



Athira Pharma Reports Third Quarter 2021 Financial Results and Business Update

November 10, 2021

– Completed enrollment of ACT-AD trial with topline data expected in the first half of 2022; LIFT-AD is actively recruiting with topline data expected by the end of 2022 –

– Presented program updates and baseline data from ATH-1017's ongoing Phase 2 and Phase 2/3 clinical trials at the 2021 CTAD conference –

BOTHELL, Wash., Nov. 10, 2021 (GLOBE NEWSWIRE) -- [Athira Pharma, Inc.](#) (NASDAQ: ATHA), a late clinical-stage biopharmaceutical company focused on developing small molecules to restore neuronal health and stop neurodegeneration, today reported its financial results for the third quarter ended September 30, 2021, and provided an update on the company's operations.

"We remained focused on our development efforts during the third quarter of 2021, and our initiatives remain on track as we enter a potentially transformative phase with multiple near-term clinical events," said Mark Litton, Ph.D., President and Chief Executive Officer at Athira. "The completion of enrollment in our ACT-AD trial is an important step forward in advancing the development of ATH-1017 with the goal of improving the lives for those suffering from Alzheimer's disease. We look forward to sharing topline results from this Phase 2 trial in the first half of 2022. In parallel, our LIFT-AD trial is actively recruiting with topline results targeted by the end of 2022, and SHAPE, our Phase 2 trial for patients with Parkinson's disease dementia or dementia with Lewy bodies, is expected to initiate later this year. As we evaluate the year ahead, we are well-funded for the continued execution of our planned clinical development and look forward to advancing our pipeline of small molecule therapeutics."

Clinical Development and Upcoming Milestones

ATH-1017: A small molecule therapeutic specifically designed to enhance the activity of hepatocyte growth factor (HGF) and its receptor, MET, to impact neurodegeneration and regenerate brain tissue. ATH-1017 is currently being evaluated in two randomized, double-blind, placebo-controlled trials, LIFT-AD and ACT-AD, designed to evaluate the safety and efficacy of the investigational therapeutic in individuals with mild-to-moderate Alzheimer's disease.

Recent Advancements

- **ACT-AD Phase 2 trial:** Completed enrollment with topline data expected in the first half of 2022. This Phase 2 randomized, double-blind, placebo-controlled, parallel-group study of ATH-1017 in patients with mild-to-moderate Alzheimer's disease has enrolled 77 subjects across 14 sites in the United States and Australia. The primary endpoint for ACT-AD is Event-Related-Potential (ERP) P300 latency, a functional measure of working memory processing speed, and secondary endpoints measuring cognition, function and behavior.
- **2021 Clinical Trials on Alzheimer's Disease Conference (CTAD):** Provided program updates and baseline data from ATH-1017's ongoing Phase 2 and Phase 2/3 clinical trials in an oral presentation at CTAD.
- **Open Label Extension Study for LIFT-AD and ACT-AD trials of ATH-1017:** The study is ongoing and was initiated in June 2021. Following completion of the 26-week treatment period during the LIFT-AD or ACT-AD trials, study participants may elect to continue on the open label extension and receive treatment with ATH-1017 at the high dose (70 mg/day) for up to an additional 26 weeks.

Upcoming Milestones

- **LIFT-AD Phase 2/3 trial** of ATH-1017 in patients with mild-to-moderate Alzheimer's disease is actively recruiting, with top-line data expected by the end of 2022.
- **SHAPE Phase 2 trial** of ATH-1017 in patients with Parkinson's disease dementia or dementia with Lewy bodies is anticipated to initiate by the end of 2021.

Pipeline Advancements

ATH-1020: A novel, small molecule therapeutic designed to be an orally available, once-daily treatment. ATH-1020 is intended to enhance the HGF/MET system and distribute to the central nervous system as a potential candidate for neuropsychiatric indications.

Upcoming Milestone

- **IND filing expected by end of 2021.** IND-enabling studies are proceeding for ATH-1020. Athira is targeting an IND submission to the U.S. Food and Drug Administration (FDA) by the end of 2021.

