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 2, 2018

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 2, 2018, Sage Therapeutics, Inc. issued a press release announcing the results of the previously announced joint public meeting of the Psychopharmacologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee of the Food and Drug Administration held on November 2, 2018.

A copy of this press release is furnished hereto as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by Sage Therapeutics, Inc. on November 2, 2018, furnished herewith.

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 2, 2018

SAGE THERAPEUTICS, INC.

By: /s/ Jennifer Fitzpatrick
Jennifer Fitzpatrick
Vice President, Corporate Counsel

EXHIBIT 99.1

Sage Therapeutics Announces FDA Advisory Committee Votes 17-1 in Support of Benefit-Risk Profile of ZULRESSO™ (brexanolone) Injection for Treatment of Postpartum Depression

If approved, ZULRESSO would be the first medicine specifically indicated for the treatment of postpartum depression (PPD)

CAMBRIDGE, Mass. Nov. 2, 2018 – Sage Therapeutics (NASDAQ: SAGE), a clinical-stage biopharmaceutical company developing novel medicines to treat life-altering central nervous system (CNS) disorders, today announced that the U.S. Food and Drug Administration (FDA) Psychopharmacologic Drugs Advisory Committee (PDAC) and Drug Safety and Risk Management Advisory Committee (DSaRM) jointly voted (17 yes, 1 no) that data support the favorable benefit-risk profile of ZULRESSO™ (brexanolone) injection for the treatment of postpartum depression (PPD) when administered by qualified staff in a facility that has been certified under a Risk Evaluation and Mitigation Strategies (REMS) program. The committees based their joint recommendation on the safety and efficacy data from three placebo-controlled clinical studies.

“We are pleased the FDA Advisory Committee agreed that the benefit/risk profile of ZULRESSO supports this novel approach to treating PPD, reflecting the need for an innovative treatment option that may rapidly alleviate suffering for women with PPD and their families,” said Jeff Jonas, M.D., chief executive officer of Sage. “This is another step forward in Sage’s effort to maximize patient benefit by bringing game-changing new treatments to the market.”

ZULRESSO is the first medicine under FDA review specifically for the treatment of PPD, the most common medical complication of childbirth. It is estimated that PPD affects approximately one in nine women who have given birth in the U.S. and 400,000 women annually. Symptoms of PPD may include sadness, anxiety, irritability, withdrawing from friends or family, having trouble bonding with her baby and thinking about harming herself or, more rarely, her baby.

Sage will further discuss the advisory committee’s outcome during the company’s next financial results conference call on November 6, 2018 at 8:00 AM ET. 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 the conference ID 1891169. 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 the most common medical 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. Postpartum depression is estimated to affect approximately one in nine women who have given birth in the U.S. and 400,000 women annually. More than half of these cases may go undiagnosed without proper screening. There are no FDA approved therapies specifically indicated for PPD and there is a high unmet medical need for improved pharmacological therapy in PPD.

About ZULRESSO™ (brexanolone) Injection

Brexanolone is an allosteric modulator of both synaptic and extrasynaptic GABAA receptors. Allosteric modulation of neurotransmitter receptor activity results in varying degrees of desired activity rather than

complete activation or inhibition of the receptor. ZULRESSO™ (brexanolone) injection has completed Phase 3 clinical development for postpartum depression and a New Drug Application is currently under review with the U.S. Food and Drug Administration. ZULRESSO for the treatment of PPD has been granted Breakthrough Therapy Designation by the FDA and PRIority MEdicines (PRIME) designation from the European Medicines Agency (EMA). The FDA has conditionally accepted the proprietary name ZULRESSO for Sage's intravenous formulation of brexanolone.

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 CNS disorders. Sage's lead product candidate, ZULRESSO™ (brexanolone) injection, has completed Phase 3 clinical development for postpartum depression and a New Drug Application is currently under review with the U.S. Food and Drug Administration. Sage is developing a portfolio of novel product candidates targeting critical CNS receptor systems, including SAGE-217, which is in Phase 3 development in major depressive disorder and postpartum depression. 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 statements regarding: our expectations regarding the possible approval of our NDA filing for ZULRESSO™ (brexanolone) injection; the potential for ZULRESSO to be the first medication specifically indicated for PPD; the potential impact of ZULRESSO as a treatment option for PPD, if approved; our estimates of the prevalence of PPD; and other statements regarding our business and portfolio. 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 FDA may not agree with the recommendations of the joint Advisory Committee, and, despite the recommendation, may determine that the clinical and non-clinical data we have generated to date are insufficient to gain regulatory approval to launch and commercialize our product in PPD or may determine that additional trials or data are necessary in order to obtain approval; the FDA may not complete its review of our filing within the target timelines; the actual size of the PPD patient population may be significantly lower than our estimates and, even if ZULRESSO is successfully approved for PPD, it may only be used to treat a subset of the PPD population, particularly given the intravenous (IV) mode of administration, limitations on site of administration to a certified healthcare facility monitored by a qualified healthcare provider, and the necessity for a REMS; we may encounter unexpected safety, tolerability or other issues with ZULRESSO in ongoing clinical trials or in commercial use, if approved; 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 of any of our product candidates in early stage clinical trials may not be repeated or observed in ongoing or future studies of our product candidates; ongoing and future clinical results may not support further development or be sufficient to gain regulatory approval to market our product candidates; 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, 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. We explicitly disclaim any obligation to update any forward-looking statements.

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