

**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): April 7, 2020

Sage Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

DELAWARE
(State or other jurisdiction
of incorporation)

001-36544
(Commission
File Number)

27-4486580
(I.R.S. Employer
Identification No.)

215 First Street
Cambridge, MA
(Address of principal executive offices)

02142
(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 April 7, 2020, Sage Therapeutics, Inc. (the “Company”) issued a press release announcing a restructuring intended to enable the Company to advance its corporate strategy and pipeline. The Company is reducing its workforce by approximately 53% of its current headcount, or approximately 340 employees. This workforce reduction will take place primarily during the second quarter of 2020.

As a result of the reduction in force, the Company estimates that it will incur aggregate charges of approximately \$31 million, in one-time cash expenditures for severance and employee termination-related costs. The Company expects that the restructuring and other anticipated cost-saving efforts will result in approximately \$170 million in annualized cost savings. These estimates of the costs that the Company expects to incur and potential cost savings, and the timing thereof, are subject to a number of assumptions and actual results may differ.

Item 8.01. Other Events.

On April 7, 2020, the Company issued a press release titled “Sage Therapeutics Announces Restructuring to Advance Corporate Strategy and Pipeline.” A copy of the press release is filed herewith as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference into this Item 8.01.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	<u>Press release issued by Sage Therapeutics, Inc. on April 7, 2020</u>

Cautionary Note Regarding Forward-Looking Statements

The Company cautions you that statements included in this Current Report on Form 8-K that are not a description of historical facts are forward-looking statements. In some cases, you can identify forward-looking statements because they contain words such as “may,” “will,” “could,” “should,” “expects,” “intends,” “target,” “contemplates,” “plans,” “anticipates,” “believes,” “estimates,” “predicts,” “projects,” “potential,” or “continue,” or the negative of these words or other similar terms or expressions that concern its expectations, strategy, plans, prospects or intentions. Such statements include, without limitation, statements regarding the Company’s business strategy, pipeline, structure and operations; the size, timing and impact of the Company’s reduction in workforce and related activities; the estimated charges and costs expected to be incurred in connection with such reduction; and the projected cost savings resulting from the restructuring and other cost-saving efforts. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. The Company’s actual future results may differ materially from its current expectations due to the risks and uncertainties inherent in its business. These risks include, but are not limited to: the risk that the Company may not realize cost savings from the restructuring and other planned cost saving efforts at the levels it expects; the risk that the costs associated with the restructuring may be higher than expected and the timing of such costs may be different than the Company expects; the risk that internal and external costs required for the Company’s ongoing and planned activities, and the resulting impact on expense and use of cash, may be higher than expected, including as a result of challenges that may be encountered in the course of planned activities or related to the Company’s business; the risk that the spread of COVID-19 and related fears in the U.S. and outside the U.S., measures taken to curb the spread of the virus, and avoidance of healthcare settings and public interactions as a result of the foregoing may negatively impact the Company’s activities and significantly impact costs, plans or other aspects of the Company’s business; and other risks set forth under the caption “Risk Factors” in the Company’s most recent Annual Report on Form 10-K, as updated by the Company’s other subsequently filed SEC filings. The Company assumes no obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

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: April 7, 2020

SAGE THERAPEUTICS, INC.

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

Sage Therapeutics Announces Restructuring to Advance Corporate Strategy and Pipeline

Changes are expected to result in annualized cost savings of approximately \$170 million, including SG&A savings of \$150 million

Headcount reduction of 340 – approximately 53 percent of workforce

Current balance of cash, cash equivalents, restricted cash, and marketable securities expected to support operations into 2022

Based on current information, anticipated 2020 and 2021 R&D milestones remain unchanged

Conference call today at 4:30 p.m. EDT

CAMBRIDGE, Mass., April 7, 2020 — Sage Therapeutics, Inc. (NASDAQ: SAGE), a biopharmaceutical company committed to developing novel therapies with the potential to transform the lives of people with debilitating disorders of the brain, today announced a restructuring intended to enable the Company to advance its corporate strategy and pipeline. The resulting cost savings are comprised of a reduction in the workforce of approximately 53 percent, in addition to an expected decrease in external expenses that together are anticipated to result in annualized savings of approximately \$170 million, of which \$150 million is related to SG&A. The workforce reduction will primarily affect the ZULRESSO™ (brexanolone) CIV injection commercial operation and related SG&A support functions. The Company remains committed to working with healthcare providers and patients seeking access to ZULRESSO, but commercial efforts will be focused on geographies that have existing, active ZULRESSO treating sites.

“The headwinds we are facing individually and collectively, along with a recognition of our need to move forward as a company, have led to this difficult decision. We believe this cost reduction and reallocation of resources will help Sage advance our portfolio in a way that is consistent with our mission of delivering medicines that matter to people with serious brain health disorders,” said Jeff Jonas, M.D., chief executive officer at Sage Therapeutics. “Unfortunately, we will be saying goodbye to some of our valued colleagues and I want to thank them for their dedication to always doing what’s best for patients. Moving forward, we are confident that we have a great team that will continue to execute on our multi-franchise strategy. We believe Sage’s mission is more important than ever, especially as mental health issues are coming to the forefront and will continue to have significant impact, even after the current phase of the pandemic.”

