UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
Date of Report (Date of earliest event reported): May 15, 2024

Athira Pharma, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-39503**	**45-3368487**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

18706 North Creek Parkway, Suite 104
Bothell, WA 98011
(Address of principal executive offices, including zip code)

(425) 620-8501
(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.0001 par value per share	ATHA	The Nasdaq Stock Market LLC (The Nasdaq Global Select Market)

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging Growth Company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act). ☐

Item 2.02 Results of Operations and Financial Condition.

On May 15, 2024, Athira Pharma, Inc. (the "Company") issued a press release reporting its financial results for the quarter ended March 31, 2024. A copy of the press release is furnished herewith as Exhibit 99.1.

Item 7.01 Regulation FD Disclosure.

The Company announces material information to the public through a variety of means, including filings with the Securities and Exchange Commission, press releases, public conference calls, the Company's website (www.athira.com), its investor relations website (investors.athira.com), and its news site (investors.athira.com/news-and-events/press-releases). The Company uses these channels, as well as social media, including its X account (formerly known as Twitter)(@athirapharma), LinkedIn account (www.linkedin.com/company/athirapharma), Instagram account (@athirapharma) and Facebook page (www.facebook.com/athirapharmainc), to communicate with investors and the public about the Company, its product candidates, and other matters. Therefore, the Company encourages investors, the media, and others interested in the Company to review the information it makes public in these locations, as such information could be deemed to be material information.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Athira Pharma, Inc. press release dated May 15, 2024
104	Cover Page Interactive Data File (formatted as Inline XBRL)

The information furnished in this Current Report under Items 2.02 and 7.01 and the exhibit attached hereto shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Athira Pharma, Inc.

Date: May 15, 2024

By: /s/ Mark Litton

Mark Litton

President and Chief Executive Officer

Exhibit 99.1

Athira Pharma Reports First Quarter 2024 Financial Results and Pipeline and Business Updates

Topline data from Phase 2/3 LIFT-AD clinical trial of fosgonimeton as a potential treatment for mild-to-moderate Alzheimer's disease expected in second half of 2024

Submitted Investigational New Drug application to U.S. Food and Drug Administration for ATH-1105 for the treatment of amyotrophic lateral sclerosis; On track to dose subjects in a first-in-human study in second quarter of 2024

Strong balance sheet to support innovative pipeline through key clinical inflection points

BOTHELL, Wash., May 15, 2024 – Athira Pharma, Inc. (NASDAQ: ATHA), a late clinical-stage biopharmaceutical company focused on developing small molecules to restore neuronal health and slow neurodegeneration, today reported financial results for the quarter ended March 31, 2024, and provided recent pipeline and business updates.

"We are on the cusp of a potentially transformative milestone as we are fast approaching the expected topline data readout from our Phase 2/3 LIFT-AD clinical trial of fosgonimeton in Alzheimer's disease (AD) in the second half of this year," said Mark Litton, Ph.D., President and Chief Executive Officer of Athira. "The totality of clinical and nonclinical data to date support our confidence in the LIFT-AD trial and underscore the potential of our differentiated approach in targeting the neurotrophic HGF system to induce neuroprotective effects across a number of neurodegenerative diseases."

"We were delighted to welcome Javier San Martin, M.D. as our new Chief Medical Officer. His insight and expertise will be invaluable as we move toward the LIFT-AD data readout and the potential opportunity to deliver fosgonimeton as a new treatment option for AD patients in need of better therapies. In parallel, we continue to progress ATH-1105 in amyotrophic lateral sclerosis (ALS) and expect to initiate a first-in-human study of this oral small molecule drug candidate in the coming months," added Dr. Litton.

Clinical Development & Pipeline Programs

Athira's drug development pipeline includes potential first-in-class (fosgonimeton) and next-generation (ATH-1105 and ATH-1020) small molecule drug candidates designed to promote the neurotrophic hepatocyte growth factor (HGF) system, which activates neuroprotective, neurotrophic and anti-inflammatory pathways in the central nervous system. Athira's drug candidates have distinct properties, which the Company believes may be applicable to a broad range of neurodegenerative diseases.

Fosgonimeton (ATH-1017) – A potentially first-in-class, once daily, subcutaneously administered drug candidate initially targeted for the potential treatment of Alzheimer's disease.

LIFT-AD Phase 2/3 clinical trial of fosgonimeton in mild-to-moderate Alzheimer's disease *(NCT04488419)*

- Athira expects to report topline data from LIFT-AD in the second half of 2024.
- In January 2024, Athira announced the completion of enrollment of the LIFT-AD study.
- The LIFT-AD study is investigating the effects of fosgonimeton 40 mg compared with placebo in mild-to-moderate AD patients who are not receiving background therapy. The primary endpoint is the Global Statistical Test (GST), combining the results from the co-key secondary endpoints of cognition (ADAS-Cog11) and function (ADCS-ADL23), which Athira believes is a comprehensive measure of overall disease burden. Other secondary and exploratory endpoints include changes in plasma biomarkers of neurodegeneration, protein pathology, and neuroinflammation.

