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 13, 2022

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.

Zuranolone New Drug Application Update

As previously announced, Sage Therapeutics, Inc. (the "Company") began a rolling submission of a new drug application (an "NDA") to the U.S. Food and Drug Administration ("FDA") in April 2022 seeking the approval of the Company's product candidate zuranolone for the treatment of major depressive disorder ("MDD"). The Company also previously announced its expectation that it would complete the NDA submission for MDD in the second half of 2022 and make an associated but separate NDA filing seeking the approval of zuranolone for the treatment of postpartum depression ("PPD") in early 2023, pending the completion and results of its SKYLARK Study, a Phase 3 placebo-controlled clinical trial evaluating the efficacy and safety of a two-week course of zuranolone 50 mg compared to placebo in women with severe PPD. The Company is jointly developing zuranolone in the U.S. with Biogen MA Inc. ("BIMA") and Biogen International GmbH (together with BIMA, "Biogen").

The Company is reporting that, in lieu of separate NDA filings, the Company and Biogen have decided to submit a single NDA seeking approval of zuranolone for the treatment of both MDD and PPD. The Company has informed the FDA of this update, and the FDA raised no objections and stated it looked forward to continuing discussions with the Company. The Company and Biogen expect to complete the submission of this single NDA in the second half of 2022, and to seek priority review of the filing. This represents an acceleration of the planned PPD timelines. If the Company meets its planned filing timelines and the NDA receives priority review, the Company expects the PDUFA target action date for zuranolone to be in the third quarter of 2023.

Forward Looking Statements

This disclosure under this Item 8.01 contains forward-looking statements regarding future events that are subject to the safe harbor created under the Private Securities Litigation Reform Act of 1995 and other federal securities laws, including statements concerning the Company's expectation regarding filing of a single NDA seeking approval of zuranolone for the treatment of both MDD and PPD, the anticipated timing of such filing, the Company's expectation that it will seek priority review of such NDA and the potential timing of the PDUFA target action date. 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 the Company's control, which could cause actual results to differ materially from those contemplated in these forward-looking statements, including the risks that: the Company may experience delays or unexpected hurdles in its efforts to complete the NDA submission; the NDA may not receive priority review or the Company may encounter hurdles in seeking such review; the FDA may not accept the NDA for filing; even if the FDA accepts the NDA for review, the FDA may require additional trials or data which may significantly delay and put at risk the Company's efforts to obtain approval; other decisions or actions of the FDA may affect the Company's efforts with respect to zuranolone and its plans, progress or results; results of ongoing or future studies and adverse events at any stage of development may negatively impact further development or impact the Company's plans with respect to zuranolone and the Company's regulatory strategy; as well as those risks more fully discussed in the section entitled "Risk Factors" in the Company's most recent quarterly report on Form 10-Q filed with the Securities and Exchange Commission ("SEC"), as well as discussions of potential risks, uncertainties, and other important factors in the Company's subsequent filings with the SEC. In addition, any forward-looking statements herein represent the Company's views as of the date of this Current Report on Form 8-K, and should not be relied upon as representing the Company's views as of any subsequent date. The Company explicitly disclaims any obligation to update any forward-looking statements.

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: June 13, 2022

SAGE THERAPEUTICS, INC.

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