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): October 17, 2022

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 8.01 Other Events.

On October 17, 2022, Athira Pharma, Inc. (the "Company") issued a press release announcing that, following an unblinded interim efficacy and futility analysis, an independent data monitoring committee recommended continuation of the LIFT-AD study of fosgonimeton (ATH-1017) in patients with mild-to-moderate Alzheimer's disease.

A copy of the Company's press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 7.01 Regulation FD Disclosure.

The Company will host a live webcast to discuss the LIFT-AD interim analysis in greater detail at 8:30 a.m. ET today, Monday, October 17, 2022. To access the live webcast, please visit the "Events and Presentations" page within the Investors section of the Athira website: https://investors.athira.com/news-and-events/events-and-presentations. As part of the webcast, the Company will present certain slides relating to the LIFT-AD interim analysis, which slides are attached as Exhibit 99.2 hereto.

The information in Item 7.01 of this Current Report on Form 8-K, including the slides to be used during the webcast and attached as Exhibit 99.2 hereto, are being furnished and not filed pursuant to Item 7.01 of Form 8-K. Such information shall not be deemed to be "filed" for purposes of Section 18 of the Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, and shall not be deemed to be incorporated by reference into any of the Company's filings under the Securities Act of 1933, as amended, or the Exchange Act whether made before or after the date hereof and regardless of any general incorporation language in such filings, except to the extent expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Athira Pharma, Inc. press release dated October 17, 2022.
99.2	Athira Pharma, Inc. presentation slides.
104	Cover Page Interactive Data File (formatted as Inline XBRL)

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: October 17, 2022

By: /s/ Mark Litton
Mark Litton
President and Chief Executive Officer

Athira Pharma Advances Phase 2/3 LIFT-AD Clinical Study of Fosgonimeton in Mild-to-Moderate Alzheimer's Patients Following Independent, Unblinded Interim Analysis

Results support potential clinically meaningful activity of fosgonimeton without background therapy and mitigate program risk

Updated study well powered for primary endpoint with addition of fewer than 150 patients

Company targets completion of enrollment in mid-2023 and topline results in early 2024

Company to host live webcast today at 8:30 a.m. Eastern

BOTHELL, Wash., Oct. 17, 2022 — 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 that following an unblinded interim efficacy and futility analysis, an independent data monitoring committee recommended continuation of the LIFT-AD study of fosgonimeton (ATH-1017) in patients with mild-to-moderate Alzheimer's disease (AD). The committee also determined that, with the additional enrollment of fewer than 150 patients for a total enrollment of less than 300 patients without background therapy (acetylcholinesterase inhibitors), the study will be well powered for the primary endpoint given the preliminary effect size observed. The primary endpoint of LIFT-AD is the Global Statistical Test, an unweighted composite score comprising measures of cognition (Alzheimer's Disease Assessment Scale-Cognitive Subscale [ADAS-Cog11]) and function (Alzheimer's Disease Cooperative Study-Activities of Daily Living [ADCS-ADL23]).

Results from the completed exploratory ACT-AD Phase 2 study showed a favorable safety profile and suggested positive effects on measures of cognition (ADAS-Cog11), function (ADCS-ADL23) and neurodegeneration (plasma neurofilament light chain or NfL) in patients taking fosgonimeton without background therapy. Guided by these results, the Company proactively amended LIFT-AD to focus on patients not on background therapy. The unblinded interim analysis was then conducted in approximately 100 patients not on background therapy to corroborate observations from ACT-AD and ensure LIFT-AD is well powered to determine the effect of fosgonimeton on clinically meaningful and commercially relevant endpoints.

"The results from the data monitoring committee's unblinded analysis give us confidence in a potentially positive outcome for LIFT-AD, as stringent evaluation criteria were applied based on validated and clinically meaningful cognitive and functional outcomes," said Hans Moebius, M.D., Ph.D., Chief Medical Officer of Athira. "This analysis supports the potential clinical benefits of fosgonimeton treatment and underscores the rationale for continued development of this promising new therapy."

