
**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 15, 2015

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))
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Item 8.01 Other Events

On December 15, 2015, Sage Therapeutics, Inc. issued a press release titled, "SAGE Updates Guidance for Top-Line Results of Phase 3 STATUS Trial of SAGE-547" (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 December 15, 2015.
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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.

SAGE THERAPEUTICS, INC.

Date: December 16, 2015

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 December 15, 2015.



SAGE Updates Guidance for Top-Line Results of Phase 3 STATUS Trial of SAGE-547

Top-Line Data Expected in Second Half of 2016 for SAGE's Global Phase 3 Trial in Super-Refractory Status Epilepticus

CAMBRIDGE, Mass., Dec. 15, 2015 — Sage Therapeutics (NASDAQ: SAGE) today announced updated guidance for the expected readout of top-line results for its STATUS Trial (SAGE-547 Treatment as Adjunctive Therapy Utilized in Status Epilepticus), a global, Phase 3, randomized, double-blind, placebo-controlled clinical trial evaluating SAGE-547 as a treatment for patients with super-refractory status epilepticus (SRSE). SRSE is a rare, life-threatening condition of persistent seizure where treatment regimens normally sufficient in stopping seizure activity have failed, and for which there are no approved therapies. Top-line results for the Phase 3 clinical trial are now expected in the second half of 2016.

“We are pleased to revise our timeline forward for the Phase 3 STATUS Trial top-line results based on current enrollment trends and our team’s continued execution in opening sites. We are excited about the interest in our trial to date,” said Jeff Jonas, M.D., Chief Executive Officer of SAGE.

“2016 will be an important and milestone-rich year for SAGE. In the first half of 2016, we expect data readouts from our placebo-controlled Phase 2 trial of SAGE-547 in severe postpartum depression and from the SAGE-217 Phase 1 clinical program. In the second half of the year, in addition to the SAGE-547 Phase 3 data, we expect to launch multiple Phase 2 trials evaluating SAGE-217 in essential tremor, orphan epilepsies and potentially postpartum depression, assuming successful replication of earlier stage work. We also expect to initiate the SAGE-689 Phase 1 development program in the second half of 2016. Along with these clinical milestones, SAGE is also committed to continuing its groundbreaking work studying the NMDA neurotransmitter system and its impact on CNS diseases, and we plan to present additional scientific data on this work in 2016,” added Dr. Jonas.

SAGE initiated the Phase 3 STATUS Trial in August 2015. The STATUS Trial is evaluating the efficacy and safety of SAGE-547, and is expected to enroll approximately 126 patients with SRSE, ages two years or older, in the U.S., Canada and Europe. In the double-blind trial, patients are randomized 1:1 to receive either SAGE-547 or placebo in addition to standard-of-care third-line anti-seizure agents for six days. The primary endpoint is successful resolution of status epilepticus (SE) after weaning the patient off all third-line agents, and SAGE-547 or placebo, without resumption of SE within 24 hours after completion of blinded SAGE-547 or placebo administration. The STATUS Trial is being conducted under a Special Protocol Assessment (SPA) agreement with the U.S. Food and Drug Administration (FDA).

About SAGE-547

SAGE-547 is an allosteric modulator of both synaptic and extra-synaptic GABA_A receptors. SAGE-547 is an intravenous agent in Phase 3 clinical development as an adjunctive therapy for the treatment of super-refractory status epilepticus (SRSE). SAGE-547 has been granted both Fast Track and orphan drug designations by the U.S. Food and Drug Administration (FDA) for the treatment of SRSE. SAGE-547 is being evaluated as a treatment for patients with SRSE in the global Phase 3 STATUS Trial. For more information about the STATUS Trial, please visit www.statustrial.com.

About Super-Refractory Status Epilepticus

Status epilepticus (SE) is an acute medical emergency of persistent, unremitting seizure lasting greater than five minutes. An SE patient is first treated with benzodiazepines, and if no response, is then treated with other, second-line, anti-seizure drugs. If the seizure persists after the second-line therapy, the patient is diagnosed as having refractory SE (RSE), admitted to the ICU and placed into a medically induced coma. Physicians typically use anesthetic agents to induce the coma, along with antiepileptic drugs in an attempt to stop the ongoing seizure, in RSE patients. After a period of 24 hours, an attempt is made to wean the patient from the anesthetic agents to evaluate whether or not the seizure condition has resolved. Unfortunately, not all patients respond to weaning attempts, in which case the patient must be maintained in the medically induced coma. At this point, the patient is diagnosed as having SRSE. We estimate that there are 25,000 cases of SRSE in the U.S.¹⁻³ each year. Currently, there are no therapies specifically approved for SRSE.

About Sage Therapeutics

Sage Therapeutics (NASDAQ: SAGE) 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. SAGE is developing its next generation modulators, including SAGE-217 and SAGE-689, 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 concerning SAGE's future expectations, plans and prospects, including without limitation, SAGE's expectations regarding the timing of top-line results of the SAGE-547 STATUS trial and the results of other ongoing clinical trials, SAGE's expectations on the potential timing of commencement of clinical trials of SAGE-217 and SAGE-689, and SAGE's plans for other development activities, constitute forward-looking statements for the purposes of the safe harbor provisions under 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 our control, which could cause actual results to differ materially from those indicated by these forward-looking statements, including, without limitation: the possibility that we may experience slower than expected clinical site initiation or slower than expected identification and enrollment of evaluable patients; the potential for delays or problems in analyzing data or the need for additional analysis, data or patients; the potential that future pre-clinical and clinical results may not support further development of our product candidates; actions or decisions of regulatory agencies,

which may affect the initiation, timing and progress of clinical trials; the potential for unexpected adverse events in the conduct of one of our clinical trials to impact our ability to continue the clinical trial or further development of a product candidate; the risk that we may encounter other unexpected hurdles or issues in the development and manufacture of our product candidates that may impact our timing or progress, as well as those risks more fully discussed in the section entitled “Risk Factors” in SAGE’s most recent quarterly report on Form 10-Q, as well as discussions of potential risks, uncertainties, and other important factors in SAGE’s subsequent filings with the Securities and Exchange Commission. In addition, any forward-looking statements represent SAGE’s views only as of today and should not be relied upon as representing its views as of any subsequent date. SAGE explicitly disclaims any obligation to update any forward-looking statements.

¹ DeLorenzo RJ, Pellock JM, Towne AR, Boggs JG. J Clin Neuro 1995; 12(4): 316-325.

² Claassen J, Hirsch LJ, Emerson RG, Mayer SA. Epilepsia 2002; 43(2): 146-153.

³ Novy J, Logroscino G, Rossetti AO. Epilepsia 2010; 51(2): 251-256.

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