Athira Pharma Reports Full Year 2021 Financial Results and Provides Clinical Update

March 24, 2022

On track to report topline data from ACT-AD Phase 2 Alzheimer's disease study in 2Q22

Expect to complete enrollment in LIFT-AD Phase 3 Alzheimer's disease study in 3Q22

Conference call today at 4:30 pm Eastern time

BOTHELL, Wash., March 24, 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 year ended December 31, 2021 and provided a clinical update.

"We entered 2022 with strong momentum from the solid foundation established throughout 2021 and have made considerable progress across a number of areas key to our success," stated Mark Litton, Ph.D., President & Chief Executive Officer of Athira Pharma. "To date, the new year has been highlighted by the publication of our Phase 1 study results with fosgonimeton and presentation of preclinical data that support our novel, innovative approach to restoring neuronal health and slowing neurodegeneration across our lead program with fosgonimeton and our first oral candidate, ATH-1020. This growing body of scientific and clinical evidence is compelling and gives us further confidence in our robust clinical development programs."

"Importantly, we remain on track to report the topline data from our Phase 2 ACT-AD study in Alzheimer's disease in the coming months and look forward to other value-creating milestone opportunities that we believe will bring hope to patients living with progressive neurological and neuropsychiatric diseases and enhance shareholder value for our company," continued Dr. Litton.

Recent Highlights:

- Presented baseline Event Related Potential (ERP) P300 latency data from the ACT-AD study at the AD/PD™ conference that showed the study patient population enrolled in the Phase 2 trial are representative of the mild-to-moderate Alzheimer's population and is appropriate to evaluate the effectiveness of fosgonimeton on ERP P300 latency, a functional, objective measure of working memory processing speed;
- Highlighted preclinical data that demonstrate the mechanism of action of the active metabolite of fosgonimeton is through positive modulation of HGF/MET and results in neurotrophic and procognitive effects in an oral presentation at the American Society for Experimental Neurotherapeutics (ASENT) Annual Meeting;
- Presented preclinical data at ASENT showing that ATH-1020, a novel orally available brain-penetrant small molecule, demonstrated neuroprotective effects, mitigated depression-like behaviors and normalized an electroencephalography (EEG) hallmark of schizophrenia in animal models;
- Published results from a Phase 1 clinical trial of fosgonimeton in healthy volunteers and subjects with Alzheimer's disease in the peer-reviewed *Journal of Alzheimer's Disease* showing that fosgonimeton demonstrated a statistically significant improvement of ERP P300 latency as compared with placebo in Alzheimer's disease patients;
- Announced fosgonimeton as World Health Organization's recommended international nonproprietary name for lead product candidate, ATH-1017;
- Dosed the first patient in the SHAPE Phase 2 clinical trial of fosgonimeton in mild-to-moderate Parkinson's disease dementia and Dementia with Lewy bodies; and
- Appointed life science industry leaders, Grant Pickering and Dr. Michael Panzara, to the Board of Directors.

Clinical Pipeline 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)

- Enrollment in ACT-AD completed in October 2021 with 77 participants with mild-to-moderate Alzheimer's disease across 14 sites in the United States and Australia. The primary endpoint for ACT-AD is change in ERP P300 Latency, a functional, objective measure of working memory processing speed, and includes secondary endpoints measuring cognition, function, and behavior.

- Athira remains on track to report top-line data in the second quarter of 2022.
- ACT-AD trial is 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.
- Athira increased the study sample size from 300 to approximately 420, in order to strengthen the statistical power of co-key secondary endpoints, including ADAS-Cog11.
- The company expects to complete enrollment of this potentially pivotal study in the third quarter of 2022 and to report top-line data in the first half of 2023.

Open Label Extension Study (NCT04886063)

- Following completion of the 26-week treatment period during the LIFT-AD or ACT-AD trials, patients may elect to continue on the open label extension and receive treatment with fosgonimeton at the high dose (70 mg/day) for up to an additional 26 weeks. Investigators and patients remain blinded to treatment group assignment in the original trials.
- The majority of eligible patients who have completed the LIFT-AD and ACT-AD studies have opted to participate in the open label extension study.

SHAPE Phase 2 Study in mild-to-moderate 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 mild-to-moderate Parkinson's disease dementia or Dementia with Lewy bodies.
- The company forecasts completion of enrollment of the SHAPE study in the first half of 2023.

