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): June 14, 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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	**SAGE**	**The Nasdaq Global Market**

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 June 14, 2019, Sage Therapeutics, Inc. (the "Company") issued a press release titled "Sage Therapeutics Announces U.S. Drug Enforcement Administration Scheduling of ZULRESSO™ (brexanolone) Injection." A copy of the press release is attached as Exhibit 99.1 to this Form 8-K and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release issued by Sage Therapeutics, Inc. on June 14, 2019

SIGNATURE

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: June 14, 2019

SAGE THERAPEUTICS, INC.

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

Exhibit 99.1

Sage Therapeutics Announces U.S. Drug Enforcement Administration Scheduling of ZULRESSO™ (brexanolone) Injection

On track for full commercial launch in the U.S. in late June

CAMBRIDGE, Mass., June 14, 2019 – Sage Therapeutics (NASDAQ: SAGE), a biopharmaceutical company developing novel medicines to treat life-altering central nervous system (CNS) disorders, today announced that the U.S. Drug Enforcement Administration (DEA) has placed ZULRESSO™ (brexanolone) injection into Schedule IV of the Controlled Substances Act. ZULRESSO, which was approved by the U.S. Food and Drug Administration (FDA) on March 19, 2019, is the first and only treatment specifically approved for postpartum depression (PPD), the most common medical complication of childbirth.

With this decision, the product label for ZULRESSO will be finalized. The Company expects to launch ZULRESSO in late June as planned. ZULRESSO is administered via continuous intravenous (IV) infusion for 2.5 days under the supervision of healthcare providers in sites of care certified under the ZULRESSO Risk Evaluation and Mitigation Strategy (REMS) program. The one-time infusion offers the potential for rapid resolution of depressive symptoms of PPD.

"Historically, women suffering from PPD may have avoided seeking help because of the stigma, lack of a specifically approved treatment and the complicated journey to care – challenges that have been difficult for women with PPD and their families to overcome," said Mike Cloonan, chief business officer at Sage. "Sage is taking on those challenges and creating a family-centric approach to ZULRESSO availability by enabling pathways to care including building our patient support organization, where we will provide a range of meaningful support resources to women with PPD and their families to help navigate the ZULRESSO treatment journey. We also continue to activate Centers of Excellence across the country with the goal of supporting a positive patient experience and broad availability to ZULRESSO for women with PPD."

The Company continues to focus on identifying and activating Centers of Excellence (COE) and other healthcare settings capable of administering ZULRESSO to women with PPD. The key criteria for identifying a potential COE or other sites of care include: a PPD healthcare provider champion; the ability to secure appropriate payer reimbursement for ZULRESSO; and the capability to meet the requirements for certification under the ZULRESSO REMS, which includes monitoring by qualified trained staff, adherence to specific protocols and the maintenance of a patient registry. The Company continues to execute against its planned go-to-market strategy with a focus on the commercial launch of ZULRESSO in late June.

For more information on ZULRESSO, including the final product label, visit www.sagerx.com.

About Postpartum Depression

Postpartum depression (PPD) is the most common medical complication of childbirth. PPD is a distinct and readily identified major depressive episode 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. PPD can be a life-threatening condition due to the risk of suicide, a leading cause of maternal death following childbirth. PPD 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.

About ZULRESSO™ (brexanolone) injection

ZULRESSO, the first medicine specifically approved by the U.S. Food and Drug Administration (FDA) for the treatment of postpartum depression (PDD) in adults, is a positive 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.

What is ZULRESSO?

ZULRESSO™ (brexanolone) CIV 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 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. 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: our expectations regarding the timing of availability and launch of ZULRESSO in the treatment of PPD; our plans regarding commercial activities and patient support; our expectations regarding availability of REMS-certified sites of care for the administration of ZULRESSO; our expectations regarding access to treatment for women with PPD; our statements regarding the potential benefit of ZULRESSO in the treatment of PPD; our estimates as to the number of women who suffer from PPD; and other statements regarding the potential and our plans and expectations for ZULRESSO and our other programs and business. These statements 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: availability and launch of ZULRESSO may not occur on the timelines we expect; we may encounter issues or other challenges in launching and commercializing ZULRESSO, including issues related to market acceptance by healthcare providers, healthcare settings and women with PPD, issues related to availability of sites of care, challenges with reimbursement, other issues related to limitations on the site of administration of ZULRESSO to REMS-certified supervised healthcare settings and the other requirements of the REMS, and challenges associated with execution of our marketing, sales and patient support activities, which in each case could limit the potential of ZULRESSO; results achieved with use of 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; the number of women with PPD or the unmet need for additional treatment options may be significantly smaller than we expect; we may encounter unexpected safety or tolerability issues with ZULRESSO or any of our product candidates; we may encounter supply issues with respect to ZULRESSO or any of our product candidates; we may not be successful in our development of any of our current or future 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 studies of any of our product candidates; ongoing and future clinical results may not support further development or be sufficient to gain regulatory approval of our product candidates; we may decide that a development pathway for one of our product candidates in one or more indications is no longer feasible or advisable or that the unmet need no longer exists; the FDA may decide that the development program for any of our product candidates, even if positive, is not sufficient for a new drug application filing or approval; and we may encounter technical and other unexpected hurdles in the

commercialization of ZULRESSO or in the development of our product candidates; as well as those risks more fully discussed in the section entitled "Risk Factors" in our most recent report 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.

Investor Contact:
Maren Killackey, 617-949-4113
maren.killackey@sagerx.com

Media Contact:
Alexis Smith, 617-588-3740
alexis.smith@sagerx.com

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