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 8, 2023

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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.0001 per share	SAGE	The Nasdaq Global Market

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.

On January 9, 2023, Sage Therapeutics, Inc. (the "Company") made available an updated corporate presentation, which it plans to use for meetings with investors and analysts at the 41st Annual J.P. Morgan Healthcare Conference. A copy of the presentation is being furnished hereto as Exhibit 99.1 and is incorporated herein by reference.

The information in Item 7.01 of this Current Report on Form 8-K, including 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, 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 filing.

Item 8.01. Other Events.

On January 8, 2023, the Company issued a press release titled "Sage Therapeutics to Provide Update on 2023 Key Initiatives at J.P. Morgan Healthcare Conference." A copy of the press release is filed as Exhibit 99.2 hereto and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Corporate Presentation dated January 2023.
99.2	Press release issued by Sage Therapeutics, Inc. on January 8, 2023.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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 9, 2023

SAGE THERAPEUTICS, INC.

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

Exhibit 99.1

Sage Therapeutics®

J.P. Morgan Healthcare Conference

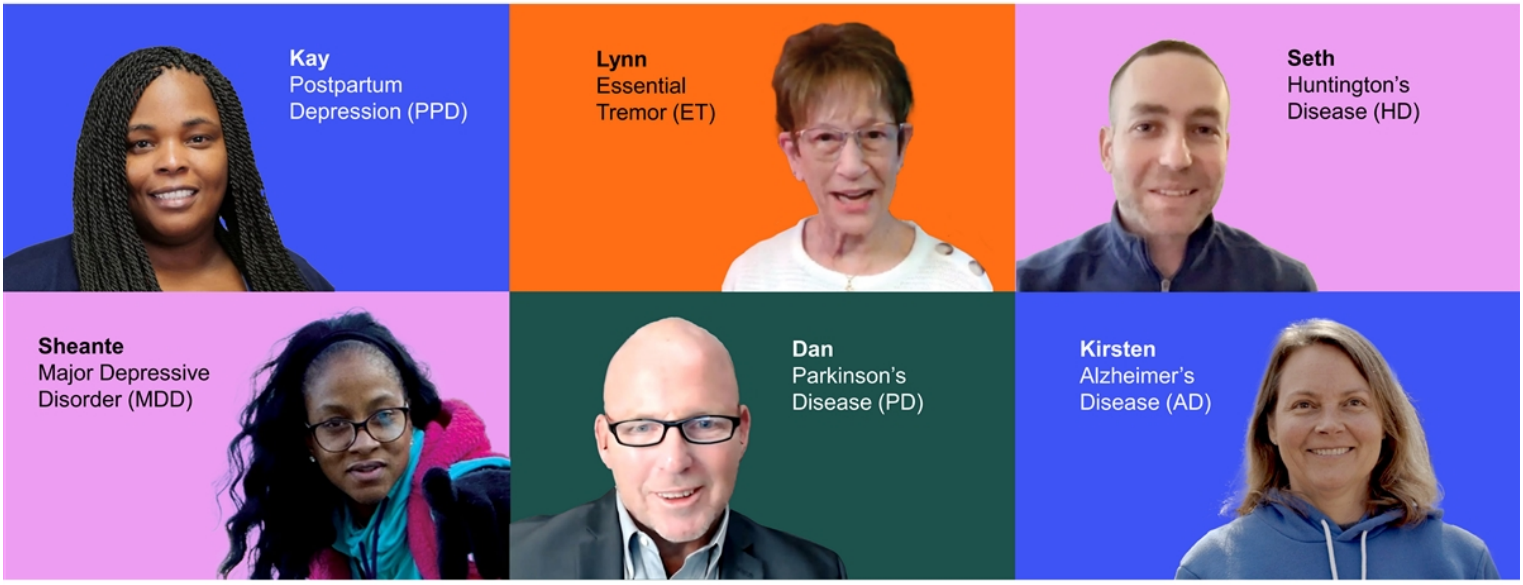
January 2023

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,” “can,” “expect,” “plan,” “anticipate,” “believe,” “estimate,” “project,” “intend,” “future,” “opportunity”, “goal”, “mission”, “potential,” “target”, or “continue,” and other similar expressions.
- Forward-looking statements in this presentation include statements regarding: our clinical development plans, including expected timelines for activities and our expectations as to potential results; our belief that our NDA for zuranolone will be accepted and the possibility of priority review; the potential for approval and launch of zuranolone and potential timelines; our belief in the potential benefit and profile of zuranolone and in its potential to be successful and to meet an unmet need in the treatment of MDD and PPD; the potential for commercialization of zuranolone and our commercialization plans, including plans to help enable access; our expectations as to the types of MDD patients who may benefit from zuranolone, if approved; the potential for success of our other product candidates in various indications, including the potential profile and benefit of our other product candidates; our estimates as to the number of patients with disorders and diseases of interest to us and that we hope to help and the potential market for our product candidates, if approved; the goals, opportunity, mission and vision for business; and our views with respect our financial strength and potential value creation opportunities.
- 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 accept our NDA for zuranolone for review or may accept the filing for review but not grant approval or may grant approval for a narrower indication than we expect or with unexpected limitations. The FDA may ask for additional clinical trials, nonclinical studies or other data in order for us to file for or obtain regulatory approval of zuranolone. The FDA may not grant priority review of our NDA for zuranolone. Our expectations for timing of review of our NDA and of launch of zuranolone, if approved, may not be accurate. The FDA may ultimately decide that the design or results of our clinical trials for our product candidates are not sufficient to successfully file for or obtain regulatory approval.
  - Our clinical trials may not meet their primary endpoints or key secondary endpoints. Success in non-clinical studies or in prior clinical trials of our product candidates may not be repeated or observed in ongoing, planned or future studies involving the same compound or other product candidates. Non-clinical and clinical results from ongoing or future trials may not support further development of the product candidate or filing for or obtaining regulatory approval on the timelines we expect or at all and we may be required to conduct additional clinical trials or nonclinical studies which may not be successful.
  - 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.
  - We may encounter unexpected safety or tolerability issues with respect to any of our product candidates or marketed products; we may encounter different or more severe adverse events at the higher doses, different frequency or length of dosing or in new indications we are studying or may study in ongoing or planned trials.
  - At any stage, regulatory authorities may ask for additional clinical trials, nonclinical studies or other data in order for us to proceed further in development or to file for or obtain regulatory approval. Other decisions or actions of the FDA or other regulatory authorities may affect the initiation, timing, design, size, progress and cost of clinical trials and our ability to proceed with further development.
  - Even if zuranolone is approved, we may not achieve market acceptance or use of zuranolone in the MDD and PPD patient types we expect and we may not achieve reimbursement of zuranolone at the levels or with the type of access we expect. The benefit and safety profile of zuranolone in clinical practice, if approved, may not meet our expectations. We may not be successful in execution of our planned commercialization activities or we may change our plans. We may never be successful or achieve our goals with respect to commercialization of zuranolone, if approved.
  - Even if zuranolone or our other product candidates are successfully developed and approved, the number of patients with the diseases or disorders our products treat or the subset of such patients we believe will use our products, the need for new treatment options, and the actual market for such products may be smaller than our current estimates.
  - The anticipated benefits of our collaborations, including our collaboration with Biogen, may never be achieved. The need to align with our collaborators may hamper or delay our development and commercialization efforts or increase our costs; our business may be adversely affected and our costs may increase if any of our key collaborators fails to perform its obligations or terminates our collaboration.
  - We may not be able to obtain and maintain adequate intellectual property protection or other forms of data and marketing exclusivity for our products, or to defend our patent portfolio against challenges from third parties.
  - We may face competition from others developing products or with approved products for similar uses as those for which our product candidates are being developed.
  - Our operating expenses may be higher than forecasted, our revenues may be lower than we expect, or we may face unexpected expenditures, which could cause us to change our plans. We may need or choose to raise additional funding, which may not be available on acceptable terms, or at all.
  - We may not be able to establish and maintain key business relationships with third parties on acceptable terms or we may encounter problems with the performance of such third parties.
  - We may encounter technical and other unexpected hurdles in the manufacture, development or commercialization of our products.
  - Any of the foregoing or other factors may negatively impact our ability to achieve our goals, mission, opportunities, plans or expectations for our business.
- For additional disclosure regarding these and other risks Sage faces, see the disclosure contained in the "Risk Factors" section of our most recent 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.

