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): December 7, 2017

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))

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 December 7, 2017, Sage Therapeutics, Inc. issued a press release titled, “Sage Therapeutics Reports Positive Top-line Results from Phase 2 Placebo-Controlled Trial of SAGE-217 in Major Depressive Disorder” (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 the Registrant on December 7, 2017.

* * *

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: December 7, 2017

SAGE THERAPEUTICS, INC.

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

Sage Therapeutics Reports Positive Top-line Results from Phase 2 Placebo-Controlled Trial of SAGE-217 in Major Depressive Disorder

– SAGE-217 met primary endpoint and provided rapid, profound and durable effects through 2-week treatment period and additional 4-week follow-up –

– Well-tolerated and demonstrated highly statistically significant mean reduction in the HAM-D score compared to placebo at 15 days ($p<0.0001$) beginning after one dose and maintained through Week 4 with numerical superiority though Week 6 –

– All secondary endpoints were consistent with primary endpoints at Day 15, including remission in 64% of SAGE-217 patients versus 23% of placebo patients ($p=0.0005$) –

– Data support further development of SAGE-217 for MDD and related disorders –

– Conference call scheduled today at 8:00 A.M. ET –

CAMBRIDGE, Mass., December 7, 2017 – Sage Therapeutics (NASDAQ: SAGE), a clinical-stage biopharmaceutical company developing novel medicines to treat life-altering central nervous system (CNS) disorders, today announced positive top-line results from the Phase 2, double-blind, placebo-controlled clinical trial of SAGE-217 in the treatment of 89 adult patients with moderate to severe major depressive disorder (MDD). In the trial, treatment for 14 days with SAGE-217 was associated with a statistically significant mean reduction in the Hamilton Rating Scale for Depression (HAM-D) 17-Item total score from baseline to Day 15 (the time of the primary endpoint) of 17.6 points for SAGE-217, compared to 10.7 for placebo ($p<0.0001$). Statistically significant improvements were observed in the HAM-D compared to placebo by the morning following the first dose through Week 4 and the effects of SAGE-217 remained numerically greater than placebo through the end of follow-up at Week 6. At Day 15, 64 percent of patients who received SAGE-217 achieved remission, defined as a score of 7 or less on the HAM-D scale, compared with 23 percent of patients who received placebo ($p=0.0005$). Other secondary endpoints were all similarly highly significant at Day 15 ($p<0.002$).

SAGE-217 was generally well-tolerated with no serious or severe adverse events; the most common adverse events (AEs) in the SAGE-217 group were headache, dizziness, nausea, and somnolence. A low rate of discontinuations due to AEs was reported; overall reports of AEs were similar between drug (53%) and placebo (46%), with a safety profile consistent with that seen in earlier trials. SAGE-217 was granted Fast Track Designation by the U.S. Food and Drug Administration (FDA) in May 2017.

“These very encouraging data suggest the potential of SAGE-217 in the treatment of MDD as well as other mood-related disorders that we may pursue,” said Jeff Jonas M.D., chief executive officer of Sage Therapeutics. “There has been little innovation in the discovery and development of treatments for depression in the last two decades. Coupled with our recent positive Phase 3 data read-out evaluating brexanolone for the treatment of postpartum depression, the findings in this study suggest our pipeline of proprietary $GABA_A$ modulators may impact novel and fundamental brain mechanisms, offering potential development opportunities in a variety of indications. The positive activity and safety findings of SAGE-217 in MDD support advancing the program into later stage clinical development and we will work with the FDA to determine next steps in the further development of SAGE-217.”

The GABA system is the major inhibitory signaling pathway of the central nervous system (CNS), and contributes significantly to regulating CNS function. SAGE-217 is a novel, highly potent and selective, next generation $GABA_A$ receptor positive allosteric modulator that is being developed as a once-daily, oral therapy for the treatment of various CNS disorders. SAGE-217 was discovered by Sage, and the Company maintains worldwide rights to the compound.

“There are currently significant gaps in the disease management of depression and our development goal at Sage is to change patients’ expectations by transforming the treatment landscape for MDD,” said Steve Kanes, M.D., Ph.D., chief medical officer of Sage Therapeutics. “If successfully developed, SAGE-217 has the potential to offer the first truly new mechanism of action in the pharmacologic treatment of depression in more than 20 years. If the results from this trial are replicated in Phase 3 trials, SAGE-217 may meet the needs of patients with MDD for a once-daily oral treatment that potentially provides a rapid, well-tolerated and durable response with a high rate of remission.”

Summary of Top-line Results from the Placebo-Controlled Phase 2 Trial

Effect on Depressive Symptoms through end of Treatment (Day 15):

- Treatment with SAGE-217 was associated with a statistically significant mean reduction from baseline in the Hamilton Rating Scale for Depression (HAM-D) total score at Day 15 of 17.6 points compared with a 10.7 point mean reduction associated with placebo ($p<0.0001$).
- The majority of patients (64%) who received SAGE-217 achieved remission at Day 15 as determined by a HAM-D total score less than or equal to 7 (compared with 23% of patients who received placebo, $p=0.0005$).
- Other secondary endpoints (e.g., MADRS, CGI-I) were similarly highly significant at Day 15 ($p<0.002$).

