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): January 7, 2019

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))

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. ☐

Item 7.01. Regulation FD Disclosure.

Sage Therapeutics, Inc. (the "Company") from time to time presents and/or distributes to the investment community, at various industry and other conferences, slide presentations to provide updates and summaries of its business. A copy of its current corporate slide presentation is attached to this Current Report on Form 8-K as Exhibit 99.1. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.1.

The information in Item 7.01 of this Form 8-K, including Exhibit 99.1 attached hereto, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (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, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 8.01. Other Events.

On January 7, 2019, the Company issued a press release titled "Sage Therapeutics Announces SAGE-217 Meets Primary and Secondary Endpoints in Phase 3 Clinical Trial in Postpartum Depression" (the "Data Press Release"). A copy of the Data Press Release is filed herewith as Exhibit 99.2 and is incorporated herein by reference.

On January 7, 2019, the Company issued a press release titled "Sage Therapeutics to Provide Update on Key 2019 Initiatives at J.P. Morgan Healthcare Conference" (the "Strategy Press Release"). A copy of the Strategy Press Release is filed herewith as Exhibit 99.3 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Corporate slide presentation of Sage Therapeutics, Inc., dated January 7, 2019.
99.2	Data Press Release, issued by the Registrant on January 7, 2019.
99.3	Strategy Press Release, issued by the Registrant on January 7, 2019.

* * *

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: January 7, 2019

SAGE THERAPEUTICS, INC.

By: /s/ Jennifer Fitzpatrick
Jennifer Fitzpatrick
Vice President, Corporate Counsel

Exhibit 99.1

SAGE THERAPEUTICS

January 2019

J.P. Morgan Healthcare Conference

Rethinking CNS

Safe Harbor Statement

The slides presented today and the accompanying oral presentations contain forward-looking statements, which may be identified by the use of words such as "may," "might," "will," "should," "expect," "plan," "anticipate," "believe," "estimate," "project," "intend," "future," "opportunity", "potential," or "continue," and other similar expressions. Forward-looking statements in this presentation include statements regarding: our expectations regarding the potential for approval by the FDA of our NDA submission for ZULRESSO; our expectations as to the timing of a potential approval and launch; our planned commercial activities, goals and strategy, if ZULRESSO is approved; our anticipated development activities and timelines; the estimated number of patients with certain disorders or diseases or that may benefit from our drugs in the future; the potential for development of our other products candidates in various indications; the target product profile and goals for our product candidates and their potential to change treatment paradigms and improve lives, if we are successful; and our views on our ability to become the leading CNS company. 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 risk that:

- The FDA may not approve ZULRESSO and may require additional trials, analyses or data;
- Even if ZULRESSO is approved, we may encounter issues, delays or unexpected challenges in launching or commercializing the product, including issues related to timing of DEA scheduling, issues related to market acceptance and reimbursement, challenges associated with restrictions or conditions that may be imposed by regulatory authorities, including challenges related to limiting the site of administration to a certified healthcare facility monitored by a qualified healthcare provider, and the necessity for a REMS; and challenges associated with the execution of our sales and patient support activities, which in each case could limit the potential of our product;
- Success in 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 for our product candidates may not support further development of the product candidate or regulatory approval on the timelines we expect or at all or may require additional clinical trials or nonclinical studies;
- Even if our planned development programs are successful, we still may not achieve review or approval;
- We may experience slower than expected enrollment in our clinical trials or may encounter other delays or problems, including in analyzing data or requiring the need for additional analysis, data or patients, and such issues with any trial could cause delay in completion of the trial, availability of results and timing of future activities;
- Even if our products are successfully developed and approved, the number of patients with the diseases or disorders our products treat, and the actual market for such products may be smaller than our current estimates; or we may not achieve market acceptance or reimbursement at acceptable levels;
- We may encounter unexpected safety or tolerability issues with respect to any of our product candidates;
- We may not be able to obtain and maintain adequate intellectual property protection or other forms of data and marketing exclusivity for its products, or to defend ours patent portfolio against challenges from third parties;
- We may face competition from others developing products for similar uses as those for which our products are being developed;
- Our operating expenses may be higher than forecasted, and we may also face unexpected expenditures or decide to expand our activities, in either case which may result in the need for additional funding to support our business activities earlier than anticipated;
- Funding to support operations may not be available, when needed, on reasonable terms or at all, or may result in significant dilution to existing shareholders;
- We may not be able to establish and maintain key business relationships with third parties on We may encounter technical and other unexpected hurdles in the manufacture and development of our products.

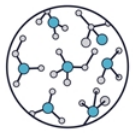
For additional disclosure regarding these and other risks Sage faces, see the disclosure contained in the "Risk Factors" section of our most recent quarterly report, and in our other public filings with the Securities and Exchange Commission, available on the SEC's website at http://www.sec.gov. Any forward-looking statement represent our views only as of today, and should not be relied upon as representing our views as of any subsequent date. We undertake no obligation to update or revise the information contained in this presentation, whether as a result of new information, future events or circumstances or otherwise.

Delivering on *the promise*…

- ✓ Taking on the brain.
- ✓ To make it real.
- ✓ To make it treatable.

