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): September 12, 2017

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))

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 September 12, 2017, Sage Therapeutics, Inc. issued a press release titled, “Sage Therapeutics Reports Top-Line Results from Phase 3 STATUS Trial of Brexanolone in Super-Refractory Status Epilepticus” (the “Press Release”). A copy of the Press Release is filed herewith as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, issued by the Registrant on September 12, 2017.

* * *

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: September 12, 2017

SAGE THERAPEUTICS, INC.

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

Exhibit Index

Exhibit No.	Description
99.1	Press Release, issued by the Registrant on September 12, 2017.

Sage Therapeutics Reports Top-Line Results from Phase 3 STATUS Trial of Brexanolone in Super-Refractory Status Epilepticus

— Study did not achieve its primary endpoint in first-of-its kind trial for patients suffering from life-threatening seizure condition —

CAMBRIDGE, Mass., September 12, 2017 — Sage Therapeutics (NASDAQ: SAGE), a clinical-stage biopharmaceutical company developing novel medicines to treat life-altering central nervous system (CNS) disorders, today reported top-line results from its Phase 3 STATUS Trial of brexanolone (SAGE-547) in the treatment super-refractory status epilepticus (SRSE). The study did not meet the primary endpoint, comparing success in weaning of third-line agents and resolution of potentially life-threatening status epilepticus with brexanolone vs. placebo (43.9% vs 42.4%; p=0.8775) when added to standard-of-care.

Demographics and baseline characteristics were well-balanced between treatment groups in the study. Due to the severity and complexity of their underlying medical conditions, serious adverse events commonly occur in patients with SRSE and were similar in frequency and type between the two treatment groups. SRSE, a life-threatening persistent state of seizure that does not respond to first-, second- or third-line treatments, is a neurological emergency that may cause death or life-altering outcomes. There are no treatments for SRSE currently approved by the U.S. Food and Drug Administration (FDA).

“I’m proud of the Sage team for the significant progress they have made in improving our understanding of how to best treat these critically ill patients,” said Jeff Jonas, M.D., Chief Executive Officer of Sage. “SRSE is a complicated condition that is poorly understood, and I want to thank the patients, their families, and the investigators who participated in the STATUS Trial. Although we did not meet the primary endpoint, this first-ever trial in a highly variable and complex patient population confirms that research in a critical care unit is possible and deepens our understanding of GABA mechanisms and their effect on brain circuitry. As we continue examining data from the STATUS Trial in the coming weeks, I’m hopeful this information will inform current treatments, and aid in the development of future treatments for patients with SRSE.”

The STATUS Trial was conducted under a Special Protocol Assessment (SPA) agreement with the FDA and was designed to evaluate the efficacy and safety of brexanolone in patients with SRSE, ages two years or older, in the U.S., Canada and Europe. In the double-blind trial, 132 patients were randomized 1:1 to receive either brexanolone or placebo in addition to standard-of-care third-line anti-seizure agents for six days. Patients who failed to respond to brexanolone or placebo were subsequently eligible for an open-label infusion of brexanolone at a higher dose over a 6-day period.

“SRSE is an extremely complicated condition to treat and there is a significant unmet need for new treatments,” said Eric Rosenthal, M.D., co-Principal Investigator of the STATUS Trial, Associate Director of the Neurosciences Intensive Care Unit and faculty member of the Epilepsy Service at Massachusetts General Hospital. “We have learned a great deal from the STATUS

Trial and while I share the disappointment of patients and their families who participated in the trial, the STATUS Trial represents a significant contribution to SRSE research and I hope these data will provide a foundation for development of future treatments for patients with this devastating condition."

Summary of Top-line Brexanolone Phase 3 STATUS Trial Results

Efficacy:

- The study did not meet the primary endpoint of the trial, with 43.9 percent of patients treated with brexanolone versus 42.4 percent of patients treated with placebo (p=0.8775) successfully weaned from third-line agents during the double-blind period, and remaining free of status epilepticus activity for at least the 24 hours following the end of treatment without the need to reinstate the third-line agents.
- Secondary endpoint results were consistent with the primary endpoint.
- Approximately 37 percent of patients treated with open-label brexanolone after the end of the double-blind period achieved treatment response.
- Demographics and baseline characteristics were well-balanced between patients randomized to brexanolone and placebo.

Safety:

- Consistent with the severity and complexity of SRSE, patients' underlying conditions, and ongoing ICU treatment nearly all patients experienced adverse events.
- Serious adverse events were similar between the two treatment groups.
- The rate of death was similar in the brexanolone and placebo groups.
- The rate of adverse events leading to discontinuation of study drug was similar in the brexanolone and placebo groups and was low overall.

Sage intends to present detailed results from the STATUS Trial at an upcoming medical meeting.

