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): March 19, 2019

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 March 19, 2019, Sage Therapeutics, Inc. (the "Company") issued a press release announcing that the United States Food and Drug Administration ("FDA") has approved the Company's lead product, ZULRESSO™ (brexanolone) injection, for the treatment of postpartum depression. The Company anticipates launching ZULRESSO in late June following scheduling by the U.S. Drug Enforcement Administration, which is expected to occur within 90 days of FDA approval. ZULRESSO will be available only through certified healthcare settings under a Risk Evaluation and Mitigation Strategy (REMS) called the ZULRESSO REMS. The goal of the REMS is to mitigate the risk of serious harm resulting from excessive sedation and sudden loss of consciousness during the ZULRESSO infusion. The full text of the press release issued in connection with this announcement is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

The initial list price for ZULRESSO in the United States will be $7,450 per vial, resulting in a projected average course of therapy cost of $34,000 per patient before discounts based on an assumption of an average of 4.5 vials used per patient. The actual number of vials used and resulting cost of therapy per patient before discounts will vary from patient to patient and healthcare setting to healthcare setting. Given this variability, our assumptions as to the average number of vials used per patient and our projections as to average cost of a course of therapy per patient without discounts may prove not to have been correct, and the actual numbers in any period may differ from our expectations and estimates.

Cautionary note on forward-looking statements

Various statements in this report concerning Sage's future expectations, plans and prospects, including without limitation: our expectations regarding scheduling and future availability of ZULRESSO in the treatment of PPD and our projections as to average number of vials used per patient and average cost of a course of therapy per patient without discounts, 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 our control, which could cause actual results to differ materially from those contemplated in these forward-looking statements, including the risks that: Drug Enforcement Administration scheduling and our launch of ZULRESSO may not occur on the timelines we expect; we may encounter issues, delays or other challenges in launching ZULRESSO; sites may use on average fewer or more vials per patient than we expect and the average course of therapy cost may be different than we expect; as well as those risks more fully discussed in the section entitled "Risk Factors" in our most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC), and discussions of potential risks, uncertainties, and other important factors in our subsequent filings with the SEC. 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by Sage Therapeutics, Inc. on March 19, 2019.

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.

SAGE THERAPEUTICS, INC.

Date: March 20, 2019

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

Exhibit 99.1

Sage Therapeutics Announces FDA Approval of ZULRESSO™ (brexanolone) Injection, the First and Only Treatment Specifically Indicated for Postpartum Depression

Approval based on results from three pivotal trials showing treatment with ZULRESSO provided significant and rapid reduction of depressive symptoms within days

Postpartum depression is the most common medical complication of childbirth, estimated to affect approximately 400,000 women annually in the U.S.

CAMBRIDGE, Mass. March 19, 2019 – Sage Therapeutics (NASDAQ: SAGE), a biopharmaceutical company developing novel medicines to treat life-altering central nervous system (CNS) disorders, announced today the U.S. Food and Drug Administration (FDA) has approved ZULRESSO™ (brexanolone) injection for the treatment of postpartum depression (PPD). ZULRESSO is the first and only medicine specifically approved to treat PPD, the most common medical complication of childbirth. ZULRESSO is expected to be available in late June following scheduling by the U.S. Drug Enforcement Administration, which is expected to occur within 90 days.

“Today’s approval of ZULRESSO represents a game-changing approach to treating PPD,” said Samantha Meltzer Brody, M.D., M.P.H., Ray M Hayworth Distinguished Professorship of Mood and Anxiety Disorders and director of the Perinatal Psychiatry Program, UNC Center for Women’s Mood Disorders and primary investigator of the ZULRESSO clinical trials. “The potential to rapidly reduce symptoms in this critical disorder is an exciting milestone in women’s mental health. PPD is recognized to have a significant and long-term impact on women and their families, but with ZULRESSO we may finally have the opportunity to change that.”

PPD can affect women during pregnancy or after childbirth. It is estimated PPD affects approximately one in nine women who have given birth in the U.S. Symptoms 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. Without proper screening, up to half of PPD cases may go undiagnosed.