…becoming the *leading CNS company*

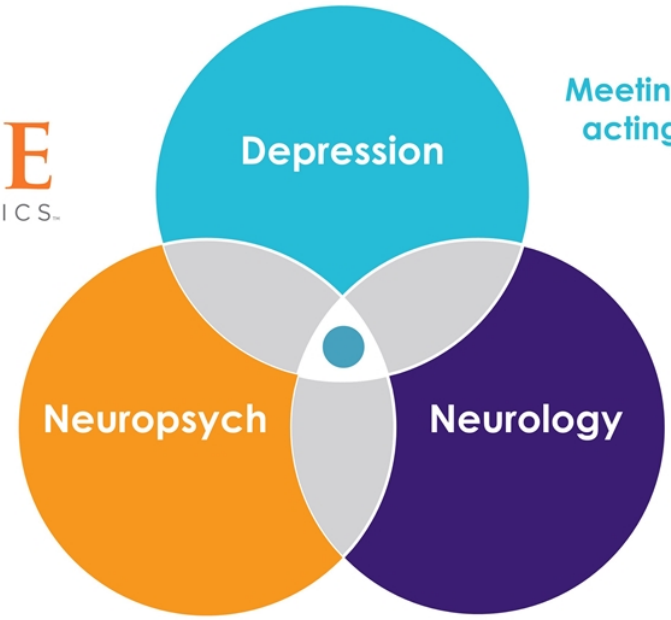
Successfully Establishing a Leading CNS Company in 8 Years

	 CLINICAL PRODUCT CANDIDATES	 CLINICAL INDICATIONS	 LIBRARY COMPOUNDS	 FINANCING
2011	0	0	0	$35M Series A
2014	1	1	>1k	$117M IPO
2019	4	7	>6K	~$5B Market cap[1] $1.7B Gross proceeds to date

1. As of market close on 1/4/2019

Establishing a Multi-Franchise CNS Company

SAGE THERAPEUTICS



Meeting unmet need for rapid-acting treatment-as-needed

Exploring 1st-in-class approach for cognition-related disorders

Exploring novel mechanism for chronic diseases

Building a Unique Depression Franchise

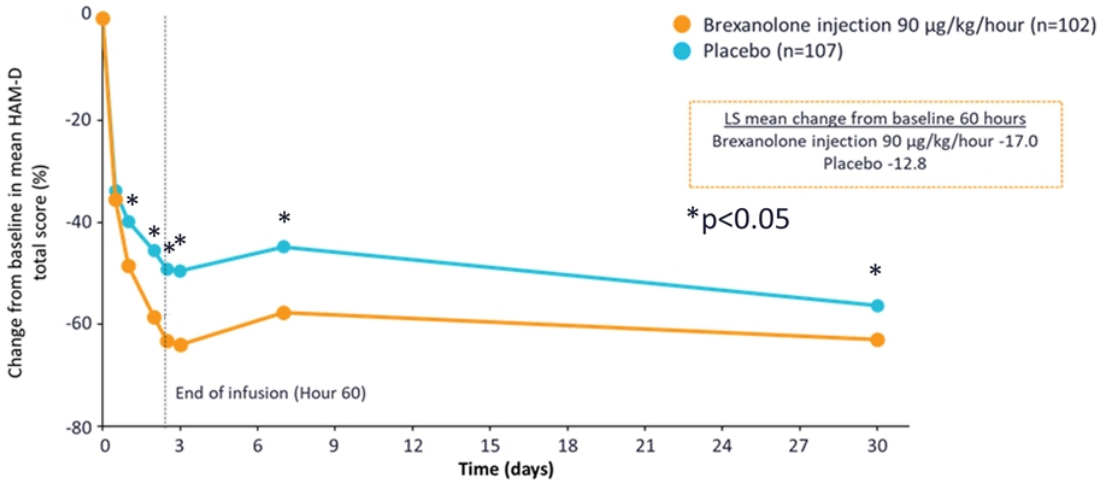
1st-in-class approach to treat mood disorders with the goal of rapid-acting short course therapy

Potential for ZULRESSO™ (brexanolone) injection to be first therapy specifically indicated for PPD

Broad opportunity with SAGE-217 to impact millions of patients

ZULRESSO™ (brexanolone) Injection in PPD

Integrated Hummingbird Study Data Demonstrate Rapid and Durable HAM-D Reduction

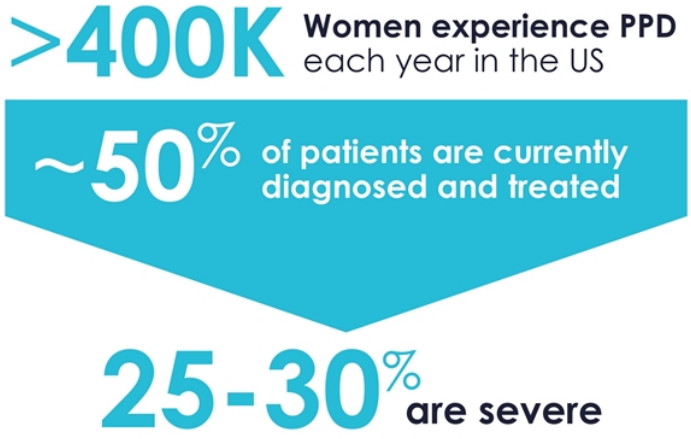


ZULRESSO was generally well tolerated in all three studies. The most common AEs were headache, somnolence/sedation and dizziness/vertigo. The most common adverse events leading to dose reduction or interruption were related to sedation (including loss of consciousness) or the infusion site.

HUMMINGBIRD STUDY

ZULRESSO Approval Would Provide Opportunity to Take on Stigma of PPD

- PPD is the most common medical complication of childbirth
- ZULRESSO is the first medicine under FDA review specifically for the treatment of PPD
- PPD can lead to devastating consequences for a woman and for her family
- Suicide is the leading cause of maternal death following childbirth



1. CDC, https://www.cdc.gov/mmwr/volumes/66/wr/mm6606a1.htm, 2017. 2. Bonthapally, ISPOR Annual International meeting, 2017. 3. PACT, The Lancet, 2015. 4. McCabe-Beane, Journal of Reproductive and Infant Psychology, 2016. All estimates represent management's assessment of total number of patients in U.S. based on relevant literature. Other estimates exist in the literature or using claims analysis which are smaller than our estimates. We attribute differences to differences in methodologies and other factors. As a result, more in-depth studies are needed to better understand prevalence in each case.

