Athira Pharma Reports Second Quarter 2022 Financial Results and Recent Clinical and Corporate Updates

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Presented clinical and preclinical data at Alzheimer's Association International Conference 2022

Strong balance sheet to support clinical development pipeline

BOTHELL, Wash., Aug. 15, 2022 (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 announced the company's financial results for the second quarter ended June 30, 2022 and reviewed recent clinical and corporate updates.

"We are encouraged by the biologic activity and safety topline results from the ACT-AD trial in Alzheimer's disease. While the primary endpoint did not reach statistical significance, the trial results are the first ever to show potential cognitive improvement through positive modulation of the HGF/MET receptor by fosgonimeton. This is an important achievement supporting our conviction that we have a unique opportunity to reshape the course of neurodegenerative diseases," stated Mark Litton, Ph.D., President and Chief Executive Officer of Athira.

"The growing body of clinical and preclinical data with fosgonimeton and our other novel HGF/MET positive modulators support the potential for this pathway to improve neuronal health in a number of neurodegenerative diseases. Importantly, we are pleased to have a strong balance sheet that can support our programs through a number of key inflection points," concluded Dr. Litton.

Clinical Update:

Fosgonimeton (ATH-1017) is a small molecule specifically designed to enhance the activity of Hepatocyte Growth Factor (HGF) and its receptor, MET.

ACT-AD Phase 2 Study in mild-to-moderate Alzheimer's disease (NCT04491006)

- Announced topline results in June 2022 from the proof-of-concept ACT-AD Phase 2 study of fosgonimeton (ATH-1017) in patients with mild-to-moderate Alzheimer's disease (AD).
    - The study did not meet the primary endpoint of a statistically significant change in event related potential (ERP) P300 latency for the protocoled modified intent to treat (mITT) population by a mixed model repeated measures (MMRM) analysis (-6.02 milliseconds) when compared with placebo at 26 weeks in a pooled analysis of the 40 mg and 70 mg dose groups.
    - A post hoc analysis, based on the mITT population on fosgonimeton monotherapy, showed potentially beneficial, but not statistically significant, changes in ERP P300 latency compared to placebo at 26 weeks (-28 milliseconds) as well as cognitive improvement as measured by ADAS-Cog11 (-3.3 points) compared with placebo at 26 weeks.
- Additional data from the ACT-AD Phase 2 study were presented in August 2022 at the Alzheimer's Association International Conference 2022 (AAIC 2022) by Hans Moebius, M.D., Ph.D., Athira's Chief Medical Officer. Highlights of the additional data showed:
    - A numerical, but not statistically significant, improvement in the functional measure of ADCS-ADL23, a secondary endpoint which evaluates improvements in patients' activities of daily living as assessed by their caregivers, compared to placebo at 26 weeks in the protocoled mITT population by MMRM analysis (+2.12 points, n.s.).
    - A statistically significant improvement in plasma levels of neurofilament light chain (NfL), a validated fluid biomarker of neurodegeneration, in a prespecified subgroup of subjects treated with fosgonimeton monotherapy compared with placebo at 26 weeks (difference of 6.89 pg/ml (p=0.018)), and showed a numerical, but not statistically significant, improvement in all fosgonimeton treated patients compared with placebo at 26 weeks (difference of 1.67 pg/ml), regardless of background therapy.
- The ACT-AD trial was supported by a grant from the National Institute on Aging of the National Institutes of Health under Award Number R01AG06268. The information presented in this press release is solely the responsibility of Athira and does not necessarily represent the official views of the National Institutes of Health.

LIFT-AD Phase 3 Study in mild-to-moderate Alzheimer's Disease (NCT04488419)

- Recruitment in the LIFT-AD trial is ongoing, with over 300 patients enrolled to-date.

- With feedback from its Scientific Advisory Board and the Data Safety Monitoring Board, Athira continues to evaluate the best next steps for the LIFT-AD trial.

