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): August 28, 2023

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 2.05 Costs Associated with Exit or Disposal Activities

On August 28, 2023, Sage Therapeutics, Inc. (the "Company") committed to a plan to reorganize the Company's business operations and pipeline priorities in order to support goals for long-term business growth, including the planned commercial launch of ZURZUVAE™ (zuranolone) for the treatment of adults with postpartum depression ("PPD") in late 2023. As part of the reorganization, the Company plans to focus its development efforts on its product candidates SAGE-718 and SAGE-324, pause certain earlier-stage programs, implement a reduction of the Company's workforce by approximately 40%, and align its leadership team structure to scale with its pipeline and commercial priorities.

The Company expects a non-recurring charge for severance and related employee costs associated with the workforce reduction of approximately $36 million to $38 million, primarily incurred in the third quarter of 2023. The Company expects that the workforce reduction will be substantially completed by the end of the third quarter of 2023.

Item 8.01 Other Events

On August 31, 2023, in connection with its announcement of the corporate reorganization, the Company announced that, based on the post-reorganization operating plan which includes the Company's pipeline prioritization, workforce reduction, and planned additional incremental commercial hires, it anticipates that its cash, cash equivalents, and marketable securities of approximately $1.0 billion as of June 30, 2023, along with anticipated funding from ongoing collaborations and anticipated revenue, will support its ongoing operations into 2026. The Company has based this estimate on assumptions that may prove to be wrong, and it could use its capital resources sooner than it currently expects.

Cautionary Note on Forward Looking Statements

Various statements in this 8-K concern the Company's future expectations, plans and prospects, including without limitation the statements regarding: the potential cost savings from the Company's reorganization; the amount and timing of the expected non-recurring charge associated with the reorganization; the Company's expectations regarding its cash runway; the Company's expectations as to the planned launch of ZURZUVAE in the treatment of women with PPD; and the mission and goals for the Company, including the Company's goals for the launch and the potential for success. 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 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 not realize expected cost savings from the reorganization, including the anticipated decrease in spend, at the levels it expects; the internal and external costs required for the Company's ongoing, planned and other future activities, and the resulting impact on expense and use of cash, may be higher than expected which may cause the Company to use cash more quickly than it expects or change or curtail some of the Company's plans, or both; the Company may realize additional charges or expenses associated with the reorganization; the Company's expectations as to expenses, cash usage, potential revenue, funding from collaborations, including milestones, cash runway and cash needs may prove not to be correct for other reasons such as changes in plans or actual events being different than its assumptions; the Company's launch and commercialization efforts in the U.S. with respect to ZURZUVAE for the treatment of women with PPD may not be successful, and it may be unable to generate revenues at the levels or on the timing it expects or at levels or on the timing necessary to support its goals; the number of women with PPD, the unmet need for additional treatment options, and the potential market for ZURZUVAE in this indication may be significantly smaller than the Company expects; the Company may never achieve regulatory approval of zuranolone in major depressive disorder ("MDD"); the FDA has taken the position that an additional clinical trial or clinical trials of zuranolone are required to support approval in MDD and may not change that position; such trial or trials could be time-consuming, significantly increase the Company's expenses, and may not be feasible; even if we conduct such clinical trials, they may not be successful; the FDA may decide that the design, conduct or results of such clinical trials, even if positive, are not sufficient for approval in MDD or may find other deficiencies in the Company's development program, data,

processes, or manufacturing sites; even if the Company receives regulatory approval of zuranolone for the treatment of MDD, the FDA may approve zuranolone for only a subset of MDD patients or with limitations or restrictions; the Company may not be successful in its development of any of its product candidates in any indication the Company is currently pursuing or may in the future pursue; success in the Company's non-clinical studies or in earlier clinical trials may not be repeated or observed in ongoing or future studies, and ongoing and future non-clinical and clinical results may not meet their primary or key secondary endpoints or be sufficient to file for or gain regulatory approval to market the product without further development work or may not support further development at all; the Company may encounter delays in conduct of its ongoing clinical trials, including slower than expected site initiation or enrollment, that may impact the Company's ability to meet the Company's expected time-lines and increase the Company's costs; the Company may encounter adverse events for ZURZUVAE at any stage that negatively impact commercialization in women with PPD; the Company may encounter adverse events for any of its product candidates that impact further development or the potential for future regulatory approval; decisions or actions of the FDA may affect the initiation, timing, design, size, progress, cost and potential for success of clinical trials of the Company's product candidates and the Company's ability to proceed with further development or may impair the potential for successful development; the Company's need to align with its collaborators may hamper or delay development and commercialization efforts or increase the Company's costs; and the Company's business may be adversely affected and costs may increase if any of the Company's key collaborators fails to perform its obligations or terminates the collaboration; as well as those risks more fully discussed in the section entitled "Risk Factors" in the Company's most recent quarterly report, as well as discussions of potential risks, uncertainties, and other important factors in its subsequent filings with the Securities and Exchange Commission. In addition, any forward-looking statements represent the Company's views only as of the date of this filing and should not be relied upon as representing its 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: August 31, 2023

SAGE THERAPEUTICS, INC.

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