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): July 12, 2016

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))

Item 8.01 Other Events

On July 12, 2016, Sage Therapeutics, Inc. issued a press release titled, “Sage Reports Positive Top-line Results Including Demonstration of 30-Day Durability from Phase 2 Clinical Trial of SAGE-547 in Severe Postpartum Depression” (the “Press Release”). A copy of the Press Release is filed herewith as Exhibit 99.1 and is 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 July 12, 2016.

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: July 13, 2016

SAGE THERAPEUTICS, INC.

By: /s/ Anne Marie Cook
Anne Marie Cook
Senior Vice President, General Counsel

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release issued by Sage Therapeutics, Inc. on July 12, 2016.

Exhibit 99.1

Sage Reports Positive Top-line Results Including Demonstration of 30-Day Durability from Phase 2 Clinical Trial of SAGE-547 in Severe Postpartum Depression

Primary endpoint achieved with statistical significance at 60 hours maintained through 30 days

70% remission achieved at 60 hours of SAGE-547 treatment and maintained at 30-day follow-up

Company expects to pursue further development of SAGE-547 and SAGE-217 for PPD in a global clinical program

Conference call scheduled for 8:00 AM ET today

CAMBRIDGE, Mass., July 12, 2016 — Sage Therapeutics (NASDAQ:SAGE), a clinical-stage biopharmaceutical company developing novel medicines to treat life-altering central nervous system disorders, today announced positive top-line results from its Phase 2 clinical trial of SAGE-547 for the treatment of severe postpartum depression (PPD). SAGE-547 achieved the primary endpoint of a significant reduction in the HAM-D score compared to placebo at 60 hours (p=0.008). This represented a greater than 20 point mean reduction in the depression scores of the SAGE-547 group at the primary endpoint of 60 hours through trial completion with a greater than 12 point difference from placebo. The statistically significant difference in treatment effect began at 24 hours, (p=0.006) with an effect that was maintained at similar magnitude through to the 30-day follow-up (p=0.01). Remission from depression, as determined by a HAM-D £7, measured at 60 hours, was seen in 7 of 10 of the SAGE-547 group compared with 1 of 11 in the placebo group (p=0.008). Similarly, at 30 days, 7 of 10 of the SAGE-547 group and 2 of 11 in the placebo group were in remission (p=0.03). SAGE-547 was found to be generally well-tolerated with no serious adverse events reported during the treatment and follow-up periods. A greater number of adverse events were reported in the placebo arm than in the treatment arm of the trial. There are no approved therapies specifically for PPD and therapeutic options in severe PPD are limited.

“This is potentially one of the most important clinical findings in the pharmacologic treatment of postpartum depression to date,” said Samantha Meltzer-Brody, M.D., M.P.H., Associate Professor and Director of the UNC Perinatal Psychiatry Program of the UNC Center for Women’s Mood Disorders and primary investigator for the PPD-202 Trial. “The rapid onset of action of this drug observed in the trial is unlike anything else available in the field to date. The data show the potential of the drug to provide relief from the debilitating symptoms of PPD, and to markedly decrease suffering in women who are severely affected.”

This was a Phase 2, multi-center, placebo-controlled, double-blind, 1:1 randomization trial that was designed to enroll up to 32 women. The population studied were women with severe PPD (HAM-D ³26) who developed severe depression either in the third trimester or within four weeks of childbirth. At baseline, the mean HAM-D scores for both groups was greater than 28. The primary objective of the trial was to evaluate the effect of SAGE-547 on depression as measured by the HAM-D score, compared to placebo, at 60 hours. In addition, patients were monitored during a 30-day follow-up period to assess both safety and efficacy.

“These data speak for themselves. The unmet need in the PPD patient population cannot be overstated. Given the societal impact of this condition, and the possible identification of a biological basis for treating these women, we are hopeful these data will point to a new understanding of this disorder and the development of effective therapies” said Jeff Jonas, M.D., Chief Executive Officer of Sage. “Further, as the second positive placebo-controlled trial involving SAGE-547, the first being in essential tremor, this demonstrates the potential broad utility of our differentiated GABA mechanism and the candidate molecules in our pipeline, not only for neurological disorders, but now for mood and affective disorders as well. I am extremely proud of the great work from the Sage team and we are thankful to our patients and investigators.”

