NEWS RELEASE

# Sage Therapeutics Announces Third Quarter 2023 Financial Results and Highlights Pipeline and Business Progress

11/7/2023

ZURZUVAE™ (zuranolone), first and only oral treatment approved for adults with postpartum depression (PPD), designated Schedule IV by the DEA; progressing towards planned commercial availability in December

Announces expected wholesale acquisition cost of ZURZUVAE of $15,900

SAGE-718 granted FDA Orphan Drug Designation for the treatment of Huntington's Disease

Sage product pipeline provides potential for significant value creation with topline data expected from multiple ongoing Phase 2 trials in 2024

Strong financial foundation with $876 million of cash, cash equivalents and marketable securities as of September 30, 2023

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Sage Therapeutics, Inc. (Nasdaq: SAGE) today reported business highlights and financial results for the third quarter ended September 30, 2023.

"It has been an exciting time at Sage as we prepare for the upcoming commercial launch of ZURZUVAE, the first and only oral treatment specifically indicated for adults with postpartum depression. Women with PPD are waiting for new treatment options and we have an incredible opportunity to support them. Our goal is to make ZURZUVAE

available later this year and to enable broad and equitable access for women with PPD who are prescribed this drug," said Barry Greene, Chief Executive Officer at Sage Therapeutics. "We see the same opportunity to break new ground for patients as we work to advance treatments that address cognitive impairment associated with certain diseases and essential tremor where novel and meaningful new options are long overdue."

## Third Quarter 2023 Portfolio Updates

Sage is advancing a portfolio of clinical-stage programs with internally discovered novel chemical entities that have the potential to address urgent unmet needs in brain health by targeting the GABAA and NMDA receptor systems. Dysfunction in these systems is thought to be at the core of numerous neurological and neuropsychiatric disorders.

### Postpartum Depression Franchise

ZURZUVAE was approved by the U.S. Food and Drug Administration (FDA) in August 2023 as the first and only oral treatment specifically indicated for adults with PPD. ZURZUVAE is being developed and commercialized in collaboration with Biogen Inc. Sage also commercializes ZULRESSO® (brexanolone) CIV injection in the treatment of PPD.

## ZURZUVAE

ZURZUVAE (zuranolone) received a Schedule IV classification from the U.S. Drug Enforcement Administration (DEA). Schedule IV drugs, substances or chemicals are defined as drugs with a low potential for abuse and low risk of dependence. ZURZUVAE is expected to be commercially available for adults with PPD in December 2023 with the broader complement of commercialization capabilities expected to roll out in early 2024.

The recent FDA approval of ZURZUVAE has helped reinforce that PPD is an urgent medical condition that is best treated with prompt diagnosis and immediate intervention. Delayed improvements in depressive symptoms associated with PPD have been shown to significantly worsen outcomes for the woman and her child.1-3 As the first and only oral, once-daily, 14-day treatment that can provide rapid improvements in depressive symptoms by Day 15 and as early as Day 3, ZURZUVAE provides women with PPD with an option that may help address an important gap in the current treatment of women with this condition.

Postpartum depression results in significantly higher healthcare resource utilization and associated costs.4-6

- According to a 2017 model, the multi-year average cost of untreated perinatal mood and anxiety disorders per affected mother-child pair was approximately $32,000.7
- Women with PPD have more hospital admissions6 and overall higher healthcare resource utilization and

health expenditures than women who do not have PPD.5,6

- Perinatal mood and anxiety disorders are also associated with delayed or impaired long-term developmental, psychological, cognitive, and physical outcomes in children. 8-12 In one study, societal costs for these outcomes were estimated at nearly $2.0 billion for all impacted children through their first 5 years of life. 7

The goal of broad affordable access for women with PPD who are prescribed ZURZUVAE has been a key consideration for Sage and Biogen in setting the planned wholesale acquisition cost of $15,900 for a full 14-day treatment course. The two companies are working to enable women with PPD who are prescribed ZURZUVAE to be able to access treatment with minimal restrictions and, where possible, with little to no co-pay regardless of financial means. To this end, Sage and Biogen are actively engaged with national, regional and government payors. The companies are also planning to help women with PPD through patient support programs that provide PPD education, as well as financial assistance for eligible patients prescribed ZURZUVAE to help cover costs, or free drug, and other support.

Sage and Biogen plan to share details on these patient support programs after the product becomes commercially available.

