# 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): August 12, 2015**

# 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 2.02 Results of Operations and Financial Condition**

On August 12, 2015, Sage Therapeutics, Inc. announced its financial results for the quarter ended June 30, 2015. A copy of the press release is being furnished as Exhibit 99.1 to this Report on Form 8-K.

The information in this Report on Form 8-K and Exhibit 99.1 attached hereto is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

| Exhibit No. | Description |
|---|---|
| 99.1 | Press release issued by Sage Therapeutics, Inc. on August 12, 2015, furnished herewith. |

**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: August 12, 2015

**SAGE THERAPEUTICS, INC.**

By: /s/ Jeffrey M. Jonas
Jeffrey M. Jonas, M.D.
Chief Executive Officer, President and Director

**EXHIBIT INDEX**

| Exhibit No. | Description |
| --- | --- |
| 99.1 | Press release issued by Sage Therapeutics, Inc. on August 12, 2015, furnished herewith. |

**NEWS RELEASE**

***FOR IMMEDIATE RELEASE***

**SAGE Therapeutics Announces Second Quarter 2015 Financial Results and Highlights Recent Progress**

*Global Phase 3 STATUS Trial to Evaluate SAGE-547 as a Treatment for SRSE Now Open for Enrollment*

*Novel, Proprietary Second-Generation Product Candidates Poised to Enter Phase 1 in 2015*

**Cambridge, Mass. – August 12, 2015 –** SAGE Therapeutics (NASDAQ: SAGE) today reported business highlights and financial results for the second quarter ended June 30, 2015.

"We are pleased to have moved SAGE-547 into Phase 3 development with the initiation of the STATUS Trial, which will be conducted with U.S. Food and Drug Administration (FDA) agreement under a Special Protocol Assessment, and look forward to enrolling patients expeditiously," said Jeff Jonas, M.D., Chief Executive Officer of SAGE. "We have a number of important milestones in the second half of 2015 that we believe will position SAGE as a leading neuroscience company developing novel medicines for life-altering CNS disorders with significant unmet need."

Kimi Iguchi, Chief Financial Officer of SAGE, added, "SAGE continues to maintain a strong cash position with $224.2 million in cash at the end of the second quarter. We have had a very successful year to date, including our April financing, which leaves us well-positioned to advance our pipeline, including funding SAGE-547 Phase 3 development, moving our second-generation modulators into Phase 1 this year, continuing our exploratory development in broader CNS indications and potentially expanding our allosteric modulation platform with our first development candidate focused on NMDA-related dysfunction."

**Pipeline Updates and Upcoming Milestones**

- **SAGE-547 in Super-Refractory Status Epilepticus (SRSE):** The STATUS Trial, a global, Phase 3, randomized, double-blind, placebo-controlled clinical trial of SAGE-547 for the treatment of patients with SRSE, is now open for enrollment. SAGE also announced it has reached agreement with the FDA under a Special Protocol Assessment on the trial design, endpoints and statistical approach of the Phase 3 STATUS Trial.
- **Proprietary Follow-On Candidates:** SAGE's novel, second-generation $GABA_A$ receptor allosteric modulators, SAGE-689 and SAGE-217, continue to advance on track in preclinical development and SAGE plans to initiate Phase 1 clinical trials of these molecules in late 2015. SAGE believes that the potential attributes of these new molecules may provide substantial advantages over existing compounds. SAGE-689 is being developed as an adjunctive IV therapy for the treatment of status epilepticus, while SAGE-217

is being developed as an oral therapy for orphan epilepsies, such as Dravet syndrome and Rett syndrome. Both SAGE-689 and SAGE-217 are designed to have pharmacological properties similar to SAGE-547, but with optimized pharmacokinetic profiles with potential for higher potency and selectivity than first-generation neurosteroids.

