Athira Pharma Reports Third Quarter 2023 Financial Results and Pipeline and Business Updates

November 9, 2023

Continues to report clinical and preclinical findings supporting the potential benefits of its small molecule therapeutic candidates targeting the neurotrophic HGF system as potential novel treatments for neurodegenerative diseases

Expects to complete enrollment of Phase 2/3 LIFT-AD clinical trial of fosgonimeton in mild-to-moderate Alzheimer's disease patients by the first quarter of 2024 with topline data expected in second half 2024

Maintains strong balance sheet to support innovative clinical development pipeline through key inflection points

BOTHELL, Wash., Nov. 09, 2023 (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 September 30, 2023, and provided pipeline and business updates.

"We enter the balance of the year more encouraged than ever by our increasing understanding of the power of modulating the neurotrophic HGF system as a potential strategy for treating a wide range of neurodegenerative diseases. Our pipeline of small molecule HGF system modulators has the potential to become the basis of a future product line of neurodegenerative disease treatments," said Mark Litton, Ph.D., President and Chief Executive Officer of Athira. "During the third quarter and recent weeks, we continued to present new data at key medical meetings that provide further evidence supporting the promise of both our fosgonimeton and ATH-1105 programs, and neurotrophic HGF system modulation in general, to modify the disease course for patients across a broad range of neurodegenerative diseases, including Alzheimer's disease (AD) and amyotrophic lateral sclerosis (ALS). We believe we have a leading position in understanding the neurotrophic HGF system biology."

"We remain keenly focused on advancing the ongoing Phase 2/3 LIFT-AD study, where we have added clinical sites and continued to engage with investigators to ensure completion of enrollment of this important study by the first quarter of 2024. This summer, we had a productive end-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA) which enabled alignment with the FDA on important aspects of the fosgonimeton program. We look forward to continued communication with the FDA, including discussions regarding our biomarker strategy and the LIFT-AD topline results, which are expected in the second half of 2024," concluded Dr. Litton.

Clinical Development & Pipeline Programs

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

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

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

- In September 2022, an independent, unblinded interim efficacy and futility analysis was performed on 100 patients without concomitant acetylcholinesterase inhibitors (AChEIs) who completed the LIFT-AD Phase 2/3 trial. The positive outcome from the independent data monitoring committee supports the potential clinically meaningful activity of fosgonimeton and its potential to achieve the primary endpoint of the trial.
- LIFT-AD's primary endpoint is the Global Statistical Test (GST), a composite of the co-key secondary endpoints ADAS-Cog11 and ADCS-ADL23. The Company expects the GST endpoint to increase the understanding of the clinical impact of fosgonimeton, while elucidating the key drivers of potential treatment effect.
- Key secondary and exploratory endpoints include changes in plasma biomarkers of neurodegeneration, protein pathology, and neuroinflammation.
- In a protocol amendment submitted to FDA in May 2023, the LIFT-AD trial was modified to focus prospectively only on 40 mg dosing and to use this dose group compared to placebo for the primary analysis of results.
- The Company expects to complete patient enrollment by the first quarter of 2024 and to report topline LIFT-AD results in the second half of 2024.
- Based on interactions with the FDA, the Company believes that all registrational pathways remain viable and contingent on LIFT-AD results. The FDA is open to ongoing dialogue with the Company regarding the LIFT-AD trial once completed as well as other aspects of our program to develop fosgonimeton as a potential treatment for mild-to-moderate AD.

Open Label Extension (OLEX) fosgonimeton trial (NCT04886063)

- Eligible participants who completed 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.
- The Company believes OLEX will complement the Company's long-term safety database and provide insights into fosgonimeton's long-term effects for up to three years.
- OLEX continues to enroll with greater than 85% of participants who completed either study having elected to enroll in the OLEX study.

ATH-1105 – A next-generation, orally administered drug candidate developed for the potential treatment of amyotrophic lateral sclerosis (ALS) as the Company's initial indication.

- ATH-1105 is supported by preclinical findings that demonstrated statistically significant improvements on nerve and motor function, biomarkers of inflammation and neurodegeneration, and survival in various ALS animal models.
- IND-enabling studies will continue through the remainder of 2023 in order to support the potential initiation of first-in-human studies in the first half of 2024 to evaluate this promising drug candidate as a treatment for ALS.

Recent and Upcoming Presentations
Athira continues to expand the body of clinical and preclinical findings supporting the potential benefits of its pipeline of small molecule therapeutic candidates targeting the neurotrophic HGF system to deliver novel treatments for neurodegenerative diseases.

The Company presented new data at the Alzheimer's Association International Conference 2023 (AAIC) that included:

- A post-hoc analysis of the Phase 2 ACT-AD study and data from the OLEX study in subjects with mild-to-moderate AD. The data suggested that improvements in plasma biomarkers of neurodegeneration (NfL) and neuroinflammation (glial fibrillary acidic protein, or GFAP) significantly correlate with GST, a composite score of cognition and function, further supporting the potential clinical utility of these biomarkers.
- Preclinical data demonstrating that fosgonimeton attenuates amyloid-β-mediated toxicity in vitro and highlighting its potential as a therapeutic candidate to slow disease progression and restore neuronal health.
- Preclinical data demonstrating that ATH-1105 offers protection against several pathologies common to ALS and frontotemporal dementia and supporting its therapeutic potential for the treatment of these indications.