Sage expects the following milestones for ZURZUVAE in 2023 and 2024:

- Late 2023:
  - Commercial availability of ZURZUVAE in December 2023
- Early 2024:
  - Broader complement of commercialization capabilities for ZURZUVAE in early 2024

## Neuropsychiatry Pipeline

SAGE-718, the Company's first-in-class NMDA receptor positive allosteric modulator (PAM), is in development as a potential oral therapy for cognitive disorders associated with NMDA receptor dysfunction. SAGE-718 has received Fast Track Designation and Orphan Drug Designation (ODD) from the FDA, and Orphan Drug Designation from the European Medicines Agency (EMA) for the potential treatment of Huntington's Disease. SAGE-324, the Company's next-generation PAM of GABAA receptors, is in development as a potential oral therapy for movement disorders, such as essential tremor (ET). SAGE-324 is being developed in collaboration with Biogen Inc.

### SAGE-718

Sage is advancing a robust clinical program for SAGE-718 with multiple ongoing Phase 2 studies, including the

DIMENSION and SURVEYOR Studies in people with Huntington's Disease (HD) cognitive impairment, the lead indication for SAGE-718, the PRECEDENT Study in people with mild cognitive impairment (MCI) associated with Parkinson's Disease (PD) and a Phase 2 study (LIGHTWAVE) in people with MCI and mild dementia due to Alzheimer's Disease (AD). In October 2023, Sage announced the FDA granted ODD to SAGE-718 for the treatment of HD. Ongoing studies in the SAGE-718 clinical program include:

- DIMENSION (CIH-201) Study: The DIMENSION Study is a double-blind, placebo-controlled Phase 2 study in people with cognitive impairment associated with HD. The study is designed to evaluate the efficacy of once-daily SAGE-718 dosed over three months, with a target enrollment of approximately 178 people. The DIMENSION Study is enrolling across 40 clinical sites.
- SURVEYOR (CIH-202) Study: The SURVEYOR Study is a double-blind, placebo-controlled Phase 2 study in people with cognitive impairment associated with HD. The SURVEYOR Study is being conducted with the goal of generating evidence linking efficacy signals on cognitive performance to domains of real-world functioning and is not designed or powered to demonstrate a statistically significant difference between SAGE-718 and placebo.
- PURVIEW (CIH-301) Study: The PURVIEW Study is an open-label Phase 3 safety study of SAGE-718 in people with cognitive impairment associated with HD. The study is designed to evaluate the long-term safety profile of those treated for one year or more.
- PRECEDENT (CNP-202) Study: The PRECEDENT Study is a double-blind, placebo-controlled Phase 2 study in people with MCI due to PD. The study is designed to evaluate the safety and efficacy of SAGE-718 dosed over 6 weeks.
- LIGHTWAVE (CNA-202) Study: The LIGHTWAVE Study is a double-blind, placebo-controlled Phase 2 study of SAGE-718 in people with MCI and mild dementia due to AD. The study is designed to evaluate the safety and efficacy of SAGE-718 dosed over a 12-week period.

The Company expects the following milestones for SAGE-718 in 2023 and 2024:

- Late 2023:
  - Progress recruitment in the ongoing DIMENSION, SURVEYOR, PURVIEW, PRECEDENT and LIGHTWAVE Studies
- 2024:
  - Report topline data from the DIMENSION, SURVEYOR, PRECEDENT and LIGHTWAVE Studies

## SAGE-324

Sage and its collaborator, Biogen, are actively enrolling participants in the Phase 2b KINETIC 2 placebo-controlled study of SAGE-324 in ET following positive results from the KINETIC Study. The KINETIC 2 Study is a Phase 2b dose-

ranging study with the primary goal of defining the dose for SAGE-324 in ET with a tolerability profile appropriate for chronic treatment and a dosing schedule to maintain plasma concentrations needed for sustained tremor symptom control in treating ET. Enrollment in the KINETIC 2 Study is on track for completion in late 2023 with an expected topline data readout in mid-2024.

Sage is also currently enrolling patients in a Phase 2 long-term open label safety study to evaluate the long-term safety and tolerability of SAGE-324 in ET. The primary endpoint of the open-label study is incidence of treatment-emergent adverse events.

The Company expects the following milestones for SAGE-324 in 2023 and 2024:

- Late 2023:
  - Targeted completion of enrollment in the Phase 2b KINETIC 2 Study
- Mid-2024:
  - Report topline data from the Phase 2b KINETIC 2 Study