Open Label Extension (OLEX) fosgonimeton trial *(NCT04886063)*

- Eligible participants who complete the Company's LIFT-AD or ACT-AD clinical trials and elect to participate in the ongoing OLEX are able to receive up to 48 months of open-label treatment.
- Greater than 85% of participants who completed either study have elected to enroll in OLEX to date.
- Currently, more than 65 patients are continuing fosgonimeton treatment beyond 18 months, which is unexpected in a progressive mild-to-moderate Alzheimer's disease population.
- Athira believes the OLEX will complement its long-term safety database and provide insights into fosgonimeton's long-term effects for potentially over four years of investigational treatment.

SHAPE Phase 2 clinical trial of fosgonimeton in Parkinson's disease dementia and dementia with Lewy bodies *(NCT04831281)*

- In December 2023, Athira announced encouraging findings from the exploratory SHAPE Phase 2 clinical trial of fosgonimeton for the potential treatment of Parkinson's disease dementia and dementia with Lewy bodies.
- Treatment with fosgonimeton 40 mg (n=5) compared to placebo (n=7) showed directional improvements in certain cognitive, functional and biomarker measurements, including ADAS-Cog13, MMSE, and COWAT over the 6-month double-blind treatment period.
- The primary endpoint of the trial, a composite score of the change in Event-Related-Potential (ERP) P300 latency and cognitive assessment (ADAS-Cog13), was not met by protocoled analysis compared with placebo.
- Fosgonimeton was generally well tolerated, with a favorable safety profile. There were no treatment-related serious adverse events observed in the study. The most common adverse event in the treatment groups was injection site reactions.

ATH-1105 – A next-generation, orally administered, small molecule drug candidate in development for the potential treatment of ALS.

- Athira submitted an Investigational New Drug (IND) application to the U.S. Food and Drug Administration for the evaluation of ATH-1105 as a potential treatment for ALS.
- Athira expects to initiate a first-in-human study of ATH-1105 in the second quarter of 2024.
- ATH-1105's potential is supported by a growing body of preclinical evidence demonstrating statistically significant improvements on nerve and motor function, biomarkers of inflammation and neurodegeneration, and survival in various models of ALS.
- These data have been presented at a variety of key scientific and medical meetings including the American Association of Neurology (AAN), the Alzheimer's Association International Congress (AAIC), the Northeast Amyotrophic Lateral Sclerosis Consortium® (NEALS), and the Motor Neurone Disease Association (MNDA).

Corporate

- In April 2024, the Company announced the appointment of Javier San Martin, M.D., as Chief Medical Officer. Dr. San Martin is an experienced clinical development executive with a strong track record of advancing therapeutics from early development to approval and through commercialization. He joins Athira with more than 25 years of drug development experience, most recently as Chief Medical Officer of Arrowhead Pharmaceuticals.

Recent Presentations and Publications

- In April 2024, Athira presented a poster at the American Academy of Neurology (AAN) 2024 Annual Meeting, which highlighted preclinical data supporting the continued development of its small molecule candidates targeting the neurotrophic HGF system. The presentation was titled: "Targeting Neurotrophic HGF Signaling for the Treatment of Neurodegenerative Disorders."
- In April 2024, Athira published preclinical data supporting the therapeutic potential of fosgonimeton in Alzheimer's disease in the peer-reviewed journal, *Neurotherapeutics*. The original research article is titled: "Fosgonimeton attenuates amyloid-beta toxicity in preclinical models of Alzheimer's disease."
    - The findings described several mechanisms by which fosgonimeton may disrupt the neurodegenerative cascade of Alzheimer's disease downstream of Aβ toxicity, including reduction of mitochondrial oxidative stress and excitotoxicity, improvement of autophagic pathway function, and attenuation of tau hyperphosphorylation.
- In March 2024, Athira presented new clinical and preclinical data further highlighting the therapeutic potential of fosgonimeton at the AD/PD™ 2024 International Conference on Alzheimer's and Parkinson's Diseases and Related Neurological Disorders.
    - Results from the exploratory SHAPE Phase 2 clinical trial in Parkinson's disease dementia and dementia with Lewy bodies indicated a favorable safety and tolerability profile for fosgonimeton in trial participants. In addition, changes in ADAS-Cog13 observed in the fosgonimeton 40 mg dose arm were suggestive of a pro-cognitive effect, which was assessed for fosgonimeton for the first time in these disease states.
    - In Alzheimer's preclinical disease models, results showed the neuroprotective effects of fosgonimeton against glutamate toxicity in vitro are driven, in part, by activation of pro-survival signaling pathways that may help to counteract neurodegenerative hallmarks of disease such as tau pathology and mitochondrial dysfunction.