Sage Therapeutics

The time is now…



Brain health is *fundamental to good health*

Sage Therapeutics

Building impact and scale

Millions of people have been waiting **decades for new treatment options**

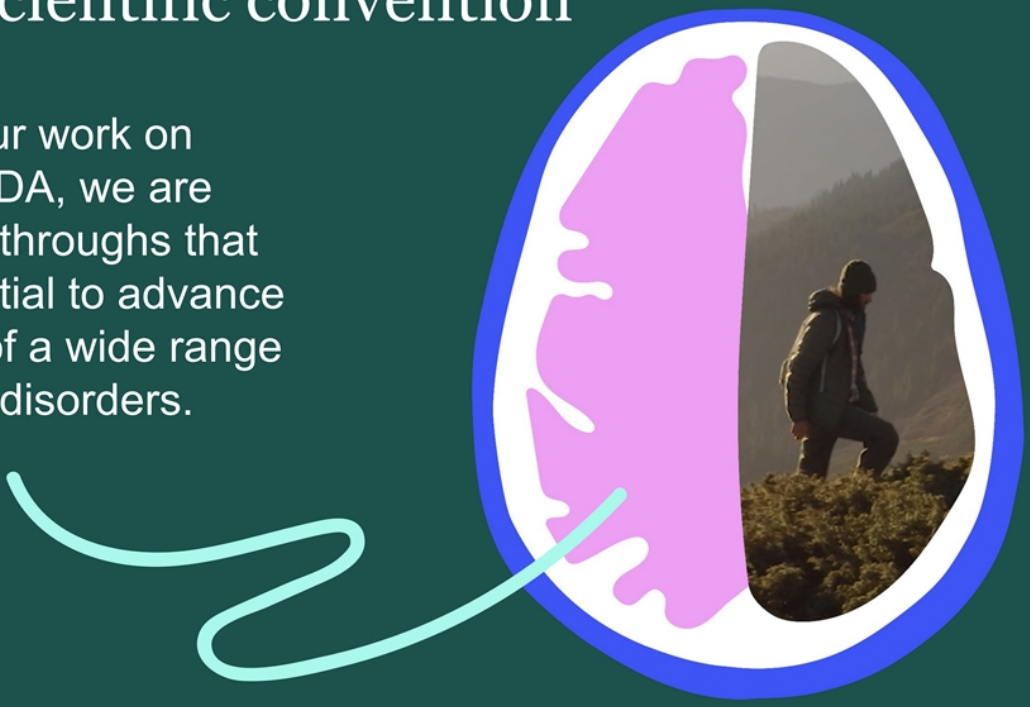
Patients, providers, and society can and **must be better served**

Relentless focus on developing **new and effective treatments to address brain health disorders**

The time is now…

Challenge scientific convention

Starting with our work on GABA and NMDA, we are pursuing breakthroughs that have the potential to advance the treatment of a wide range of brain health disorders.