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)

- Athira submitted an Investigational New Drug application for ATH-1020 in the fourth quarter of 2021 and received FDA clearance in January. The Phase 1 study will evaluate the safety, tolerability, and pharmacokinetics of ATH-1020 in approximately 68 healthy young and elderly volunteers.
- The company initiated the Phase 1 clinical trial for ATH-1020 in the first quarter of 2022.

Other Highlights

Expanded the senior management team with new hires and promotions, including the:

- Promotion of Josh Pan, Ph.D. to Vice President Corporate Development. Dr. Pan has been with Athira since 2015 and has been instrumental in supporting and leading several activities including private and public financings, business development, communications and new product planning.
- Promotion of Robert Renninger to Vice President Finance & Accounting. Mr. Renninger has been with Athira since 2020. He has led the development of our finance department to support Athira's growth and brings a wealth of knowledge having worked as both a public auditor and finance professional throughout his career.
- Addition of Simon Daggett as Vice President Clinical Operations. Mr. Daggett brings more than 30 years drug development experience, including 19 years at Allergan. He has considerable global expertise leading all aspects of clinical studies from pre-IND through Phase 3 to approval.
- Addition of Lana Gloukhova, M.D, as Vice President Drug Safety and Pharmacovigilance. Dr. Gloukhova has a proven track record leading global safety and clinical teams at multinational pharmaceutical companies including CSL Behring, AbbVie, Merck and Schering-Plough.

Financial Results

- **Cash Position**. Cash, cash equivalents and investments were $319.7 million as of December 31, 2021, compared with $268.2 million as of December 31, 2020. Cash used in operations was $43.1 million for the year ended December 31, 2021, compared with $24.1 million for the year ended December 31, 2020.

- **Research and Development (R&D) Expenses**. R&D expenses were $42.8 million for the year ended December 31, 2021, compared with $13.3 million for the year ended December 31, 2020. 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 $21.2 million for the year ended December 31, 2021, compared with $6.7 million for the year ended December 31, 2020, 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 2021 were the result of increases related to insurance, legal, facilities, and investor relations costs.

- **Net Loss**. Net loss was $54.9 million, or $1.49 per share, for the year ended December 31, 2021, compared with a net loss of $19.9 million, or $1.67 per share, for the year ended December 31, 2020.

Conference Call Details
Athira management will host a conference call to discuss the Company's progress today at 4:30 pm Eastern time. In order to participate in the conference call, please dial 833-614-1520 (domestic) or 516-575-8710 (international) and refer to conference ID 3597642. A live webcast of the conference call can be accessed under "Events & Presentations" in the Investor Relations section of the Company's website at www.athira.com, where it will also be archived.

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; 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 fosgonimeton 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; 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 preliminary data for Athira's fosgonimeton product candidate from the Phase 1a/b trials will not continue or persist in current or planned clinical trials; cessation or delay of any of the ongoing clinical trials and/or Athira's development of fosgonimeton and other product candidates may occur; 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 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 regulatory process for Athira 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; 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; 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; 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)

	December 31, 2021	December 31, 2020
Assets		
Cash and cash equivalents	$ 110,537	$ 60,625
Short-term investments	143,222	124,057
Other short-term assets	7,040	7,655

Long-term investments	65,936	83,509
Other long-term assets	5,273	3,717
Total assets	$ 332,008	$ 279,563
Liabilities and stockholders' equity		
Current liabilities	$ 9,292	$ 4,405
Long-term liabilities	1,632	876
Total liabilities	10,924	5,281
Stockholders' equity	321,084	274,282
Total liabilities and stockholders' equity	$ 332,008	$ 279,563

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

	Year Ended December 31,	
	2021	**2020**
Operating expenses:		
Research and development	$ 42,794	$ 13,286
General and administrative	$ 21,228	$ 6,709
Total operating expenses	64,022	19,995
Loss from operations	(64,022)	(19,995)
Grant income	8,835	1,321
Other income (expense), net	334	(1,281)
Net loss	$ (54,853)	$ (19,955)
Unrealized (loss) gain on available-for-sale securities	(421)	33
Comprehensive loss attributable to common stockholders	$ (55,274)	$ (19,922)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.49)	$ (1.67)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	36,921,172	11,966,912