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 9, 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 November 9, 2017, Sage Therapeutics, Inc. issued a press release titled, "Sage Therapeutics Announces Brexanolone Achieves Primary Endpoints in Both Phase 3 Clinical Trials in Postpartum Depression" (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 November 9, 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: November 9, 2017

SAGE THERAPEUTICS, INC.

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

Exhibit 99.1

Sage Therapeutics Announces Brexanolone Achieves Primary Endpoints in Both Phase 3 Clinical Trials in Postpartum Depression

Statistically significant mean reduction in the HAM-D score compared to placebo at 60 hours demonstrated in both trials

Brexanolone provided a rapid and durable reduction over 30 days in depressive symptoms as measured by HAM-D in both placebo-controlled multi-center trials

Positive results support planned regulatory submissions; Company to host conference call today at 8:00 A.M. ET

CAMBRIDGE, Mass. November 9, 2017 – Sage Therapeutics (NASDAQ: SAGE), a clinical-stage biopharmaceutical company developing novel medicines to treat life-altering central nervous system (CNS) disorders, today announced positive top-line results from two Phase 3 clinical trials with its proprietary i.v. formulation of brexanolone (USAN; formerly SAGE-547); Study 202B in severe postpartum depression (PPD) and Study 202C in moderate PPD. Brexanolone achieved the primary endpoint in both trials, a mean reduction from baseline in the Hamilton Rating Scale for Depression (HAM-D) total score compared to placebo at 60 hours (Study 202B: p=0.0242 for 90 µg/kg/h dose and p=0.0011 for 60 µg/kg/h dose; Study 202C: p=0.0160 for 90 µg/kg/h dose). Patients treated with brexanolone demonstrated mean reductions from baseline in HAM-D total scores of 14 to 20 points at 60 hours maintained to 30 days in both trials. Brexanolone was generally well tolerated and showed a similar safety profile as seen in earlier studies.

PPD is a common biological complication of childbirth affecting a subset of women typically commencing in the third trimester of pregnancy or within four weeks after giving birth. It is estimated that PPD affects approximately 10 to 20 percent of women giving birth in the U.S. and up to half of these cases may go undiagnosed without proper screening. There are no approved therapies for PPD and there is a clear unmet medical need for treatment.

“PPD is commonly viewed as a disorder solely experienced by the mother, but it also seriously impacts the child and family members – both immediate and extended,” said Dr. Samantha Meltzer-Brody, M.D., M.P.H., associate professor and director of UNC Perinatal Psychiatry Program of the UNC Center for Women’s Mood Disorders and primary investigator of the studies. “Symptoms of PPD should not be overlooked by new moms or those in their support networks and the healthcare community should encourage discussion and appropriate action. These data meaningfully advance our understanding of PPD and may prompt medical professionals to evaluate how PPD is perceived, identified and treated within their practices in the future. In these studies, brexanolone provided a profound and durable effect over the study period that could be an important step in potentially changing the way health care providers think about treating this disorder.”

The Hummingbird Phase 3 program included two Phase 3, multicenter, randomized, double-blind, parallel-group, placebo-controlled trials designed to evaluate the safety and effectiveness of brexanolone in women with moderate and severe PPD. Entry criteria for participants included depressed mood and/or loss of interest and associated symptoms of depression, including appetite problems, sleep problems, motor problems, lack of concentration, loss of energy, poor self-esteem and suicidality that began no earlier than the third trimester and no later than the first four weeks following delivery.

“This is the first Phase 3 program conducted specifically in women with PPD and these results exemplify the value of Sage’s distinct approach to clinical research,” said Jeff Jonas, M.D., chief executive officer of Sage. “We are pleased with the findings, specifically the rapid onset of action and duration of effect observed in all arms of the Hummingbird program. We believe the data represent an unprecedented opportunity in the development of treatments for PPD, and may serve as the catalyst for a paradigm shift in how the disease is approached and, if approved, may change how PPD is treated.”

