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): July 24, 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.)**

215 First Street **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 July 24, 2024, Sage Therapeutics, Inc. issued a press release titled "Sage Therapeutics and Biogen Announce Topline Results from Phase 2 KINETIC 2 Study of SAGE-324 (BIIB124) for the Treatment of Essential Tremor." 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 July 24, 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: July 24, 2024

SAGE THERAPEUTICS, INC.

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

Exhibit 99.1

Sage Therapeutics and Biogen Announce Topline Results from Phase 2 KINETIC 2 Study of SAGE-324 (BIIB124) for the Treatment of Essential Tremor

- *SAGE-324 (BIIB124) did not demonstrate a statistically significant dose-response relationship on the primary endpoint in participants with essential tremor*
- *No statistically significant differences were demonstrated between any dose of SAGE-324 and placebo in the change from baseline for the primary endpoint*

CAMBRIDGE Mass. – July 24, 2024 – Sage Therapeutics, Inc. (NASDAQ: Sage) and Biogen Inc. (NASDAQ: BIIB) announced topline results from the Phase 2 KINETIC 2 dose-range study of the oral investigational drug SAGE-324 (BIIB124) as a potential treatment in essential tremor (ET). The KINETIC 2 Study did not demonstrate a statistically significant dose-response relationship in change from baseline to Day 91 based on the primary endpoint, The Essential Tremor Rating Assessment Scale (TETRAS) Performance Subscale (PS) Item 4 (upper limb) total score, in participants with ET. In addition, there were no statistically significant differences demonstrated for any dose of SAGE-324 versus placebo in the change from baseline to Day 91 on the TETRAS PS Item 4 Total Score or the TETRAS Activities of Daily Living (ADL) Composite Score. Given these results, Sage and Biogen will close the ongoing open label safety study of SAGE-324 in ET and do not plan to conduct further clinical development of SAGE-324 in ET. The companies are evaluating next steps, if any, for other potential indications.

“There has been little innovation in the pharmacological treatment of essential tremor over the past 50 years, and people living with this debilitating condition have a pressing need for new treatment options. We are disappointed that the results of the KINETIC 2 Study do not support further development of SAGE-324 in ET. We are grateful to the essential tremor community and study investigators for their contributions to this research,” said Laura Gault, MD, PhD, Chief Medical Officer, Sage Therapeutics. “As always, Sage remains steadfast in our work to develop new treatments for people suffering from brain health conditions.”

“We wish to thank the study participants and investigators who made this important research possible. While we share in their disappointment, we believe that the findings add to the collective understanding of this debilitating condition and may help inform the field on potential future research and therapeutic approaches,” said Katherine Dawson, MD, Head of Therapeutics Development Unit, Biogen.

KINETIC 2 Study Results

The KINETIC 2 Study was designed to evaluate the dose-response relationship of different doses of SAGE-324 on upper limb tremor. The study also evaluated the safety and tolerability of SAGE-324. The primary outcome measure was TETRAS PS Item 4 Total Score at Day 91, and the primary analysis assessed the dose-response relationship across SAGE-324 doses on this measure. Additional analyses evaluated the change from baseline to Day 91 on the TETRAS PS Item 4 Total Score and the secondary endpoint, TETRAS ADL Composite Score, for each dose of SAGE-324 versus placebo.

In the study, 147 participants (129 monotherapy and 18 adjunct therapy, on a stable dose of propranolol prior to and during the study) were randomized in approximately equal proportions to placebo, 15 mg, 30 mg, and 60 mg (with uptitration) for a three-month treatment period.

- SAGE-324 did not demonstrate a statistically significant dose-response relationship on the primary endpoint in participants with ET.
- No statistically significant differences were demonstrated between any dose of SAGE-324 and placebo in the change from baseline at Day 91 on the TETRAS PS Item 4 Total Score or TETRAS ADL Composite Score.
- Overall, there was a dose-relationship observed in the incidence of CNS depressant treatment emergent adverse events (TEAEs) and in the frequency of TEAEs leading to study drug discontinuation.
- The most common TEAEs reported in any treatment group were somnolence, dizziness, fatigue, feeling abnormal, headache, and balance disorder. The majority of TEAEs were mild or moderate in intensity.

About SAGE-324 / BIIB124

SAGE-324 is an investigational oral neuroactive steroid (NAS) $GABA_A$ receptor positive allosteric modulator (PAM). NAS $GABA_A$ receptor PAMs bind to both synaptic and extrasynaptic $GABA_A$ receptors, enhancing inhibitory activity of the GABAergic system, the major inhibitory neurotransmission system in the brain. GABA is the primary inhibitory neurotransmitter in the central nervous system and plays a critical role in maintaining balanced neuronal activity in the brain. GABA dysregulation has been implicated in the pathophysiology of ET. The safety and effectiveness of SAGE-324 have not been established.