“We are very excited by the results of this independent review as we believe they mitigate the risk of the fosgonimeton development plan, support the potential clinical benefit of fosgonimeton and inform the sample size needed to achieve success with LIFT-AD,” said Mark Litton, Ph.D., President and Chief Executive Officer of Athira. “We are now targeting to complete enrollment in mid-2023 and report topline data in early 2024. Importantly, we have a strong balance sheet to execute our plans through key data readouts and beyond. Moving forward, we remain keenly focused on advancing this novel investigational therapy with the hope of positively impacting the lives of millions of Alzheimer’s patients.

“Our goal with fosgonimeton is to demonstrate its ability to improve cognition and function and to ultimately provide neuroprotection. The ACT-AD study suggested these benefits, and the results of the LIFT-AD interim analysis corroborate those findings,” added Dr. Litton. “We believe any drug that can demonstrate neuroprotection could become a treatment of choice for mild-to-moderate Alzheimer’s patients.”

Live Webcast

Athira will host a live webcast to discuss the LIFT-AD interim analysis in greater detail at 8:30 a.m. Eastern Time today, Monday, Oct. 17, 2022. To access the live webcast, please visit https://us02web.zoom.us/webinar/register/WN_AtJ3jgG1RtmRRlcU_cYb-Q or the "Events and Presentations" page within the Investors section of the Athira website: https://investors.athira.com/news-and-events/events-and-presentations-investor. An archived replay will also be available on the website for at least 90 days following the event.

About the LIFT-AD Clinical Study

LIFT-AD is a randomized, double-blind, placebo-controlled, parallel-group study of fosgonimeton for patients with mild-to-moderate Alzheimer’s disease. Patients are randomized across two dose groups and one placebo group on a 1:1:1 basis to receive a subcutaneous injection of fosgonimeton or placebo once daily over a treatment course of 26 weeks. The primary endpoint for LIFT-AD is the Global Statistical Test, an unweighted composite score comprising measures of cognition (Alzheimer's Disease Assessment Scale-Cognitive Subscale [ADAS-Cog11]) and function (Alzheimer’s Disease Cooperative Study-Activities of Daily Living [ADCS-ADL23]). Additional information on the LIFT-AD study can be found at: NCT04488419.

About Fosgonimeton

Fosgonimeton is a small molecule designed to enhance the activity of hepatocyte growth factor (HGF) and its receptor, MET, to impact neurodegeneration and regenerate brain tissue. The function of the HGF/MET receptor system may be impaired in the brain under conditions of neurodegeneration. In addition to Alzheimer’s disease, fosgonimeton has the potential to address the broader dementia population, including Parkinson’s disease dementia and Dementia with Lewy bodies, as the mode of action focuses on network recovery and synaptic signal transmission in the brain.

The ACT-AD trial was 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.

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 of therapeutic candidates targeting the HGF/MET neurotrophic system for Alzheimer's and Parkinson's disease dementia, Dementia with Lewy bodies and neuropsychiatric 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 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 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; expectations regarding the potential efficacy and commercial potential of Athira's product candidates; the anticipated reporting of data; the potential learnings from the ACT-AD trial and 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," 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 or preclinical and clinical trials will not support the safety, efficacy and tolerability of our product candidates; cessation or delay of any of the ongoing clinical trials and/or Athira's development of fosgonimeton and other product candidates may occur; regulatory authorities could object to protocols, amendments and other submissions, 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 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:

