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): November 5, 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 November 5, 2015, Sage Therapeutics, Inc. announced its financial results for the quarter ended September 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 November 5, 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: November 5, 2015

SAGE THERAPEUTICS, INC.

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release issued by Sage Therapeutics, Inc. on November 5, 2015, furnished herewith.

Exhibit 99.1

SAGE Announces Third Quarter 2015 Financial Results and Recent Pipeline Progress

Expands Pipeline with Selection of Three Next Generation GABA and NMDA Modulators as Development Candidates

Initiated Placebo-Controlled, Proof-of-Concept Trial of SAGE-547 in Severe Postpartum Depression

Cambridge, Mass. – November 5, 2015 – Sage Therapeutics (NASDAQ: SAGE) today reported business highlights and financial results for the third quarter ended September 30, 2015.

“SAGE continues to execute on its mission to be a leading CNS company focusing on life-altering disorders with few or no treatment options,” said Jeff Jonas, M.D., Chief Executive Officer of SAGE. “Enrollment of our Phase 3 STATUS Trial evaluating SAGE-547 as a treatment for super-refractory status epilepticus is on track, and we have made important recent progress in advancing our earlier stage next generation pipeline. SAGE-217, our first oral New Chemical Entity, is now in Phase 1 clinical development with broad potential across multiple GABA-related disorders. We have initiated our placebo-controlled proof-of-concept study of SAGE-547 in severe postpartum depression. We are also pleased to have selected three new compounds as development candidates, including our first NMDA modulator targeted at two orphan indications where no approved therapies exist. These activities exemplify SAGE’s focus on innovation to address treatment of CNS diseases.”

GABA Program Updates

- **SAGE-547 in Super-Refractory Status Epilepticus (SRSE)**: Enrollment is on track for the STATUS Trial, a global, Phase 3, randomized, double-blind, placebo-controlled clinical trial of SAGE-547 for the treatment of patients with SRSE. In August, SAGE reached agreement with the U.S. Food and Drug Administration (FDA) under a Special Protocol Assessment (SPA) for the STATUS Trial.
- **Postpartum Depression (PPD):** SAGE has initiated its placebo-controlled proof-of-concept clinical trial of SAGE-547 in patients with PPD. The multi-center, placebo-controlled study is planned to enroll up to 32 patients diagnosed with severe PPD. The Company expects to report top-line results in the first half of 2016. The placebo-controlled study is intended to validate the activity signal observed in an initial open-label study of SAGE-547 as a treatment for PPD.
- **SAGE-217:** SAGE is currently dosing subjects 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. SAGE-217 is a next generation positive allosteric modulator that has been optimized for selectivity of synaptic and extrasynaptic $GABA_A$ receptors and for a pharmacokinetic profile allowing 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 September 2015, SAGE announced positive top-line proof-of-concept data from an exploratory, placebo-controlled study of SAGE-547 in patients with essential tremor.

- **SAGE-689:** SAGE is delaying the commencement of Phase 1 clinical development of SAGE-689 to respond to requests from the U.S. Food and Drug Administration for additional non-clinical study data unrelated to toxicology. SAGE-689, a next generation positive allosteric modulator of $GABA_A$ receptors, is being developed as an acute parenteral therapy for the treatment of indications where a high degree of anti-seizure activity and sedation are desirable prior to the introduction of general anesthesia, such as status epilepticus.
- **SAGE-105 and SAGE-324:** SAGE has selected SAGE-105 and SAGE-324 as its next GABA development candidates. Both molecules are differentiated, next generation positive allosteric modulators of $GABA_A$ receptors, and are intended to be studied for undisclosed $GABA_A$ dysfunction-related disorders.
- **Publication on SAGE Extrasynaptic-Selective $GABA_A$ Modulator:** In August, SAGE scientists and collaborators published an article in *The Journal of Neuroscience Research* describing preclinical data from animal studies of a next generation extrasynaptic-selective $GABA_A$ positive allosteric modulator, SGE-872, suggesting a potential novel therapeutic approach to treat disorders associated with $GABA_A$-related dysfunction.

NMDA Program Updates

- **SAGE-718:** SAGE announced today the selection of SAGE-718 as its first NMDA development candidate planned to enter IND-enabling studies. SAGE-718 is being developed as a first-in-class, oxysterol-based positive allosteric modulator of NMDA receptors, a critical excitatory receptor system implicated in a broad range of CNS disorders. In 2013, SAGE scientists and collaborators published an article in *The Journal of Neuroscience* describing data from animal studies demonstrating that 24(S)-Hydroxycholesterol (cerebrosterol), a naturally occurring oxysterol, is a potent and selective positive allosteric modulator of NMDA receptors acting at a novel oxysterol modulatory site. SAGE-718 has been designed to be a highly potent and selective modulator with an optimized pharmacokinetic profile intended to support oral dosing. SAGE-718 has demonstrated robust activity in preclinical models of NMDA receptor hypofunction. The initial indications selected by SAGE for development are two NMDA-related orphan disorders—Smith-Lemli-Opitz Syndrome and Anti-NMDA Receptor Encephalitis, for which there are currently no approved treatments. The focus of SAGE-718 development efforts will be the potential treatment of the neurological symptoms of these disorders through enhancing NMDA receptor function.
- **Smith-Lemli-Opitz Syndrome (SLOS):** SLOS is a rare metabolic disorder caused by a mutation in the DHCR7 (7-dehydrocholesterol reductase) gene which codes for an enzyme that is involved in the production of cholesterol in the brain. SLOS is associated with significantly decreased plasma levels of cerebrosterol, suggesting that normal oxysterol-based modulation of NMDA receptors is disrupted in these patients. People affected by SLOS are unable to make enough of the necessary cholesterol in the brain to support normal growth and development, and are affected by a broad range of neuropsychiatric and neurodevelopmental symptoms. Decreased cerebrosterol levels may also represent a biomarker to identify for future study a range of indications with broader

patient populations characterized by certain phenotypes of cognitive dysfunction and neuropsychiatric symptoms resulting from NMDA receptor hypofunction.