The Company presented preclinical data that further supports the potential of fosgonimeton to treat neurodegenerative diseases such as AD at the 16th Annual Clinical Trials on Alzheimer's Disease conference (CTAD). The data presented:

- Demonstrated the ability of fosgonimeton to counteract mechanisms of amyloid-β (Aβ)-induced toxicity, reduce tau pathology, and promote neuronal survival in vitro.
- Showed treatment with fosgonimeton leads to improved cognitive performance in an Aβ-driven rat model of AD, suggesting that the in vitro activity of fosgonimeton Aβ-toxicity translates to functional benefits in vivo.

The Company presented preclinical data demonstrating the neuroprotective properties of ATH-1105 in several preclinical models of ALS at the 22nd Annual Northeast ALS Consortium (NEALS) Meeting that demonstrated:

- In vitro, ATH-1105 protected motor neurons from excitotoxicity, reduced TDP-43 mis-localization, preserved metabolic stability, and maintained neuromuscular junction integrity.
- In vivo, treatment with ATH-1105 improved motor and nerve function, mitigated inflammation and neurodegeneration, and reduced plasma NfL and pTDP-43 accumulation in ALS mice when administered alone or in combination with riluzole.

Athira will be presenting new preclinical data supporting the potential therapeutic benefit of fosgonimeton for the treatment of Alzheimer's disease at Neuroscience 2023. The event is hosted by the Society for Neuroscience and will take place at the Walter E. Washington Convention Center in Washington, D.C., November 11-15, 2023.

Presentation Details:

Title: Fosgonimeton, a small-molecule positive modulator of the neurotrophic HGF system, protects against amyloid beta-induced pathological alterations in Alzheimer's disease models in vitro and in vivo
Format: Oral Nanosymposium
Session: NAN076
Development of Novel Therapies for Neurodegenerative and Neuromuscular Diseases
Presenter: Sharay Setti, PhD, Senior Scientist, Athira Pharma
Time/Date: Wednesday, November 15, Session time: 8:00 a.m. – 12:00 p.m. Eastern Time, Presentation time: 8:15 a.m. – 8:30 am. Eastern Time

Title: Fosgonimeton, a small-molecule positive modulator of the neurotrophic hepatocyte growth factor system, inhibits LPS-mediated neuroinflammation in BV2 microglia
Format: Poster
Session: PSTR 203.06. Neuroinflammation: Microglia
Presenter: Wei Wu, PhD, Senior Scientist II, Athira Pharma
Time/Date: Monday, November 13, Session time: 8:00 a.m. – 12:00 p.m. Eastern Time, Presentation time: 9:00 a.m. – 10:00 a.m. Eastern Time

Financial Results

- **Cash Position.** Cash, cash equivalents and investments were $172.9 million as of September 30, 2023, compared with $245.2 million as of December 31, 2022. Net cash used in operations was $74.5 million for the nine months ended September 30, 2023, compared with $56.8 million for the nine months ended September 30, 2022.

- **Research and Development (R&D) Expenses.** R&D expenses were $27.2 million for the quarter ended September 30, 2023, compared with $17.0 million for the quarter ended September 30, 2022. The increase was driven primarily by costs related to increased clinical trial activities, manufacturing activities and personnel expense.

- **General and Administrative (G&A) Expenses.** G&A expenses were $7.8 million for the quarter ended September 30, 2023, compared with $7.2 million for the quarter ended September 30, 2022. The increase was primarily due to increases in personnel expenses, partially offset by a decrease in business development expenses.

- **Net Loss.** Net loss was $32.7 million, or $0.87 per share, for the quarter ended September 30, 2023, compared with a net loss of $20.2 million, or $0.53 per share, for the quarter ended September 30, 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 therapeutic 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: product candidates as a potential treatment for neurodegenerative diseases such as Alzheimer's disease and amyotrophic lateral sclerosis; Athira's platform technology and potential therapies; future development plans; expectations regarding the potential efficacy and commercial potential of Athira's product candidates; the anticipated reporting of data; the impact of Athira's July 2023 End of Phase 2 Meeting with the U.S. Food and Drug Administration on its future development plans and pipeline candidates; and Athira's ability to advance its product 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 product candidates; development of product candidates may cease or be delayed; regulatory authorities could object to protocols, amendments and other submissions; future potential regulatory milestones for product 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 product candidates with other treatments; Athira's assumptions regarding 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 product 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.

Investor & Media Contact
Julie Rathbun
Athira Pharma
Julie.rathbun@athira.com
206-769-9219

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

	September 30, 2023	December 31, 2022
	(unaudited)	
Assets		
Cash and cash equivalents	$ 110,334	$ 95,966
Short-term investments	62,614	104,378
Other short-term assets	5,556	7,189
Long-term investments	—	44,829
Other long-term assets	6,196	5,791

Total assets	$ 184,700	$ 258,153
Liabilities and stockholders' equity		
Current liabilities	$ 28,622	$ 21,431
Long-term liabilities	1,314	1,585
Total liabilities	29,936	23,016
Stockholders' equity	154,764	235,137
Total liabilities and stockholders' equity	$ 184,700	$ 258,153

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,	
	2023	**2022**
Operating expenses:		
Research and development	$ 27,202	$ 16,965
General and administrative	7,840	7,168
Total operating expenses	35,042	24,133
Loss from operations	(35,042)	(24,133)
Grant income	—	2,959
Other income, net	2,072	985
Net loss	$ (32,970)	$ (20,189)
Unrealized gain (loss) on available-for-sale securities	261	(547)
Comprehensive loss attributable to common stockholders	$ (32,709)	$ (20,736)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.87)	$ (0.53)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	38,054,583	37,817,724