Effect on Depressive Symptoms over Time:

- Statistically significant mean reductions from baseline in the Hamilton Rating Scale for Depression (HAM-D) total score were observed following the first dose (Day 2) and maintained through Week 4, two weeks after end of treatment ($p<0.0318$).
- At Week 4, the mean reduction from baseline in HAM-D total score was 15.6 for the SAGE-217 group and 11.9 for the placebo group ($p=0.0243$).
- At Week 6, the mean reduction in HAM-D total score for the SAGE-217 group was 15.0 and numerically, but not statistically improved compared to the placebo group reduction of 13.0.
- Rates of remission at Week 4 and Week 6 for patients treated with SAGE-217 were 52 percent and 45 percent compared to 28 percent and 33 percent for placebo, with statistical significance maintained at Week 4 ($p=0.0221$) but not Week 6.

Safety and Tolerability:

- SAGE-217 was generally well tolerated in the trial. The overall incidence of patients who experienced adverse events was 53 percent for the SAGE-217 treatment group and 46 percent for the placebo group.
- There were no deaths, serious or severe adverse events.
- Rates of discontinuation from dosing of study drug due to adverse events were low; two patients (4.4%) treated with SAGE-217 and none treated with placebo.

- The most common adverse events in the SAGE-217 group were headache, dizziness, nausea and somnolence.
- There was no signal for increased risk for patients treated with SAGE-217 as measured by structured assessments of suicidality and sedation.

Conference Call Information

Sage will host a conference call and webcast today at 8:00 A.M. ET to discuss the top-line results from the Phase 2 SAGE-217 trial in MDD. 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 866-450-8683 (toll-free domestic) or 281-542-4847 (international) and using the conference ID 2675527. 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 Placebo-controlled Phase 2 trial of SAGE-217 in MDD:

In the randomized, double-blind, parallel-group, placebo-controlled trial, 89 eligible patients (with a minimum total score of 22 on the Hamilton Rating Scale for Depression) were stratified based on use of antidepressant treatment (current/stable or not treated/withdrawn ³30 days) and randomized in a 1:1 ratio to receive SAGE-217 Capsules (30mg) (n=45) or matching placebo (n=44). All doses of study drug were administered at night with food. The study consisted of a 14-day treatment period, and a 4-week follow-up period. The mean HAM-D total scores at baseline were 25.2 for the SAGE-217 group and 25.7 for the placebo group (overall range 22-33), representing patients with moderate to severe MDD. Approximately 90 percent of patients in each group completed the study.

About Major Depressive Disorder

Major depressive disorder (MDD) is a common but serious mood disorder in which patients exhibit depressive symptoms, such as a depressed mood or a loss of interest or pleasure in daily activities consistently for at least a two-week period, and demonstrate impaired social, occupational, educational or other important functioning. It is estimated that approximately 16 million people in the U.S. suffer from MDD each year. While antidepressants are widely used for treatment, large scale studies have demonstrated the need for additional therapies.

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 in clinical research to rate the severity of a patient's depression by probing mood, feelings of guilt, suicide ideation, insomnia, agitation, anxiety, weight loss, and somatic symptoms.

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 daily oral dosing. The GABA system is the major inhibitory signaling pathway of the brain and CNS, and contributes significantly to regulating CNS function. SAGE-217 is currently being developed for MDD and certain other mood and movement 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, a proprietary IV formulation of brexanolone (SAGE-547), is in Phase 3 clinical development for postpartum depression. Sage is developing its next generation modulators, including SAGE-217 and SAGE-718, in various 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 the potential for SAGE-217 in the treatment of MDD and related disorders; our statements regarding plans for further development of SAGE-217 and related regulatory activities and the potential for successful development; our view of the potential of the GABA mechanism and our product candidates, including SAGE-217, in the treatment of CNS diseases and disorders; our views as to the unmet need for additional treatment options in MDD and the potential of SAGE-217 to meet the unmet need, and our estimates as to the number of patients with MDD. 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 SAGE-217 or any of our other product candidates at each stage of development; success in early stage clinical trials may not be repeated or observed in ongoing or future studies of SAGE-217 or any of our other product candidates; ongoing and future clinical results may not support further development or be sufficient to gain regulatory approval to market SAGE-217 or any of our other product candidates; 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; 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; we may encounter unexpected safety or tolerability issues with SAGE-217 or any of our other product candidates in ongoing or future development; the actual size of the MDD patient population may be significantly lower than our estimates and, even if SAGE-217 is successfully developed and approved for MDD, it may only be approved or used to treat a subset of the MDD population; and we may encounter technical and other unexpected hurdles in the development and manufacture of SAGE-217 or any of our other 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, and 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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