"Today illustrates what an exciting time it is in CNS research and drug development," said Steve Kanes, M.D., Ph.D., chief medical officer of Sage. "Sage is deliberately pursuing a translational clinical strategy that can expedite medical innovation and potentially transform the lives of patients. This strategy begins with open label trials in a carefully selected disease indication, such as PPD, where patients are in need of transformative treatment options. Our approach seeks to establish signals for safety and activity and if a signal is observed, we move efficiently into later stage development. Our brexanolone research for a treatment in PPD followed this path, resulting in the successful data we are announcing today."

Summary of Top-line Brexanolone Phase 3 Results

Effect on Postpartum Depressive Symptoms:

- In both trials at all doses, brexanolone achieved the primary endpoint, a significant mean reduction from baseline in the HAM-D total score at 60 hours compared to placebo.
    - Study 202B - Patients with severe PPD (n=122):
        - Patients were randomized to one of three treatment groups (brexanolone 90 µg/kg/hour, brexanolone 60 µg/kg/hour, or placebo) on a 1:1:1 basis.
        - Brexanolone 90 µg/kg/hour treatment was associated with a statistically significant mean reduction in HAM-D total score of 17.7 points from baseline compared with a 14.0 point mean reduction in HAM-D total score associated with placebo (p=0.0242).
        - Brexanolone 60 µg/kg/hour treatment was associated with a statistically significant mean reduction in HAM-D total score of 19.9 points from baseline compared with a 14.0 point mean reduction in HAM-D total score associated with placebo (p=0.0011).
        - Statistically significant differences in the reduction in HAM-D total score of brexanolone versus placebo were first observed at 48 hours and the effect at 60 hours was maintained through the 30-day follow-up with statistical significance for both brexanolone dose groups.
        - Improvement in the Clinical Global Impression – Improvement scale (CGI-I) at 60 hours was consistent with the primary endpoint (p=0.0096 for 90 µg/kg/h dose and p=0.0124 for 60 µg/kg/h dose).
    - Study 202C - Patients with moderate PPD (n=104):
        - Patients were randomized to one of two treatment groups (brexanolone 90 µg/kg/hour or placebo) on a 1:1 basis.
        - Brexanolone treatment was associated with a statistically significant mean reduction in HAM-D total score of 14.2 points from baseline at 60 hours (p=0.0160) compared with a 12.0 point mean reduction in HAM-D total score associated with placebo.
        - Statistical significance was first observed at 48 hours and remained through Day 7, but not at Day 30. However, the effect observed at 60 hours in the brexanolone group was maintained through the 30-day follow-up.
        - Improvement in the Clinical Global Impression – Improvement scale (CGI-I) at 60 hours was consistent with the primary endpoint (p=0.0005).

Safety and Tolerability:

- Brexanolone was generally well tolerated in both studies with similar rates of adverse events across all treatment groups.
- In each trial, there was one patient who experienced a serious adverse event; neither required hospitalization and one of which was deemed by the investigator not to be study-drug related.
- The most common adverse events in the studies were headache, dizziness, and somnolence.

Detailed study results, including additional secondary endpoints, will be submitted for presentation at an upcoming medical meeting and for publication. Sage believes these data will be sufficient to support submissions of regulatory applications seeking approval of brexanolone for PPD. Sage plans to file a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) in 2018.

About the Hummingbird Program: 202B and 202C

The Hummingbird program included two Phase 3 multicenter, randomized, double-blind, parallel-group, placebo-controlled trials (Study 202B and Study 202C), designed to evaluate the safety and effectiveness of brexanolone in women with moderate and severe postpartum depression (PPD), aged between 18 and 45 years (inclusive) who were ≤6 months postpartum at screening in the United States.

- Patients enrolled in both trials (202B; 202C) were required to have had a Major Depressive Episode that began no earlier than the third trimester and no later than the first four weeks following delivery, and to also be less than six months postpartum at the time of enrollment.
- Trial participants in 202B were required to have a HAM-D score of 26 or above prior to treatment. These patients were randomized to one of three treatment groups (brexanolone 90 μg/kg/hour, brexanolone 60 μg/kg/hour, or placebo) on a 1:1:1 basis.
- Trial participants in 202C were required to have a HAM-D score of between 20 and 25 prior to treatment. These patients were randomized to one of two treatment groups (brexanolone 90 μg/kg/hour or placebo) on a 1:1 basis.

