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): November 20, 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 November 20, 2024, Sage Therapeutics, Inc. issued a press release titled "Sage Therapeutics Announces Topline Results from the Phase 2 DIMENSION Study of Dalzanemdor (SAGE-718) in the Treatment of Cognitive Impairment Associated with Huntington'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 November 20, 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: November 20, 2024

SAGE THERAPEUTICS, INC.

By: /s/ Greg Shiferman
Greg Shiferman
Senior Vice President, General Counsel

Exhibit 99.1

Sage Therapeutics Announces Topline Results from the Phase 2 DIMENSION Study of Dalzanemdor (SAGE-718) in the Treatment of Cognitive Impairment Associated with Huntington's Disease

- The Phase 2 DIMENSION Study did not meet its primary endpoint

- Dalzanemdor was generally well-tolerated; no new safety signals were observed

- Based on these data, the Company does not plan further development of dalzanemdor

CAMBRIDGE, Mass. – November 20, 2024 – Sage Therapeutics, Inc. (Nasdaq: SAGE) today announced topline results from the Phase 2 DIMENSION Study of dalzanemdor (SAGE-718) in participants with cognitive impairment (CI) associated with Huntington's Disease (HD). In the study, dalzanemdor did not demonstrate a statistically significant difference versus placebo on the primary endpoint, the change from baseline on the Symbol Digit Modalities Test (SDMT) at Day 84. Analyses of secondary endpoints did not demonstrate statistically significant or clinically meaningful differences in participants treated with dalzanemdor compared to placebo. Based on these results, the Company does not plan further development of dalzanemdor.

"We are disappointed by the results of the DIMENSION Study, especially for the individuals and families affected by Huntington's Disease who have long awaited new treatment options," said Barry Greene, Chief Executive Officer, Sage Therapeutics. "Innovation is desperately needed, and we are immensely grateful to the participants, investigators, and the entire Huntington's Disease community whose unwavering commitment to advancing research helped make this study possible."

DIMENSION Study Results

The DIMENSION Study was a 12-week, double-blind, placebo-controlled Phase 2 study to evaluate the effects of dalzanemdor in participants with CI associated with HD. A total of 189 participants were randomized.

- The DIMENSION Study did not demonstrate a statistically significant difference from baseline in participants treated with dalzanemdor versus placebo on the SDMT, a measure of cognitive function, at Day 84, the primary endpoint.
- 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 of secondary endpoints did not demonstrate statistically significant or clinically meaningful differences between the dalzanemdor and placebo treatment groups.

Given these findings, the Company also will close the ongoing PURVIEW Study, an open-label safety study of dalzanemdor in participants with HD.

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 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 plan not to further develop dalzanemdor and to close the PURVIEW Study; 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 ongoing, planned or future clinical trials or nonclinical work with respect to any of our product candidates may be negative like the results we announced today from the DIMENSION Study; 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; 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.

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