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): March 23, 2023

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 March 23, 2023, Athira Pharma, Inc. (the "Company") issued a press release reporting its financial results for the year ended December 31, 2022. 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 Twitter account (@athirapharma), LinkedIn account (www.linkedin.com/company/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 March 23, 2023
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: March 23, 2023

By: /s/ Mark Litton

Mark Litton

President and Chief Executive Officer

Athira Pharma Reports Full Year 2022 Financial Results and Recent Pipeline and Business Updates

On track to complete enrollment in Phase 2/3 LIFT-AD trial of fosgonimeton for mild-to-moderate Alzheimer's disease in mid-2023 with topline data in early 2024

Continuing to advance development of ATH-1105 as a potential clinical candidate for amyotrophic lateral sclerosis

Strong balance sheet to support innovative clinical development pipeline in neurodegenerative diseases through key inflection points

BOTHELL, Wash., March 23, 2023 – 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, 2022, and reviewed recent pipeline and business updates.

"The progress we made throughout 2022 and in recent months continues to support our strategy to advance our small molecule therapeutic candidates, such as fosgonimeton, to impact neurodegenerative diseases, as both clinical and preclinical data suggest potential neuroprotective, neurotrophic, anti-inflammatory, procognitive and disease-modifying effects," stated Mark Litton, Ph.D., President and Chief Executive Officer of Athira. "Furthermore, recent and upcoming presentations at medical and scientific meetings provide the opportunity to highlight our diverse and robust clinical and preclinical data supporting the therapeutic potential of enhancing the HGF/MET system in a variety of neurodegenerative diseases including Alzheimer's disease, Parkinson's disease and ALS.

"We believe the independent, unblinded interim efficacy and futility analysis of the Phase 2/3 LIFT-AD trial reported in October 2022 mitigates fosgonimeton program risk, supports the potential clinical benefits of fosgonimeton treatment, and underscores the rationale for continued development of this promising potential new therapy for mild-to-moderate Alzheimer's disease. We are targeting to complete enrollment of the LIFT-AD trial in mid-2023 and to have topline data in early 2024. Additionally, we continue to advance IND-enabling studies with ATH-1105 and expect to initiate a Phase 1 study in 2024 to evaluate its potential as a treatment for ALS.

"We ended 2022 with a strong balance sheet that enables us to continue to explore the potential of fosgonimeton in Alzheimer's and to advance our other pipeline candidates in neurodegenerative diseases, such as ATH-1105 in ALS, through key inflection points," concluded Dr. Litton.

Recent Highlights

- Presented multiple preclinical datasets that continue to support the therapeutic potential of enhancing the hepatocyte growth factor (HGF) and its receptor, MET, or the HGF/MET system,

in a variety of neurodegenerative disease models at the American Society for Experimental Neurotherapeutics (ASENT) 2023 Annual Meeting;
- Promoted Kevin Church, Ph.D. to Chief Scientific Officer in recognition of his leadership directing the Company's efforts to elucidate and evaluate the promise of enhancing the HGF/MET system and its potential applications for the treatment of neurodegenerative diseases;
- Published a review paper highlighting the need for novel treatment approaches to address Alzheimer's disease and the therapeutic potential of fosgonimeton, one of the Company's novel small molecule positive modulators of the HGF/MET system in *the Journal of Alzheimer's Disease*; and
- Published preclinical data demonstrating the neuroprotective, neurotrophic and procognitive effects of fosgonimeton in models of dementia in the peer-reviewed journal *Neurotherapeutics*.

Clinical Development & Pipeline Programs

Fosgonimeton (ATH-1017) - Small molecule designed to enhance the activity of the HGF/MET system with the potential to protect and repair neuronal networks.

LIFT-AD phase 2/3 trial in mild-to-moderate Alzheimer's disease (NCT04488419)
- Following results from the exploratory Phase 2 ACT-AD trial, Athira proactively amended the entry criteria for the LIFT-AD trial in September 2022 to investigate the effects of fosgonimeton compared with placebo, without background acetylcholinesterase inhibitors (AChEIs).
- In October 2022, following an unblinded interim efficacy and futility analysis, an independent data monitoring committee recommended continuation of the LIFT-AD trial in participants with mild-to-moderate AD.
- The committee also determined that, with the additional enrollment of fewer than 150 participants for a total enrollment of less than 300 participants without background AChEIs, the trial would be well powered for the primary endpoint given the preliminary effect size observed.
- The Company is targeting to complete enrollment of the LIFT-AD trial in mid-2023 and to report topline data in early 2024.

Open Label Extension (OLEX) trial (NCT04886063)
- The Open Label Extension (OLEX) for the ACT-AD and LIFT-AD trials continue, with more than 200 participants currently enrolled. As of year-end 2022, greater than 85% of participants who have completed either study have elected to enroll in the OLEX trial.

SHAPE phase 2 trial in mild-to-moderate Parkinson's disease dementia and dementia with Lewy bodies (NCT04831281)
- Athira enrolled 28 participants in the exploratory Phase 2 SHAPE trial of fosgonimeton in people with Parkinson's disease dementia or dementia with Lewy bodies.
- The Company expects to complete the trial with 28 participants and to evaluate the learnings from trial results to determine next steps for this program.
- With the compelling preclinical data recently presented at the Society for Neuroscience Annual Conference in November 2022 on the broader potential of fosgonimeton to improve motor function in Parkinson's disease, the Company will seek to evaluate study designs to further explore its potential in this complex disease.