Julie Rathbun
Athira Pharma
Julie.rathbun@athira.com
206-769-9219

Exhibit 99.2

Athira PHARMA

Phase 2/3 LIFT-AD Interim Analysis Results and Next Steps

October 17, 2022

ADVANCING NEW THERAPIES FOR NEURONAL HEALTH

Forward-Looking Statements

This presentation and the accompanying oral commentary contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "could," "expect," "plan," anticipate," "believe," "estimate," "predict," "intend," "potential," "would," "continue," "ongoing" or the negative of these terms or other comparable terminology. Forward-looking statements include all statements other than statements of historical fact contained in this presentation, including information concerning our future financial performance, business plans and objectives, timing and success of our planned development activities, our ability to obtain regulatory approval, the potential therapeutic benefits and economic value of our product candidates, potential growth opportunities, competitive position, industry environment and potential market opportunities, the anticipated reporting of data; the potential learnings from the ACT-AD trial and LIFT-AD unblinded interim efficacy and futility analysis and their ability to inform and improve future clinical development plans, regulatory authorities' response to protocols, amendments and other submissions, and the impact of the COVID-19 pandemic on our business and operations.

Forward-looking statements are subject to known and unknown risks, uncertainties, assumptions and other factors. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. These factors, together with those that are described in greater detail in our filings with the Securities and Exchange Commission ("SEC") may cause our actual results, performance or achievements to differ materially and adversely from those anticipated or implied by our forward-looking statements.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this presentation, and although we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted a thorough inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and readers are cautioned not to unduly rely upon these statements. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

By attending or receiving this presentation you acknowledge that you will be solely responsible for your own assessment of the market and our market position and that you will conduct your own analysis and be solely responsible for forming your own view of the potential future performance of our business. This presentation contains estimates, projections and other information concerning market, industry and other data. We obtained this data from our own internal estimates and research and from academic and industry research, publications, surveys, and studies conducted by third parties, including governmental agencies. These data involve a number of assumptions and limitations, are subject to risks and uncertainties, and are subject to change based on various factors, including those discussed in our filings with the SEC. These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us. While we believe such information is generally reliable, we have not independently verified any third-party information.

The ACT-AD trial was 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 presentation is solely the responsibility of Athira and does not necessarily represent the official views of the National Institutes of Health.

This presentation concerns drug candidates that are under clinical investigation and which have not yet been approved for marketing by the U.S. Food and Drug Administration. The drug candidates are currently limited by federal law to investigational use, and no representation is made as to their safety or effectiveness for the purposes for which they are being investigated.

We announce material information to the public through a variety of means, including filings with the SEC, press releases, public conference calls, our website (www.athira.com/), our investor relations website (investors.athira.com), and our news site (investors.athira.com/news-and-events/press-releases). We use these channels, as well as social media, including our Twitter account (@athirapharma) and Facebook page (https://www.facebook.com/athirapharmainc), to communicate with investors and the public about Athira, our products, and other matters. Therefore, we encourage investors, the media, and others interested in Athira to review the information we make public in these locations, as such information could be deemed to be material information.

Phase 2/3 LIFT-AD Study Advances

INDEPENDENT UNBLINDED INTERIM ANALYSIS SUPPORTS POTENTIAL CLINICALLY MEANINGFUL ACTIVITY OF FOSGONIMETON WITHOUT BACKGROUND THERAPY AND MITIGATES PROGRAM RISK

- Phase 2 exploratory ACT-AD study results suggested congruent positive effects
  - Cognition (ADAS-Cog11); Function (ADCS-ADL23); Neurodegeneration (neurofilament light chain or NfL)
- Data driven approach was used to determine best path forward to optimize ongoing Phase 2/3 LIFT-AD study in the same patient population as in ACT-AD
- Analysis of ~100 patients supports potential clinically meaningful effects of cognition and function and informs the sample size required to power LIFT-AD
  - Enrollment target of <150 additional patients enables LIFT-AD to be well-powered for the primary endpoint
  - Enrollment completion target by mid 2023 with topline data in early 2024

Athira PHARMA

ADAS-Cog11, Alzheimer's Disease Assessment Scale–Cognitive Subscale; ADCS-ADL23, Alzheimer's Disease Cooperative Study–Activities of Daily Living; NfL, neurofilament light chain.