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.

About Biogen

Founded in 1978, Biogen is a leading biotechnology company that pioneers innovative science to deliver new medicines to transform patients' lives and to create value for shareholders and our communities. We apply deep understanding of human biology and leverage different modalities to advance first-in-class treatments or therapies that deliver superior outcomes. Our approach is to take bold risks, balanced with return on investment to deliver long-term growth.

The company routinely posts information that may be important to investors on its website at www.biogen.com. Follow Biogen on social media – Facebook, LinkedIn, X, YouTube.

Sage Forward-Looking Statements

Various statements in this release concern future expectations, plans and prospects, including without limitation statements regarding: Sage's work to develop new treatments for people suffering from brain health conditions; plans to evaluate next steps for the program and the mission, goals, opportunity and potential for Sage's 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 Sage's control, which could cause actual results to differ materially from those contemplated in these forward-looking statements, including the risks that: Sage and Biogen may, jointly or individually, decide not to pursue any further development of SAGE-324 in any indication; the results of

ongoing, planned or future clinical studies or nonclinical work with respect to any of Sage's product candidates may be negative like the results announced today from the KINECTIC 2 Study of SAGE-324 in essential tremor; results of earlier trials of any of Sage's other product candidates may not be replicated in ongoing or future trials; clinical and nonclinical data Sage generates in the course of any development program may not be sufficient to move to the next phase of development for an indication or may not support further development at all; additional analysis of clinical trial results may not result in a path forward for development; Sage 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; Sage may encounter delays in initiation, conduct or completion of ongoing or future clinical trials or reporting of clinical trial results, including as the result of the need to meet with regulatory authorities, or as a result of actions arising from those meetings, that may impact Sage's ability to meet its expected time-lines; the FDA may not agree with Sage's view of the data Sage generates from its development efforts at any stage; 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 Sage's product candidates in an indication or its 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 such product candidates in any indication or of any of Sage's product candidates in any indications that are the focus of development programs and plans; the internal and external costs required for ongoing and planned activities may cause Sage to change or curtail some of its plans; Sage may encounter technical and other unexpected hurdles in the development and manufacture of its product candidates which may delay its timing or change its plans; as well as those risks more fully discussed in the section entitled "Risk Factors" in Sage's most recent Quarterly Report on Form 10-Q, and discussions of potential risks, uncertainties, and other important factors in subsequent filings with the Securities and Exchange Commission. In addition, any forward-looking statements represent Sage's views only as of today, and should not be relied upon as representing its views as of any subsequent date. Sage explicitly disclaims any obligation to update any forward-looking statements.

Biogen Safe Harbor

This news release contains forward-looking statements, including statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, relating to the potential, benefits, safety and efficacy of SAGE-324; the potential clinical effects of SAGE-324; the clinical development program, clinical trials, data readouts and presentations related to SAGE-324; the treatment of essential tremor; the potential of Biogen's commercial business and pipeline programs, including SAGE-324; the anticipated benefits and potential of Biogen's collaboration arrangements with Sage; and risks and uncertainties associated with drug development and commercialization. These forward-looking statements may be accompanied by words such as "aim," "anticipate," "believe," "could," "estimate," "expect," "forecast," "hope," "intend," "may," "plan," "potential," "possible," "will," "would" and other words and terms of similar meaning. Drug development and commercialization involve a high degree of risk and only a small number of research and development programs result in commercialization of a product. Results in early-stage clinical trials may not be indicative of full results or results from later stage or larger scale clinical trials and do not ensure regulatory approval. You should not place undue reliance on these statements, or the scientific data presented.

These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements, including without limitation, uncertainty of success in the development and potential commercialization of SAGE-324; unexpected concerns may arise from additional data, analysis or results obtained during the KINETIC Study; regulatory authorities may require additional information or further studies, or may fail or refuse to approve or may delay approval of Biogen's drug candidates, including SAGE-324; the occurrence of adverse safety events; the risks of other unexpected hurdles, costs or delays; uncertainty of success in the development of SAGE-324; failure to protect and enforce data, intellectual property and other proprietary rights and uncertainties relating to intellectual property claims and challenges; the direct and indirect impacts of the ongoing COVID-19 pandemic on Biogen's business, results of operations and financial condition; product liability claims; and third party collaboration risks. The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from Biogen's expectations in any forward-looking statement. Investors should consider this cautionary statement as well as the risk factors identified in Biogen's most recent annual or quarterly report and in other reports Biogen has filed with the U.S. Securities and Exchange Commission. These statements are based on Biogen's current beliefs and expectations and speak only as of the date of this news release. Biogen does not undertake any obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise.

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