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 18, 2020

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 March 18, 2020, Sage Therapeutics, Inc. (the "Company") issued a press release titled "Sage Therapeutics Announces Development Plan for Zuranolone (SAGE-217) Following Breakthrough Therapy Guidance Meeting with the U.S. Food & Drug Administration." 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 March 18, 2020
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: March 18, 2020

SAGE THERAPEUTICS, INC.

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

Exhibit 99.1

Sage Therapeutics Announces Development Plan for Zuranolone (SAGE-217) Following Breakthrough Therapy Guidance Meeting with the U.S. Food & Drug Administration

Expected regulatory pathway for episodic treatment of major depression remains unchanged with plan for one new additional efficacy study

Pursuing two additional pathways with the goal of accelerating patient access to zuranolone while continuing development for the episodic treatment of depression

Plans to pursue novel development and filing pathway for acute, rapid treatment of major depressive episodes when co-initiated with new antidepressant with one additional short-term pivotal study

Filing pathway for postpartum depression anticipated to require one additional study without long-term follow-up

CAMBRIDGE, Mass. – March 18, 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 next steps in the Landscape Program, the clinical program evaluating zuranolone (SAGE-217) for the treatment of postpartum depression (PPD) and major depressive disorder (MDD), following a Breakthrough Therapy guidance meeting with the U.S. Food and Drug Administration (FDA). Sage has identified three potential pathways intended, if successful, to support a possible filing for approval of zuranolone in the U.S. in two novel indications – PPD and acute treatment of MDD when co-initiated with a new antidepressant – along with the previously disclosed development plan for the treatment of MDD as an episodic therapy.

“Following FDA guidance, Sage has several potential pathways to bring zuranolone to patients, if we are successful, with two pathways that would represent unique indications that we believe we can progress quickly and efficiently, while in tandem we pursue our original approach to develop zuranolone for the episodic treatment of depression,” said Jeff Jonas, M.D., chief executive officer of Sage Therapeutics. “The development program for zuranolone is an example of Sage’s ability to think differently about depression, with the goal of providing treatment options that help people with depression get better, sooner. Sage is well-positioned for the path forward, and to continue advancing our multi-franchise strategy.”

Zuranolone Landscape Program

The Landscape Program is evaluating the potential of zuranolone as a rapid-acting, short-course oral treatment for PPD and MDD. It includes three completed pivotal efficacy studies evaluating zuranolone 30 mg in PPD (ROBIN Study) and MDD (MDD-201, MOUNTAIN Study), the results of which have been previously reported.

Planned studies to support multiple filing pathways

Following discussions with the FDA, Sage plans to initiate three new short-term clinical studies in 2020, with the potential, if successful, for three distinct indications: PPD, acute rapid response therapy in MDD when co-initiated with a new standard antidepressant, and episodic treatment of MDD. These planned studies include:

1. For use as an oral therapy in women with PPD: one additional positive pivotal trial, along with data from previously completed studies, is expected to be required to support an efficacy claim in PPD. No additional long-term follow-up is expected to be required to support an efficacy claim in this indication:
    - Placebo-controlled trial evaluating a two-week course of zuranolone 50 mg in women with PPD, with additional short-term follow-up. Topline data from this study is anticipated in 2021.
2. For use as an acute rapid response therapy (RRT) in patients with MDD when co-initiated with new standard antidepressant therapy: one additional positive treatment study, along with data from previously completed acute treatment studies, is expected to be required to support an efficacy claim in this indication:
    - Placebo-controlled trial evaluating a two-week course of zuranolone 50 mg, when co-initiated with an open-label SSRI, in patients with MDD, with additional short-term follow-up. Topline data from this study is anticipated in 2021.
3. For use as an episodic therapy in patients with MDD: one additional positive pivotal trial, along with previously completed acute treatment studies and long-term safety data, including data from REDWOOD (MDD-302), are expected to be required to support an NDA filing for episodic treatment of depression:
    - Placebo-controlled trial evaluating a two-week course of zuranolone 50 mg in patients with MDD, with additional short-term follow-up. Topline data from this study is anticipated in 2021.