Hans Moebius, M.D., Ph.D

Chief Medical Officer

Summary of Phase 2 ACT-AD Study Results

EXPLORATORY STUDY TO INFORM LARGER LIFT-AD IN PATIENTS WITHOUT BACKGROUND THERAPY

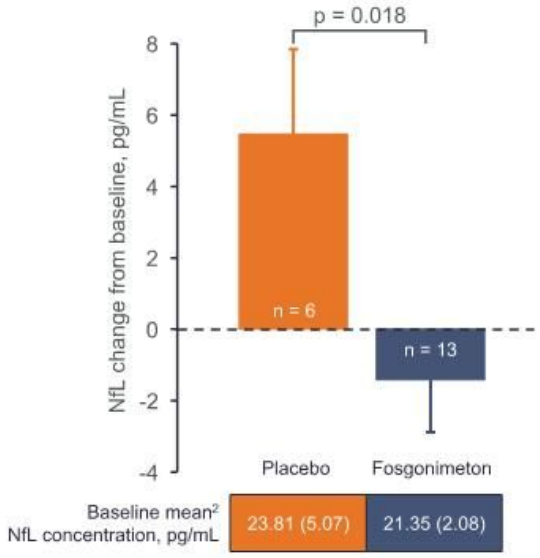
Favorable safety and tolerability profile

Fosgonimeton signals without background therapy compared to placebo (limited subgroup size)

- Reduced ERP P300 latency (n.s.)
- Improved cognition as measured by ADAS-Cog11 (n.s.)
- Improved function as measured by ADCS-ADL23 (n.s.)
- Showed a statistically significant improvement in plasma levels of NfL (p=0.018)

ACT-AD was a similar study design to LIFT-AD to help inform larger LIFT-AD Both are randomized, double-blind, placebo-controlled, parallel-group studies of fosgonimeton for patients with mild-to-moderate Alzheimer's disease

NfL at week 26 (fosgonimeton without background therapy)[1]



ADAS-Cog11, Alzheimer's Disease Assessment Scale–Cognitive Subscale; ADCS-ADL23, Alzheimer's Disease Cooperative Study–Activities of Daily Living; ERP, event related potential; NfL, neurofilament light chain.
[1] Data presented are least squares mean ± SE. [2] Data shown as mean NfL concentration (SEM).

Fosgonimeton Phase 2/3 LIFT-AD Study Design

LEARNINGS FROM ACT-AD INFORM STUDY DESIGN OPTIMIZATION

POPULATION

LIFT-AD: Target N=TBD, informed by interim analysis

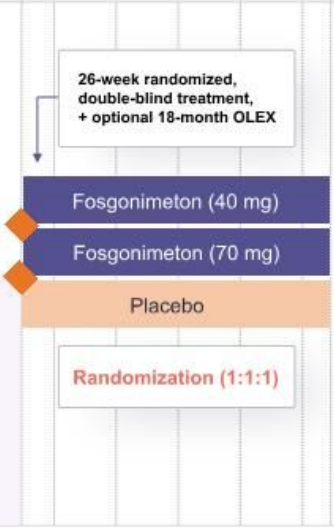
Mild-to-moderate AD subjects

- 55-85 years
- CDR 1 and 2
- MMSE 14-24
- Approximately 40% of patients not on background AChEI

Path Forward:

- Exclusion criterion added for subjects on background AChEIs (Sept 2022)
- Independent, unblinded interim analysis to inform sample size for primary endpoint (Oct 2022)

TREATMENT DURATION



RESULTS

PRIMARY ENDPOINT

- Global Statistical Test (GST) – unbiased composite of data from two key co-secondary endpoints (ADAS-Cog11 and ADCS-ADL23)
- Safety

