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): February 23, 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))

Item 2.02 Results of Operations and Financial Condition

On February 23, 2017, Sage Therapeutics, Inc. announced its financial results for the fourth quarter and full year ended December 31, 2016. 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 February 23, 2017, 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: February 23, 2017

SAGE THERAPEUTICS, INC.

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 February 23, 2017, furnished herewith.

Sage Therapeutics Announces Fourth Quarter and Full Year 2016 Financial Results and Provides Corporate Update

Continued momentum expected in 2017 with several programs anticipating clinical trial results this year, including two Phase 3 programs

Phase 2 placebo-controlled study of SAGE-217 in major depressive disorder expected to begin in 1H 2017

First NMDA candidate, SAGE-718, planned to enter Phase 1 clinical testing in 1H 2017

Jim Doherty, Ph.D., promoted to Chief Research Officer to lead Sage's new Experimental Medicine group

Conference call today at 8:00 AM ET

CAMBRIDGE, Mass., February 23, 2017 — Sage Therapeutics, Inc. (NASDAQ: SAGE) today reported business highlights and financial results for the fourth quarter and full year ended December 31, 2016.

"Sage is continuing its vision to "rethink" the development of treatments for central nervous system disorders and, in doing so, attempting to close the innovation gap in an area of disease that represents approximately one-third of the worldwide burden of illness. We are now at a point of significant momentum following the pipeline transformation witnessed in 2016, resulting in at least eight anticipated data readouts across multiple different mood, movement and neurological disorders this year, including the results we announced earlier this month. In addition, plans are underway for our potential first commercial launch in 2018," said Jeff Jonas, M.D., Chief Executive Officer of Sage. "We believe that a key element of our success to date has been our utilization of novel and efficient approaches to translational science facilitating the discovery and clinical development of our differentiated investigational medicines. Our new Experimental Medicine group, led by Jim Doherty, Ph.D., will further build on this expertise by establishing a translational foundation across our discovery and clinical programs that we believe will better position Sage for long-term success."

Recent Corporate Highlights

- **Jim Doherty, Ph.D., promoted to Chief Research Officer:** Dr. Doherty joined Sage in 2012 and most recently served as Senior Vice President of Research. Before Sage, he served as Director and Head of the Neuroscience Department for the CNS and Pain Innovative Medicine Unit of AstraZeneca Pharmaceuticals in Sodertalje, Sweden, and prior to that, he was Director and Head of the Neuroscience Department at AstraZeneca Pharmaceuticals in Wilmington, Delaware. He has experience with discovery, translational science and early development in several areas of neuroscience research,

including psychiatry, neurology, cognition, epilepsy and analgesia. He has authored more than 30 peer-reviewed research and review articles. Dr. Doherty holds a B.A. in biology from the University of Delaware and a Ph.D. in neuroscience from Georgetown University. He was a postdoctoral fellow at Emory University Medical School.

- **Experimental Medicine group to lead translational neuroscience strategy:** As part of his new role as Chief Research Officer, Dr. Doherty will build and lead a new Experimental Medicine capability within Sage. The Experimental Medicine group will have four key goals:
    - Identify functional biomarkers in animals that respond to target engagement and can be deployed in human clinical trials
    - Identify genetic and biochemical criteria to identify patient populations to increase the technical probability of success of a clinical trial
    - Translate insights between compounds and indications for better odds of success across the pipeline
    - Oversee small, exploratory human studies in new disease areas
- **Patent issued on SAGE-217:** Sage was recently granted a patent by the United States Patent and Trademark Office, patent number 9,512,165, with claims covering the composition of matter of SAGE-217.
- **SAGE-547 receives United States Adopted Name (USAN), brexanolone:** Sage was recently informed that the USAN Council adopted brexanolone (pronunciation: brek san' oh lone) as the USAN (nonproprietary or generic name) for SAGE-547. Brexanolone is also under review as an international nonproprietary name (INN) by the World Health Organization (WHO).

Pipeline Update

Sage is advancing a portfolio of novel central nervous system (CNS) product candidates targeting the GABA and NMDA receptor systems. Dysfunction in these systems is known to be at the core of numerous psychiatric and neurological disorders. Sage is pursuing a data-driven approach to CNS drug development by employing efficient human proof-of-concept studies to uncover both activity signals and to help understand future trial methodology, before investing in larger clinical programs.