Creating New Pathways to Care in PPD

1 Enable Centers of Excellence

- ✓ Identify HCP Champions
- ✓ Drive REMS certification and formulary review
- ✓ Identify potential alternate sites of care

2 Support Access and Reimbursement

- ✓ Educate payers on high unmet need in PPD
- ✓ Support hospital reimbursement pathways beyond DRG
- ✓ Price to clinical value

3 Focus on Patient Experience

- ✓ Enable referral pathways
- ✓ Minimize barriers for appropriate PPD patients
- ✓ Customize case management services

Commercial infrastructure build is complete

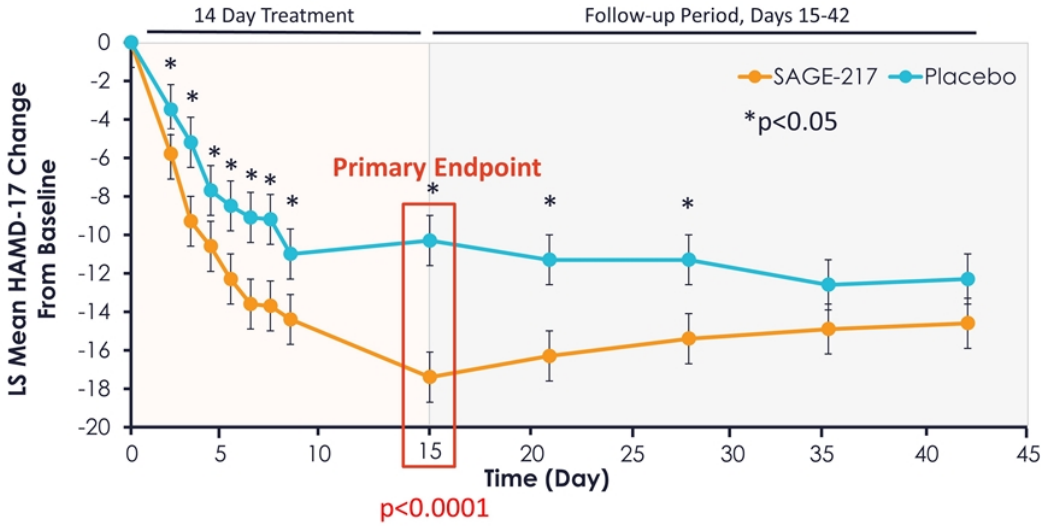
SAGE-217's Potential to Reshape Depression Landscape

Broad Depression Program Underway Across Numerous Studies, Indications and Phases

STUDY	MDD-201	PPD-201	MDD-301	MDD-303	MDD-304	BPD-201
	ROBIN STUDY		MOUNTAIN STUDY	SHORELINE STUDY	RAINFOREST STUDY	ARCHWAY STUDY
Indication	MDD	PPD	MDD	MDD treatment-free intervals	Co-morbid MDD and Insomnia	Bipolar Depression
Phase	Pivotal	Pivotal	Pivotal	Pivotal Open-Label	Pivotal	Phase 2 Open-Label
Status	**Complete**	**Complete**	Initiated	Initiated	Initiated	Initiated

SAGE-217: Positive Pivotal MDD Results (MDD-201)

Demonstrated Rapid, Profound and Durable Treatment Response

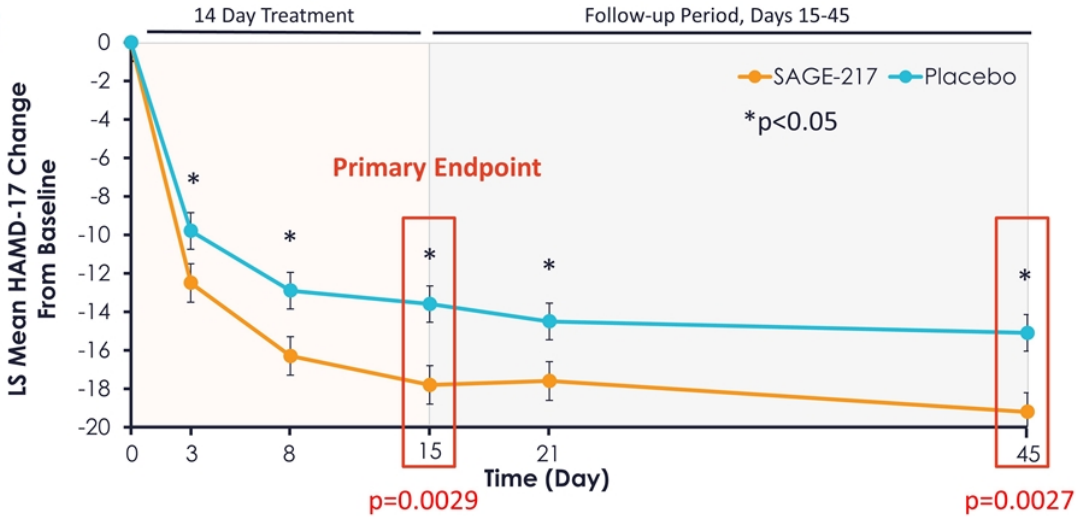


SAGE-217 was generally well-tolerated in the study. The most common AEs included headache, dizziness, nausea and somnolence.

