



Athira Pharma Reports Second Quarter 2021 Financial Results and Business Update

August 16, 2021

- Initiated open label extension for LIFT-AD and ACT-AD trials of ATH-1017 allowing for an additional six months of treatment

- ACT-AD and LIFT-AD are actively recruiting; topline data of ACT-AD are targeted by first half 2022 and topline data from LIFT-AD are targeted by end of 2022

BOTHELL, Wash., Aug. 16, 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 second quarter ended June 30, 2021 and provided an update on the company's operations.

"In the second quarter of 2021, we made significant advancements across our corporate and clinical initiatives," said Mark Litton, Ph.D., MBA, Chief Operating Officer at Athira. "We recently initiated an open label extension study for our ongoing Phase 2/3 LIFT-AD and Phase 2 ACT-AD studies of ATH-1017 in patients living with mild-to-moderate Alzheimer's disease, allowing for all study participants to receive active drug treatment for an additional 26 weeks. We anticipate that the additional data obtained from this extension will provide a more comprehensive understanding of the long-term safety and efficacy profile, and when combined with the promising preclinical and early clinical data generated both internally and externally, will inform our clinical development strategy."

Dr. Litton continued, "We remain encouraged by the therapeutic potential of ATH-1017 to improve clinical outcomes and restore neuronal health through an approach that focuses on neuronal regeneration, agnostic to the underlying disease pathology. In addition to Alzheimer's disease, we plan to evaluate ATH-1017 in Parkinson's disease dementia, and we remain committed to advancing our expanding pipeline of small molecule compounds. We look forward to providing updates on our progress as we deliver on our strategic plan and our mission to improve the lives of those suffering from neurological diseases."

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 designed to evaluate the safety and efficacy of the investigational therapeutic in individuals with mild-to-moderate Alzheimer's disease.

Recent Advancements

- **Initiated Open Label Extension Study for LIFT-AD and ACT-AD trials of ATH-1017**
 - Following completion of the 26-week treatment period during the LIFT-AD or ACT-AD trials, patients from both the placebo and active groups may elect to continue the open label extension and receive treatment with ATH-1017 at the high dose (70 mg/day) for up to an additional 26 weeks. Investigators and patients will remain blinded to treatment group assignment in the original trials.
- **Presented Ph1a/b ATH-1017 data at the Alzheimer's Association International Conference 2021 (AAIC)**
 - Results support the clinical utility of quantitative electroencephalogram (qEEG) biomarker of brain circuitry activity, and the translational utility for PK/PD modeling and dose-optimization across preclinical and clinical models of mild-to-moderate Alzheimer's disease.

Upcoming Milestones

- The company anticipates reporting topline data from ACT-AD by the first half of 2022, and topline data from LIFT-AD by the end of 2022.
- A Phase 2 trial of ATH-1017 for treatment of Parkinson's disease dementia is targeted to initiate by the end of 2021.

Pipeline

ATH-1020: Novel, small molecule compound designed to be an orally available once-daily treatment, to activate the HGF/MET system and to distribute to the central nervous system as a potential candidate for neurodegenerative disorders.

Upcoming Milestones

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

Recent Corporate Updates:

- Mark Litton, Ph.D., MBA, in his capacity as Chief Operating Officer, has assumed day-to-day leadership responsibilities for the Company.
- Rachel Lenington, MBA, has been appointed as Chief Technology Officer, Head of Product Development Strategy.

- Ms. Lenington brings more than 20 years of biopharmaceutical leadership experience at leading organizations including Seagen Inc, the Bill & Melinda Gates Foundation and Amgen, with roles spanning R&D decision making, drug development and commercialization, and partnership management.
- Mark Worthington, J.D., has been appointed as General Counsel.
 - Mr. Worthington previously worked with Athira as outside corporate counsel. He brings more than 20 years of experience advising both private and public companies on a wide range of corporate governance, compliance and transactional matters, including public offerings, mergers and acquisitions, and joint ventures, and worked closely with executive management teams on strategic business and legal matters.
- On August 5, 2021, we announced that Dr. Tadataka Yamada, M.D., a director and Chair of our board of directors, died unexpectedly of natural causes on August 4, 2021.
- On August 5, 2021, the board of directors appointed Kelly A. Romano as Chair of the board, and Barbara Kosacz as Chair of each of the Compensation Committee and the Nominating and Corporate Governance Committee.

Second Quarter 2021 Financial Results

- **Cash Position.** Cash, cash equivalents and investments were \$349.9 million as of June 30, 2021 compared to \$268.2 million as of December 31, 2020.
- **Research and Development (R&D) Expenses.** R&D expenses were \$12.0 million for the quarter ended June 30, 2021, as compared to \$1.7 million for the same quarter in 2020.
- **General and Administrative (G&A) Expenses.** G&A expenses were \$4.6 million for the quarter ended June 30, 2021, as compared to \$0.6 million for the same quarter in 2020.
- **Net Loss.** Net loss was \$14.0 million, or \$0.38 per share basic and diluted, for the quarter ended June 30, 2021 compared to a net loss of \$2.0 million, or \$0.48 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. We aim 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 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 IND submission with respect to ATH-1020 and the timing of the Phase 2 clinical trial of ATH-1017 for treatment of Parkinson's disease; expectations regarding the potential efficacy and commercial potential of Athira's product candidates; the anticipated reporting of data; 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 and phrases 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 trial 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 the investigation of the special committee of our board of directors; 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 its planned expenditures and sufficiency of its cash, cash equivalents and investments to fund 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, we may not successfully establish a connection between these P300 latency results and improved cognition; adverse conditions in the general domestic and global economic markets; 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; 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)
(Unaudited)

	June 30, 2021	December 31, 2020
Assets		
Cash and cash equivalents	\$ 131,701	\$ 60,625
Short-term investments	153,239	124,057
Other short-term assets	5,557	7,655
Long-term investments	64,939	83,509
Other long-term assets	4,688	3,717
Total assets	<u>\$ 360,124</u>	<u>\$ 279,563</u>
Liabilities stockholders' equity		
Current liabilities	\$ 7,634	\$ 4,405
Long-term liabilities	1,781	876
Total liabilities	9,415	5,281
Stockholders' equity	350,709	274,282
Total liabilities and stockholders' equity	<u>\$ 360,124</u>	<u>\$ 279,563</u>

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

	Three Months Ended June 30,	
	2021	2020
Operating expenses:		
Research and development	\$ 12,024	\$ 1,677
General and administrative	\$ 4,613	\$ 575
Total operating expenses	<u>16,637</u>	<u>2,252</u>
Loss from operations	(16,637)	(2,252)
Grant income	2,589	—
Other income, net	74	260
Net loss	<u>\$ (13,974)</u>	<u>\$ (1,992)</u>
Unrealized gain on available-for-sale securities	9	—
Comprehensive loss attributable to common shareholders	<u>\$ (13,965)</u>	<u>\$ (1,992)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.38)</u>	<u>\$ (0.48)</u>
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	<u>37,214,602</u>	<u>4,127,645</u>