- **Brexanolone (SAGE-547):** Sage is currently developing brexanolone in separate Phase 3 clinical programs as an acute interventional treatment for super-refractory status epilepticus (SRSE) and postpartum depression (PPD). Brexanolone is Sage's proprietary IV formulation of allopregnanolone, a naturally occurring neuroactive steroid that acts as a synaptic and extrasynaptic modulator of the $GABA_A$ receptor.
    - **SRSE:** Sage is evaluating brexanolone (SAGE-547) in the Phase 3 STATUS Trial, a global, randomized, double-blind, placebo-controlled trial, designed to evaluate brexanolone as a potential adjunctive therapy for SRSE, a rare and life-altering seizure condition. The Phase 3 clinical program is being conducted in agreement with the U.S. Food and Drug Administration (FDA) under a Special Protocol Assessment (SPA). Sage also received positive scientific advice in the

fourth quarter of 2016 from the European Medicines Agency (EMA). Based on this advice, the Company believes the Phase 3 clinical program, if successful, will be sufficient to support a marketing authorization application (MAA) to the EMA seeking approval of brexanolone for SRSE in the EU.

- **PPD:** Sage is currently enrolling its Phase 3 clinical program evaluating brexanolone (SAGE-547) as a potential treatment for PPD, consisting of separate placebo-controlled trials in severe PPD patients (202B) and in moderate PPD patients (202C), collectively known as the Hummingbird Study. In 2016, the FDA granted Breakthrough Therapy Designation and the EMA granted PRIority MEdicines (PRIME) designation to brexanolone for the treatment of PPD.

- **SAGE-217:** Sage's most advanced, next-generation product candidate is SAGE-217, a novel, orally-active neuroactive steroid that, like brexanolone (SAGE-547), is a positive allosteric modulator of $GABA_A$ receptors, targeting both synaptic and extrasynaptic $GABA_A$ receptors. In the fourth quarter of 2016, Sage initiated Phase 2 development for SAGE-217 in both mood and movement disorders, with four Phase 2 clinical programs now underway.

  - **Mood Disorders:**

    - **Major Depressive Disorder (MDD):** Earlier this month, Sage reported positive clinical results from Part A of a two-part Phase 2 clinical trial evaluating the safety, tolerability, pharmacokinetics and efficacy of SAGE-217 in patients with moderate to severe MDD. Part A of the Phase 2 trial was an open-label study evaluating SAGE-217 in 13 patients. The primary endpoint for the Part A study was to evaluate the safety and tolerability of SAGE-217. The secondary endpoint was to evaluate the effect of SAGE-217 compared to baseline following two weeks of once-nightly treatment as measured by the HAM-D total score. The Part B phase, a randomized, double-blind, parallel-group, placebo-controlled study evaluating SAGE-217 as a treatment for MDD, is expected to be initiated in the first half of 2017.

    - **PPD:** Sage is currently enrolling its Phase 2 clinical trial of SAGE-217 in PPD based on positive results to date from the brexanolone (SAGE-547) PPD clinical program. The Phase 2a multi-center, double-blind, placebo-controlled, randomized trial will evaluate the efficacy, safety, tolerability, and pharmacokinetics of SAGE-217 in the treatment of patients with severe PPD. Top-line results from the PPD study are expected in the second half of 2017.

  - **Movement Disorders:**

    - **Essential tremor:** Sage is currently enrolling its Phase 2 clinical trial of SAGE-217 in essential tremor. The efficacy, safety, tolerability, and pharmacokinetics of SAGE-217 are being evaluated in the Phase 2a multi-center, double-blind, placebo-controlled, randomized withdrawal trial in the treatment of patients with essential tremor. Top-line results from the essential tremor study are expected in the second half of 2017.

- **Parkinson's disease:** Sage is currently enrolling Part A of a two-part Phase 2 clinical trial of SAGE-217 in Parkinson's disease. Part A of the Phase 2 trial is an open-label, proof-of-concept study which, if positive, may lead to a randomized, placebo-controlled Part B of the Phase 2 trial. Top-line results from the Part A study are expected in the first half of 2017.