SAGE-217: Positive Phase 3 PPD Results (PPD-201)

Statistically Significant HAMD-17 Improvement Observed on Day 3 and Maintained through Day 45

ROBIN STUDY

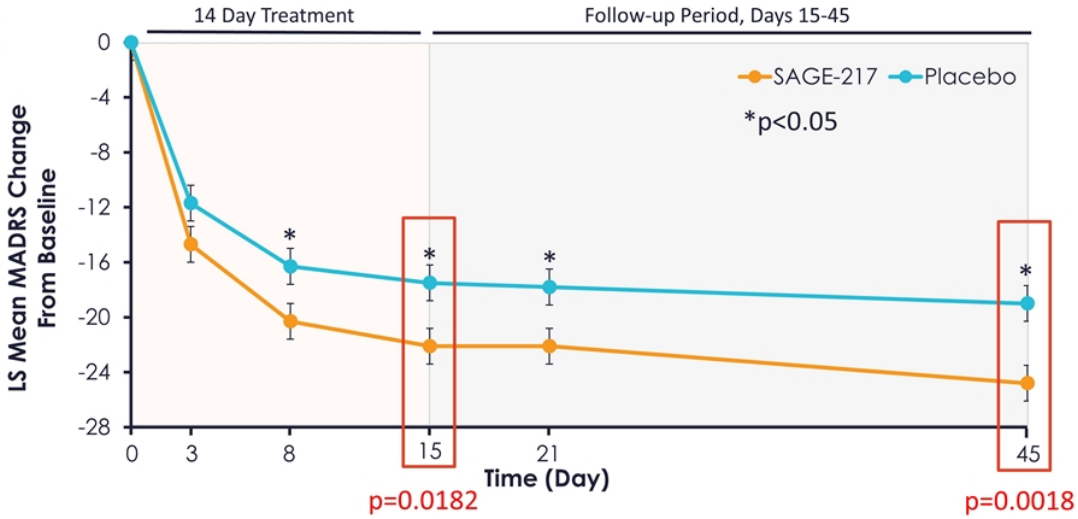


SAGE-217 was generally well-tolerated in the study. The most common adverse events (>5%) in the SAGE-217 treatment group were somnolence, headache, dizziness, upper respiratory tract infection, diarrhea, and sedation. Two subjects experienced SAEs, one subject in each treatment group.

SAGE-217: Positive Phase 3 PPD Results (PPD-201)

Improvement in MADRS Scale Consistent with HAMD-17 Results

ROBIN STUDY



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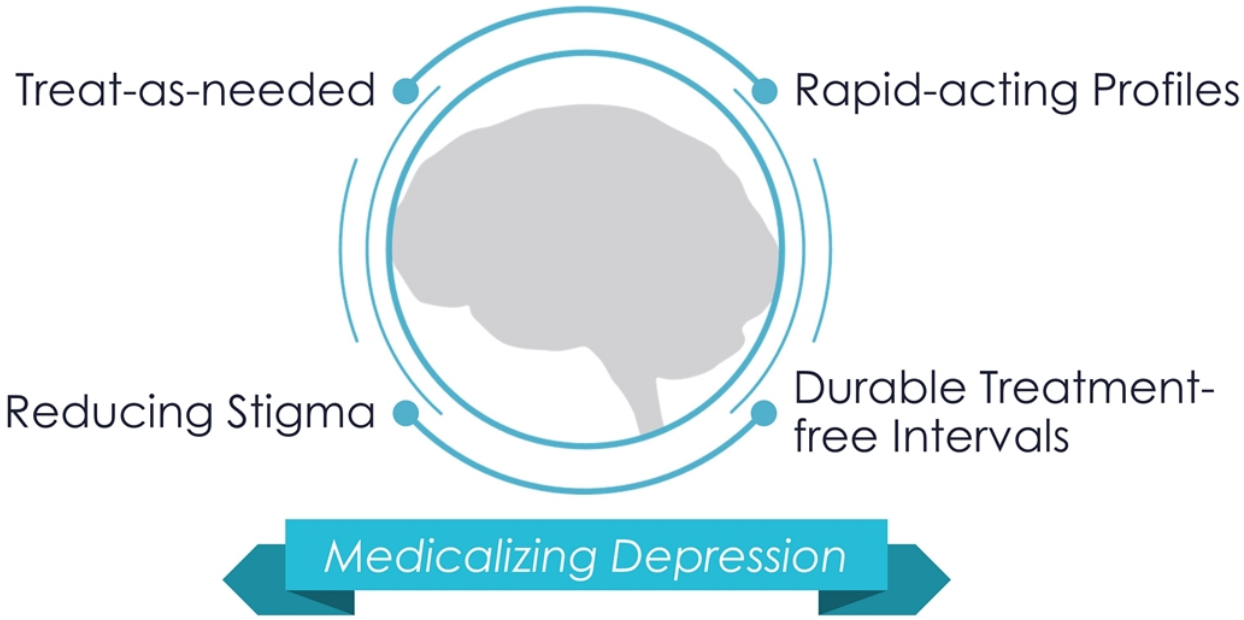
SAGE-217: Positive Phase 3 PPD Results (PPD-201)

Secondary Endpoints were Statistically Significant and Consistent with the Primary Endpoint

ROBIN STUDY

	Primary Endpoint	Secondary Endpoints			
	HAMD-17 Change from Baseline	HAMD-17 Change from Baseline	HAMD-17 Remission	HAMD-17 Response	MADRS Change from Baseline
SAGE-217	Day 15: -17.8	Day 45: -19.2	Day 15: 45%	Day 15: 72%	Day 15: -22.1
			Day 45: 53%	Day 45: 75%	Day 45: -24.8
Placebo	Day 15: -13.6	Day 45: -15.1	Day 15: 23%	Day 15: 48%	Day 15: -17.5
			Day 45: 30%	Day 45: 57%	Day 45: -19.0
Difference	**Day 15: -4.2 (p=0.0029)**	**Day 45: -4.1 (p=0.0027)**	**Day 15: (p=0.0122)**	**Day 15: (p=0.0050)**	**Day 15: -4.6 (p=0.0182)**
			Day 45: (p=0.0102)	**Day 45: (p=0.0220)**	**Day 45: -5.8 (p=0.0018)**

