Athira Pharma Reports First Quarter 2022 Financial Results and Provides Pipeline and Business Updates

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

BOTHELL, Wash., May 12, 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 quarter ended March 31, 2022 and provided pipeline and business updates.

"Throughout the first quarter of 2022 we made significant progress advancing our strategy across Athira's clinical development programs, with a focus on bringing our lead drug candidate, fosgonimeton, and the other molecules in our pipeline to patients while continuing to create lasting shareholder value," stated Mark Litton, Ph.D., MBA, President and Chief Executive Officer of Athira. "During the first quarter, we published and presented a growing body of clinical and preclinical evidence in support of targeting the HGF/MET neurotrophic system. We were pleased to initiate two new studies in the first quarter: the Phase 2 SHAPE study of fosgonimeton in Parkinson's disease dementia and Dementia with Lewy Bodies and a Phase 1 study of ATH-1020 to evaluate its safety, tolerability, and pharmacokinetics in healthy volunteers."

"In addition to our considerable clinical progress, we advanced our corporate strategy through the expansion of our senior management team, as well as the expansion of our Board of Directors with two talented industry leaders – Grant Pickering, a proven life sciences leader with over 30 years of experience across all stages of corporate and clinical development, and Dr. Michael Panzara, an industry veteran with more than 20 years of CNS drug development and commercialization experience.

"We are looking forward to reporting topline data from our Phase 2 ACT-AD study in Alzheimer's disease by the end of 2Q22 as we expect to gain insights into the safety and efficacy of our novel intervention as well as optimize the analysis plan for our potentially pivotal LIFT-AD study. We continue to advance these important studies in order to bring this potentially transformative medicine to the millions of patients impacted by Alzheimer's disease," concluded Dr. Litton.

First Quarter and Recent Highlights:

- Announced it is extending the ongoing Open Label Extension study for the LIFT-AD and ACT-AD clinical trials of fosgonimeton for mild-to-moderate Alzheimer's disease, enabling eligible patients who have completed either trial, and elect to participate in the ongoing open label extension, to now receive up to 18 months of open-label treatment with fosgonimeton;
- Presented baseline Event Related Potential (ERP) P300 latency and patient demographic data from the ACT-AD study at the AD/PD™ conference that showed the study patient population enrolled in the Phase 2 trial is representative of the mild-to-moderate Alzheimer's population and is appropriate to evaluate the effect of fosgonimeton on ERP P300 latency, a functional, objective measure of working memory processing speed and executive function that highly correlates with cognition;
- 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 Phase 1 clinical trial of fosgonimeton in healthy volunteers and patients 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 the World Health Organization's recommended international nonproprietary name for lead product candidate ATH-1017, and the United States Adopted Names (USAN) Council has adopted fosgonimeton as a USAN;
- Dosed the first patient in the SHAPE Phase 2 clinical trial of fosgonimeton in Parkinson's disease dementia and Dementia with Lewy bodies;
- Dosed the first subject in a Phase 1 study of ATH-1020, designed to target neuropsychiatric conditions;
- Appointed life science industry leaders Grant Pickering and Michael Panzara, M.D. to the Board of Directors; and

- Expanded the senior management team with new hires, including the addition of:
    - Donald Mackenzie, Ph.D., Senior Vice President CMC and Technical Operations. Dr. Mackenzie brings more than 30 years of experience in developing and launching new medicines at GlaxoSmithKline (GSK), including 15 new products over the last decade;
    - Arthur Rosenthal, Vice President of Drug Regulatory Affairs. Mr. Rosenthal brings more than 30 years of regulatory experience and has a proven track record of bringing neurology products to approval at companies including Avanir Pharmaceuticals and Valeant;
    - Lana Gloukhova, M.D., Vice President Drug Safety and Pharmacovigilance. Dr. Gloukhova has extensive experience leading global safety and clinical teams at multinational pharmaceutical companies including CSL Behring, AbbVie, Merck and Schering-Plough; and
    - Simon Daggett, Vice President Clinical Operations. Mr. Daggett brings more than 30 years of 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.

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, with secondary endpoints measuring cognition, function, and behavior.
- Athira remains on track to report top-line data by the end of 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 is targeting completion of enrollment of this potentially pivotal study in the third quarter of 2022 and top-line data in the first half of 2023.