## FINANCIAL RESULTS FOR THE THIRD QUARTER 2023

- Cash Position: Cash, cash equivalents and marketable securities as of September 30, 2023 were $0.9 billion compared to $1.0 billion at June 30, 2023.
- Revenue: Net revenue from sales of ZULRESSO was $2.7 million in the third quarter of 2023 compared to $1.7 million in the same period of 2022.
- R&D Expenses: Research and development expenses were $101.9 million, including $6.9 million of non-cash stock-based compensation expense, in the third quarter of 2023 compared to $81.6 million, including $6.0 million of non-cash stock-based compensation expense, in the same period of 2022. The increase in spending was primarily due to expenses related to cancelling excess purchase commitments for manufacturing as a result of the complete response letter received from the FDA for zuranolone for the treatment of MDD. This purchase commitment cancellation also contributed to an increase in the reimbursement from Biogen to Sage pursuant to the Sage/Biogen Collaboration and License Agreement, which was $28.2 million in the third quarter of 2023 compared to $17.9 million in the same period of 2022.
- SG&A Expenses: Selling, general and administrative expenses were $78.1 million, including $21.0 million of non-cash stock-based compensation expense, in the third quarter of 2023 compared to $61.5 million, including $7.2 million of non-cash stock-based compensation expense, in the same period of 2022. The increase in SG&A expenses was primarily due to the recognition of $13.6 million of stock-based compensation expense related to performance-based vesting criteria during the third quarter of 2023. The reimbursement from Sage to Biogen pursuant to the Sage/Biogen Collaboration and License Agreement was $5.8 million in the third quarter of 2023 compared to $0.5 million of reimbursement from Biogen to Sage in the same period

of 2022. The primary reason for the decrease in net reimbursement was an increase in the collaboration costs incurred by Biogen in anticipation of the expected commercialization of ZURZUVAE.

- Restructuring Expenses: Restructuring expenses were $33.6 million in the third quarter of 2023 due to the August 2023 corporate reorganization. No restructuring expenses were incurred in the same period of 2022.
- Net Loss: Net loss was $201.6 million in the third quarter of 2023 compared to $137.3 million in the same period of 2022.

## FINANCIAL GUIDANCE

- Sage expects that, based on its current estimates, its current cash, cash equivalents and marketable securities, along with anticipated funding from ongoing collaborations, collaboration revenue from sales of ZURZUVAE, and a potential milestone payment of $75.0 million from Biogen for the first commercial sale of ZURZUVAE for the treatment of women with PPD, will support operations into 2026.
- Additionally, Sage underwent a strategic reorganization and pipeline reprioritization in August 2023. The company expects annualized net savings of approximately $240 million, of which 60% is related to R&D. The annualized net savings include $100 million related to the workforce reduction.

## Conference Call Information

Sage will host a conference call and webcast today, Tuesday, November 7, at 8:00 a.m. ET to review its third quarter 2023 financial results and discuss recent corporate updates. The live webcast 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 following the completion of the event and will be archived for up to 30 days.

## 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: plans for launch, commercial availability and commercialization of ZURZUVAE as a treatment for women with PPD, and potential timing of such activities; our goals and planned activities for commercial launch of ZURZUVAE in this indication and to enable access; the potential benefit of ZURZUVAE in the treatment of women with PPD; the number of women with PPD and the potential market for ZURZUVAE for the treatment of women with PPD; our belief in the potential of ZURZUVAE to be successful and to meet an unmet need

in the treatment of women with PPD; anticipated timelines for completion of enrollment in clinical trials and reporting of results with respect to certain of our other programs; 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 potential for value creation opportunities; the mission and goals for our business; our anticipated cash runway and related assumptions and estimates; the expected annualized net savings from our recent restructuring; and our expectations with respect to potential receipt of milestones from collaborations and potential future revenue. 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: our launch and commercialization efforts in the U.S. with respect to ZURZUVAE for the treatment of women with PPD may not be successful, and we may be unable to generate revenues from sales of ZURZUVAE at the levels or on the timing we expect or at levels or on the timing necessary to support our goals; the number of women with PPD, the unmet need for additional treatment options, and the potential market for ZURZUVAE in women with PPD, may be significantly smaller than we expect; ZURZUVAE may not achieve the clinical benefit, clinical use or market acceptance in the treatment of PPD we expect or we may encounter reimbursement-related or other market-related issues that impact the success of our commercialization efforts, including our ability to achieve access goals; we may encounter delays in initiation, conduct, completion of enrollment or completion and reporting of data with respect to any of our ongoing 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 may increase our costs; success in earlier clinical trials of any of our 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; decisions or actions of the FDA 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 encounter adverse events at any stage that negatively impact further development and the potential for approval of our product candidates or the potential for successful commercialization of any our products or that require additional nonclinical and clinical work which may not yield positive results; the need to align with our collaborators may hamper or delay our development and commercialization efforts for the products or product candidates that are part of the collaboration or increase our costs; the anticipated benefits of our ongoing collaborations, including the receipt of milestone payments or the successful development or commercialization of products and generation of revenue, may never be achieved; 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 to change or curtail some of our plans or both; we may not be successful in our efforts to gain regulatory approval of products beyond ZURZUVAE and ZULRESSO; we may not achieve revenues from other of our products that may be successfully developed in the future, at levels we expect; our expectations as to cash runway, cost savings from our recent restructuring and the 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; any of the foregoing events could impair the value creation opportunities for our business; and we may encounter technical and other unexpected hurdles in the development and manufacture of our product candidates or the commercialization of any current or future marketed product which may delay our timing or change our plans, increase our costs or otherwise negatively impact our business; 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.