ZULRESSO was evaluated by the FDA under Priority Review, which is reserved for investigational therapies that, if approved, may offer significant improvements in the treatment, prevention or diagnosis of a serious condition. In 2016, ZULRESSO was also granted Breakthrough Therapy Designation status, underscoring the significant unmet need in women with PPD.

“We are proud to be a part of this important moment in mental health, creating the opportunity for an unprecedented change in the way postpartum depression is thought about and treated moving forward,” said Jeff Jonas, M.D., chief executive officer of Sage. “We are grateful for the patients, researchers, healthcare providers, advocates, caregivers and Sage employees who helped secure the approval of the first medicine specifically for postpartum depression. Not only do we believe ZULRESSO will address an important need for women’s mental health, the impact of PPD is multi-generational, and we look forward to bringing ZULRESSO to patients in urgent need of a new treatment option. We believe ZULRESSO will be a catalyst in starting a new dialogue emphasizing the importance of women’s mental health, and the importance of diagnosing and treating PPD.”

The FDA approval of ZULRESSO is based on findings from three multicenter, randomized, double-blind, parallel-group, placebo-controlled trials, designed to evaluate the safety and effectiveness of ZULRESSO in women with moderate and severe PPD, aged between 18 and 45 years 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 all trials at all doses, ZULRESSO achieved the primary endpoint, a significant mean reduction from baseline in the Hamilton Rating Scale for Depression (HAM-D) total score, a common measure of depression severity, at 60 hours compared to placebo. A reduction of depressive symptoms was also seen as early as 24 hours, and ZULRESSO maintained effect through the 30-day follow-up. The most common adverse events in the studies were sleepiness, dry mouth, loss of consciousness and flushing.

About Postpartum Depression

Postpartum depression (PPD) is the most common medical complication of childbirth. PPD is a distinct and readily identified major depressive disorder that can occur during pregnancy or after giving birth. Expert opinions vary as to the timing of the onset of PPD, ranging from onset during pregnancy up to 4-weeks postpartum and onset during pregnancy up to 12-months postpartum. 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. PPD affects 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.

About ZULRESSO® (brexanolone) injection

ZULRESSO, the first medicine specifically approved by the U.S. Food and Drug Administration for the treatment of postpartum depression, 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. ZULRESSO is approved by the FDA for the treatment of PPD in adults, pending DEA scheduling. ZULRESSO has been granted PRIority MEdicines (PRIME) designation from the European Medicines Agency.

Important Safety Information:

What is ZULRESSO™?

ZULRESSO is a prescription medicine used in adults to treat a certain type of depression called Postpartum Depression.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about ZULRESSO?

ZULRESSO can cause serious side effects, including:

- **Excessive sedation and sudden loss of consciousness.** ZULRESSO may cause you to feel very sleepy (excessive sedation) or pass out (loss of consciousness). Your healthcare provider should check you for symptoms of excessive sleepiness every 2 hours while you are awake.
    - During your ZULRESSO infusion, tell your healthcare provider right away if you feel like you cannot stay awake during the time you are normally awake or if you feel like you are going to pass out. Your healthcare provider may lower your dose or stop the infusion until symptoms go away.
    - You must have a caregiver or family member with you to help care for your child(ren) during your ZULRESSO infusion.
- Because of the risk of serious harm resulting from excessive sedation or sudden loss of consciousness, ZULRESSO is only available through a restricted program called the ZULRESSO REMS.

Before receiving ZULRESSO, tell your healthcare provider about all your medical conditions, including if you:

- drink alcohol
- have kidney problems
- are pregnant or think you may be pregnant. It is not known if ZULRESSO will harm your unborn baby.
    - There is a pregnancy registry for females who are exposed to ZULRESSO during pregnancy. The purpose of the registry is to collect information about the health of females exposed to ZULRESSO and their baby. If you become pregnant during treatment with ZULRESSO, talk to your healthcare provider about registering with the National Pregnancy Registry for Antidepressants at 1-844-405-6185 or visit https://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/antidepressants/
- are breastfeeding or plan to breastfeed. ZULRESSO passes into breast milk. Talk to your healthcare provider about the risks and benefits of breastfeeding and about the best way to feed your baby while receiving ZULRESSO.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

ZULRESSO and some medicines may interact with each other and cause serious side effects.