Psychiatry as Medicine

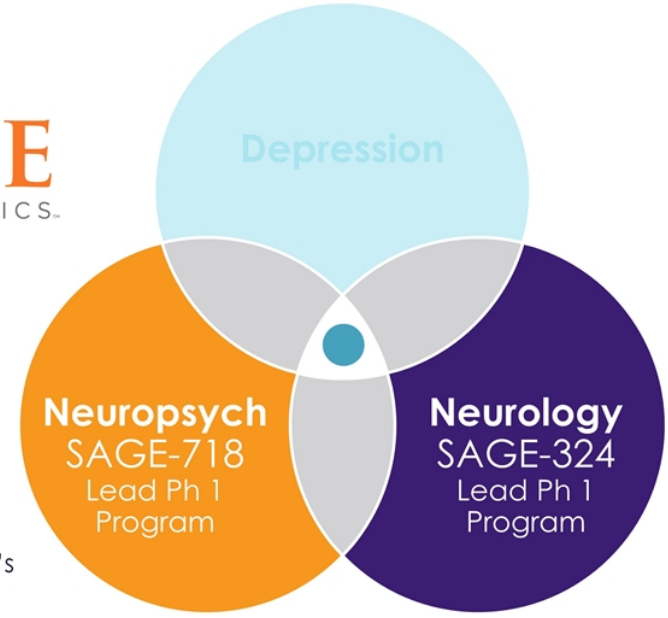


Medicalizing Depression

Substantial Portfolio Franchise Opportunities

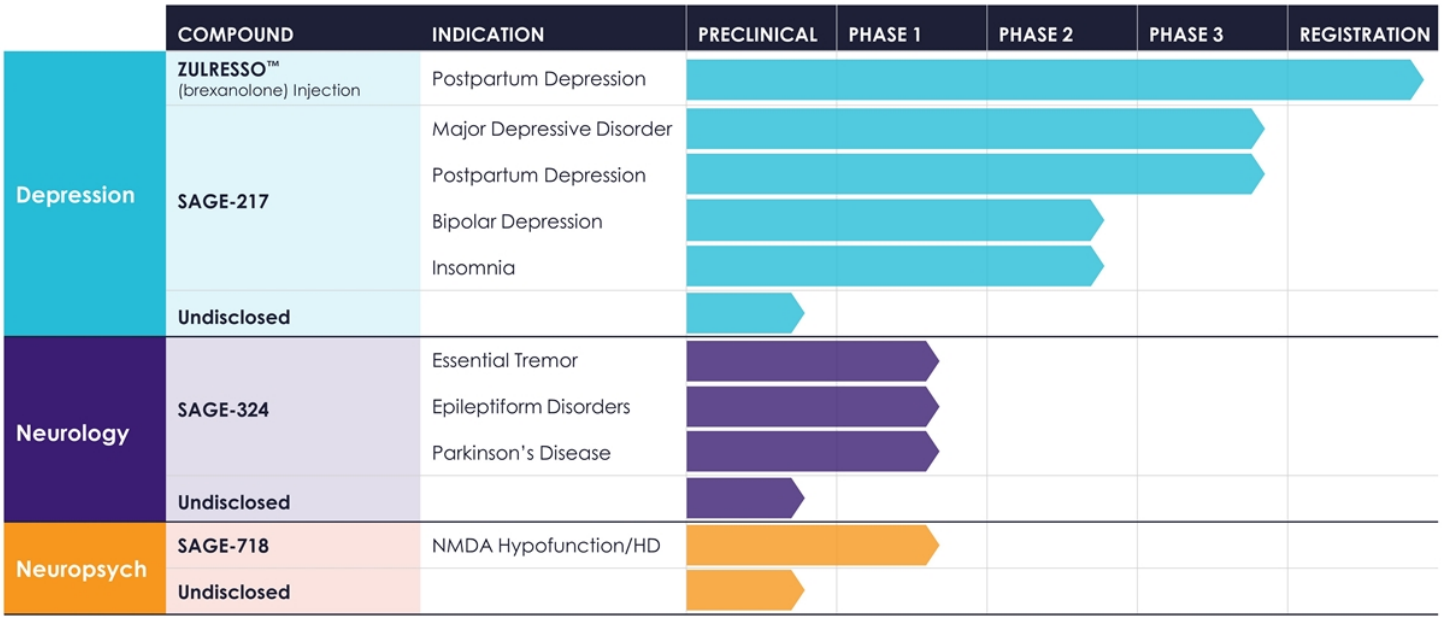
SAGE THERAPEUTICS

- 1st-in-class Oxysterol-based NMDAr modulator
- Strong preclinical basis for role of NMDA receptor system in cognition
- Multiple diseases associated with low NMDA function
- Initiated Phase 1 Huntington's Disease cohort



- Ongoing Phase 1 program
- Potent anti-seizure preclinical data
- Mechanistic POC in essential tremor
- Targeting essential tremor and epileptiform disorders as lead clinical programs

Advancing a Leading CNS Clinical Portfolio



Significant Milestones Over Next 12-18 Months

FRANCHISE	PROGRAM	ANTICIPATED MILESTONE
DEPRESSION	ZULRESSO	PPD PDUFA target date (March 19th)
		PPD commercial launch in U.S., if approved (June)
	SAGE-217	Bipolar depression Phase 2 ARCHWAY Study open-label data (1H 2019)
		MDD Phase 3 MOUNTAIN Study data (2020)
		MDD with co-morbid insomnia Phase 3 RAINFOREST Study data (2020)
		MDD Phase 3 SHORELINE Study open-label treatment-free interval data (2020)
NEUROLOGY	SAGE-324	Phase 1 SAD and MAD data (1H 2019)
		Phase 1 target engagement data (1H 2019)
		Essential tremor Phase 1 cohort data (2H 2019)
NEUROPSYCH	SAGE-718	Phase 1 SAD and MAD data (1H 2019)
		Phase 1 target engagement data (1H 2019)
		Huntington's Disease Phase 1 cohort data (2H 2019)

Committed to Becoming the CNS Leader

Delivering on *the promise…*

Seeing the brain differently
makes a world of difference.

