximately 315 patients.
- In December 2023, the Company announced encouraging results from the exploratory Phase 2 SHAPE clinical trial to evaluate fosgonimeton in patients with Parkinson's disease dementia and dementia with Lewy bodies.
- In December 2023, the Company presented preclinical data at the Motor Neurone Disease Association (MNDA) 34th International Symposium on ALS/MND demonstrating ATH-1105 is neuroprotective, extends survival, reduces motor and nerve function decline when administered early or late in disease progression and is effective in combination with riluzole in a transgenic mouse model of ALS.
- In November 2023, the Company presented new preclinical data at the Society for Neuroscience (SfN) Annual Meeting 2023 highlighting the anti-inflammatory activity of fosgonimeton in microglial models, as well as the neuroprotective and procognitive effects of fosgonimeton in amyloid-β models of Alzheimer's disease.

Corporate

- In February 2024, Rachel Lenington, the Company's Chief Operating Officer, was appointed as Chief Operating Officer and Chief Development Officer, and Samantha Willing was appointed as Chief People Officer.

Upcoming Presentations

- Athira will present clinical and preclinical data at the 18th International Conference on Alzheimer's and Parkinson's Diseases (AD/PD 2024) taking place March 5-9, 2024, in Lisbon, Portugal. Presentation details include:
  - Abstract Title: *Results from SHAPE: A Phase 2 Study of Fosgonimeton in Patients with Parkinson's Disease Dementia and Dementia with Lewy Bodies* – Poster #: P1050/#1857: Presenter: Hans Moebius, M.D., Ph.D., Senior Scientific Advisor

- Abstract Title: *Neuroprotective mechanisms of Fosgonimeton Against Excitotoxicity in Primary Neuron Culture* – Poster #: P0256/#1757; Presenter: Sherif Reda, Ph.D., Associate Director, Discovery Biology
- Abstract Title: *Fosgonimeton protects against α-synuclein-mediated pathology in preclinical models of Parkinson's disease* – Poster #: P1046/#1243; Presenter: Sharay Setti, Ph.D., Senior Scientist II

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)*

- The LIFT-AD study is investigating the effects of fosgonimeton 40 mg compared with placebo in mild-to-moderate AD patients who are not receiving background therapy.
- In October 2022, following an unblinded interim efficacy and futility analysis, an independent data monitoring committee recommended continuation of the LIFT-AD study in patients with mild-to-moderate AD who are not receiving background therapy. The committee also determined that the study would be well powered to achieve the primary endpoint with approximately 300 patients given the preliminary effect observed in the unblinded interim analysis of approximately 100 patients treated.
- In May 2023, Athira selected the 40 mg dose for further development and potential regulatory approval.
- In January 2024, Athira completed enrollment of the LIFT-AD study, randomizing approximately 315 patients in the primary analysis population.
- The Company expects to report topline data in the second half of 2024.

Open Label Extension (OLEX) fosgonimeton trial *(NCT04886063)*

- Eligible participants who complete the LIFT-AD or ACT-AD trials and elect to participate in the ongoing OLEX are able to receive up to 30 months of open-label treatment.
- Greater than 85% of participants who completed either study have elected to enroll in OLEX to date.
- Currently, more than 60 patients are continuing fosgonimeton treatment beyond 18 months, which is unexpected in a progressive mild-to-moderate Alzheimer's disease population.
- Athira believes the OLEX will complement its long-term safety database and provide insights into fosgonimeton's long-term effects for up to three years of investigational treatment.

