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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

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**FORM 8-K**

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**CURRENT REPORT  
Pursuant to Section 13 or 15(d)  
of The Securities Exchange Act of 1934**

**Date of Report (Date of Earliest Event Reported): January 8, 2018**

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**Sage Therapeutics, Inc.**

(Exact name of registrant as specified in its charter)

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**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)

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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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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**Item 8.01. Other Events.**

On January 8, 2018, Sage Therapeutics, Inc. issued a press release titled, “Sage Therapeutics to Provide Pipeline Update at J.P. Morgan Healthcare Conference and Outline Key 2018 Initiatives to Support Planned Evolution to a Fully-Integrated Commercial Biopharmaceutical Company” (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	<a href="#">Press Release, issued by the Registrant on January 8, 2018.</a>

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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: January 8, 2018

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



## **Sage Therapeutics to Provide Pipeline Update at J.P. Morgan Healthcare Conference and Outline Key 2018 Initiatives to Support Planned Evolution to a Fully-Integrated Commercial Biopharmaceutical Company**

*– Company evolving, as planned, to be a leading, innovative CNS company –*

*– 2018 strategy focuses on continued R&D innovation, pipeline expansion and commercialization plans for new classes of CNS therapeutics –*

**CAMBRIDGE, Mass.** – January 8, 2018 –Sage Therapeutics (NASDAQ: SAGE), a clinical-stage biopharmaceutical company developing novel medicines to treat life-altering central nervous system (CNS) disorders, today announced that in a corporate presentation at the 36<sup>th</sup> Annual J.P. Morgan Healthcare Conference in San Francisco, the Company’s Chief Executive Officer, Jeff Jonas, M.D., will discuss several components of the Company’s strategy to build the business for the long term by assembling the capabilities to fully develop and commercialize important medicines. His remarks will highlight three key areas of focus in the pursuit of new classes of CNS therapies: impacting novel, fundamental brain mechanisms; addressing treatment gaps with differentiated therapies; and discovering a potentially groundbreaking approach to depressive disorders.

“The lack of adequate treatments for CNS disorders is creating a global public health crisis due to limited innovation in neuroscience research and development – until now,” said Dr. Jonas. “Sage is taking on this challenge with a deliberate, planned approach. By thinking differently about CNS drug development, we are originating differentiated medicines with the potential to exceed expectations, customizing the playbook of commercialization, and disrupting conventional wisdom by creating a potential new methodology of care. In 2018, we expect to build on our track record of success, with the potential to create significant value by maximizing patient benefit.”

Dr. Jonas will provide additional detail on the following development programs:

### ***Brexanolone***

Sage is currently focused on launch readiness and building commercial infrastructure to ensure successful commercial execution, if Sage’s proprietary formulation brexanolone is approved to address postpartum depression (PPD), a common biological complication of childbirth.

- Filing of New Drug Application (NDA) planned in 1H 2018
- Buildout of commercial supply chain activities on track for launch
- Buildout of commercial infrastructure underway in anticipation of potential 1H 2019 launch

### ***SAGE-217 and SAGE-324***

Sage’s novel, oral, next-generation positive allosteric modulators of synaptic and extra-synaptic GABA<sub>A</sub> receptors.

## SAGE-217

- **Major Depressive Disorder (MDD):** Initiation of additional clinical studies expected in 2018
- **Postpartum Depression:** Increased Phase 2 trial size in PPD with anticipated data readout in 2Q 2018
  - o Positive results from SAGE-217 Phase 2 trial in MDD and positive Phase 3 results with brexanolone in PPD support maximizing utility of ongoing Phase 2 trial for overall depression development program
- **Bipolar Depression:** Initiation of development program planned for 2018
- **Parkinson's Disease:** Initiation of placebo-controlled Phase 2b study planned for 2018
- **Insomnia:** Results from exploratory Phase 1 placebo-controlled study expected in 1Q 2018; results to inform potential development path
- **Essential Tremor:** Completed Part C of exploratory Phase 2 trial in essential tremor
  - o Open-label design initiated to study higher doses and extended dosing in 18 patients
  - o Improved tremor symptoms, as assessed by the Kinesia Upper Limb Combined Score, by 16% on Day 15 following two weeks of dosing. Administration of SAGE-217 was generally well-tolerated
  - o The most common adverse events were somnolence, dizziness, and sedation. There were no serious adverse events reported in the study
  - o Reductions in kinetic tremor measures of up to 21% at 40mg suggest twice-daily dosing may be preferable for this indication
  - o Planned development efforts in essential tremor to be moved from SAGE-217 to SAGE-324 based on respective compound profiles and anticipated twice-daily dosing requirements for essential tremor