For more information about these trials, please visit https://thehummingbirdstudy.com/.

Conference Call Information

Sage will host a conference call and webcast today at 8:00 A.M. ET to discuss the top-line results from the Phase 3 brexanolone Hummingbird trials in PPD. 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 866-450-8683 (toll-free domestic) or 281-542-4847 (international) and use the conference ID 7592007. 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 Postpartum Depression

Postpartum depression (PPD) is a distinct and readily identified major depressive disorder that is a biological complication of childbirth, affecting a subset of women typically commencing in the third trimester of pregnancy or within four weeks after giving birth. PPD may have devastating consequences for a woman and for her family, which may include significant functional impairment, depressed mood and/or loss of interest in her newborn, and associated symptoms of depression such as loss of appetite, difficulty sleeping, motor challenges, lack of concentration, loss of energy and poor self-esteem. Suicide is the leading cause of maternal death following childbirth. It is estimated that PPD affects approximately 10 to 20 percent of women giving birth in the U.S. and up to half of these cases may go undiagnosed without proper screening. There are no approved therapies for PPD and there is a high unmet medical need for improved pharmacological therapy in PPD.

About the Hamilton Rating Scale for Depression (HAM-D)

HAM-D is a validated rating scale used to provide an assessment of depression, and as a guide to evaluate recovery. This scale is an accepted regulatory endpoint for depression. The scale is used to rate the severity of their depression by probing mood, feelings of guilt, suicide ideation, insomnia, agitation, anxiety, weight loss, and somatic symptoms.

About Brexanolone (SAGE-547)

Brexanolone (SAGE-547) is an allosteric modulator of both synaptic and extrasynaptic $GABA_A$ receptors. Allosteric modulation of neurotransmitter receptor activity results in varying degrees of desired activity rather than complete activation or inhibition of the receptor. Sage's proprietary i.v. formulation of brexanolone is 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.

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, a proprietary i.v. formulation of brexanolone (SAGE-547), 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 potential for brexanolone in the treatment of PPD; our view as to the unmet need for additional treatment options in PPD and how brexanolone might address the needs of PPD patients and families, if successfully developed and approved; our estimate as to the number of patients with PPD; our plans and expectations with respect to future regulatory submissions and activities related to brexanolone and ongoing development; our views as to the potential for approval of brexanolone and future commercialization and the impact on our company; and our expectations regarding development, planned activities and the potential for success of our other product candidates. 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 clinical and non-clinical data we have generated to date may be determined by regulatory authorities, despite prior advice, to be insufficient to file for or gain regulatory approval to launch and commercialize our proprietary formulation of brexanolone and regulatory authorities may determine that additional trials or data are necessary in order to file for or obtain approval; regulatory authorities may find fault with the data generated at particular clinical site or sites or with the activities of our trial monitor or may disagree with our analyses of the results of our trials or identify issues with our manufacturing or quality systems, and any such findings or issues could require additional data or analyses or changes to our systems that could delay or prevent us from gaining approval of brexanolone; we may encounter unexpected safety or tolerability issues with brexanolone or any of our product candidates in ongoing or future development; the number of patients with PPD or the unmet need for additional treatment options may be significantly smaller than we expect; we may not be able to successfully demonstrate the efficacy and safety of any of our other product candidates at each stage of development; success in early stage clinical trials may not be repeated or observed in ongoing or future studies; the efficacy data generated in ongoing or future clinical trials may be negative or less robust than we expect; ongoing or future clinical trials may not support further development of our other product candidates or be sufficient to gain regulatory approval to market any product; decisions or actions of regulatory agencies may affect the initiation, timing, progress, number, size and cost of clinical trials, and our ability to proceed with further clinical trials of a product candidate in a particular indication, or at all, or our ability to obtain marketing approval; we may decide that a development pathway for a product candidate in one or more indications is no longer feasible or advisable or that the unmet need no longer exists; and we may encounter technical and other unexpected hurdles in the development and manufacture of our product candidates; 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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