Open Label Extension Study (NCT04886063)

- In May 2022, Athira extended its Open Label Extension (OLEX) study for the ACT-AD and LIFT-AD studies to up to 18 months following the completion of the 26-week treatment period in the ACT-AD or LIFT-AD study.
- As of August 2022, more than 90 percent of patients who have completed the LIFT-AD and ACT-AD studies have elected to participate in the OLEX study.

SHAPE Phase 2 Study in Parkinson's disease dementia and Dementia with Lewy bodies (NCT04831281)

- Athira dosed the first patient in the SHAPE trial in January 2022. SHAPE is a randomized, double-blind, placebo-controlled, parallel-group Phase 2 proof-of-concept study of fosgonimeton in approximately 75 participants with Parkinson's disease dementia or Dementia with Lewy bodies.
- Recruitment is ongoing.

ATH-1020 is an orally available, brain-penetrant small molecule designed to enhance the HGF/MET system that is being advanced as a potential treatment candidate for neuropsychiatric indications.

Phase 1 Study in Healthy Volunteers (NCT05169671)

- In the first quarter of 2022, Athira initiated a Phase 1 study to evaluate the safety, tolerability, and pharmacokinetics of ATH-1020 in approximately 68 healthy young and elderly volunteers.
- Dose escalation is ongoing.

Research and Development Update:

***Preclinical Data Presented at* Alzheimer's Association International Conference 2022**

- Data from a poster titled, "Fosgonimeton, a novel, small molecule positive modulator of the HGF/MET system is neuroprotective in primary neuron culture," demonstrated that fosgo-AM, the active metabolite of Athira's lead pipeline candidate, fosgonimeton (ATH-1017), promotes neurotrophic effects and offers protection against neurological insults implicated in mitochondrial dysfunction, excitotoxicity, inflammation and oxidative stress central to neurodegeneration. These neuroprotective effects highlight the therapeutic potential for fosgonimeton to restore neuronal health and slow neurodegeneration.
- Data from a poster titled, "Development of stable, orally bioavailable small molecule positive modulators of HGF/MET signaling for the treatment of cognitive impairment," focused on the identification and preclinical validation of a panel of novel, small molecule HGF/MET positive modulators. These orally bioavailable molecules significantly reversed scopolamine-induced spatial memory deficits in rats. They also demonstrated favorable pharmacokinetics, including efficient distribution to the brain following administration. Based on these promising preclinical data, Athira intends to continue developing these compounds for the potential treatment of Alzheimer's disease and other neurodegenerative disorders.

Preclinical Data Presented at Peripheral Nerve Society (PNS) 2022 Annual Meeting

- Athira presented new data at the PNS 2022 Annual Meeting in a poster presentation titled, "Small Molecule HGF/MET Positive Modulator Effectively Reduces Pain-Related Behaviors in a Rat Diabetic Neuropathy Model." The data are supportive of the HGF/MET mechanism and the company's future plans to investigate its potential in a peripheral nerve application.

Corporate Update:

- In June 2022, Athira announced the formation of a Scientific Advisory Board (SAB) comprised of renowned leaders in neurology research, including John Olichney, M.D., Anton Porsteinsson, M.D., Marwan Sabbagh, M.D., Lon Schneider, M.D., Pierre Tariot, M.D., and Paul Winner, M.D. The SAB is chaired by Dr. Moebius, Athira's Chief Medical Officer, and provides expert scientific and clinical perspectives to guide the ongoing development of Athira's pipeline of novel, small molecule compounds.
- In May 2022, Athira announced stockholder approval of the election of its independent director nominees to the company's board of directors: Joseph Edelman, John M. Fluke, Jr. and Grant Pickering.

Financial Results

- **Cash Position**. Cash, cash equivalents and investments were $282.2 million as of June 30, 2022, compared with $319.7 million as of December 31, 2021. Cash used in operations was $35.2 million for the six months ended June 30, 2022,

compared with $14.6 million for the six months ended June 30, 2021.

- **Research and Development (R&D) Expenses**. R&D expenses were $14.8 million for the quarter ended June 30, 2022, compared with $12.0 million for the same period in 2021. The increase was driven primarily by costs related to increased clinical trial activities, expanded personnel, and increased preclinical research and development expenses.