## SAGE-324

- **Essential Tremor/Epileptiform Disorders:** Continuation of IND-enabling studies; initiation of Phase 1 study anticipated in 1H 2018
  - o Plans to explore SAGE-324 in essential tremor based on positive exploratory placebo-controlled clinical trial with SAGE-547 and open-label essential tremor studies with SAGE-217

## GABA Discovery Programs

- Evaluating a series of novel GABA<sub>A</sub> receptor modulators in pre-clinical development, including SAGE-689, SAGE-105, and others

## NMDA Programs

Sage's novel, oral, first-in-class oxysterol-based positive allosteric modulators of the NMDA receptor.

The Company recently selected SAGE-904 as its second NMDA receptor positive allosteric modulator product candidate for development. Positive modulation of NMDA receptors may have potential in the treatment of a range of neurological disorders associated with a variety of cognitive, neurological and behavioral symptoms.

## SAGE-718

- Initiation of Phase 1 multiple ascending dose study anticipated in 1H 2018
- Announcement of clinical development strategy, including lead indications, planned for 2018

## **SAGE-904**

- Differentiated pharmacologic and pharmacokinetic profile from SAGE-718
- Recently initiated IND-enabling studies

## **2017 Year-End Cash Guidance**

Sage ended 2017 with approximately \$518 million of cash, cash equivalents and marketable securities, including \$325.7 million in net proceeds from a public offering completed in November 2017. Based on its current operating plans, Sage expects that its operating expenses will increase year over year in 2018 to support continued pipeline advancement and potential product commercialization of brexanolone in PPD. Sage expects to provide specific 2018 financial guidance in its fourth quarter and full year 2017 financial results announcement in February 2018.

## **Webcast Information for JP Morgan Presentation**

Sage is scheduled to present on Tuesday, January 9, 2018 at 11:30 a.m. Pacific Time (2:30 p.m. Eastern Time), followed by a Q&A session. A live webcast of the presentation and Q&A session can be accessed on the investor page of Sage's website at investor.sagerx.com. 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, a proprietary IV formulation of brexanolone (SAGE-547), has completed two Phase 3 clinical trials in postpartum depression. Sage is developing its next generation modulators, including SAGE-217 and SAGE-718, in various CNS disorders. For more information, please visit [www.sagerx.com](http://www.sagerx.com).

## **Forward-Looking Statements**

*Various statements in this release concern Sage's future expectations, plans and prospects, including without limitation: our expectations regarding the timing of a potential NDA filing and launch of our proprietary formulation of brexanolone in PPD, and the expected build of commercial infrastructure and supply chain; our statements regarding plans for further development of our product candidates and related activities and our view of the potential for successful development; our views as to the opportunity represented by Sage's portfolio and business, and the potential for value creation; and our expectations with respect to future use of cash. 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: the clinical and non-clinical data we have generated with our proprietary formulation of brexanolone to date may be determined by regulatory authorities, despite prior advice, to be insufficient to file for or gain regulatory approval to launch and commercialize our product in PPD and regulatory authorities may determine that additional trials or data are necessary in order to file for or obtain approval; regulatory authorities may find fault with the data generated at particular clinical site or sites or with the activities of our trial monitor or may disagree with our analyses of the results of our trials or identify issues with our manufacturing or quality systems, and any such findings or issues could require additional data or analyses or changes to our systems that could delay or prevent us from gaining approval of brexanolone; we may encounter*

*unexpected safety or tolerability issues with brexanolone, SAGE-217 or any of our other product candidates in ongoing or future development; we may not be able to successfully demonstrate the efficacy and safety of SAGE-217 or any of our other product candidates at each stage of development; success in early stage clinical trials may not be repeated or observed in ongoing or future studies of SAGE-217 or any of our other product candidates; ongoing and future clinical results may not support further development or be sufficient to gain regulatory approval to market SAGE-217 or any of our other product candidates; we may decide that a development pathway for one of our product candidates in one or more indications is no longer feasible or advisable or that the unmet need no longer exists; decisions or actions of the FDA or other regulatory agencies may affect the initiation, timing, design, size, progress and cost of clinical trials and our ability to proceed with further development; we may experience slower than expected enrollment in ongoing clinical trials; 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 product candidates; as well as those risks more fully discussed in the section entitled “Risk Factors” in our most recent Quarterly Report on Form 10-Q, and 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.*

**Investor Contact:**

Paul Cox, 617-299-8377  
paul.cox@sagerx.com

**Media Contact:**

Maureen L. Suda, 585-355-1134  
maureen.suda@sagerx.com