- **Other GABA Programs:** Sage is currently evaluating a series of novel GABA modulators in pre-clinical development, including SAGE-105, SAGE-324 and SAGE-689. Sage recently initiated IND-enabling studies of SAGE-105 and SAGE-324, which are novel, orally-active next-generation GABA modulators that are intended to be developed for GABA-related indications, such as orphan epilepsies and other disorders involving GABA hypofunction.
- **NMDA:** Sage is also developing novel compounds that target the NMDA receptor. The first product candidate selected for development from this program is SAGE-718, an oxysterol-based NMDA positive allosteric modulator. Our initial focus for development of SAGE-718 is on cerebrosterol deficit disorders, anti-NMDA receptor encephalitis, and other indications involving NMDA hypofunction. SAGE-718 has completed IND-enabling studies and Sage expects to initiate Phase 1 clinical development for SAGE-718 in the first half of 2017.

Expected Near-Term Clinical Milestones

- **Trial Initiations:**
  - Part B of Phase 2 trial of SAGE-217 in MDD (1H 2017)
  - Phase 1 program of first NMDA candidate, SAGE-718 (1H 2017)
- **Top-Line Data Readouts:**
  - Phase 3 STATUS Trial of brexanolone (SAGE-547) in SRSE (1H 2017)
  - Part A open-label portion of Phase 2 trial of SAGE-217 in Parkinson's disease (1H 2017)
  - Phase 3 trial (202B) of brexanolone (SAGE-547) in PPD (2H 2017)
  - Phase 3 trial (202C) of brexanolone (SAGE-547) in PPD (2H 2017)
  - Phase 2 trial of SAGE-217 in essential tremor (2H 2017)
  - Phase 2 trial of SAGE-217 in PPD (2H 2017)
  - Phase 1 single-ascending dose (SAD) trial of SAGE-718 (2H 2017)

Financial Results for the Fourth Quarter and Full Year 2016

- **Cash Position:** Cash, cash equivalents and marketable securities as of December 31, 2016 were $397.5 million, compared with $186.8 million at December 31, 2015.
- **R&D Expenses:** Research and development expenses were $42.0 million, including $5.0 million of non-cash stock-based compensation expense, in the fourth quarter of 2016, compared to $20.4 million, including $1.6 million of non-cash stock-based compensation expense, for the same period of 2015. For the year ended December 31,

2016, research and development expenses were $120.8 million, including $11.2 million of non-cash stock-based compensation expense, compared to $69.4 million, including $5.9 million of non-cash stock-based compensation expense, for the same period of 2015. The increase in R&D expenses year-over-year was primarily due to the ongoing clinical development of brexanolone (SAGE-547) in SRSE and PPD; completion of Phase 1 development for SAGE-217; initiation of the Phase 2 clinical programs for SAGE-217; the ongoing IND-enabling studies for SAGE-718; and investments in R&D headcount to support the growth in Sage's pipeline and operations.

- **G&A Expenses:** General and administrative expenses were $14.4 million, including $5.1 million of non-cash stock-based compensation expense, in the fourth quarter of 2016, compared to $8.2 million, including $2.5 million of non-cash stock-based compensation expense, for the same period of 2015. For the year ended December 31, 2016, general and administrative expenses were $39.4 million, including $11.8 million of non-cash stock-based compensation expense, compared to $25.3 million, including $9.3 million of non-cash stock-based compensation expense, for the same period of 2015. The increase in G&A expenses year-over-year was primarily due to the increase in personnel-related expenses, professional fees and facilities-related costs to support expanding operations, as well as continued preparations for a potential commercial launch.
- **Net Loss:** Net loss was $55.9 million for the fourth quarter of 2016 and $159.0 million for the year ended December 31, 2016, compared to a net loss of $28.6 million and $94.5 million, respectively, for the comparable periods of 2015.
- **Financial Guidance:** Sage expects that its existing cash, cash equivalents and marketable securities will fund its anticipated level of operations, based on its current operating plans, into the second quarter of 2018.