Based on the current operating plan and assumptions, Sage expects that its balance of cash, cash equivalents, restricted cash, and marketable securities of approximately \$1.0 billion at the end of 2019 will support operations into 2022. Sage expects to incur a one-time cost of approximately \$31 million, associated with the reduction in workforce, primarily in the second quarter of 2020. The Company anticipates operating expenses in 2020 will be lower than the previous year; additional financial guidance will be provided on the Company’s 1Q 2020 quarterly earnings update in May.

The Company continues to focus on its three brain health franchises – depression, neurology and neuropsychiatry – and anticipated 2020 and 2021 R&D milestones remain unchanged.

Strategic focus areas

The restructuring will enable the Company to focus on key strategic areas and supporting ongoing development activity, including:

- Planned initiation and completion of three new zuranolone pivotal studies; completion of the 30 mg arm of zuranolone SHORELINE Study in major depressive disorder (MDD)
- Efforts to meet clinical timelines goals, including those related to SAGE-324 and SAGE-718
- Maintain a level of access to ZULRESSO by focusing on geographies with existing treating sites that administer this innovative treatment

2020 planned trial initiations

- Zuranolone (topline data anticipated in 2021)
 - o Initiate Phase 3 study evaluating zuranolone 50 mg in women with postpartum depression (PPD)
 - o Initiate Phase 3 study evaluating zuranolone 50 mg in patients with MDD
 - o Initiate Phase 3 study evaluating zuranolone 50 mg in patients with MDD as an acute rapid response treatment (RRT) when co-initiated with an SSRI
 - o Add cohort to Phase 3 SHORELINE Study evaluating zuranolone 50 mg in patients with MDD
- SAGE-324
 - o Initiate Phase 2 study evaluating SAGE-324 60 mg in essential tremor (ET) (1H 2020)
- SAGE-718
 - o Initiate Phase 2a open-label study or studies evaluating SAGE-718 in one or more disorders associated with cognitive dysfunction (2020)

Conference Call/Webcast Information:

Sage will host a conference call and webcast today, Tuesday, April 7, 2020, at 4:30 p.m. EDT to discuss the recent corporate updates. The live webcast can be accessed on the investor page of Sage's website at investor.sagerx.com. A replay of the webcast will be available on Sage's website approximately two hours after the completion of the event and will be archived for up to 30 days.

About Sage Therapeutics

Sage Therapeutics is a biopharmaceutical company committed to developing novel therapies with the potential to transform the lives of people with debilitating disorders of the brain. We are pursuing new pathways with the goal of improving brain health, and our depression, neurology and neuropsychiatry franchise programs aim to change how brain disorders are thought about and treated. Our mission is to make medicines that matter so people can get better, sooner. 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 statements as to: the potential cost savings from our restructuring; expected reductions in external expenses; the amount of the expected one-time cost associated with our restructuring; our expectations that the cost savings from the restructuring will help advance our programs and our mission; our expectations with respect to 2020 operating expenses and our belief that existing cash will support operations into 2022; our clinical development plans and expected timelines; and the goals, opportunity and potential for

our business. 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: we may not realize expected cost savings from the restructuring, including the anticipated decrease in external spend, at the levels we expect; we may encounter delays in initiation or conduct of our planned clinical trials, including slower than expected site initiation or enrollment, that may impact our ability to meet our expected time-lines and increase our costs; the internal and external costs required for our ongoing and planned activities, and the resulting impact on expense and use of cash, may be higher than expected which may cause us to use cash more quickly than we expect or change or curtail some of our plans or both; our expectations as to expenses, cash usage and cash needs may prove not to be correct for other reasons such as changes in plans or actual events being different than our assumptions; we may be opportunistic in our future financing plans even if available cash is sufficient; we may not be successful in our development of any of our product candidates in any indication we are currently pursuing or may in the future pursue; success in our 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; we may encounter adverse events at any stage of development that negatively impact further development or that require additional nonclinical and clinical work which may not yield positive results; we may encounter different or more severe adverse events at the higher doses we are planning to study in new trials; we may encounter issues with the efficacy or durability of short-term treatment, or co-initiated treatment with zuranolone or safety and efficacy concerns with respect to retreatment that require additional studies be conducted; the FDA may ultimately decide that the design or results of our completed and planned clinical trials for any of our product candidates, even if positive, are not sufficient for regulatory approval in the indications that are the focus of our development plan; other decisions or actions of the FDA or other regulatory agencies may affect the initiation, timing, design, size, progress and cost of clinical trials and our ability to proceed with further development; the spread of the COVID-19 pandemic and related fears in the U.S. and outside the U.S., measures taken to curb the spread of the virus, and avoidance of healthcare settings and public interactions as a result of the foregoing may negatively impact expected site initiation or enrollment in our clinical trials, or cause us to pause trials, in each case which may significantly impact our ability to meet our expected time-lines or may significantly impact our costs or other aspects of our business or cause us to have to change our plans; we may encounter technical and other unexpected hurdles in the development and manufacture of our product candidates which may delay our timing or change our plans or increase our costs; as well as those risks more fully discussed in the section entitled “Risk Factors” in our most recent Annual Report on Form 10-K, as well as discussions of potential risks, uncertainties, and other important factors in our subsequent filings with the Securities and Exchange Commission. 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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