Sage Therapeutics Announces SAGE-217 Meets Primary and Secondary Endpoints in Phase 3 Clinical Trial in Postpartum Depression

– Statistically significant reduction observed in depressive symptoms compared to placebo in women with postpartum depression (PPD) –

– Well-tolerated with rapid onset of statistically significant effect (Day 3) through two weeks and maintained for four weeks after treatment –

CAMBRIDGE, Mass. Jan. 7, 2019 – Sage Therapeutics (NASDAQ: SAGE), a biopharmaceutical company developing novel medicines to treat life-altering central nervous system (CNS) disorders, today reported top-line results from the Phase 3 ROBIN Study. This study evaluated the effect of SAGE-217 30 mg on depressive symptoms in women with postpartum depression (PPD). After two weeks of outpatient treatment, patients treated with SAGE-217 had a statistically significant improvement of 17.8 points in the Hamilton Rating Scale for Depression (HAMD-17) score, compared to 13.6 for placebo (primary endpoint, p=0.0029), with statistically significant reductions in HAMD-17 compared to placebo maintained through the end of the four-week follow-up. Remission was achieved in 45% of patients treated with SAGE-217 for two weeks as measured by the HAMD-17 compared with 23% of patients receiving placebo (p=0.0122). Results from secondary endpoints were statistically significant and consistent with the primary endpoint.

SAGE-217 was generally well-tolerated with a safety profile consistent with that seen in earlier SAGE-217 trials. Overall reports of AEs were similar between SAGE-217 (58%) and placebo (51%). Two subjects experienced serious adverse events (SAEs), one subject in each group.

“These are strong and consistent data demonstrating a rapid, stable, and clinically meaningful improvement in PPD depressive symptoms in the SAGE-217 treatment group compared to placebo,” said Jeff Jonas, M.D., chief executive officer of Sage. “This is our fifth consecutive positive study in mood disorders with our investigational medicines that utilize our innovative approach to GABA receptor modulation. Data from the ROBIN Study, along with earlier data from our studies with ZULRESSO in PPD and SAGE-217 in major depressive disorder, all point to the promise that our approach may hold - not only in changing the way PPD and MDD are treated, but also in potentially improving the lives of patients suffering from these mood disorders. The team at Sage has shown what rethinking CNS really means.”

The ROBIN Study is part of a pivotal program studying SAGE-217 as a short-course oral treatment for PPD and major depressive disorder.

Summary of Top-line SAGE-217 Phase 3 PPD Trial Results

Sage’s Phase 3 ROBIN Study evaluated the efficacy, safety and pharmacokinetics of SAGE-217 in 151 adult female patients diagnosed with severe PPD (HAMD-17 ³26).

Effect on Postpartum Depressive Symptoms:

- Statistically significant differences in the reduction in HAMD-17 total score of SAGE-217 versus placebo were first observed on Day 3 (-12.5 vs. -9.8; p=0.0255) and the effect was maintained at each timepoint through two weeks of treatment (-17.8 vs. -13.6; p=0.0029), the primary endpoint of the study. The effect was maintained through the four-week follow-up (-19.2 vs. -15.1; p=0.0027).
- After two weeks of treatment with SAGE-217, 45% of patients achieved remission (HAMD-17 £7) compared with 23% of patients who received placebo (p=0.0122); at the end of the four-week follow-up, 53% of patients receiving SAGE-217 achieved remission compared with 30% of patients who received placebo (p=0.0102).

- After two weeks of treatment with SAGE-217, 72% of patients achieved a response (50% improvement from baseline HAMD-17 score) compared with 48% of patients who received placebo (p=0.0050); at the end of the four-week follow-up, 75% of patients receiving SAGE-217 achieved a response compared with 57% of patients who received placebo (p=0.0220).
- Statistically significant differences in the reduction in Montgomery-Åsberg Depression Rating Scale (MADRS) score for the SAGE-217 treatment group versus placebo were observed after two weeks of treatment (-22 vs. -18; p=0.0182) and the effect was maintained through the end of the four-week follow-up (-25 vs. -19; p=0.0018).
- Other secondary endpoints, including the Hamilton Anxiety Rating Scale (HAM-A) and Clinical Global Impression – Improvement (CGI-I) Scale, also showed statistically significant improvements in favor of SAGE-217 vs placebo.

Safety and Tolerability:

- SAGE-217 was generally well tolerated in the trial. The overall incidence of patients who experienced adverse events was 58% for the SAGE-217 treatment group and 51% for the placebo group.
    - One subject experienced a serious adverse event in the SAGE-217 arm that resolved after dose reduction. One subject experienced a serious adverse event in the placebo arm.
    - There were no reports of loss of consciousness or syncope in either arm of the trial.
    - One subject in the SAGE-217 group discontinued due to an adverse event.
- The most common adverse events (≥5%) in either treatment group were somnolence (12.8% SAGE-217; 8.2% placebo), headache (9.0% SAGE-217; 12.3% placebo), dizziness (7.7% SAGE-217; 5.5% placebo), upper respiratory tract infection (7.7% SAGE-217; 1.4% placebo), diarrhea (6.4% SAGE-217; 2.7% placebo), nausea (3.8% SAGE-217; 8.2% placebo), sedation (5.1% SAGE-217; 0.0% placebo), vomiting (1.3% SAGE-217; 5.5% placebo), abnormal dreams (0.0% SAGE-217; 5.5% placebo) and hyperhidrosis (0.0% SAGE-217; 5.5% placebo).
- There was no signal for increased suicidal ideation or suicidal behavior compared to baseline, as measured by the Columbia Suicide Severity Rating Scale (C-SSRS). There was one report of self-injurious behavior in the placebo arm.

About the ROBIN Study

Sage's Phase 3 ROBIN Study evaluated the efficacy, safety and pharmacokinetics of SAGE-217 in 151 adult female patients diagnosed with severe postpartum depression (PPD). The primary endpoint of the multicenter, randomized, double-blind, parallel-group, placebo-controlled study was to determine if outpatient treatment with SAGE-217 reduces depressive symptoms in subjects with severe PPD compared to placebo as assessed by the change from baseline in the 17-item Hamilton Rating Scale for Depression (HAMD-17) total score at Day 15.

