Sage Therapeutics, Inc.
Form 8-K
March 20, 2019

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		**02142**

Cambridge, MA
(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