Building a business for the future

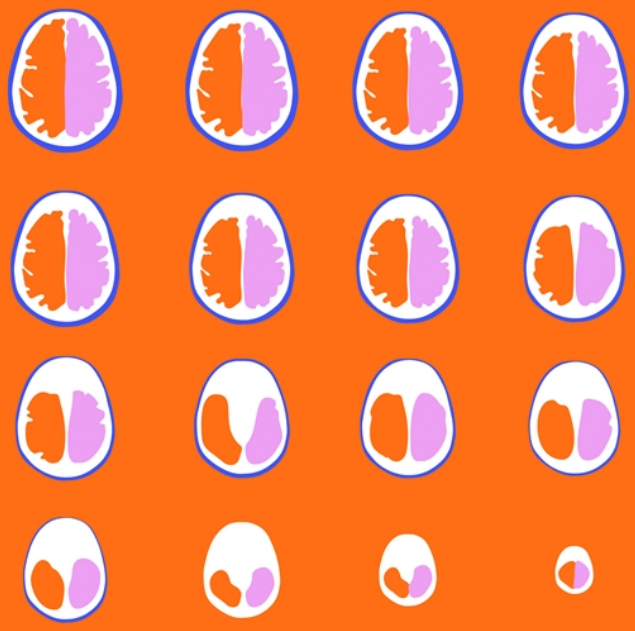
Rich innovative pipeline/product engine

Deep expertise in brain circuitry

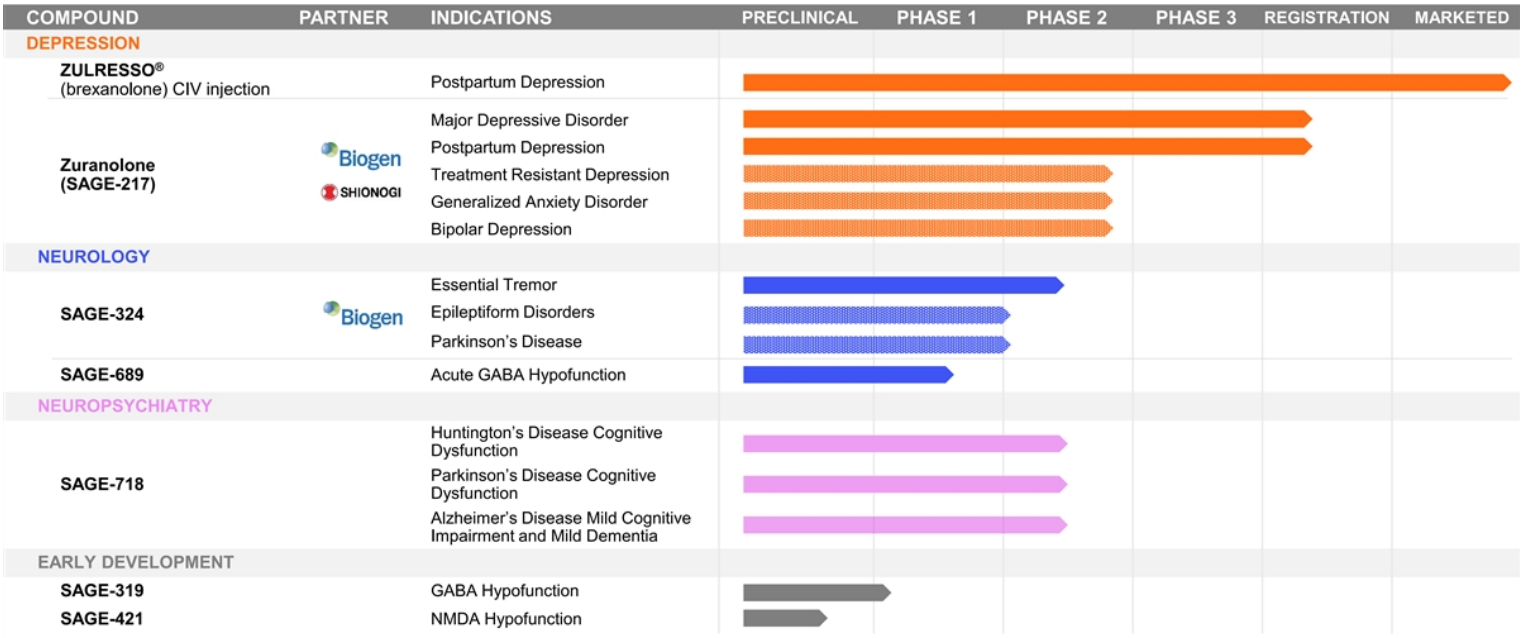
Significant potential patient impact

Strong cash position to fuel growth

Exciting business momentum into 2023



Sage has a leading brain health portfolio



Sage Therapeutics

Light shades indicate trials in the planning or evaluation stage

Significant unmet needs remain in the treatment of depression

Unmet Needs

In a survey of MDD patients (n=583) conducted by Sage, 75% of MDD patients asked about the impact of switching medications reported being frustrated or feeling that no medication was going to work for them[1]

1

STAR*D Analysis shows that patients who achieve later remission have a 1.5 times higher risk of relapse than those who remit early[1]

2

The economic burden of MDD in the United States is an estimated $326 billion in 2018[2]

3

Sage Therapeutics

MDD = major depressive disorder

1. Sage Therapeutics. Data on file. 2. Greenberg PE, et al. PharmacoEconomics. 2021; 39: 653-665.

Zuranolone clinical data supports its potential to fulfill unmet needs for people with MDD and PPD

Rapid & Sustained

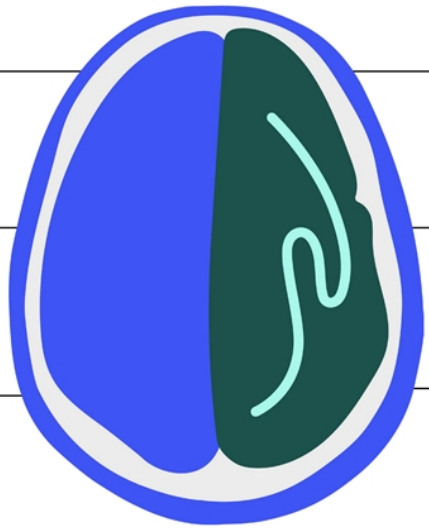
- Rapid symptom reduction observed
- Sustained effects lasted beyond completion of treatment

Well-Tolerated

- Well-tolerated profile*
- Differentiated side effect profile with no evidence of increased sexual dysfunction, weight gain or sleep disruption

Improved Feel/Functioning

- Improvements seen across domains of quality of life
- Measured benefits that patients are looking for from depression treatment



Short Course

- As-needed oral therapy
- 2-week treatment course

Novel MOA

- Selectively modulates $GABA_AR$
- May help neuronal networks rebalance[1]

Flexible Approach

- Improvement seen in depressive symptoms in MDD/PPD patients when used as mono or adjunctive therapy
- Improvements seen in MDD/PPD patients with or without elevated anxiety

*Zuranolone was generally well-tolerated across clinical studies. The most common adverse events associated with zuranolone included headache, somnolence, dizziness and sedation.

Profile based on data demonstrated in clinical studies with zuranolone to date

Note: Success of zuranolone and the product profile depend on the clinical development program and regulatory approval.

[1]Antonoudiou, P. et al. Allopregnanolone mediates affective switching through modulation of oscillatory states in the basolateral amygdala. *Biological Psychiatry*, 2021.2003.2008.434156, doi:10.1016/j.biopsych.2021.07.017 (2021).

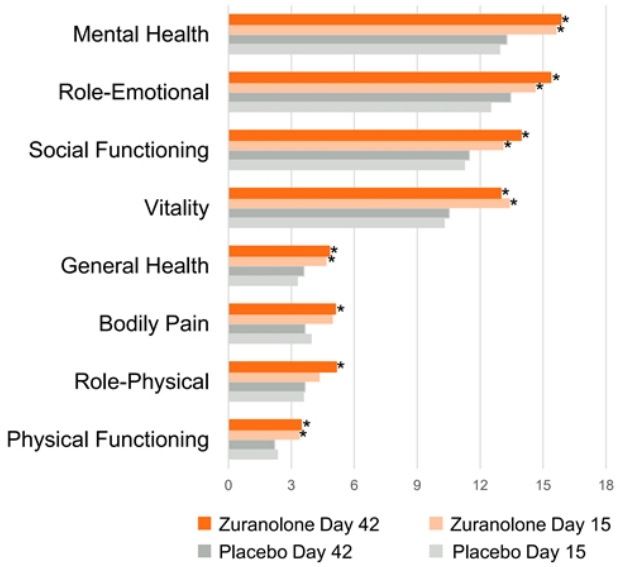
MDD = major depressive disorder, PPD = postpartum depression

Zuranolone is being developed in collaboration with Biogen.