Recent Corporate Event

- **Educational webinar:** On November 5, 2021, the company hosted an educational webinar on the clinical applications of ERP P300 latency as a functional measure of working memory processing speed, as well as its correlation to cognition. The webinar featured a discussion with John Michael Olichney, M.D., a board-certified behavioral neurologist and Professor of Neurology at UC Davis Health; Hans Moebius, M.D., Ph.D., Chief Medical Officer of Athira; and Kevin Church, Ph.D., EVP, Research at Athira. An archived replay of the webinar can be accessed from the investors' section of the Athira website at <https://investors.athira.com/news-and-events/events-and-presentations>.

Third Quarter 2021 Financial Results

- **Cash Position.** Cash, cash equivalents and investments were \$339.4 million as of September 30, 2021, compared to \$268.2 million as of December 31, 2020.
- **Research and Development (R&D) Expenses.** R&D expenses were \$10.7 million for the quarter ended September 30, 2021, as compared to \$5.8 million for the same quarter in 2020.
- **General and Administrative (G&A) Expenses.** G&A expenses were \$7.1 million for the quarter ended September 30, 2021, as compared to \$1.6 million for the same quarter in 2020.
- **Net Loss.** Net loss was \$15.7 million, or \$0.42 per share basic and diluted, for the quarter ended September 30, 2021, compared to a net loss of \$8.5 million, or \$1.12 per share basic and diluted, for the same quarter in 2020.

About Athira Pharma, Inc.

Athira, headquartered in the Seattle area, is a late clinical-stage biopharmaceutical company focused on developing small molecules to restore neuronal health and stop neurodegeneration. Athira aims to provide rapid cognitive improvement and alter the course of neurological diseases with our novel mechanism of action. Athira is currently advancing its lead therapeutic candidate, ATH-1017, a novel small molecule for Alzheimer's and Parkinson's disease dementia. 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 ATH-1017 as a potential treatment for Alzheimer's disease and other dementias; Athira's platform technology and potential therapies; future development plans; clinical and regulatory objectives and the timing thereof, including the timing of the ACT-AD and LIFT-AD clinical trials and the timing of the Phase 2 clinical trial of ATH-1017 for treatment of Parkinson's disease dementia; 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 sufficiency of Athira's cash, cash equivalents and investments to support its planned development activities; 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," "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 preliminary data for Athira's ATH-1017 product candidate from the Phase 1a/b trials will not continue or persist; cessation or delay of any of the ongoing clinical trials and/or Athira's development of ATH-1017 and other product candidates may occur; future potential regulatory milestones of ATH-1017 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 results of operations, including impact on Athira's clinical trial sites and contractors who act for or on Athira's behalf, may be more severe and more prolonged than currently anticipated; 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; 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; while P300 latency is a functional measure that is highly correlated with cognition, Athira may not successfully establish a connection between these P300 latency results and improved cognition; 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 competition; the impact of expanded product development and clinical activities on operating expenses; the impact of new or changing laws and regulations; adverse conditions in the general domestic and global economic markets; 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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Condensed Consolidated Balance Sheets
(Amounts in thousands)
(Unaudited)

	September 30, 2021	December 31, 2020
Assets		
Cash and cash equivalents	\$ 107,328	\$ 60,625
Short-term investments	128,447	124,057
Other short-term assets	3,217	7,655
Long-term investments	103,649	83,509
Other long-term assets	4,690	3,717
Total assets	\$ 347,331	\$ 279,563
Liabilities and stockholders' equity		
Current liabilities	\$ 9,386	\$ 4,405
Long-term liabilities	1,708	876
Total liabilities	11,094	5,281
Stockholders' equity	336,237	274,282
Total liabilities and stockholders' equity	\$ 347,331	\$ 279,563

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

	Three Months Ended September 30,	
	2021	2020
Operating expenses:		
Research and development	\$ 10,707	\$ 5,830
General and administrative	\$ 7,119	\$ 1,567
Total operating expenses	17,826	7,397
Loss from operations	(17,826)	(7,397)
Grant income	2,079	—
Other income (expense), net	73	(1,059)
Net loss	\$ (15,674)	\$ (8,456)
Unrealized (loss) gain on available-for-sale securities	(33)	7
Comprehensive loss attributable to common stockholders	\$ (15,707)	\$ (8,449)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.42)	\$ (1.12)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	37,312,356	7,564,538