ATH-1020 - Orally available, novel small molecule compound designed to enhance the HGF/MET system, as a potential treatment candidate for neuropathic pain or other neurodegenerative diseases.

Phase 1 trial in healthy volunteers (NCT05169671)

- The Company completed the Phase 1, single-ascending, dose escalation study of ATH-1020.
- ATH-1020 demonstrated a favorable safety profile and was well tolerated in healthy volunteers.
- The Company plans to evaluate its options with this compound and will consider its advancement in relation to other opportunities and resources.

ATH-1105 – A novel small molecule compound designed to be a positive modulator of the HGF/MET system as a potential treatment candidate for amyotrophic lateral sclerosis (ALS).

- The Company presented preclinical data in December 2022.
- ATH-1105 demonstrated consistent improvements across measures of motor function, nerve function, and neurodegeneration in a TDP-43 mouse model of ALS, among other measures.
- The Company is completing IND-enabling work in 2023 in order to initiate first-in-human studies to evaluate this promising product candidate as a treatment for ALS.

Financial Results

- **Cash Position**. Cash, cash equivalents and investments were $245.2 million as of December 31, 2022, compared with $319.7 million as of December 31, 2021. Cash used in operations was $72.5 million for the year ended December 31, 2022, compared with $43.1 million for the year ended December 31, 2021.

- **Research and Development (R&D) Expenses**. R&D expenses were $61.5 million for the year ended December 31, 2022, compared with $42.8 million for the year ended December 31, 2021. 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 $32.6 million for the year ended December 31, 2022, compared with $21.2 million for the year ended December 31, 2021, primarily due to increased personnel expenses as the Company's headcount expanded to support its continued growth. In addition, increases to G&A expenses in 2022 were the result of increases related to legal, business development, facilities, insurance, professional services, and other general corporate costs.

- **Legal Settlement Expense.** In February 2023, the Company reached an agreement in principle to resolve all claims in the Company's securities class action lawsuit. Under the proposed settlement, we have agreed to make a one-time payment of $10.0 million, and we have recorded a legal settlement expense of $10.0 million for the year ended December 31, 2022. The proposed settlement is subject to the parties finalizing a stipulation of settlement and preliminary and final approval of the U.S. District Court for the Western District of Washington.

- **Net Loss**. Net loss was $95.6 million, or $2.53 per share, for the year ended December 31, 2022, compared with a net loss of $54.9 million, or $1.49 per share, for the year ended December 31, 2021.

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 provide rapid cognitive improvement and alter the course of

neurological diseases with its novel mechanism of action. Athira is currently advancing its pipeline therapeutic candidates targeting the HGF/MET neurotrophic system for Alzheimer's and Parkinson's disease, Dementia with Lewy bodies and ALS. For more information, visit www.athira.com. You can also follow Athira on Facebook, LinkedIn, Twitter and @athirapharma on 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: product candidates as a potential treatment for Alzheimer's disease, Parkinson's disease dementia, Dementia with Lewy bodies, neuropsychiatric diseases, and other neurodegenerative diseases, such as amyotrophic lateral sclerosis; Athira's platform technology and potential therapies; future development plans; clinical and regulatory objectives and the timing thereof; expectations regarding the potential efficacy and commercial potential of Athira's product candidates; the anticipated reporting of data; the potential learnings from the LIFT-AD
unblinded interim efficacy and futility analysis and their ability to inform and improve future clinical
development plans; 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," "suggest," "potential," 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 data for our product candidates from our preclinical and clinical trials not supporting the safety, efficacy and tolerability of our product candidates; cessation or delay of Athira's development of product candidates may occur; regulatory authorities could object to protocols, amendments and other
submissions; future potential regulatory milestones for 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 the regulatory process for Athira product candidates; 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 us and certain of our directors and officers; clinical trials may not demonstrate safety and efficacy of any of Athira's product candidates; possible negative interactions of Athira's product candidates with other treatments; Athira's assumptions regarding 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; 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.

Investor & Media Contact
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Athira Pharma, Inc.
Condensed Consolidated Balance Sheets
(Amounts in thousands)

	December 31, 2022	December 31, 2021
Assets		
Cash and cash equivalents	$ 95,966	$ 110,537
Short-term investments	104,378	143,222
Other short-term assets	7,189	7,040
Long-term investments	44,829	65,936
Other long-term assets	5,791	5,273
Total assets	$ 258,153	$ 332,008
Liabilities and stockholders' equity		
Current liabilities	$ 21,431	$ 9,292
Long-term liabilities	1,585	1,632
Total liabilities	23,016	10,924
Stockholders' equity	235,137	321,084
Total liabilities and stockholders' equity	$ 258,153	$ 332,008

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

	Year Ended December 31,	
	2022	2021
Operating expenses:		
Research and development	$ 61,464	$ 42,794
General and administrative	32,552	21,228
Legal settlement	10,000	—
Total operating expenses	104,016	64,022
Loss from operations	(104,016)	(64,022)
Grant income	5,161	8,835
Other income, net	3,216	334
Net loss	$ (95,639)	$ (54,853)
Unrealized loss on available-for-sale securities	(1,568)	(421)
Comprehensive loss attributable to common stockholders	$ (97,207)	$ (55,274)
Net loss per share attributable to common stockholders, basic and diluted	$ (2.53)	$ (1.49)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	37,733,240	36,921,172