Sage Therapeutics

In an integrated analysis of zuranolone data, patients reported overall improvement in functioning and well-being†

Clinically meaningful improvements were observed *across mental health, physical and general health domains of SF-36*



*LSM treatment difference p-value <0.05 (nominal); †Integrated analyses combine doses from the ROBIN Study, MDD-201B Study, MOUNTAIN Study (≥24 HAMD-17 subgroup), and WATERFALL Study. ‡For the ROBIN study, data were collected at Day 45.; SF-36 = 36-Item Short Form Health Survey (version 2).

Zuranolone is being developed in collaboration with Biogen.

Selected responder interviews from SHORELINE Study in MDD

Examples of quotes from surveyed patients who responded to initial treatment cycle of 50 mg zuranolone in the open-label SHORELINE Study (n=32)

"It was really impressive that the results happened so quickly, and it was so dramatic. It wasn't just a slight improvement, it was night and day. **It was a 180 degree turn from how I'd been feeling even just the day before**."

"...almost like an afterglow of the two week course of treatment, that then it was just working for several months. **I didn't have to think about it constantly. I didn't have to take medication...I wasn't having to think about my depression and try to manage it."**

"I felt better both times… I started feeling better right away…and I wasn't as bad when I took it the second time as I had been before the study."

"Very satisfied because it's helping me. I feel better about myself now than I did when I first started. I know it's good…I'm doing more than I used to. I'm getting up. I'm going to church. Before, I wouldn't be anywhere, I wouldn't go outside, I would just look outside the door. It has helped me."

Rapid Onset

A substantial majority of interviewed patients noticed improvements within the first week

Durability

Most interviewed patients reported being satisfied with duration of improvements

Retreatment

A significant majority of interviewed patients who received retreatment reported feeling fine, positive, or neutral about needing to be retreated

Satisfaction

All interviewed patients reported being moderately, quite, or very satisfied with zuranolone

Among patients treated in the ongoing open-label Phase 3 SHORELINE Study, the most common TEAEs (>5%) observed in the 30 and 50 mg cohorts were headache, somnolence, dizziness, and sedation.
Patient experiences are provided solely to help illustrate the data collected from the SHORELINE Study interviews. Patient experiences in the SHORELINE Study differed patient-to-patient. Results of the survey are not intended to make claims about zuranolone's potential benefit. Survey information does not represent all patients who took zuranolone.
Interviews conducted with patients who responded to the first 50 mg zuranolone treatment cycle and had been participants in the SHORELINE Study for at least six months. Interviews were conducted at various timepoints for each patient. Based on SHORELINE Study design, patients were allowed to be on background therapy. Sample size of interviewed patients n = 32.
MDD = major depressive disorder
Zuranolone is being developed in collaboration with Biogen.

Sage Therapeutics

Goal of the planned zuranolone launch strategy is to transform the way MDD and PPD are treated

If zuranolone is approved, plan to focus on: Priority MDD and PPD patient segments

Target High Volume HCPs

- Psychiatrists
- NPs / PAs
- PCPs
- OBGYNs

Collaborate with Payers

Lead with Value

Sage Therapeutics

Sage and Biogen Zuranolone Webcast [December 6, 2022]. Accessible via: https://investor.sagerx.com/events/event-details/sage-therapeutics-and-biogen-webcast-discuss-potential-commercialization-plans

MDD = major depressive disorder, PPD = postpartum depression, NP = nurse practitioner, PA = physician assistant, PCP = primary care provider

Zuranolone is being developed in collaboration with Biogen.

Cognitive impairment is prevalent and impacts people across the lifespan

Executive Function

Planning, decision-making, working memory, multitasking, flexibility

Learning & Memory

Recall, recognition. long-term memory, implicit learning

Attention

Sustained attention, divided attention, selective attention, processing speed

Language

Object naming, word finding, fluency, grammar and syntax, receptive language

Visuospatial

Visual perception. Visuo-constructional reasoning, perceptual-motor coordination

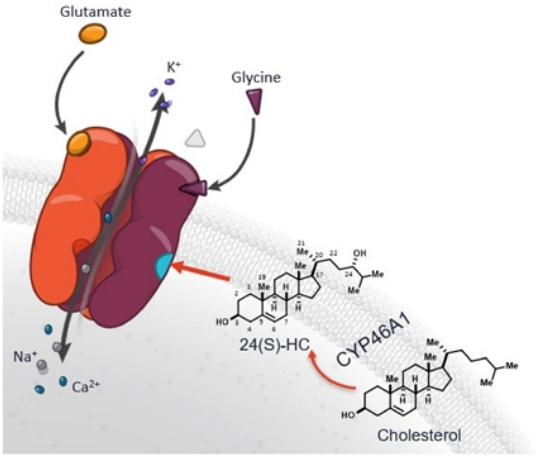
DAILY LIFE

Sage Therapeutics

Sources: SSM Popul Health. 2020 Aug; 11: 100577. Published online 2020 Mar 31. doi: 10.1016/j.ssmph.2020.100577
https://altoida.com/blog/defining-the-6-key-domains-of-cognitive-function/

Sage's first-in-class NMDA receptor PAM

Novel starting point for understanding NMDA receptor modulation



Emerging Science Drives New Thinking

- The neuroactive steroid, 24S-hydroxycholesterol (24S-HC), is an endogenous modulator of NMDA receptors
- NMDA receptors play a major role in excitatory transmission in the brain and influence cognition and other key brain functions
- NMDA receptor hypofunction has been implicated in cognitive impairment associated with disorders such as Huntington's disease, Parkinson's disease and Alzheimer's disease

SAGE-718: NMDA Positive Allosteric Modulator (PAM)

- SAGE-718 is a novel, positive allosteric modulator derived from our pharmacological understanding of 24S-HC
- SAGE-718 is believed to bind to a novel neurosteroid site on the NMDA receptor
- SAGE-718 has the potential to restore NMDA activity and improve cognitive functioning

Globally, disorders involving cognitive impairment continue to increase

Cognitive impairment has devastating impacts on *patients, families, and society*

~188K

Huntington's Disease Global Prevalence[1]

Cognitive Impairment in HD can occur up to 15 years before motor manifestation & is highly associated with overall functional decline

~8.8M

Parkinson's Disease Global Prevalence[2]