- **Anti-NMDA Receptor Encephalitis (ANRE):** ANRE is a rare autoimmune disorder in which antibodies attack NMDA receptors. Symptoms of ANRE include a highly characteristic set of neuropsychiatric deficits, including cognitive and behavioral disturbances, movement disorders and loss of consciousness. Beyond ANRE, measuring levels of anti-NMDA antibodies may represent a biomarker to identify, for future study, other indications within dementia and psychosis where neuropsychiatric deficits are associated with NMDA hypofunction.

Financial Results and Guidance

- **Cash Position:** Cash and cash equivalents as of September 30, 2015 were $204.9 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 follow-on public offering completed in April 2015.
- **R&D Expenses:** Research and development expenses were $17.5 million, including $1.5 million of non-cash stock-based compensation expense, in the third quarter of 2015, compared to $6.6 million, including $0.3 million of non-cash stock-based compensation expense, in the third quarter of 2014. The increase in R&D expenses was primarily due to increased spending on activities related to the SAGE-547 development program and its advancement into Phase 3 clinical development, increased personnel-related R&D expenses to support the advancement of SAGE's pipeline of programs, and other expenses associated with clinical, non-clinical and discovery efforts.
- **G&A Expenses:** General and administrative expenses were $6.6 million, including $2.9 million of non-cash stock-based compensation expense, in the third quarter of 2015, compared to $2.9 million, including $0.4 million of non-cash stock-based compensation expense, in the third 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 and related to general operations.
- **Net Loss:** Net loss was $24.0 million for the third quarter of 2015 compared to net loss of $9.9 million for the third 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.

Conference Call Information

SAGE will host a conference call and webcast today at 4:30 p.m. ET to discuss the results of the third quarter 2015 financial results. 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 71025439. 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 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.

Sage Therapeutics, Inc. and Subsidiaries
Consolidated Balance Sheets
(in thousands, except share and per share data)
(Unaudited)

	September 30, 2015	December 31, 2014
Assets		
Current Assets:		
Cash and cash equivalents	$ 204,877	$ 127,766
Prepaid expenses and other current assets	2,604	1,056
Total current assets	207,481	128,822
Property and equipment, net	249	163
Restricted cash	39	39
Deferred tax assets	641	641
Total assets	$ 208,410	$ 129,665
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 3,246	$ 2,429
Accrued expenses	6,404	4,687
Deferred tax liabilities	641	641
Total current liabilities	10,291	7,757
Other liabilities	15	23
Total liabilities	10,306	7,780
Commitments and contingencies		
Stockholders' Equity		
Preferred stock, $0.0001 par value; 5,000,000 shares authorized at September 30, 2015 and December 31, 2014, respectively; no shares issued or outstanding at September 30, 2015 and December 31, 2014, respectively	—	—
Common stock, $0.0001 par value; 120,000,000 shares authorized at September 30, 2015 and December 31, 2014, respectively; 28,788,885 and 25,621,791 shares issued and outstanding at September 30, 2015 and December 31, 2014, respectively	3	3
Additional paid-in capital	330,879	188,727
Accumulated deficit	(132,778)	(66,845)
Total stockholders' equity	198,104	121,885
Total liabilities and stockholders' equity	$ 208,410	$ 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 September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Operating expenses:				
Research and development	17,478	6,601	48,981	15,155
General and administrative	6,604	2,869	17,057	6,294
Total operating expenses	24,082	9,470	66,038	21,449
Loss from operations	(24,082)	(9,470)	(66,038)	(21,449)
Interest income, net	53	3	115	4
Other expense, net	(6)	(1)	(10)	(5)
Net loss and comprehensive loss	(24,035)	(9,468)	(65,933)	(21,450)
Accretion of redeemable convertible preferred stock to redemption value	—	(391)	—	(2,294)
Net loss attributable to common stockholders	$ (24,035)	$ (9,859)	$ (65,933)	$ (23,744)
Net loss attributable to common stockholders per common share—basic and diluted	$ (0.84)	$ (0.50)	$ (2.40)	$ (3.08)
Weighted-average shares outstanding—basic and diluted	28,737,743	19,581,624	27,430,275	7,711,038

Forward-Looking Statements

Various statements in this release concerning SAGE's future expectations, plans and prospects constitute forward-looking statements for the purposes of the safe harbor provisions under the Private Securities Litigation Reform Act of 1995, including without limitation, statements as to SAGE's expectations regarding development of its product candidates and their potential in the treatment of various CNS disorders; the expected timing of clinical activities; the anticipated availability of data and results from clinical trials of SAGE's product candidates; and SAGE's expectations regarding the sufficiency of its cash position to fund operations. 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, progress and cost of clinical trials, and SAGE's ability to proceed with further clinical studies of a product candidate or to obtain marketing approval; the internal and external costs required for our activities, and to build the organization in connection with such activities, may be higher than expected; 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.

###

Investor Contact:
Paul Cox, Sage Therapeutics
paul.cox@sagerx.com
617-299-8377

Media Contact:
Dan Budwick, Pure Communications
dan@purecommunicationsinc.com
973-271-6085