“There has been a long-standing need to find an effective treatment option for women with postpartum depression, not only to alleviate the suffering of those women struggling with the disease, but to mitigate the effect on their family and children. Based on our review of the literature, we believe these data represent an unprecedented opportunity for developing treatments for PPD, and believe that our findings will serve as a paradigm shift in how the disease is thought about and, if our development program is successful, how PPD might be treated in the future,” said Steve Kanes, M.D., Ph.D., Chief Medical Officer of Sage. “The results of this study replicate and extend the findings of our original, open-label probe study of PPD reported previously. Given the consistent activity signals seen in both our open-label and placebo-controlled trials, we also intend to examine the development pathways for several of our other proprietary pipeline compounds into the treatment of a variety of psychiatric disorders, such as major depression, bipolar disorder and panic disorder.”

Secondary endpoints, including the Montgomery–Åsberg Depression Rating Scale (MADRS), showed a similar pattern of significant difference (p=0.004) at 24 hours and maintained to 30 days (p=0.01). MADRS total scores at baseline were 37.5 and 37.0 for SAGE-547 and placebo groups, respectively. At 60 hours post-initiation of treatment, the mean change from baseline in MADRS total score for the SAGE-547 group was -27.9 compared with the placebo group mean change of -12.2; this treatment difference of 15.7 points was statistically significant (p=0.01). Presentation of more comprehensive data from the trial is expected at future medical meetings and in publications.

The company has initiated an expansion of this Phase 2 clinical program to determine optimal dosing of SAGE-547 in PPD. This expanded trial involves dose exploration in moderate as well as severe patients, in a multicenter, placebo-controlled trial of SAGE-547 with enrollment to begin before the end of the year. In addition, the company intends to move forward with a PPD program involving its oral molecule, SAGE-217, and to seek regulatory input to determine the appropriate pathways for developing both medications for this indication.

Summary of Top-line SAGE-547 Phase 2 Study Results

Effect on Depressive Symptoms

- The 21 patients enrolled in the trial were required to have had a Major Depressive Episode that began no earlier than the third trimester and no later than the first four weeks following delivery, and to also be less than six months postpartum at the time of enrollment. Trial participants were also required to have a HAM-D score of 26 or above prior to treatment.
- Patients were randomized one-to-one to either SAGE-547 or placebo, and were administered blinded IV inpatient treatment as a continuous infusion for 60 hours. Ten patients were randomized to SAGE-547 treatment, while 11 patients were randomized to placebo. Patients were allowed to remain on background medications that could not be adjusted during treatment. Only three patients in each group were on such medications.
- The study was designed to titrate dosing based on body weight.
- SAGE-547 achieved the primary endpoint with a significant reduction in the HAM-D scale compared to placebo at 60 hours (p=0.008).
- SAGE-547 patients experienced a 19.0 point mean reduction in their HAM-D scores at 24 hours (p=0.006), achieving a greater than 10.6 point difference from placebo at that time point and was maintained at similar magnitude through to the 30-day follow-up (p=0.01).

- Results from secondary efficacy endpoints, including other rating scales such as the MADRS, reinforced the overall efficacy observed with SAGE-547 in the trial.
- Remission from depression, as determined by a HAM-D less than or equal to 7, measured at 60 hours, was seen in 7 of 10 SAGE-547 patients and 1 of 11 placebo patients (p=0.008). The remission finding in the SAGE-547 group was maintained out to 30 days (p=0.03), demonstrating a strong durability of effect from SAGE-547 for over three weeks following the end of treatment.

Safety and tolerability:

- SAGE-547 was generally well tolerated in this study. There were no deaths, serious adverse events or discontinuations.
- Overall, fewer patients who received SAGE-547 experienced adverse events compared with placebo: 4 of 10 on SAGE-547 and 8 of 11 on placebo.
- Similar number of patients reported Nervous System Disorder Adverse Events: 3 of 10 on SAGE-547 and 4 of 11 on placebo.
- Equal number of patients reported the cluster of dizziness, sedation or somnolence: 3 in each group.
- Fewer SAGE-547 patients reported Psychiatric Disorder Adverse Events: 0 of 10 on SAGE-547 and 5 of 11 on placebo. Adverse events included abnormal dreams, insomnia and anxiety for placebo.