Mild cognitive impairment (MCI) is diagnosed in nearly half of people with PD and causes poorer treatment outcomes, greater medical costs, and caregiver distress

~134M

Alzheimer's Disease Global Prevalence[3]

Up to 50% of people with MCI due to AD progress to Alzheimer's dementia within 5-10 years

Sage Therapeutics

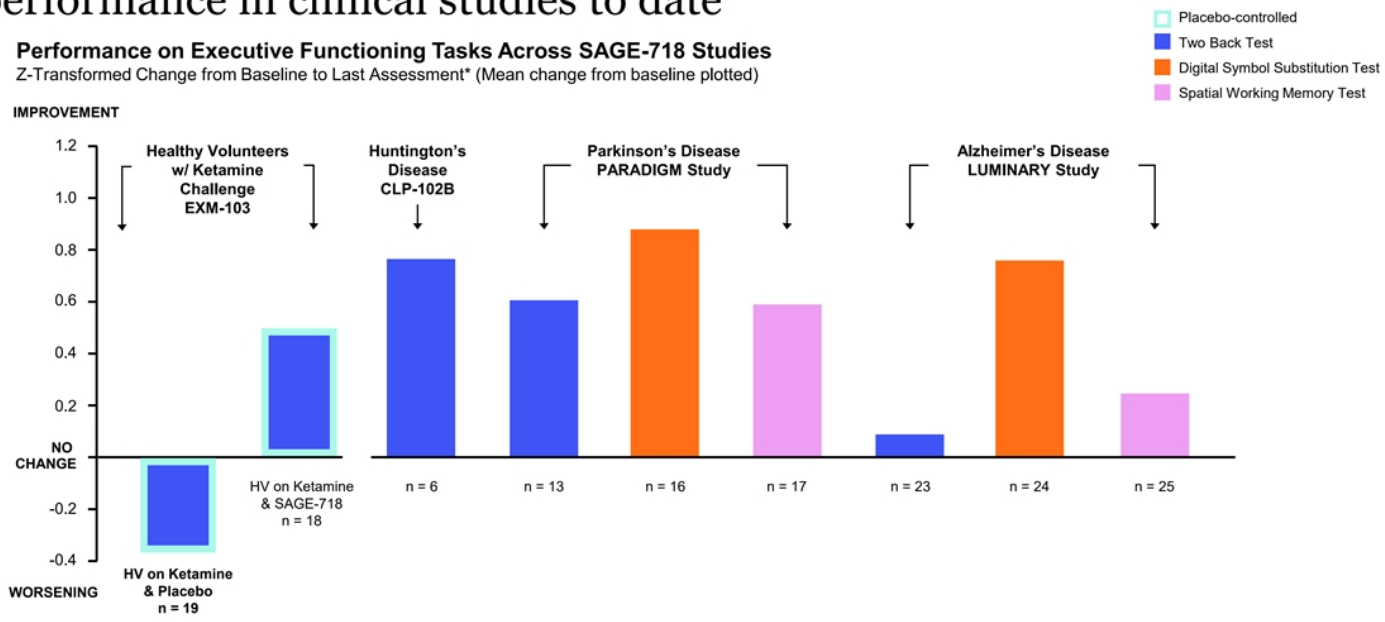
HD = Huntington's disease, PD = Parkinson's disease, AD = Alzheimer's disease

1. Pringsheim T, Wiltshire K, Day L, Dykeman J, Steeves T, Jette N. The incidence and prevalence of Huntington's disease: a systematic review and meta-analysis. Mov Disord. 2012 Aug;27(9):1083-91. doi: 10.1002/mds.25075. Epub 2012 Jun 12. PMID: 22692795. 2. Sage Therapeutics, Inc. Data on file. 3. Sage Therapeutics, Inc. Data on file.

SAGE-718 has demonstrated consistent beneficial effects on cognitive performance in clinical studies to date

Performance on Executive Functioning Tasks Across SAGE-718 Studies

Z-Transformed Change from Baseline to Last Assessment* (Mean change from baseline plotted)



HV = healthy volunteers

SAGE-718 clinical development program in Huntington's disease

PERSPECTIVE PROGRAM

Huntington's Disease

FDA Fast-track Designation

DIMENSION (CIH-201) | 3-month study

- Description: Robust RCT in patients with HD cognitive impairment, designed to evaluate efficacy
- Objective: Demonstrate difference on cognitive performance between drug and placebo at month 3
- Target enrollment: 178

ENROLLING

SURVEYOR (CIH-202) | 1 month study

- Description: Placebo-controlled RCT to demonstrate the clinical meaningfulness of improving cognition in HD
- Objective: Generate evidence linking change in cognitive performance to real-world patient functioning, benchmarked against performance of healthy volunteers
- Target enrollment: 40 people with HD, 40 healthy volunteers (assessment-only HV arm)