Conference Call Information

Sage will host a conference call and webcast today at 7:30 AM ET to discuss the top-line results from its Phase 3 STATUS Trial of brexanolone in SRSE. The live webcast can be accessed on the investor page of Sage's website at investor.sagerx.com. The conference call can be accessed by dialing 1-866-450-8683 (toll-free domestic) or 1-281-542-4847 (international) and using conference ID 84426351. A replay of the webcast will be available on Sage's website approximately two hours after the completion of the event and will be archived for up to 30 days.

About Super-Refractory Status Epilepticus

Status epilepticus (SE) is an acute medical emergency of persistent, unremitting seizure lasting greater than five minutes. An SE patient is first treated with benzodiazepines, and if no response, is then treated with other, second-line, anti-seizure drugs. If the seizure persists after the second-line therapy, the patient is diagnosed as having refractory SE (RSE), admitted to the ICU and placed into a medically induced coma. Physicians typically use anesthetic agents to induce the coma, along with antiepileptic drugs in an attempt to stop the ongoing seizure, in RSE patients. After a period of 24 hours, an attempt is made to wean the patient from the anesthetic agents to evaluate whether or not the seizure condition has resolved. Unfortunately,

not all patients respond to weaning attempts, in which case the patient must be maintained in the medically induced coma. At this point, the patient is diagnosed as having SRSE. Sage estimates that there are between 25,000 and 41,000 cases of SRSE in the U.S. each year. Currently, there are no therapies specifically approved for SRSE.

About the STATUS Trial

Sage designed the pivotal Phase 3 STATUS Trial to evaluate the efficacy and safety of brexanolone in patients with SRSE, ages two years or older, in the U.S., Canada and Europe. In the double-blind trial, 132 patients were randomized 1:1 to receive either brexanolone or placebo in addition to standard-of-care third-line anti-seizure agents for six days. The primary endpoint compared success in weaning of third-line agents and resolution of status epilepticus with brexanolone vs. placebo prior to completion of study treatment and continuing during 24 hours after completion of study treatment without the need to reinstate the third-line agents. The STATUS Trial was conducted under a Special Protocol Assessment (SPA) agreement with the FDA.

About Brexanolone (SAGE-547)

Brexanolone is an allosteric modulator of both synaptic and extrasynaptic $GABA_A$ receptors. Brexanolone is an intravenous agent that was evaluated as an adjunctive therapy for the treatment of super-refractory status epilepticus (SRSE) in the global Phase 3 STATUS Trial. Brexanolone has been granted both Fast Track and orphan drug designations by the FDA for the treatment of SRSE.

Brexanolone is also being developed for the treatment of postpartum depression (PPD) and has been granted Breakthrough Therapy designation by the FDA and PRIority MEdicines (PRIME) designation from the European Medicines Agency (EMA) in PPD. Sage is currently evaluating brexanolone in a Phase 3 development program for the treatment of PPD. For more information about these trials, please visit https://thehummingbirdstudy.com/.

About Sage Therapeutics

Sage Therapeutics is a clinical-stage biopharmaceutical company committed to developing novel medicines to transform the lives of patients with life-altering central nervous system (CNS) disorders. Sage has a portfolio of novel product candidates targeting critical CNS receptor systems, GABA and NMDA. Sage's lead program, brexanolone (SAGE-547) completed a Phase 3 trial for super-refractory status epilepticus, a rare and severe seizure disorder, and is in Phase 3 clinical development for postpartum depression. Sage is developing its next generation modulators, including SAGE-217 and SAGE-718, in various CNS disorders. For more information, please visit www.sagerx.com.

Forward-Looking Statements

Various statements in this release concern Sage's future expectations, plans and prospects, including without limitation: our expectations regarding the development of our product candidates and their potential in the treatment of various CNS disorders. 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: we may not be able to generate supportive non-clinical

or clinical data sufficient to continue clinical development or to successfully demonstrate the efficacy and safety of our product candidates at each stage of clinical development; success in our non-clinical studies or in earlier stage clinical trials may not be repeated or observed in ongoing or future studies involving the same compound or other product candidates; we may experience delays in enrollment of our clinical trials or the need for additional data; decisions or actions of regulatory agencies may affect the timing of our clinical trials or future regulatory submissions, and regulatory authorities may not agree with our interpretation of the results of our non-clinical and clinical studies, and may make decisions that negatively impact our ability to continue development or to gain approval, including the risk that regulatory authorities may, despite prior advice, decide that the clinical and non-clinical data from a development program are not sufficient to support approval; we may encounter unexpected adverse events or other safety issues related to any of our product candidates that may impact further development or our chances of obtaining regulatory approval; and we may encounter technical and other unexpected hurdles in the development and manufacture of our product candidates which may delay our timing or increase our expenses, as well as those risks more fully discussed in the section entitled "Risk Factors" in our most recent Quarterly Report on Form 10-Q, as well as 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. We explicitly disclaim any obligation to update any forward-looking statements.

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