Open Label Extension Study (NCT04886063)

- In June 2021, Athira initiated an Open Label Extension Study (OLEX). Following completion of the 26-week treatment period during the LIFT-AD or ACT-AD trials, eligible patients can elect to continue on the OLEX 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 company recently announced that it is extending the length of the current Open Label Extension (OLEX) study. The decision is in alignment with the independent Data and Safety Monitoring Board (DSMB) following its most recent review of available data. Eligible patients who have completed the LIFT-AD or ACT-AD trials and elect to participate in the ongoing open label extension may now receive up to 18 months of open-label treatment with fosgonimeton.
- The majority of eligible patients who have completed the LIFT-AD and ACT-AD studies have opted to participate in the OLEX.

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.
- The company is targeting completion of enrollment of the SHAPE study in the first half of 2023.

ATH-1020 is a novel, 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 initiated a Phase 1 clinical trial for ATH-1020 in the first quarter of 2022. The Phase 1 study will evaluate the safety, tolerability, and pharmacokinetics of ATH-1020 in approximately 68 healthy young and elderly volunteers.

Preclinical Data of novel HGF/MET positive modulators (ATH-1018 and ATH-1019) to be presented at Peripheral Nerve Society (PNS) 2022 Annual Meeting

- Athira will present new preclinical data at the upcoming 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,” on May 15, 2022. The data are supportive of the HGF/MET mechanism and the company’s future plans to continue exploring HGF/MET positive modulators for other therapeutic indications, including peripheral indications.

Financial Results

- **Cash Position**. Cash, cash equivalents and investments were $301.2 million as of March 31, 2022, compared with $319.7 million as of December 31, 2021. Cash used in operations was $16.6 million for the quarter ended March 31, 2022, compared with $7.3 million for the first quarter of 2021.

- **Research and Development (R&D) Expenses**. R&D expenses were $14.5 million for the first quarter ended March 31, 2022, compared with $7.4 million for the same period in 2021. The increase was driven primarily by costs related to increased clinical trial activities, increased personnel, and increased preclinical R&D expenses.

- **General and Administrative (G&A) Expenses.** G&A expenses were $8.9 million for the first quarter ended March 31, 2022, compared with $3.3 million for the same period in 2021, primarily due to increased personnel expense associated with the company’s headcount growth. In addition, increases to G&A expenses in 2022 were the result of costs associated with the proxy solicitation in connection with the company’s annual stockholder meeting, an increase in professional services expenses, an increase in business development expenses, and to lesser extents, increases in insurance and facilities costs.

- **Net Loss**. Net loss was $21.0 million, or $0.56 per share, for the first quarter ended March 31, 2022, compared with a net loss of $8.9 million, or $0.25 per share, for the first quarter ended March 31, 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 pipeline of therapeutic candidates, targeting the HGF/MET neurotrophic system, for Alzheimer’s and Parkinson’s disease dementia, Dementia with Lewy bodies, and neuropsychiatric and peripheral indications. 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, and 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 and ACT-AD clinical trials and the timing of the Phase 2 clinical trial of fosgonimeton for treatment of Parkinson’s disease dementia and Dementia with Lewy bodies; 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 our 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 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)
(Unaudited)

	March 31, 2022	December 31, 2021
Assets		
Cash and cash equivalents	$ 117,811	$ 110,537
Short-term investments	145,715	143,222
Other short-term assets	5,628	7,040
Long-term investments	37,644	65,936
Other long-term assets	6,204	5,273
Total assets	$ 313,002	$ 332,008
Liabilities and stockholders' equity		
Current liabilities	$ 9,471	$ 9,292
Long-term liabilities	1,554	1,632
Total liabilities	11,025	10,924
Stockholders' equity	301,977	321,084
Total liabilities and stockholders' equity	$ 313,002	$ 332,008

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

	Year Ended December 31, 2022	2021
Operating expenses:		
Research and development	$ 14,460	$ 7,445
General and administrative	$ 8,927	$ 3,336
Total operating expenses	23,387	10,781
Loss from operations	(23,387)	(10,781)
Grant income	2,234	1,831
Other income, net	173	84
Net loss	$ (20,980)	$ (8,866)
Unrealized loss on available-for-sale securities	(1,068)	(5)
Comprehensive loss attributable to common stockholders	$ (22,048)	$ (8,871)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.56)	$ (0.25)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	37,593,328	35,775,454