ENROLLING

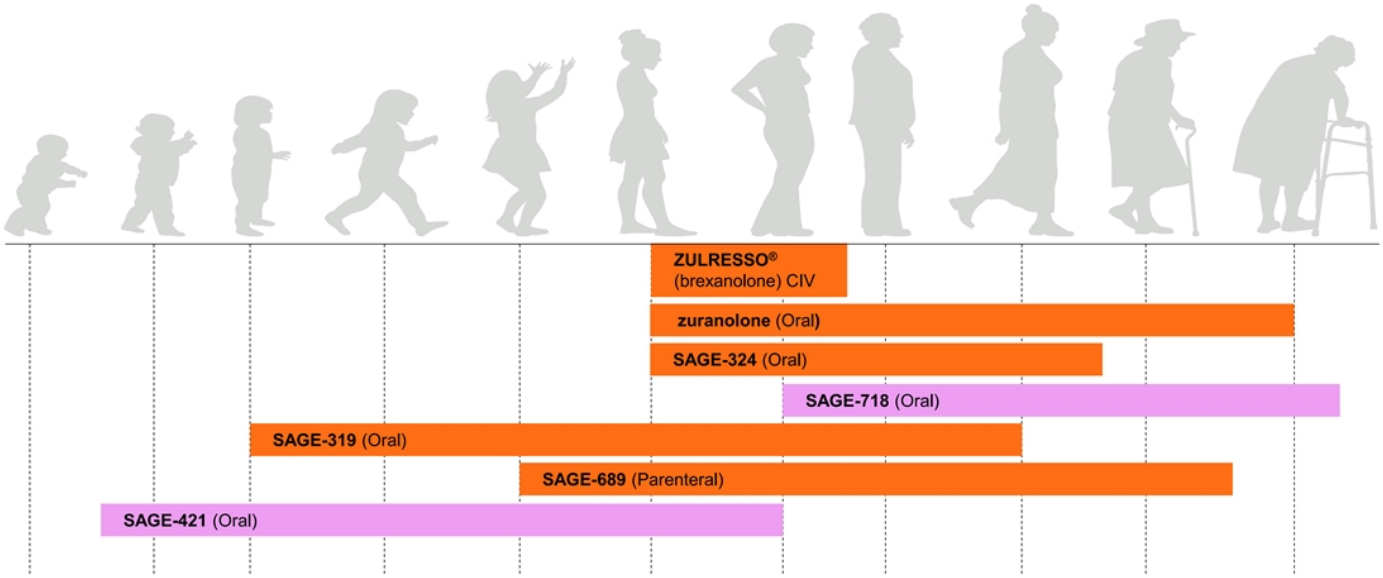
PURVIEW (CIH-301) | 13-month study

- Description: Open-label safety study, enrolling participants from DIMENSION, SURVEYOR, and an additional de novo cohort
- Objective: Designed to evaluate the long-term safety profile and benchmark performance against HD natural history studies
- Target enrollment: 300

ENROLLING

Sage Therapeutics

Sage's robust portfolio features NCEs with differentiated target profiles that may be suited for study across the lifespan



Sage Therapeutics

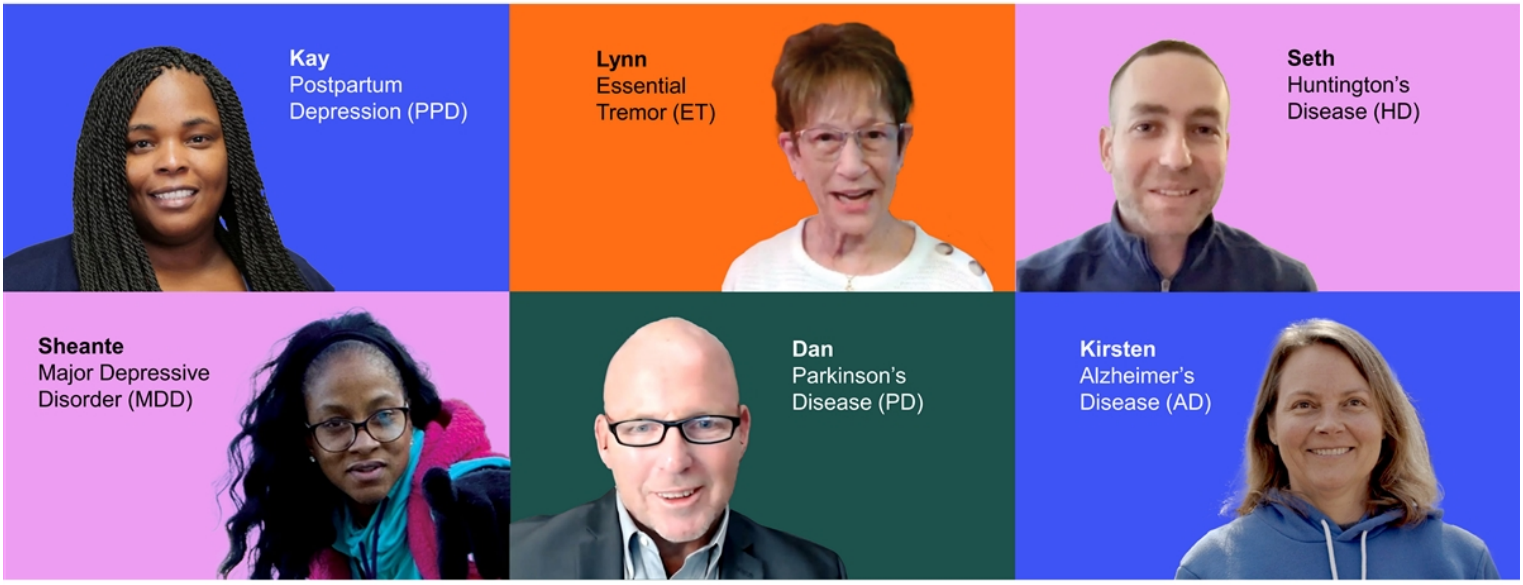
GABA NMDA

Anticipated 2023 Milestones

	Early	Mid	Late	*Early:Q1-Q2; Mid:Q2-Q3; Late: Q3-Q4
DEPRESSION				
Zuranolone (SAGE-217)	●			FDA acceptance of rolling NDA submission for zuranolone in MDD and PPD
		●		Present additional data from SHORELINE Study
			●	PDUFA date for zuranolone in MDD and PPD, if accepted for review by the FDA
			●	Commercial availability of zuranolone in MDD and PPD, if priority review is granted and zuranolone is approved
			●	Initiate a lifecycle innovation study with zuranolone
	●	●	●	Present additional analyses of data from LANDSCAPE and NEST clinical programs, including health economics and patient reported outcomes
NEUROLOGY				
SAGE-324			●	Complete enrollment in Phase 2b KINETIC 2 Study
	●	●	●	Present additional analyses of data from clinical development program as well as disease state and burden of disease research in ET
NEUROPSYCHIATRY				
SAGE-718	●	●	●	Progress recruitment in the ongoing DIMENSION, SURVEYOR, PURVIEW, PRECEDENT, and LIGHTWAVE Studies
	●	●	●	Present additional analyses of data from clinical development program as well as disease state and burden of disease research in HD, PD and AD
ADDITIONAL CLINICAL PROGRAMS & MILESTONES				
Additional Pipeline Programs			●	Provide update on next steps for pipeline programs (e.g., SAGE-319)
Cash Balance	●	●	●	Maintain strong balance sheet

