
**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): October 6, 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 October 6, 2015, Sage Therapeutics, Inc. issued a press release titled, "SAGE Announces Initiation of Phase 1 and First Dosing of SAGE-217" (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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued by Sage Therapeutics, Inc. on October 6, 2015.

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: October 6, 2015

SAGE THERAPEUTICS, INC.

By: /s/ Anne Marie Cook

Anne Marie Cook

Senior Vice President and General Counsel

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued by Sage Therapeutics, Inc. on October 6, 2015.



NEWS RELEASE

FOR IMMEDIATE RELEASE**SAGE Announces Initiation of Phase 1 and First Dosing of SAGE-217***SAGE's First Oral Compound from Its Pipeline of Next Generation CNS Modulators Enters Clinical Development*

Cambridge, Mass., October 6, 2015 – Sage Therapeutics (NASDAQ: SAGE) today announced it has initiated dosing in a Phase 1 single ascending dose trial evaluating SAGE-217 in healthy volunteers. Initial top-line results from the study are expected in the first half of 2016.

“Administering the first dose of SAGE-217 is another significant milestone for SAGE’s R&D organization,” said Albert Robichaud, Ph.D., Chief Scientific Officer of SAGE. “SAGE-217 is a novel GABA_A modulator, selected for its high potency and potential to be developed for once- daily oral administration, and is a good example of our leading drug discovery capabilities. We plan to continue our focus on pipeline expansion with next generation GABA and NMDA product candidates for CNS disorders.”

SAGE-217 is a next generation positive allosteric modulator that has been optimized for greater selectivity of GABA_A receptors and a pharmacokinetic profile intended to support once-daily oral dosing. SAGE is developing SAGE-217 for high frequency seizures associated with select neurological disorders, including orphan epilepsies, and other GABA_A dysfunction-related disorders, such as essential tremor. In preclinical development, SAGE-217 demonstrated anti-seizure and anxiolytic activity in multiple animal models, including potent activity in seizure models such as Dravet and Fragile X syndromes.

James Doherty, Senior Vice President of Research at SAGE, said, “With SAGE-217, our preclinical testing revealed robust and dose-related activity, a wide therapeutic index and good oral bioavailability across a broad range of animal models. SAGE-217 also exhibited high selectivity for synaptic and extrasynaptic GABA_A receptors with very limited secondary pharmacology and few off-target effects in animals, making it a desirable candidate for clinical development. This suggests that, if SAGE-217 successfully completes Phase 1, it has the potential to be studied across several orphan epilepsies characterized by high seizure burden, as well as in other disorders, such as essential tremor and postpartum depression, where GABA_A dysfunction may play a role.”

The Phase 1 single ascending dose study of SAGE-217 is a double-blind, placebo-controlled trial to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamic effects of SAGE-217 administered orally in approximately 80 healthy adult volunteers.

About SAGE-217

SAGE-217 is a next generation positive allosteric modulator that has been optimized for greater selectivity of synaptic and extrasynaptic GABA_A receptors and a pharmacokinetic profile intended for once-daily oral dosing. SAGE is developing SAGE-217 for high frequency seizures

associated with select neurological disorders, including orphan epilepsies, and other GABA_A dysfunction-related disorders, such as essential tremor. The GABAergic system is the major inhibitory signaling pathway of the brain and CNS and contributes significantly to regulating CNS function.

About High Frequency Seizures Associated with Orphan Epilepsies

Orphan epilepsies, such as Dravet syndrome, Lennox-Gastaut syndrome, Tuberous sclerosis complex, Rett syndrome and PCDH19 epilepsy, are rare and severe neurological disorders characterized by high frequency seizure burden. Frequent seizure activity caused by these disorders severely impacts patients' lives, and can lead to significant mental and physical deficits, including epileptic encephalopathy and progressive dementia. Patients often have suboptimal therapeutic options and significant pharmaco-resistance to available therapies.

About Essential Tremor

Essential tremor is a common neurological condition that affects an estimated 10 million Americans and millions more worldwide. Essential tremor causes a rhythmic trembling of the hands, head, voice, legs or trunk. Symptoms generally evolve over time and are both visible and persistent following onset, which commonly occurs either between 15-20 or 50-70 years of age. First-line treatments for essential tremor include the anticonvulsant primidone and the β -adrenergic blocker propranolol. One out of three patients abandons current treatments due to side effects or poor efficacy.

About SAGE Therapeutics

Sage Therapeutics (NASDAQ: SAGE) is a clinical-stage biopharmaceutical company committed to developing novel medicines to transform the lives of patients living with life-altering central nervous system (CNS) disorders. SAGE is advancing a portfolio of novel product candidates targeting critical CNS receptor systems, GABA and NMDA, in multiple neurological and psychiatric indications. 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, across a broad range of rare, 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 development of SAGE-217 and its potential in the treatment of various CNS disorders; the expected timing of availability of data from the Phase 1 study of SAGE-217; and the potential for SAGE's other product candidates, including SAGE-547, 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 contemplated in these forward-looking statements, including the risks that: SAGE may not be able to successfully demonstrate the efficacy and safety of its product candidates at each stage of development; success in SAGE's pre-clinical studies or 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 future pre-clinical and clinical results

may not support further development of product candidates; decisions or actions of regulatory agencies may affect the initiation, timing and progress of clinical trials, and SAGE's ability to proceed with further clinical studies of a product candidate or to obtain marketing approval; SAGE may not be able to obtain or maintain adequate intellectual property protection and other forms of marketing and data exclusivity for its products; SAGE may not be successful in enforcing its patents against infringers or defending its patent portfolio against challenges from third parties; SAGE may face competition from others developing products for similar uses; SAGE may not be able to obtain or maintain key relationships with third parties necessary for development and manufacture of its product candidates; and SAGE may encounter technical and other unexpected hurdles in the manufacture and development of its products, 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.

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