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

August 10, 2023

Completed end of Phase 2 meeting and continued engagement with U.S. Food and Drug Administration

Appointed Andrew Gengos as Chief Financial Officer and Chief Business Officer

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

BOTHELL, Wash., Aug. 10, 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 June 30, 2023, and provided pipeline and business updates.

"During the second quarter, we advanced and strengthened our pipeline of small molecule therapeutic candidates, with particular focus on continued enrollment of the Phase 2/3 LIFT-AD trial of investigational fosgonimeton for the treatment of mild-to-moderate Alzheimer's disease and advancement of our preclinical ATH-1105 program toward clinical testing, initially targeting amyotrophic lateral sclerosis," said Mark Litton, Ph.D., President and Chief Executive Officer of Athira. "At the July Alzheimer's Association International Conference, we presented new findings regarding both our fosgonimeton and ATH-1105 programs. These data, along with the totality of evidence generated to date, strengthen our view that our pipeline of drug candidates, which are designed to positively modulate the HGF/MET neurotrophic system, have the potential to deliver novel treatments for neurodegenerative diseases."

"Our end of Phase 2 meeting with the U.S. Food and Drug Administration was very productive and enabled alignment with senior leadership from the Office of Neuroscience and Division of Neurology 1 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 results, now expected in the second half of 2024," concluded Dr. Litton.

Clinical Development & Pipeline Programs

Fosgonimeton (ATH-1017) – Small molecule designed to enhance the HGF/MET system with the potential to protect and repair neuronal networks.

End of Phase 2 Meeting (EOP2) with the U.S. Food and Drug Administration (FDA)

- In July, the Company completed an EOP2 meeting with the FDA to gain alignment on its plans for the continued clinical development of fosgonimeton as a potential treatment for mild-to-moderate Alzheimer's disease (AD).
- The Company provided an update and discussed with FDA the ongoing LIFT-AD trial including use of the 40 mg dose, concomitant acetylcholinesterase inhibitor (AChEIs) use, biomarker analyses including neurofilament light (NfL), and the statistical analysis plan.
- The FDA noted the importance of showing effects on both cognition (ADAS-Cog11) and function (ADCS-ADL23) in this population.
- Based on FDA interactions, 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.

LIFT-AD Phase 2/3 trial 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 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 despite the limited trial size, while elucidating the key drivers of potential treatment effect.
- Key secondary and exploratory endpoints include changes in plasma biomarkers of neurodegeneration, protein pathology, and inflammation.
- 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 dosing group compared to placebo for the primary analysis of results.
- The Company now expects to report topline LIFT-AD results in the second half of 2024.

Open Label Extension (OLEX) trial (NCT04886063)

- In May, the Company extended the OLEX study for the Phase 2/3 LIFT-AD and Phase 2 ACT-AD trials of fosgonimeton for

the treatment of mild-to-moderate AD by an additional 12 months. Eligible participants who have completed the LIFT-AD or ACT-AD trials and elect to participate in the ongoing OLEX are now able to receive up to 30 months of open-label treatment. The extension addressed investigator and patient interest in continuing treatment with fosgonimeton beyond 18 months.
- The Company believes the extension will also further enhance its long-term safety database and provide insights into fosgonimeton's long-term effects for up to 3 years.
- The 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 novel, orally available, small molecule designed to be a positive modulator of the HGF/MET system as a potential treatment candidate initially for amyotrophic lateral sclerosis (ALS).

- 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 an ALS animal model.
- 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.

Presentations and Publications

In July, the Company presented three posters at the Alzheimer's Association International Conference 2023 (AAIC) that highlighted its pipeline of small molecule therapeutic candidates targeting HGF/MET. Data presented included:

- A post-hoc analysis of the Phase 2 ACT-AD study and data from the OLEX study in patients 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.

Corporate Updates

The Company appointed seasoned finance and corporate strategy executive Andrew Gengos as Chief Financial Officer and Chief Business Officer.

- Most recently, Mr. Gengos served as the Chief Business Officer at Cyteir Therapeutics and has held executive roles at ImmunoCellular Therapeutics, Neuraltus Pharmaceuticals, AOBiome Therapeutics, and Synlogic. Previously, Mr. Gengos was Vice President of Strategy and Corporate Development at Amgen for eight years.
- Mr. Gengos holds a Master of Business Administration from the UCLA Anderson School of Management and a Bachelor of Science in Chemical Engineering from the Massachusetts Institute of Technology.

Financial Results

- **Cash Position.** Cash, cash equivalents and investments were $196.3 million as of June 30, 2023, compared with $245.2 million as of December 31, 2022. Net cash used in operations was $50.5 million for the six months ended June 30, 2023, compared with $35.2 million for the six months ended June 30, 2022.

- **Research and Development (R&D) Expenses.** R&D expenses were $21.6 million for the quarter ended June 30, 2023, compared with $14.8 million for the quarter ended June 30, 2022. The increase was driven primarily by costs related to increased clinical trial activities, manufacturing activities, headcount and increased preclinical R&D.

- **General and Administrative (G&A) Expenses.** G&A expenses were $10.0 million for the quarter ended June 30, 2023, compared with $8.8 million for the quarter ended June 30, 2022. The increase was primarily due to increases in consulting, professional services, and business development expenses, and an increase in personnel expenses as the Company's headcount expanded to support its growth, partially offset by a decrease in legal expenses.

- **Net Loss.** Net loss was $29.6 million, or $0.78 per share, for the quarter ended June 30, 2023, compared with a net loss of $24.3 million, or $0.65 per share, for the quarter ended June 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 disease by advancing its pipeline of therapeutic candidates targeting the HGF/MET neurotrophic system for Alzheimer's and Parkinson's disease, Dementia with Lewy bodies, and amyotrophic lateral sclerosis. For more information, visit www.athira.com. You can also follow Athira on Facebook, LinkedIn and @athirapharma on 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 Alzheimer's disease and other neurodegenerative diseases, such as amyotrophic lateral sclerosis and frontotemporal dementia; 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 other similar expressions, among others. 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 for our product candidates from our preclinical and clinical trials not supporting the safety, efficacy and tolerability of our product candidates; cessation or delay of Athira's development of product candidates may occur; 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; the impact of the COVID-19 pandemic on Athira's business, research and clinical development plans and timelines, and the regulatory process for Athira product candidates; 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 us and certain of our directors and officers; clinical trials may not demonstrate safety and efficacy of any of Athira's product candidates; 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 the COVID-19 pandemic, 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. 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, 2023	December 31, 2022
	(unaudited)	
Assets		
Cash and cash equivalents	$ 113,628	$ 95,966
Short-term investments	72,462	104,378
Other short-term assets	6,043	7,189
Long-term investments	10,217	44,829
Other long-term assets	5,698	5,791
Total assets	$ 208,048	$ 258,153
Liabilities and stockholders' equity		
Current liabilities	$ 21,662	$ 21,431
Long-term liabilities	1,407	1,585
Total liabilities	23,069	23,016
Stockholders' equity	184,979	235,137
Total liabilities and stockholders' equity	$ 208,048	$ 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 June 30,	
	2023	2022
Operating expenses:		

Research and development	$ 21,615	$ 14,803
General and administrative	10,025	8,766
Total operating expenses	31,640	23,569
Loss from operations	(31,640)	(23,569)
Grant income	—	(1,259)
Other income, net	2,043	493
Net loss	$ (29,597)	$ (24,335)
Unrealized gain (loss) on available-for-sale securities	90	(469)
Comprehensive loss attributable to common stockholders	$ (29,507)	$ (24,804)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.78)	$ (0.65)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	37,999,578	37,667,971