For more information about this trial, please visit https://therobinstudy.com/.

About Postpartum Depression

Postpartum depression (PPD) is a distinct and readily identified major depressive disorder that is the most common medical complication of childbirth, affecting a subset of women typically commencing in the third trimester of pregnancy or within four weeks after giving birth. PPD may have devastating consequences for a woman and for her family, which may include significant functional impairment, depressed mood

and/or loss of interest in her newborn, and associated symptoms of depression such as loss of appetite, difficulty sleeping, motor challenges, lack of concentration, loss of energy and poor self-esteem. Suicide is the leading cause of maternal death following childbirth. Postpartum depression affects approximately one in nine women who have given birth in the U.S. and 400,000 women annually. More than half of these cases may go undiagnosed without proper screening.

About SAGE-217

SAGE-217 is a next generation positive allosteric modulator that has been optimized for selectivity to synaptic and extrasynaptic $GABA_A$ receptors and a pharmacokinetic profile intended for daily oral dosing. The GABA system is the major inhibitory signaling pathway of the brain and central nervous system (CNS), and contributes significantly to regulating CNS function. SAGE-217 is currently being developed for MDD, PPD and certain other mood disorders.

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 CNS disorders. Sage's lead product candidate, ZULRESSO™ (brexanolone) injection, has completed Phase 3 clinical development for postpartum depression and a New Drug Application is currently under review with the U.S. Food and Drug Administration. Sage is developing a portfolio of novel product candidates targeting critical CNS receptor systems, including SAGE-217, which is in Phase 3 development in major depressive disorder and postpartum depression. 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 views as to the potential of SAGE-217 in PPD and MDD and of ZULRESSO in PPD to change the ways those disorders are treated and to potentially improve lives; our estimates as to the number of patients with PPD; and our other statements regarding the potential of our product candidates. 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 not be successful in our development of SAGE-217 or of any of our other product candidates in any indication we are currently pursuing or may in the future pursue; success in earlier stage clinical trials or in nonclinical studies may not be repeated or observed in ongoing or future studies, and ongoing and future non-clinical and clinical results, including with respect to SAGE-217, may not support further development or be sufficient to gain regulatory approval to market the product; we may not be successful in our efforts to gain FDA approval of ZULRESSO; we may encounter adverse events at any stage of development of our product candidates or in commercialization of our products, if approved, that may negatively impact further development or limit market acceptance of any product we may commercialize; the actual size of the PPD patient population may be significantly lower than our estimates and, even if ZULRESSO or SAGE-217 is approved, it may only be approved or used to treat a subset of the relevant patient populations; and we may encounter technical and other unexpected hurdles in the development and manufacture of SAGE-217 or any of our other product candidates which may delay our timing or change our plans, 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.

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

Media Contact:
Maureen Suda, 585-355-1134
maureen.suda@sagerx.com

# # #

Sage Therapeutics to Provide Update on Key 2019 Initiatives at J.P. Morgan Healthcare Conference

– Multi-franchise strategy ongoing in depression, neurology and neuropsychiatry –

– Commercial infrastructure build completed for ZULRESSO™ (brexanolone) injection ahead of March 19, 2019 target PDUFA date –

– Statistically significant results achieved in Phase 3 trial of SAGE-217 in postpartum depression –

– First patient dosed in second pivotal trial of SAGE-217 in major depressive disorder –

CAMBRIDGE, Mass., Jan. 7, 2019 – Sage Therapeutics, Inc. (NASDAQ: SAGE), a clinical-stage biopharmaceutical company developing novel medicines to treat life-altering central nervous system (CNS) disorders, today announced that Chief Executive Officer, Jeff Jonas, M.D., will discuss the Company's progress as a leading, multi-franchise CNS company in a corporate presentation at the 37th Annual J.P. Morgan Healthcare Conference in San Francisco. As part of the presentation, Dr. Jonas will highlight key programs in the expanding portfolio of product candidates across Sage's depression, neurology, and neuropsychiatry franchises, all using novel mechanisms and approaches with the potential to treat patients with serious disorders impacting significant patient populations.

"We've made significant progress over the last eight years and our innovative approach to discovery and development has resulted in five consecutive positive trials in mood disorders," said Jeff Jonas, M.D., chief executive officer at Sage. "We had a vision to change the way brain disorders were thought about, studied and treated. As we prepare to advance our lead product candidate from development to planned commercialization, we believe we are delivering on that promise. By taking on the stigma of mental health and challenging the conventional wisdom of how mood disorders are treated, we hope to become the leading CNS company."

Dr. Jonas will discuss the following milestones anticipated in the next 12-18 months:

Depression Franchise:

Led by ZULRESSO™ (brexanolone) injection, which has been designated as a breakthrough therapy by the U.S. Food and Drug Administration (FDA) for the treatment of postpartum depression (PPD), and SAGE-217, which has been designated as a breakthrough therapy for the treatment of major depressive disorder (MDD).

- Buildout of the commercial infrastructure to support the potential launch of ZULRESSO for the treatment of PPD is complete.
    - The FDA recently extended the Prescription Drug User Fee Act (PDUFA) goal date for its Priority Review of the New Drug Application (NDA) for ZULRESSO in the treatment of PPD.
        - Previously disclosed December 19, 2018 PDUFA goal date was extended by a period of three months to March 19, 2019; launch of ZULRESSO in the U.S., if approved, will follow the anticipated scheduling of brexanolone by the Drug Enforcement Administration (DEA), and is projected for June 2019.
    - Commercial activities, if the NDA is approved, will focus on executing across key pillars of the go-to-market strategy by enabling Centers of Excellence while identifying patient access and reimbursement pathways to optimize the patient experience.