- **General and Administrative (G&A) Expenses.** G&A expenses were $8.8 million for the quarter ended June 30, 2022, compared with $4.6 million for same period in 2021. The change was primarily due to increased personnel expense as the company's headcount expanded to support its continued growth. In addition, increases to G&A expenses in 2022 were the result of costs associated with legal proceedings and the proxy contest in connection with the company's 2022 annual stockholders meeting.

- **Net Loss**. The company reported a net loss of $24.3 million, or $0.65 per share, for the second quarter ended June 30, 2022, compared with a net loss of $14.0 million, or $0.38 per share, for the second quarter ended June 30, 2021.

About Athira Pharma, Inc.
Athira Pharma, Inc., headquartered in the Seattle area, is a late clinical-stage biopharmaceutical company focused on developing small molecules to restore neuronal health and slow neurodegeneration. Athira aims to provide rapid cognitive improvement and alter the course of neurological diseases with its novel mechanism of action. Athira is currently advancing its lead therapeutic candidate, fosgonimeton, a novel small molecule for Alzheimer's and Parkinson's disease dementia and Dementia with Lewy bodies. For more information, visit www.athira.com. You can also follow Athira on Facebook, LinkedIn and @athirapharma on Twitter and Instagram.

Forward-Looking Statements
This release 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 fosgonimeton as a potential treatment for Alzheimer's disease, Parkinson's disease dementia, Dementia with Lewy bodies, and other dementias; ATH-1020 as a potential treatment for neuropsychiatric indications; Athira's platform technology and potential therapies; future development plans; clinical and regulatory objectives and the timing thereof, including the timing of the LIFT-AD clinical trial, the Phase 2 clinical trial of fosgonimeton for treatment of Parkinson's disease dementia and the Phase 1 clinical trial to evaluate the safety, tolerability, and pharmacokinetics of ATH-1020; interactions with regulators and the timing thereof, including anticipated timing of IND or equivalent submissions; expectations regarding the potential efficacy and commercial potential of Athira's product candidates; the anticipated reporting of data; the potential learnings from the ACT-AD clinical trial and their ability to inform and improve future clinical development plans; anticipated sufficiency of cash resources; 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," 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 will not support the safety, efficacy and tolerability of our product candidates; cessation or delay of any of the ongoing clinical trials and/or Athira's development of fosgonimeton and other product candidates may occur; Athira may not be able to recruit sufficient patients for its clinical trials; future potential regulatory milestones of fosgonimeton and other 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's product candidates; the outcome of legal proceedings which 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; Athira's research and development efforts and its ability to advance product candidates into later stages of development may fail; any one or more of Athira's product candidates may not be successfully developed, approved or commercialized; 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, 2022	December 31, 2021
	(unaudited)	

Assets		
Cash and cash equivalents	$ 95,057	$ 110,537
Short-term investments	157,347	143,222
Other short-term assets	3,456	7,040
Long-term investments	29,844	65,936
Other long-term assets	6,307	5,273
Total assets	$ 292,011	$ 332,008
Liabilities and stockholders' equity		
Current liabilities	$ 9,692	$ 9,292
Long-term liabilities	1,754	1,632
Total liabilities	11,446	10,924
Stockholders' equity	280,565	321,084
Total liabilities and stockholders' equity	$ 292,011	$ 332,008

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

	Three Months Ended June 30,	
	2022	**2021**
Operating expenses:		
Research and development	$ 14,803	$ 12,024
General and administrative	$ 8,766	$ 4,613
Total operating expenses	23,569	16,637
Loss from operations	(23,569)	(16,637)
Grant income	(1,259)	2,589
Other income, net	493	74
Net loss	$ (24,335)	$ (13,974)
Unrealized (loss) gain on available-for-sale securities	(469)	9
Comprehensive loss attributable to common stockholders	$ (24,804)	$ (13,965)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.65)	$ (0.38)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	37,667,971	37,214,602