- **Exploratory Development Programs:** SAGE is using SAGE-547 to explore additional potential uses of $GABA_A$ receptor modulators in broader CNS disorders and to help guide the design of second-generation molecules for development in the applicable diseases.
    - **Postpartum Depression (PPD):** In June 2015, SAGE reported top-line data from an exploratory, open-label clinical trial of SAGE-547 as a treatment for PPD, a distinct and readily identified form of major depressive disorder estimated to affect up to 20% of women following childbirth, that indicated a statistically significant improvement from baseline in depression in four of four women with severe PPD within 24 hours after administration of intravenous SAGE-547. In late 2015, SAGE plans to initiate a placebo-controlled trial of SAGE-547 in patients with PPD to validate the activity signal observed in the open-label trial.
    - **Essential Tremor (ET):** SAGE is also exploring the potential use of $GABA_A$ receptor modulators in a proof-of-principle clinical trial for ET, a debilitating neurological disorder that causes involuntary, rhythmic shaking with no known cause, affecting over 10 million people in the United States. SAGE is in the final stages of enrollment in the exploratory trial and expects to report top-line results imminently.

**Financial Results and Guidance**

- **Cash Position:** Cash and cash equivalents as of June 30, 2015 were $224.2 million, compared with $127.8 million at December 31, 2014. The increase was primarily due to net proceeds of $129.1 million from the company's public offering completed in April 2015.
- **R&D Expenses:** Research and development expenses were $18.6 million, including $2.3 million of non-cash stock-based compensation expense, in the second quarter of 2015, compared to $4.4 million, including $0.2 million of non-cash stock-based compensation expense, in the second quarter of 2014. The increase in R&D expenses was primarily due to increased spending on clinical activities related to the SAGE-547 development program and its advancement into Phase 3, increased personnel-related R&D expenses to support the advancement of SAGE's pipeline of programs, and expenses associated with non-clinical and discovery efforts.
- **G&A Expenses:** General and administrative expenses were $6.5 million, including $3.1 million of non-cash stock-based compensation expense, in the second quarter of 2015, compared to $1.8 million, including $0.2 million of non-cash stock-based compensation expense, in the second quarter of 2014. The increase in G&A expenses was primarily due to personnel-related costs and professional fees associated with operating as a public company.

- **Net Loss:** Net loss was $25.0 million for the second quarter of 2015 compared to net loss of $7.8 million for the second quarter of 2014.
- **Financial Guidance:** SAGE reiterates its expectation that its cash and cash equivalents on hand as of the date hereof will be sufficient to fund its operations through mid-2017.

**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. The active pharmaceutical ingredient has been contributed under agreement by the Regents of the University of California and the University of California, Davis.

**About Status Epilepticus**

Status epilepticus (SE) is a life-threatening seizure condition that occurs in approximately 150,000 people each year in the U.S., of which 30,000 SE patients die.[1] 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.

Currently, there are no therapies that have been specifically approved for RSE; however, physicians typically use anesthetic agents to induce the coma and stop the seizure immediately. 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 is a clinical-stage biopharmaceutical company committed to developing and commercializing novel medicines to treat life-threatening, rare central nervous system, or CNS, disorders. SAGE's lead program, SAGE-547, is in Phase 3 clinical development for super-refractory status epilepticus (SRSE) and is the first of several compounds the Company is developing in its portfolio of potential CNS medicines. SAGE's proprietary chemistry platform has generated multiple new compounds that target $GABA_A$ and NMDA receptors, which are broadly accepted as impacting many psychiatric and neurological 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 SAGE-547 as a treatment for SRSE, essential tremor and postpartum depression, statements concerning the potential safety and efficacy of SAGE-547 and durability of response, the potential importance and impact of the Phase*