Conference Call Information

Sage will host a conference call and webcast today at 8:00 AM ET to discuss the SAGE-547 top-line Phase 2 results from the PPD-202 trial. The live webcast can be accessed on the investor page of Sage's website at investor.sagerx.com. The conference call can be accessed by dialing 1-866-450-8683 (toll-free domestic) or 1-281-542-4847 (international) and using the conference ID 47918013. 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 the Hamilton Rating Scale for Depression (HAM-D)

HAM-D is a validated rating scale used to provide an assessment of depression, and as a guide to evaluate recovery. This scale is an accepted regulatory endpoint for depression. The scale is used to rate the severity of their depression by probing mood, feelings of guilt, suicide ideation, insomnia, agitation, anxiety, weight loss, and somatic symptoms.

About Postpartum Depression

Postpartum depression (PPD) is an affective disorder impacting women after childbirth. PPD may have devastating consequences for a woman and for her family, which may include 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. Women with severe PPD may be hospitalized to provide a safe and stable environment for recovery if they are severely ill or unable to function and care for themselves. Suicide is the leading cause of maternal death following childbirth. According to the Centers for Disease Control and Prevention, there were approximately four million live births in the US in 2014. We estimate that PPD affects 10%-15% of mothers. A subset of these are severe enough to require hospitalization. There are no approved therapies for severe PPD and there is a high unmet medical need for improved pharmacological therapy in PPD.

About SAGE-547

SAGE-547 is an allosteric modulator of both synaptic and extra-synaptic GABAA receptors. SAGE-547 is an intravenous agent evaluated in the PPD-202 trial, a multi-center, randomized, double-blind, parallel-group, placebo-controlled study evaluating the efficacy, safety and pharmacokinetics of SAGE-547 in the treatment of adult female subjects with severe postpartum depression requiring inpatient treatment. For more information about this trial please visit https://clinicaltrials.gov/show/NCT02614547.

SAGE-547 is also being developed as an adjunctive therapy for the treatment of super-refractory status epilepticus (SRSE) in the global Phase 3 STATUS Trial. For more information about the STATUS Trial, please visit www.statustrial.com. SAGE-547 has been granted both Fast Track and orphan drug designations by the FDA for the treatment of SRSE.

About SAGE-217

SAGE-217 is a next generation positive allosteric modulator that has been optimized for selectivity to synaptic and extrasynaptic GABA receptors and a pharmacokinetic profile intended for once-daily oral dosing. The GABA system is the major inhibitory signaling pathway of the brain and CNS, and contributes significantly to regulating CNS function. In a recent Phase 1 clinical program, SAGE-217 was well-tolerated in single and multiple ascending doses and the results were consistent with the predicted pharmacokinetic and pharmacologic profile. Sage plans to develop SAGE-217 for PPD, essential tremor, and other GABA dysfunction-related disorders.

About Sage Therapeutics

Sage Therapeutics is a clinical-stage biopharmaceutical company committed to developing novel medicines to transform the lives of patients with life-altering central nervous system (CNS) disorders. Sage has a portfolio of novel product candidates targeting critical CNS receptor systems, GABA and NMDA. Sage's lead program, SAGE-547, is in Phase 3 clinical development for super-refractory status epilepticus, a rare and severe seizure disorder, and is being developed for severe PPD. Sage is developing its next generation modulators, including SAGE-217, SAGE-689 and SAGE-718, with a focus on acute and chronic CNS disorders. 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 expectations regarding further development of SAGE-547 and SAGE-217 in the treatment of PPD; our plans to commence additional clinical trials of these product candidates, and the potential timing of such efforts; our view of the potential of SAGE-547 and SAGE-217 as a treatment for PPD; our view of the potential of the GABA mechanism and our product candidates in the treatment of other indications; our plans to pursue development of our product candidates in those indications, and in other diseases; and our views as to the unmet need for additional treatment options in PPD and estimated number of patients with PPD. 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 be able to successfully demonstrate the efficacy and safety of our product candidates at each stage of development; success in early stage clinical trials may not be repeated or observed in ongoing or future studies involving the same compound or other product candidates; and ongoing and future clinical results may not support further development of a product candidate or be sufficient to gain regulatory approval to market any product; decisions or actions of regulatory agencies may affect the initiation, timing, progress and cost of clinical trials, and our ability to proceed with further clinical trials of a product candidate in a particular indication or at all or our ability to obtain marketing approval; we may decide that a development pathway for one of our product candidates in one or more indications is no longer feasible or advisable or that the unmet need no longer exists; the number of patients with a particular disease or the unmet need for additional treatment options in a disease may be significantly smaller than we expect; and we may encounter technical and other unexpected hurdles in the development and manufacture of our product candidates;

as well as those risks more fully discussed in the section entitled "Risk Factors" in our most recent Quarterly Report on Form 10-Q, 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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