Especially tell your healthcare provider if you take other antidepressants, opioids, or Central Nervous System (CNS) depressants (such as benzodiazepines).

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine. Your healthcare provider will decide if other medicines can be taken with ZULRESSO.

How will I receive ZULRESSO?

ZULRESSO is given to you by continuous intravenous (IV) infusion into your vein. The infusion will last for a total of 60 hours (2.5 days).

What should I avoid while receiving ZULRESSO?

- ZULRESSO may make you feel dizzy and sleepy. Do not drive a car or do other dangerous activities after your ZULRESSO infusion until your feeling of sleepiness has completely gone away. See "**What is the most important information I should know about ZULRESSO?**"
- Do not drink alcohol while receiving ZULRESSO.

What are the possible side effects of ZULRESSO?

ZULRESSO can cause serious side effects, including:

- See "**What is the most important information I should know about ZULRESSO?**"
- **Increased risk of suicidal thoughts or actions.** ZULRESSO and other antidepressant medicines may increase suicidal thoughts and actions in some people 24 years of age and younger. Depression or other serious mental illnesses are the most important causes of suicidal thoughts or actions.

How can I watch for and try to prevent suicidal thoughts and actions?

- Pay close attention to any changes, especially sudden changes in mood, behavior, thoughts, or feelings, or if you develop suicidal thoughts or actions.
- Tell your healthcare provider right away if you have any new or sudden changes in mood, behavior, thoughts, or feelings.
- Keep all follow-up visits with your healthcare provider as scheduled. Call your healthcare provider between visits as needed, especially if you have concerns about symptoms.

Tell your healthcare provider right away if you have any of the following symptoms, especially if they are new, worse, or worry you:

- Attempts to commit suicide, thoughts about suicide or dying, new or worse depression, other unusual changes in behavior or mood

The most common side effects of ZULRESSO include:

- Sleepiness, dry mouth, passing out, flushing of the skin or face.

These are not all the side effects of ZULRESSO.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Please see full Prescribing Information, including Boxed WARNING, and Medication Guide for ZULRESSO™ and discuss any questions you may have with your healthcare provider.

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. ZULRESSO™ (brexanolone) injection is a rapidly acting GABA modulator now approved by the U.S. Food and Drug Administration as the first and only treatment specifically indicated for postpartum depression, pending DEA scheduling. 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 concerning Sage's future expectations, plans and prospects, including without limitation: our expectations regarding scheduling and future availability of ZULRESSO in the treatment of PPD; our statements regarding the potential for ZULRESSO to rapidly resolve PPD symptoms; our view of the potential of ZULRESSO to change the way PPD is treated; our estimates as to the number of women with PPD in the U.S. and rates of diagnosis; and our statements regarding our portfolio of product candidates and our business 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 our control, which could cause actual results to differ materially from those contemplated in these forward-looking statements, including the risks that: Drug Enforcement Administration scheduling and launch of ZULRESSO may not occur on the timelines we expect; we may

encounter issues, delays or other challenges in launching or commercializing ZULRESSO, including issues related to market acceptance and reimbursement, challenges related to limiting the site of administration of the product to a certified healthcare facility monitored by a qualified healthcare provider, and the necessity for a Risk Evaluation and Mitigation Strategies plan; and challenges associated with execution of our sales and patient support activities, which in each case could limit the potential of our product; results achieved with ZULRESSO in the treatment of PPD once we have launched the product may be different than observed in clinical trials, and may vary among patients; we may encounter unexpected safety or tolerability issues with ZULRESSO or any of our product candidates; 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 successful in our development of any of our other product candidates in any indication we are currently pursuing or may in the future pursue; success in early stage clinical trials may not be repeated or observed in ongoing or future clinical trials; and we may encounter technical and other unexpected hurdles in the commercialization of ZULRESSO or in the development, manufacture and potential future commercialization of our product candidates; as well as those risks more fully discussed in the section entitled "Risk Factors" in our most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC), and discussions of potential risks, uncertainties, and other important factors in our subsequent filings with the SEC. 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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