- Statistically significant topline results from the Phase 3 ROBIN Study of SAGE-217 in severe PPD patients demonstrated a rapid, profound and sustained reduction in depressive symptoms compared to placebo.
    - After two weeks of outpatient treatment, patients treated with SAGE-217 had a statistically significant improvement of 17.8 points in the Hamilton Rating Scale for Depression (HAMD-17) score, compared to 13.6 for placebo (p=0.0029).
    - Remission was achieved in 45 percent of patients treated with SAGE-217 for two weeks as measured by the HAMD-17 compared with 23 percent of patients receiving placebo (p=0.0122), with a remission maintained through the end of the 4-week follow-up.
    - Results from secondary endpoints were statistically significant and consistent with the primary endpoint.
    - SAGE-217 was generally well-tolerated with a safety profile consistent with that seen in earlier SAGE-217 trials. Two subjects experienced serious adverse events (SAEs), one subject in each group. Overall reports of AEs were similar between SAGE-217 (58%) and placebo (51%). The most common adverse events (>5%) in either treatment group were somnolence (12.8% SAGE-217; 8.2% placebo), headache (9.0% SAGE-217; 12.3% placebo), dizziness (7.7% SAGE-217; 5.5% placebo), upper respiratory tract infection (7.7% SAGE-217; 1.4% placebo), diarrhea (6.4% SAGE-217; 2.7% placebo), nausea (3.8% SAGE-217; 8.2% placebo), sedation (5.1% SAGE-217; 0.0% placebo), vomiting (1.3% SAGE-217; 5.5% placebo), abnormal dreams (0.0% SAGE-217; 5.5% placebo) and hyperhidrosis (0.0% SAGE-217; 5.5% placebo).
- Additional topline results in the pivotal program for SAGE-217 in MDD anticipated in 2020:
    - Phase 3 MOUNTAIN Study in patients with MDD;
        - First patient dosed in Q4 2018
    - Phase 3 RAINFOREST Study in patients with MDD and co-morbid insomnia;
    - Phase 3 SHORELINE Study evaluating SAGE-217 open-label treatment, treatment-free intervals and as-needed retreatment for return of major depressive episodes.
- Data from Part A open-label portion of the Phase 2 ARCHWAY Study of SAGE-217 in patients with bipolar depression expected in 1H 2019.

Neurology Franchise:

Led by SAGE-324, a next-generation positive allosteric modulator (PAM) of $GABA_A$ receptors

- Phase 1 studies ongoing with further clinical development to be explored for neurological conditions, including essential tremor and epileptiform disorders.
    - Phase 1 multiple ascending dose (MAD) trial evaluating the safety, tolerability, pharmacokinetic and pharmacodynamic profile of SAGE-324 ongoing.
    - Phase 1 single ascending dose (SAD) trial of SAGE-324 in healthy volunteers recently completed.
    - Topline results from the Phase 1 SAD and MAD studies expected in 1H 2019.
    - Plan to initiate a Phase 1 open-label study in 1H 2019 to determine the safety, tolerability and pharmacokinetics of SAGE-324 in approximately 10 patients with essential tremor. Topline results are anticipated in 2H 2019.

Neuropsychiatry Franchise:

Led by first-in-class NMDA receptor PAM, SAGE-718

- First-in-class NMDA receptor PAM being explored in certain cognition-related disorders impacted by NMDA receptor dysfunction currently in Phase 1 development. The healthy volunteer portions of the Phase 1 SAD and MAD trials are complete.
    - Initiated target engagement biomarker studies in healthy volunteers, focusing on electrophysiology and imaging, to further evaluate SAGE-718. Results of these Phase 1 healthy volunteer studies, including SAD, MAD and the target engagement studies, are anticipated in 1H 2019.

- Initiated a Phase 1 double-blind, placebo-controlled MAD study to determine the safety, tolerability and pharmacokinetics of SAGE-718 in approximately 10 patients with early manifest Huntington's disease. Topline results are anticipated in 2H 2019.

Webcast Information for J.P. Morgan Healthcare Conference Presentation

Sage is scheduled to present at the 37th Annual J.P. Morgan Healthcare Conference on Tuesday, January 8, 2019 at 3:30 p.m. PST (6:30 p.m. EST), 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.

Forward-Looking Statements

Various statements in this release concern Sage's future expectations, plans and prospects, including without limitation statements regarding: our expectations regarding the possible approval of our NDA filing for ZULRESSO™ (brexanolone) injection, including the target timing of a decision by the FDA; our plans regarding the timing of launch of ZULRESSO in PPD and future commercial activities, if approved; our statements regarding plans and timelines for clinical development of SAGE-217, SAGE-324 and SAGE-718, including potential indications and the potential timing of data availability; and our views as to the opportunity represented by Sage's portfolio and business. 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 FDA may decide not to approve ZULRESSO as a treatment for PPD and may determine that additional trials or data are necessary in order to obtain approval; the FDA may not complete its review of our filing within the target timelines; even if ZULRESSO is successfully approved for PPD in the U.S., we may encounter issues, delays or other challenges in launching or commercializing the product, including issues related to timing of DEA scheduling, issues related to market acceptance and reimbursement, challenges associated with restrictions or conditions that may be imposed by regulatory authorities, including challenges related to limiting the site of administration to a certified healthcare facility monitored by a qualified healthcare provider, and the necessity for a REMS, and challenges associated with the execution of our sales and patient support activities, which in each case could limit the potential of our product; we may encounter unexpected safety or tolerability issues with ZULRESSO, SAGE-217, SAGE-324, SAGE-718 or any of our other product candidates in ongoing or future development; we may not be successful in our development of SAGE-217, SAGE-718, SAGE-324 or any of our other product candidates in any indication we are currently pursuing or may in the future pursue; success in early stage clinical trials may not be repeated or observed in ongoing or future studies of any of our product candidates; ongoing and future clinical results may not support further development or be sufficient to gain regulatory approval of our 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 or may impact the regulatory pathway; we may experience slower than expected enrollment in ongoing or planned 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 which could delay, slow or limit our efforts; and we may encounter technical and other unexpected hurdles in the development, manufacture and potential future commercialization 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.

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