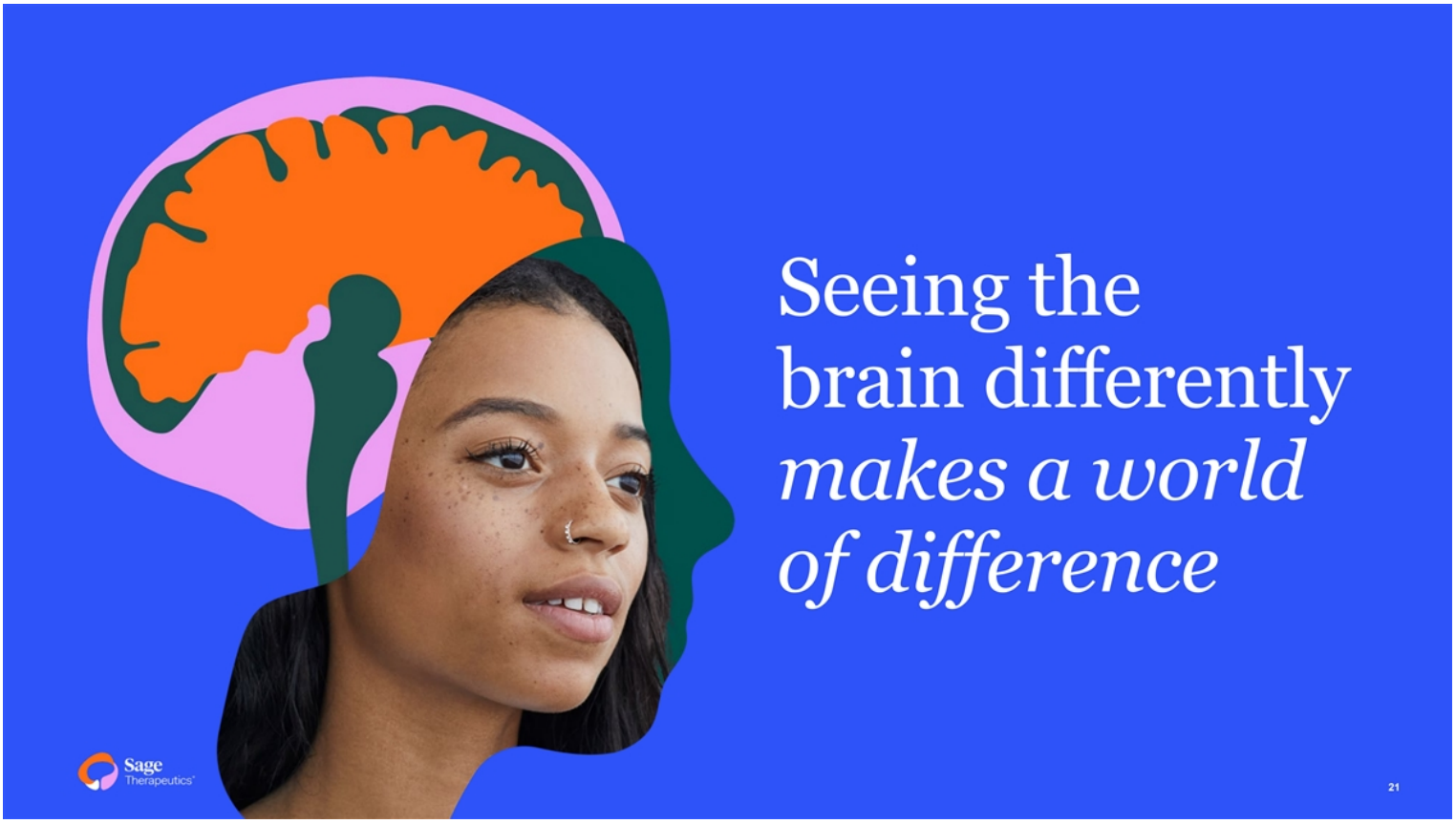
MDD = major depressive disorder, PPD = postpartum depression, ET = essential tremor, HD = Huntington's disease, PD = Parkinson's disease, AD = Alzheimer's disease

The time is now…



Brain health is *fundamental to good health*

Sage Therapeutics


Seeing the
brain differently
makes a world
of difference
Sage
Therapeutics
21

Sage Therapeutics to Provide Update on 2023 Key Initiatives at 41st Annual J.P. Morgan Healthcare Conference

Robust pipeline provides potential for long-term value creation, establishing Sage as a leader in brain health

Rolling New Drug Application (NDA) submission for zuranolone in MDD and PPD complete, with potential for PDUFA date as early as the third quarter of 2023 if priority review is received and other timelines meet expectations

Progressing nine ongoing studies across zuranolone, SAGE-718, SAGE-324 and early pipeline programs

CAMBRIDGE, Mass. – January 8, 2023 – Sage Therapeutics, Inc. (Nasdaq: SAGE), a biopharmaceutical company leading the way to create a world with better brain health, today announced that Chief Executive Officer, Barry Greene, will discuss the Company's progress in developing a leading brain health pipeline at the 41st Annual J.P. Morgan Healthcare Conference in San Francisco, California.

As part of this presentation, Mr. Greene will provide key updates on programs across Sage's depression, neuropsychiatry and neurology portfolios. Sage is advancing a portfolio of clinical programs featuring internally discovered novel chemical entities with the potential to become differentiated products designed to improve brain health by targeting the $GABA_A$ and NMDA receptor systems. Dysfunction in these systems is thought to be at the core of numerous neurological and neuropsychiatric disorders.

"It's time to begin a new era in the treatment of brain health disorders. We at Sage have a tremendous sense of urgency to create innovative medicines that address what matters most for people who currently lack adequate treatment options," said Barry Greene, Chief Executive Officer at Sage Therapeutics. "We enter 2023 having completed the submission of the rolling NDA for zuranolone in the treatment of major depressive disorder and postpartum depression with our collaborator Biogen. We've also made progress in initiating multiple studies across our pipeline, including SAGE-718 and SAGE-324. We believe that this momentum will help us achieve our mission to improve the lives of millions of people and advance the way brain health is viewed and treated."

Sage and its collaborator Biogen recently announced the submission of the zuranolone New Drug Application to the FDA for the treatment of major depressive disorder (MDD) and postpartum depression (PPD). Zuranolone, Sage's next-generation positive allosteric modulator (PAM) of $GABA_A$ receptors, is being evaluated as a potential rapid-acting treatment for MDD and PPD. If approved, zuranolone could represent the first oral, short course (14-day) medication for these indications. In the clinical development program to date, zuranolone has shown rapid and sustained improvement of depressive symptoms with a generally well-tolerated and consistent safety profile.

Sage and Biogen are focused on preparing for a potential launch of zuranolone for both MDD and PPD in 2023, if approved, with the ultimate goal of transforming the way depression is treated. Current efforts are focused on disease state education in MDD and PPD, scientific exchange and permitted interactions with payers. Sage expects these efforts and other permitted pre-launch activities to continue to broaden and ramp up in the coming year.

Sage continues to advance a robust clinical program for SAGE-718, the Company's first-in-class NMDA receptor PAM and lead neuropsychiatric drug candidate. SAGE-718 is in development as a potential oral therapy for cognitive disorders associated with NMDA receptor dysfunction, with multiple ongoing or planned Phase 2 studies across multiple disease areas, including its potential lead indication, Huntington's disease (HD), as well as Alzheimer's (AD) and Parkinson's diseases (PD). The company recently initiated LIGHTWAVE (CNA-202), a Phase 2 study of SAGE-718 in people with mild cognitive impairment and mild dementia due to AD and PURVIEW (CIH-301), a Phase 3 extension study in people with HD.