Updates to three ongoing or paused studies:

- SHORELINE Study (MDD-303): The Company is on track to report topline data in 2020 from patients with MDD who received zuranolone 30 mg in the SHORELINE Study.
    - The protocol has been amended to allow currently enrolled patients to receive retreatment with zuranolone 50 mg. Additionally, the Company expects to enroll a new cohort of patients with MDD who will receive zuranolone 50 mg.
- REDWOOD Study (MDD-302): The Company paused enrollment in the REDWOOD study in the fourth quarter of 2019 and plans to reevaluate timing for reinitiating the study while resources and activities focus on enrollment in the three new planned Phase 3 clinical studies.
- RAINFOREST Study (MDD-304): The Company paused enrollment in the RAINFOREST study in the fourth quarter of 2019. The Company plans to evaluate data from ongoing and planned short-term studies prior to reinitiating enrollment.

The updated development plan is expected to create flexibility, if successful, to pursue an efficient and expedited pathway to filing based on data from an additional positive efficacy study (e.g. in MDD when co-initiated with a new antidepressant or in PPD), which the Company believes can be achieved without further long-term follow-up data.

The Company is also currently evaluating the ongoing zuranolone clinical pharmacology and safety program and plans to finalize requirements to support a potential future new drug application (NDA) with the FDA.

Financial Guidance

Based on its current operating plan and assumptions with respect to future plans and resource allocation decisions, Sage anticipates that its balance of cash, cash equivalents, restricted cash, and marketable securities of approximately $1.0 billion as of December 31, 2019, will support operations into 2022. The Company is currently re-assessing its resource allocation and prioritization strategy in light of the development of zuranolone, the uptake of ZULRESSO™ (brexanolone) CIV injection, and factoring in the potential impact on its business of the unprecedented global public health crisis. The Company plans to share its updated resource allocation strategy during its first quarter earnings call.

About Zuranolone

Zuranolone (SAGE-217) is a once-daily, two-week therapy in development for the treatment of major depressive disorder (MDD) and postpartum depression (PPD). Zuranolone is an investigational oral neuroactive steroid (NAS) $GABA_A$ receptor positive allosteric modulator (PAM). The GABA system is the major inhibitory signaling pathway of the brain and central nervous system and contributes significantly to regulating brain function. Zuranolone has been granted Breakthrough Therapy Designation by the U.S. Food & Drug Administration.

About Major Depressive Disorder

Major depressive disorder (MDD), commonly referred to as depression, is a brain health disorder that affects an estimated 17 million adults in the U.S. each year. It is one of the largest contributors to disability in the U.S. and worldwide and is characterized by symptoms of depressed mood and/or loss of interest in pleasurable activities. MDD causes significant impairment in daily life and can limit a person's ability to fulfill work, school, family, or social responsibilities; enjoy leisure activities; or maintain health and hygiene. While antidepressants are widely used to treat MDD, large-scale studies have demonstrated that there is an unmet need in the treatment of MDD, including during the weeks between initiation of treatment and onset of effect, as well as the need for new therapeutic options.

About Postpartum Depression

Postpartum depression (PPD) is one of the most common medical complications during and after pregnancy. PPD can have a serious negative impact on a woman, including 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 is estimated to affect approximately one in nine women who have given birth in the U.S. or approximately 400,000 women annually.

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 various potential development and regulatory pathways for zuranolone in MDD and PPD; our expectations as to the timing of initiation of clinical trials and reporting of results; our expectations regarding the potential sufficiency of the planned development program, if successful, to support regulatory filings and

approvals of zuranolone in MDD and PPD; our estimates as to the number of patients with MDD and PPD; our statements regarding the potential for efficient and expedited development of zuranolone and being well-positioned for the path forward; the potential profile and benefit of zuranolone and our other product candidates; our expectations with respect to use of cash based on the current operating plan and assumptions as to future decisions and plans; 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 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; we may not be successful in our development of zuranolone in MDD or PPD or in our development of any of our other product candidates in any indication we are currently pursuing or may in the future pursue; success in our non-clinical studies or in earlier stage 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 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 zuranolone, 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 actual size of the MDD and PPD patient populations may be significantly lower than our estimates and, even if zuranolone is approved, it will only be approved or used to treat a subset of the relevant patient populations; the spread of the coronavirus 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 impact expected site initiation or enrollment in our clinical trials and our ability to meet our expected time-lines or may significantly impact other aspects of our business causing us to have to change our plans; we may encounter technical and other unexpected hurdles in the development and manufacture of zuranolone or any of our other products which may delay our timing or change our plans; 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 change or curtail some of our plans; and our expectations as to 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; 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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