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): May 30, 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 May 30, 2018, Sage Therapeutics, Inc. issued a press release titled, “Sage Therapeutics Announces FDA Acceptance of NDA Filing and Grant of Priority Review for Brexanolone IV in the Treatment of 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 May 30, 2018.

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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: May 30, 2018

SAGE THERAPEUTICS, INC.

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

Sage Therapeutics Announces FDA Acceptance of NDA Filing and Grant of Priority Review for Brexanolone IV in the Treatment of Postpartum Depression

Priority Review status expected to accelerate review period; PDUFA date set for December 19, 2018

If approved, brexanolone IV would be the first and only medication indicated for the treatment of postpartum depression

CAMBRIDGE, Mass. May 30, 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) has accepted the filing of a New Drug Application (NDA) for Sage's lead product candidate, an intravenous formulation of brexanolone (SAGE-547) for the treatment of postpartum depression (PPD). The NDA was granted Priority Review status and the FDA assigned a Prescription Drug User Fee Act (PDUFA) target date of December 19, 2018. As expected for a new molecular entity with a new mechanism of action, the FDA is currently planning to hold an advisory committee meeting to discuss the brexanolone IV application.

If approved, brexanolone IV would be the first medication indicated for the treatment of PPD and would be Sage Therapeutics' first commercial product. The FDA grants Priority Review to investigational therapies that, if approved, may offer significant improvements in the treatment, prevention or diagnosis of a serious condition. Brexanolone IV received Breakthrough Therapy Designation in September 2016, underscoring the significant unmet need in women with PPD.

PPD is the most common medical complication of childbirth affecting a subset of women typically commencing in the third trimester of pregnancy or in the months after giving birth. In the U.S., estimates of new mothers identified with PPD each year vary by state from eight to 20 percent, with an overall average of 11.5 percent. There are no approved therapies for PPD, and there is a clear unmet medical need for treatment.

The NDA is supported by data from the Hummingbird Program, two Phase 3 multicenter, randomized, double-blind, parallel-group, placebo-controlled trials in the U.S. (Study 202B and Study 202C), designed to evaluate the safety and effectiveness of brexanolone in women with moderate and severe PPD, aged between 18 and 45 years (inclusive) who were £6 months postpartum at screening and who had onset of symptoms no earlier than the third trimester and no later than the first four weeks following delivery. In both trials at all doses, brexanolone achieved the primary endpoint, a significant mean reduction from baseline in the Hamilton Rating Scale for Depression (HAM-D) total score at 60 hours compared to placebo. Brexanolone was generally well-tolerated in both studies with similar rates of adverse events (AEs) across all treatment groups. The most common AEs in the studies were headache, dizziness and somnolence.

About FDA Breakthrough Therapy Designation

The FDA's Breakthrough Therapy Designation is intended to expedite the development and review of a drug candidate that is planned for use, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition when preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing

therapies on one or more clinically significant endpoints. The benefits of Breakthrough Therapy Designation include the same benefits as Fast Track Designation, plus an organizational commitment involving the FDA's senior managers with more intensive guidance from the FDA. Breakthrough Therapy Designation does not change the standards for approval.

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 the months 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. In the U.S., estimates of new mothers identified with PPD each year vary by state from 8 to 20 percent, with an overall average of 11.5 percent. More than half of these cases may go undiagnosed without proper screening. There are no FDA approved therapies for PPD and there is a high unmet medical need for improved pharmacological therapy in PPD.

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 intravenous (IV) 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 CNS disorders. Sage has a portfolio of novel product candidates targeting critical CNS receptor systems, $GABA_A$ and NMDA. Sage's lead program, a proprietary IV formulation of brexanolone (SAGE-547), 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 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 statements regarding: the potential timing of FDA review of our NDA seeking approval of brexanolone IV in the treatment of PPD; the potential for expedited review of the NDA as a result of Priority Review status and Breakthrough Therapy Designation from the FDA; our expectations regarding the possible approval of our NDA filing, and the potential for brexanolone IV to be the first medication indicated for PPD; our estimates of the prevalence of PPD; and other statements regarding our technology, 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 clinical and non-clinical data we have generated with our proprietary formulation of brexanolone to date may be determined by the FDA, despite prior advice, to be insufficient to gain regulatory approval to launch and commercialize our

product in PPD and the FDA may determine that additional trials or data are necessary in order to obtain approval; the FDA 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 IV; we may not achieve expedited review of brexanolone IV as a result of Priority Review status or Breakthrough Therapy Designation from the FDA, and 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 brexanolone IV is successfully approved for PPD, it may only be approved or used to treat a subset of the PPD population; we may encounter unexpected safety or tolerability issues with brexanolone IV in ongoing clinical trials; 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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