    - In Parkinson's preclinical disease models, results highlighted the ability of fosgonimeton to mitigate pathological alterations associated with α-synuclein toxicity in vitro and in vivo.
    - In an aged mouse preclinical model of Parkinson's disease that included α-synuclein pathology and GBA1 inhibition, fosgonimeton improved motor function, promoted dopaminergic neuron survival, reduced α-synuclein aggregation, and protected against microglial activation.
- In February 2024, Athira published research highlighting the neuroprotective and anti-inflammatory effects of ATH-1105 in preclinical models of ALS in the peer-reviewed journal, *Frontiers in Neuroscience.* The original research article is titled: "ATH-1105, a small-molecule positive modulator of the neurotrophic HGF system, is neuroprotective, preserves neuromotor function, and extends survival in preclinical models of ALS."
- All presentations and publications can be accessed on the Athira website at Medical Affairs – Athira Pharma.

Financial Results

- **Cash Position**. Cash, cash equivalents and investments were $122.1 million as of March 31, 2024, compared to $147.4 million as of December 31, 2023. Net cash used in operations was $25.8 million for the quarter ended March 31, 2024, compared to $26.2 million for the quarter ended March 31, 2023.

- **Research and Development (R&D) Expenses**. R&D expenses were $21.2 million for the quarter ended March 31, 2024, compared to $21.3 million for the quarter ended March 31, 2023. The decrease was driven primarily by decreases in ATH-1020 program costs and personnel costs, partially offset by an increase in other indirect costs. Fosgonimeton program costs for the quarter ended March 31, 2024, were flat compared to the quarter ended March 31, 2023, as decreases in manufacturing and contract research organization costs were offset by increases in program consulting expenses and clinical site visit costs.

- **General and Administrative (G&A) Expenses**. G&A expenses were $6.5 million for the quarter ended March 31, 2024, compared to $8.5 million for the quarter ended March 31, 2023. The decrease was driven by decreases in legal costs, business development expenses, professional services expenses, personnel costs, and other general corporate expenses.

- **Net Loss**. Net loss was $26.3 million, or $0.69 per share, for the quarter ended March 31, 2024, compared to a net loss of $27.8 million, or $0.73 per share, for the quarter ended March 31, 2023.

About Athira Pharma, Inc.

Athira Pharma, Inc., headquartered in the Seattle, Washington area, is a late clinical-stage biopharmaceutical company focused on developing small molecules to restore neuronal health and slow neurodegeneration. Athira aims to alter the course of neurological diseases by advancing its pipeline of drug candidates that modulate the neurotrophic HGF system. For more information, visit www.athira.com. You can also follow Athira on Facebook, LinkedIn, X (formerly known as Twitter) and Instagram.

Forward-Looking Statements

This communication 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: Athira’s drug candidates as potential treatments for Alzheimer’s disease, Parkinson’s disease, Parkinson’s disease dementia, dementia with Lewy bodies, amyotrophic lateral sclerosis, and other neurodegenerative diseases; future development plans; the anticipated reporting of data; the potential learnings from preclinical studies and other nonclinical data, the ACT-AD and SHAPE trials, and LIFT-AD unblinded interim efficacy and futility analysis and their ability to inform and improve future clinical development plans; expectations regarding the potential efficacy and commercial potential of Athira’s drug candidates; and Athira’s ability to advance its drug 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,” “suggest,” “potential,” and similar expressions. 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 from preclinical and clinical trials may not support the safety, efficacy and tolerability of Athira’s drug candidates; development of drug candidates may cease or be delayed; regulatory authorities could object to protocols, amendments and other submissions; future potential regulatory milestones for drug candidates, including those related to current and planned clinical studies, may be insufficient to support regulatory submissions or approval; Athira may not be able to recruit sufficient patients for its clinical trials; the outcome of legal proceedings that have been or may in the future be instituted against Athira, its directors and officers; possible negative interactions of Athira's drug candidates with other treatments; Athira’s assumptions regarding its financial condition and the sufficiency of its cash, cash equivalents and investments to fund its planned operations may be incorrect; adverse conditions in the general domestic and global economic markets; the impact of competition; the impact of expanded drug candidate 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 from time to time. 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)

	March 31, 2024	December 31, 2023
	(unaudited)	
Assets		
Cash and cash equivalents	$ 77,821	$ 90,584
Short-term investments	44,267	56,835
Other short-term assets	6,548	7,310
Other long-term assets	4,822	5,516
Total assets	$ 133,458	$ 160,245
Liabilities and stockholders' equity		
Current liabilities	$ 25,598	$ 28,840
Long-term liabilities	1,118	1,217
Total liabilities	26,716	30,057
Stockholders' equity	106,742	130,188
Total liabilities and stockholders' equity	$ 133,458	$ 160,245

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

	Three Months Ended March 31,	
	2024	2023
Operating expenses:		
Research and development	$ 21,236	$ 21,293
General and administrative	6,451	8,477
Total operating expenses	27,687	29,770
Loss from operations	(27,687)	(29,770)
Grant income	—	157
Other income, net	1,350	1,793
Net loss	$ (26,337)	$ (27,820)
Unrealized gain on available-for-sale securities	212	927
Comprehensive loss attributable to common stockholders	$ (26,125)	$ (26,893)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.69)	$ (0.73)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	38,321,573	37,923,402