*3 STATUS trial and the open-label expanded access protocol for SAGE-547, whether the results from the Phase 3 STATUS trial together with other available clinical data for SAGE-547 will be sufficient to support submission of an NDA for this product candidate, the timing of SAGE's clinical trials for its product candidates, and SAGE's expectations relating to available cash and cash equivalents and marketable securities at the end of 2015 constitute forward-looking statements for the purposes of the safe harbor provisions under The Private Securities Litigation Reform Act of 1995. In particular, it should be noted that there is limited data concerning the safety and efficacy of SAGE-547. These data may not be repeated or observed in ongoing or future trials involving SAGE-547 or SAGE's other product candidates. Actual results may differ materially from those indicated by these forward-looking statements as a result of various important factors, including, without limitation, SAGE's ability to successfully demonstrate the efficacy and safety of its drug candidates, the pre-clinical and clinical results for its product candidates, which may not support further development of product candidates, actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials, obtaining, maintaining and protecting intellectual property, SAGE's ability to enforce its patents against infringers and defend its patent portfolio against challenges from third parties, competition from others developing products for similar uses, SAGE's ability to manage operating expenses, SAGE's ability to obtain additional funding to support its business activities and establish and maintain strategic business alliances and new business initiatives, SAGE's dependence on third parties for development, manufacture, marketing, sales and distribution of products, the outcome of litigation, and unexpected expenditures, 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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**Sage Therapeutics, Inc. and Subsidiaries**
**Consolidated Balance Sheets**
(in thousands, except share and per share data)
*(Unaudited)*

| | June 30, 2015 | December 31, 2014 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 224,234 | $ 127,766 |
| Prepaid expenses and other current assets | 3,274 | 1,056 |
| Total current assets | 227,508 | 128,822 |
| Property and equipment, net | 285 | 163 |
| Restricted cash | 39 | 39 |
| Deferred tax assets | 641 | 641 |
| Total assets | $ 228,473 | $ 129,665 |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 5,195 | $ 2,429 |
| Accrued expenses | 5,164 | 4,687 |
| Deferred tax liabilities | 641 | 641 |
| Total current liabilities | 11,000 | 7,757 |
| Other liabilities | 22 | 23 |
| Total liabilities | 11,022 | 7,780 |
| Commitments and contingencies | | |
| Stockholders' equity: | | |
| Preferred stock, $0.0001 par value; 5,000,000 shares authorized at June 30, 2015 and December 31, 2014, respectively; no shares issued or outstanding at June 30, 2015 and December 31, 2014, respectively | — | — |
| Common stock, $0.0001 par value; 120,000,000 shares authorized at June 30, 2015 and December 31, 2014, respectively; 28,625,403 and 25,621,791 shares issued and outstanding at June 30, 2015 and December 31, 2014, respectively | 3 | 3 |
| Additional paid-in capital | 326,191 | 188,727 |
| Accumulated deficit | (108,743) | (66,845) |
| Total stockholders' equity | 217,451 | 121,885 |
| Total liabilities and stockholders' equity | $ 228,473 | $ 129,665 |

**Sage Therapeutics, Inc. and Subsidiaries**
**Consolidated Statements of Operations and Comprehensive Loss**
(in thousands, except share and per share data)
*(Unaudited)*

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2015 | 2014 | 2015 | 2014 |
| Operating expenses: | | | | |
| Research and development | $ 18,603 | $ 4,381 | $ 31,503 | $ 8,554 |
| General and administrative | 6,456 | 1,807 | 10,453 | 3,424 |
| Total operating expenses | 25,059 | 6,188 | 41,956 | 11,978 |
| Loss from operations | (25,059) | (6,188) | (41,956) | (11,978) |
| Interest income (expense), net | 41 | 1 | 62 | 1 |
| Other income (expense), net | (9) | (5) | (4) | (5) |
| Net loss and comprehensive loss | (25,027) | (6,192) | (41,898) | (11,982) |
| Accretion of redeemable convertible preferred stock to redemption value | — | (1,577) | — | (1,903) |
| Net loss attributable to common stockholders | $ (25,027) | $ (7,769) | $ (41,898) | $ (13,885) |
| Net loss per share attributable to common stockholders—basic and diluted | $ (0.90) | $ (4.57) | $ (1.57) | $ (8.28) |
| Weighted average number of common shares used in net loss per share attributable to common stockholders—basic and diluted | 27,860,332 | 1,700,517 | 26,765,705 | 1,676,864 |