Conference Call Information

Sage will host a conference call and webcast today at 8:00 AM ET to discuss its fourth quarter and year-end 2016 financial results and recent corporate updates. 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 69937798. 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 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, brexanolone (SAGE-547), is in Phase 3 clinical development for super-refractory status epilepticus, a rare and severe seizure disorder, and for postpartum depression. Sage is developing its next generation modulators, including SAGE-217 and SAGE-718, 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 concern Sage's future expectations, plans and prospects, including without limitation: our expectations for 2017; our expectations regarding development

of our product candidates and their potential in the treatment of various CNS disorders; the expected timing of initiation and completion of clinical trials; the anticipated availability and announcement of data and results from clinical trials of our product candidates; our goals and expectations with respect to our discovery and translational science efforts; our plans for evaluation of new indications and new compounds; our expectations regarding the regulatory pathway for brexanolone (SAGE-547) in the treatment of SRSE in the EU, and our belief that the results of the current development program for brexanolone in SRSE, if successful, will be sufficient for an MAA filing in the EU; our expectations regarding a potential future NDA filing and commercial launch of brexanolone, if successfully developed and approved; and our expectations with respect to future cash use and cash needs. 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 continue to experience slower than expected enrollment and randomization of evaluable patients in the STATUS trial or slower than expected clinical site initiation and enrollment in our other clinical trials, or the potential need for additional analysis or data or the need to enroll additional patients, leading to possible delays in completion of trials or in the availability of data; we may not be able to generate supportive non-clinical data or to successfully demonstrate the efficacy and safety of our product candidates at each stage of clinical development; success in our non-clinical studies or in earlier stage clinical trials may not be repeated or observed in ongoing or future studies involving the same compound or other product candidates, and ongoing and future pre-clinical and clinical results may not support further development of product candidates or be sufficient to gain regulatory approval to launch and commercialize any product; decisions or actions of regulatory agencies may affect the initiation, timing, progress and cost of clinical trials, and our ability to proceed with further clinical studies of a product candidate or to obtain marketing approval, including the risk that the EMA may, despite scientific advice, decide that the data from our Phase 3 trial in SRSE are not sufficient to support approval; the internal and external costs required for our activities, and to build our organization in connection with such activities, and the resulting use of cash, may be higher than expected, or we may conduct additional clinical trials or pre-clinical studies or engage in new activities, requiring additional expenditures and using cash more quickly than anticipated; and we may encounter technical and other unexpected hurdles in the development and manufacture of our products which may delay our timing or increase our expenses and use of cash, as well as those risks more fully discussed in the section entitled "Risk Factors" in our most recent Quarterly Report on Form 10-Q, as well as 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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Sage Therapeutics, Inc. and Subsidiaries
Condensed Consolidated Balance Sheets
(in thousands)
(Unaudited)

	December 31, 2016	December 31, 2015
Assets		
Current Assets:		
Cash and cash equivalents	$ 168,517	$ 186,753
Marketable securities	228,962	—
Prepaid expenses and other current assets	5,100	1,738
Total current assets	402,579	188,491
Property and equipment and other long-term assets	1,952	525
Total assets	$ 404,531	$ 189,016
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 12,817	$ 5,159
Accrued expenses	22,352	10,148
Total current liabilities	35,169	15,307
Other liabilities	845	14
Total liabilities	36,014	15,321
Total stockholders' equity	368,517	173,695
Total liabilities and stockholders' equity	$ 404,531	$ 189,016

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

	Three Months Ended December 31,		Year Ended December 31,	
	2016	2015	2016	2015
Operating expenses:				
Research and development	$ 42,004	$ 20,376	$ 120,756	$ 69,357
General and administrative	14,375	8,236	39,407	25,293
Total operating expenses	56,379	28,612	160,163	94,650
Loss from operations	(56,379)	(28,612)	(160,163)	(94,650)
Interest income, net	494	63	1,211	178
Other expense, net	(16)	(13)	(35)	(23)
Net loss	$ (55,901)	$ (28,562)	$ (158,987)	$ (94,495)
Net loss per share – basic and diluted	$ (1.50)	$ (0.99)	$ (4.75)	$ (3.40)
Weighted average shares outstanding – basic and diluted	37,198,631	28,810,565	33,492,795	27,778,288