SHAPE Phase 2 clinical trial of fosgonimeton in mild-to-moderate Parkinson's disease dementia and Dementia with Lewy bodies *(NCT04831281)*

- In December 2023, Athira announced encouraging results from the exploratory SHAPE Phase 2 clinical trial of fosgonimeton for the potential treatment of Parkinson's disease dementia and dementia with Lewy bodies.
- Treatment with fosgonimeton 40 mg (n=5) compared to placebo (n=7) showed positive effects in cognitive measures including ADAS-Cog13, MMSE, and COWAT over the 6-month double-blind treatment period.
- The primary endpoint of the trial, a composite score of the change in Event-Related-Potential (ERP) P300 latency and cognitive assessment (ADAS-Cog13), was not met by protocoled analysis compared with placebo.
- Fosgonimeton was generally well tolerated, with a favorable safety profile. There were no treatment-related serious adverse events observed in the study. The most common adverse event in the treatment groups was injection site reactions.

ATH-1105 – A next-generation, orally administered, small molecule drug candidate in development for the potential treatment of ALS as the Company's initial indication.

- 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 animal models of ALS.
- These data were presented throughout 2023 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).
- The Company expects to initiate the first-in-human studies of ATH-1105 in the first half of 2024.

Financial Results

- **Cash Position**. Cash, cash equivalents and investments were $147.4 million as of December 31, 2023, compared to $245.2 million as of December 31, 2022. Cash used in operations was $100.8 million for the year ended December 31, 2023, compared to $72.5 million for the year ended December 31, 2022.

- **Research and Development (R&D) Expenses**. R&D expenses were $93.8 million for the year ended December 31, 2023, compared to $61.5 million for the year ended December 31, 2022. The increase was driven primarily by costs related to increased clinical trial and manufacturing activities, personnel costs, and preclinical research and development expenses.

- **General and Administrative (G&A) Expenses**. G&A expenses were $33.3 million for the year ended December 31, 2023, compared to $32.6 million for the year ended December 31, 2022.

- **Legal Settlement Expense and Insurance Recovery**. In February 2023, the Company reached an agreement in principle to resolve all claims in the Company's securities class action lawsuit. Under the proposed settlement, the Company agreed to make a one-time payment of $10.0 million and recorded a legal settlement expense of $10.0 million for the year ended December 31, 2022. Additionally, the Company recorded an insurance recovery of $1.6 million for the year ended December 31, 2023, representing the amount to be covered by the Company's insurers.

- **Net Loss**. Net loss was $117.7 million, or $3.09 per share, for the year ended December 31, 2023, compared to a net loss of $95.6 million, or $2.53 per share, for the year ended December 31, 2022.

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: drug candidates as a potential treatment for Alzheimer's disease, Parkinson's disease, Parkinson's disease dementia, 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, the ACT-AD and SHAPE trials, and LIFT-AD unblinded interim efficacy and futility analysis 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," 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; 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; regulatory agencies may be delayed in reviewing, commenting on or approving any of Athira's clinical development plans as a result of pandemics or health epidemics, which could further delay development timelines; 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)

	December 31,	
	2023	**2022**

Assets		
Cash and cash equivalents	$ 90,584	$ 95,966
Short-term investments	56,835	104,378
Other short-term assets	7,310	7,189
Long-term investments	—	44,829
Other long-term assets	5,516	5,791
Total assets	$ 160,245	$ 258,153
Liabilities and stockholders' equity		
Current liabilities	$ 28,840	$ 21,431
Long-term liabilities	1,217	1,585
Total liabilities	30,057	23,016
Stockholders' equity	130,188	235,137
Total liabilities and stockholders' equity	$ 160,245	$ 258,153

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

	Year Ended December 31,	
	2023	**2022**
Operating expenses:		
Research and development	$ 93,790	$ 61,464
General and administrative	33,304	32,552
Legal settlement	—	10,000
Insurance recovery related to legal settlement	(1,628)	—
Total operating expenses	125,466	104,016
Loss from operations	(125,466)	(104,016)
Grant income	157	5,161
Other income, net	7,637	3,216
Net loss	$ (117,672)	$ (95,639)
Unrealized gain (loss) on available-for-sale securities	1,607	(1,568)
Comprehensive loss attributable to common stockholders	$ (116,065)	$ (97,207)
Net loss per share attributable to common stockholders, basic and diluted	$ (3.09)	$ (2.53)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	38,020,182	37,733,240