"We are proud of the progress we've made in advancing the SAGE-718 development program as we work to address impaired cognition, a main driver of disability in the indications we are studying, including Huntington's, Alzheimer's and Parkinson's diseases," said Laura Gault, M.D., Ph.D., Chief Medical Officer at Sage. "Our goal with SAGE-718 is to provide rapid, meaningful, and sustained symptomatic improvement in cognitive function early in disease so that patients can maintain independence longer."

Anticipated 2023 Key Milestones

The Company anticipates the following key milestones in 2023:

- Zuranolone:
  - Early:
    - FDA acceptance of rolling NDA submission for zuranolone in MDD and PPD
  - Mid:
    - Present additional data from the SHORELINE Study
  - Late:
    - PDUFA date for zuranolone in MDD and PPD, if accepted for review by the FDA
    - Commercial availability of zuranolone in MDD and PPD, if priority review is granted and zuranolone is approved
    - Initiate a lifecycle innovation study with zuranolone
  - Present additional analyses of data from LANDSCAPE and NEST clinical programs, including health economics and patient reported outcomes
- SAGE-718:
  - Progress recruitment in the ongoing DIMENSION, SURVEYOR, PURVIEW, PRECEDENT, and LIGHTWAVE Studies
  - Present additional analyses of data from clinical development program as well as disease state and burden of disease research in Huntington's, Parkinson's and Alzheimer's diseases
- SAGE-324:
  - Late:
    - Complete enrollment in the Phase 2b KINETIC 2 Study
  - Present additional analyses of data from clinical development program as well as disease state and burden of disease research in ET

About Sage Therapeutics

Sage Therapeutics is a biopharmaceutical company fearlessly leading the way to create a world with better brain health. Our mission is to pioneer solutions to deliver life-changing brain health medicines, so every person can thrive. For more information, please visit http://www.sagerx.com.

Forward-Looking Statements

Various statements in this release concern Sage's future expectations, plans and prospects, including without limitation our statements regarding: the potential for our NDA for zuranolone in MDD and PPD to be accepted and the possibility of priority review; the potential for approval and launch of zuranolone and potential timelines; our belief in the potential benefit and profile of zuranolone and in its potential to be successful and to meet an unmet need in the treatment of MDD and PPD; the potential for commercialization of zuranolone and our commercialization strategy and plans, including plans to help enable access; our expectations as to the types of MDD patients who may benefit from zuranolone, if approved; other planned activities and next steps for the zuranolone program; anticipated timelines for commencement of trials, completion of dosing, initiation of new activities and other plans for our other programs and early stage pipeline; our belief in the potential profile and benefit of our product candidates; potential indications for our product candidates; the potential for success of our programs, and the opportunity to help patients in various indications; the number of patients with the indications we are pursuing or may in the future pursue and the unmet need; and the mission and goals for our business and potential for long-term value creation.

These statements constitute forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. 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 find inadequacies and deficiencies in our NDA for zuranolone, including in the data we submit, despite prior discussions, and may decide not to accept the NDA for filing; even if the FDA accepts the NDA for filing, the FDA may find that the data included in the NDA are not sufficient for approval and may not approve the NDA in MDD or PPD, or both; the FDA may decide that the design, conduct or results of our completed and ongoing clinical trials for zuranolone, even if positive, are not sufficient for approval in MDD or PPD and may require additional trials or data which may significantly delay and put at risk our efforts to obtain approval and may not be successful; even if our NDA is successfully filed and accepted, the FDA may not grant priority review or meet expected review timelines for our NDA which would delay our launch timelines if zuranolone is approved; other decisions or actions of the FDA may affect our efforts with respect to zuranolone and our plans, progress, results and expected timelines; our expectations for timing of review of our NDA and of launch of zuranolone, if approved, may not be accurate; results of ongoing or future studies may impact our ability to obtain approval of zuranolone or impair the potential profile of zuranolone; success in earlier clinical trials of any of our other product candidates may not be repeated or observed in ongoing or future studies, and ongoing and future clinical trials may not meet their primary or key secondary endpoints which may substantially impair development; unexpected concerns may arise from additional data, analysis or results from any of our completed studies; we may encounter adverse events at any stage for any of product candidates that negatively impact further development, the potential for approval or the potential for successful commercialization or that require additional nonclinical and clinical work which may not yield positive results; we may encounter delays in initiation, conduct, completion of enrollment or completion of our ongoing and planned clinical trials, including as a result of slower than expected site initiation, slower than expected enrollment, the need or decision to expand the trials or other changes, that may impact our ability to meet our expected timelines and increase our costs; 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 impair the potential for successful development; we may not be successful in our efforts to gain regulatory approval of any products, even if successfully developed and approved; we may not achieve revenues from any future products, including zuranolone, if approved, at the levels we expect; the number of patients with the diseases or disorders for which our product candidates are being developed, the unmet need for additional treatment options and the potential use cases and market for our current or future products, including zuranolone, if approved, may be significantly smaller than we expect; zuranolone, if approved, or any of our other products that may be approved in the future, may not have the profile we expect in clinical practice after launch or may not achieve market acceptance for other reasons or we may encounter reimbursement-related or other market-related issues that impact the success of our commercialization efforts; the anticipated benefits of our ongoing collaborations, including the achievement of events tied to milestone payments or the successful development or commercialization of products and generation of revenue, may never be achieved; the need to align with our collaborators may hamper or delay our development and commercialization efforts or increase our costs; our business may be adversely affected and our costs may increase if any of our key collaborators fails to perform its obligations or terminates our collaboration; the internal and external costs required for our ongoing and planned activities, and the resulting impact on expense and use of cash, may be higher than expected which may cause us to use cash more quickly than we expect or change or curtail some of our plans or both; we may never be able to generate meaningful revenues from sales of our marketed product or to generate revenues at levels we expect or at levels necessary to justify our investment; our expectations as to sufficiency of cash to fund future operations and expense levels may prove not to be correct for these and other reasons such as changes in plans or actual events being different than our assumptions; we may be opportunistic in our future financing plans even if available cash is sufficient; additional funding may not be available on acceptable terms when we need it; and we may encounter technical and other unexpected hurdles in the development and manufacture of our product candidates or the commercialization of any marketed product which may delay our timing or change our plans, increase our costs or otherwise negatively impact our business; any of the foregoing or other issues may negatively impact our value creation opportunity, as well as those risks more fully discussed in the section entitled "Risk Factors" in our most

recent quarterly report, 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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