SECONDARY ENDPOINTS

- Cognition: ADAS-Cog11
- Function: ADCS-ADL23
- Global clinical change: ADCS CGIC – Clinician

EXPLORATORY ENDPOINTS

- Fluid biomarkers (e.g., NfL)

TIMELINE

- Enrollment ongoing

AChEI, acetylcholinesterase inhibitor; ADAS-Cog11, Alzheimer's Disease Assessment Scale–Cognitive Subscale; ADCS-ADL23, Alzheimer's Disease Cooperative Study–Activities of Daily Living; ADCS-CGIC, Alzheimer's Disease Cooperative Study–Clinical Global Impression of Change; CDR, clinical dementia rating; GST, global statistical test; MMSE, mini-mental state examination; NfL, neurofilament light chain; OLEX, open-label extension.

Systematic and Data-driven Process to Support LIFT-AD

STEPS COMPLETED SINCE ACT-AD READOUT IN JUNE 2022

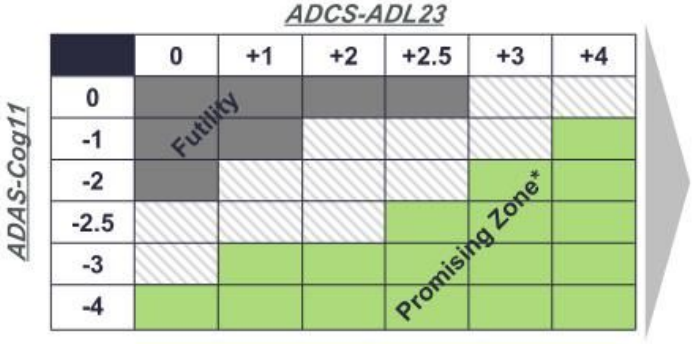
- Additional analysis of ACT-AD
- DSMB unblinded adjudication of LIFT-AD
- Blinded analysis of LIFT-AD
- Proactively amended Phase 2/3 LIFT-AD in September
- Independent unblinded interim analysis in October

Development plan optimized with mitigated risk

LIFT-AD Sample Size Well Powered for Primary Endpoint

STRINGENT CRITERIA APPLIED TO INCREASE PROBABILITY OF DEMONSTRATING A CLINICALLY MEANINGFUL EFFECT SIZE FOR COGNITION AND FUNCTION

Pre-specified Decision Framework



DMC Recommendation: "Continue LIFT-AD Study"

- **Promising Zone* confirmed**
- **<150** patients needed to complete study
- Target enrollment complete **by mid 2023 with data in early 2024**

*Mehta and Pocock, 2000, 2011

Mark Litton, Ph.D

President and Chief Executive Officer

Moving Forward

- Target enrollment completion by mid 2023 with data in early 2024
- Continued focus on LIFT-AD recruitment and completion to meet timelines
- Strong cash and cash equivalents of approximately $282M* provides support through key data points and beyond

*As of June 30, 2022

Fosgonimeton – A New Potential Therapy for Alzheimer's Disease

35 million
Estimated Alzheimer's cases worldwide[1]

Multi-Billion $ Market
Despite generic entries

Zero
New marketed products since 2003

Over 100 million globally by 2050
~900,000 new patients diagnosed annually in the US alone[1,2]

6.2 million treatment eligible patients in the US in 2021 based on prevalence data
Growing at 3% per year[2,3]

Mild to Moderate comprises 81% of all patients with Alzheimer's disease[3,4]

Significant opportunity for fosgonimeton
Limited treatment options exist today for those with Alzheimer's disease; novel approaches to improve cognition, function and neuroprotection are needed

[1] https://www.who.int/news-room/fact-sheets/detail/dementia
[2] https://www.alz.org/media/documents/alzheimers-facts-and-figures.pdf
[3] GlobalData AD prevalence data access and analysis
[4] https://www.nia.nih.gov/news/half-alzheimers-disease-cases-may-be-mild