UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 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 8, 2024

Sage Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

DELAWARE	**001-36544**	**27-4486580**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

55 Cambridge Parkway **Cambridge, MA**	**02142**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code (617) 299-8380

Not Applicable
(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:

☐ 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, par value $0.0001 per share	SAGE	The Nasdaq Global 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 8, 2024, Sage Therapeutics, Inc. issued a press release titled "Sage Therapeutics Announces Topline Results from the Phase 2 LIGHTWAVE Study of Dalzanemdor (SAGE-718) in the Treatment of Mild Cognitive Impairment and Mild Dementia in Alzheimer's Disease." A copy of the press release is filed as Exhibit 99.1 hereto and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by Sage Therapeutics, Inc. on October 8, 2024.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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.

Date: October 8, 2024

SAGE THERAPEUTICS, INC.

By: /s/ Anne Marie Cook
Anne Marie Cook
Senior Vice President, General Counsel

Sage Therapeutics Announces Topline Results from the Phase 2 LIGHTWAVE Study of Dalzanemdor (SAGE-718) in the Treatment of Mild Cognitive Impairment and Mild Dementia in Alzheimer's Disease

- *In the Phase 2 LIGHTWAVE Study, dalzanemdor (SAGE-718) did not demonstrate a statistically significant difference from baseline in participants treated with dalzanemdor versus placebo on the primary endpoint*
- *Dalzanemdor was generally well-tolerated and no new safety signals were observed*
- *Topline data from the Phase 2 DIMENSION Study of dalzanemdor in Huntington's Disease expected later this year*

CAMBRIDGE, Mass.—(BUSINESS WIRE) – October 8, 2024 – Sage Therapeutics, Inc. (Nasdaq: SAGE) announced today topline results from LIGHTWAVE, a 12-week, Phase 2 randomized, double-blind, placebo-controlled study to evaluate the effects of dalzanemdor (SAGE-718) in participants with mild cognitive impairment (MCI) or mild dementia due to Alzheimer's Disease (AD). The LIGHTWAVE Study did not demonstrate a statistically significant difference from baseline in participants treated with dalzanemdor versus placebo on the Wechsler Adult Intelligence Scale Fourth Edition (WAIS-IV) Coding Test score at Day 84, the primary outcome measure of the study.

Based on these data, the Company does not plan further clinical development of dalzanemdor in AD. The Company expects to report topline data from the Phase 2 DIMENSION Study of dalzanemdor in people with cognitive impairment associated with Huntington's Disease later this year.

"Alzheimer's Disease is an incredibly complex and devastating condition, and people with related mild cognitive impairment and mild dementia need more treatment options. While we are disappointed by the results of the LIGHTWAVE Study, we are grateful to participants, investigators, care partners, patient advocates and the Alzheimer's community who helped make this important research possible. We hope our work and these findings help to inform future research," said Barry Greene, Chief Executive Officer, Sage Therapeutics.

LIGHTWAVE Study Results

The LIGHTWAVE study was a 12-week, Phase 2 randomized, double-blind, placebo-controlled study to evaluate the effects of dalzanemdor in participants with MCI or mild dementia due to AD. A total of 174 participants were randomized.

- The LIGHTWAVE study did not demonstrate a statistically significant difference from baseline in participants treated with dalzanemdor versus placebo on the WAIS-IV Coding Test score at Day 84.
- Dalzanemdor was generally well-tolerated and no new safety signals were observed. The majority of treatment emergent adverse events were mild to moderate in severity.
- Analyses did not demonstrate any meaningful differences in the dalzanemdor-treated group versus placebo in exploratory endpoints such as RBANS total score or MoCA total score.

About dalzanemdor (SAGE-718)

Dalzanemdor (SAGE-718) is a first-in-class investigational NMDA receptor positive allosteric modulator (PAM). Sage has an ongoing placebo-controlled Phase 2 study evaluating dalzanemdor in cognitive impairment associated with Huntington's Disease.

About Sage Therapeutics

Sage Therapeutics (Nasdaq: SAGE) is a biopharmaceutical company committed to our mission of pioneering solutions to deliver life-changing brain health medicines, so every person can thrive. Sage developed the only two FDA-approved treatments indicated for postpartum depression and is advancing a robust pipeline to target unmet needs in brain health. Sage was founded in 2010 and is headquartered in Cambridge, Mass. Find out more at www.sagerx.com or engage with us on Facebook, LinkedIn, Instagram, and X.

Forward-Looking Statements

Various statements in this release concern future expectations, plans and prospects, including without limitation statements regarding: our expectations with respect to the timing of reporting of results from the ongoing clinical trial of dalzanemdor in Huntington's Disease; our belief in the unmet need for new treatment options for brain health; and the mission, goals, opportunity and potential for our business. These statements constitute forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. These forward-looking statements are neither promises nor guarantees of future performance, and are subject to a variety of risks and uncertainties, many of which are beyond our control, which could cause actual results to differ materially from those contemplated in these forward-looking statements, including the risks that: the results of our ongoing DIMENSION study of dalzanemdor in HD may be negative like the results we announced today from the LIGHTWAVE study, and may not support further development of dalzanemdor in HD; we may encounter delays in reporting results from the DIMENSION study and may not meet our expected timelines; even if data from the DIMENSION study, or any other data we generate in the development of any of our product candidates at any stage, are positive, the FDA may not agree with our view of the data; decisions or actions of the FDA or other regulatory agencies may affect the initiation, timing, design, size, or progress of ongoing or future clinical trials or the regulatory pathway for any of our product candidates or our ability to proceed with further development; the FDA may ultimately decide that the design or results of completed, ongoing and planned clinical trials, even if positive, are not sufficient for the next phase of development or ultimately for regulatory approval of any of our product candidates in any indication that is the focus of our development programs and plans; we may encounter adverse results or adverse events at any stage of development that negatively impact further development or that require additional nonclinical and clinical work which may not yield positive results; we may at any time encounter unexpected hurdles in the development and manufacture of our product candidates; and all of these factors and other developments related to our science or business could cause us not to achieve our mission or the goals for our business; as well as those risks more fully discussed in the section entitled "Risk Factors" in our most recent Quarterly Report on Form 10-Q, and discussions of potential risks, uncertainties, and other important factors in our subsequent filings with the Securities and Exchange Commission. In addition, any forward-looking statements represent our views only as of today, and should not be relied upon as representing our views as of any subsequent date. Sage explicitly disclaims any obligation to update any forward-looking statements.

Media Contact:

Francesca Dellelci
856.261.5975
Francesca.Dellelci@SageRx.com

Investors Contact:

Katie Plante
978.968.9099
Katie.Plante@sagerx.com