## Financial Tables

Sage Therapeutics, Inc. and Subsidiaries
Condensed Consolidated Balance Sheets
(in thousands)
(unaudited)

| | September 30, 2023 | December 31, 2022 |
|---|---|---|
| Cash, cash equivalents and marketable securities | $ 876,052 | $ 1,272,494 |
| Total assets | 949,663 | 1,356,449 |
| Total liabilities | 133,004 | 103,850 |
| Total stockholders' equity | 816,659 | 1,252,599 |

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2023 | 2022 | 2023 | 2022 |
| Product revenue, net | $ 2,716 | $ 1,739 | $ 8,469 | $ 4,821 |
| Collaboration revenue | - | - | 14 | - |
| Total revenue | 2,716 | 1,739 | 8,483 | 4,821 |
| Operating costs and expenses: | | | | |

| | | | | |
|---|---|---|---|---|
| Cost of goods sold | 905 | 184 | 1,339 | 670 |
| Research and development | 101,919 | 81,553 | 291,905 | 236,868 |
| Selling, general and administrative | 78,142 | 61,482 | 219,415 | 160,370 |
| Restructuring | 33,599 | - | 33,599 | - |
| Total operating costs and expenses | 214,565 | 143,219 | 546,258 | 397,908 |
| Loss from operations | (211,849) | (141,480) | (537,775) | (393,087) |
| Interest income, net | 10,274 | 4,127 | 29,276 | 7,397 |
| Other income (expense), net | (55) | 30 | (284) | 52 |
| Net loss | $ (201,630) | $ (137,323) | $ (508,783) | $ (385,638) |
| Net loss per share - basic and diluted | $ (3.37) | $ (2.31) | $ (8.51) | $ (6.51) |
| Weighted average shares outstanding - basic and diluted | 59,912,378 | 59,428,123 | 59,786,254 | 59,242,563 |

## SELECT IMPORTANT SAFETY INFORMATION FOR ZURZUVAE

ZURZUVAE (zuranolone) CIV, is a neuroactive steroid gamma-aminobutyric acid (GABA) A receptor positive modulator indicated for the treatment of postpartum depression in adults.

This does not include all the information needed to use ZURZUVAE safely and effectively. See full prescribing information for ZURZUVAE.

ZURZUVAE may cause serious side effects, including decreased awareness and alertness, which can affect your ability to drive safely or safely do other dangerous activities. Do not drive, operate machinery, or do other dangerous activities until at least 12 hours after taking each dose. You may not be able to tell on your own if you can drive safely or tell how much ZURZUVAE is affecting you. ZURZUVAE may cause central nervous system (CNS) depressant effects including sleepiness, drowsiness, slow thinking, dizziness, confusion, and trouble walking. Taking alcohol, other medicines that cause CNS depressant effects such as benzodiazepines, or opioids while taking ZURZUVAE can make these symptoms worse and may also cause trouble breathing. ZURZUVAE is a federally controlled substance schedule IV because it contains zuranolone, which can be abused or lead to dependence. Tell your healthcare provider right away if you become pregnant or plan to become pregnant during treatment with ZURZUVAE. You should use effective birth control (contraception) during treatment with ZURZUVAE and for 1 week after the final dose. ZURZUVAE and other antidepressant medicines may increase the risk of suicidal thoughts and actions in people 24 years of age and younger. ZURZUVAE is not for use in children. The most common side effects of ZURZUVAE include sleepiness or drowsiness, dizziness, common cold, diarrhea, feeling tired, weak, or having no energy, and urinary tract infection.

## SELECT IMPORTANT SAFETY INFORMATION for ZULRESSO

ZULRESSO (brexanolone) CIV, is a neuroactive steroid gamma-aminobutyric acid (GABA) A receptor positive modulator indicated for the treatment of postpartum depression in individuals 15 years and older.

This does not include all the information needed to use ZULRESSO safely and effectively. See full prescribing information for ZULRESSO.

## WARNING: EXCESSIVE SEDATION AND SUDDEN LOSS OF CONSCIOUSNESS

See full prescribing information for complete boxed warning

Patients are at risk of excessive sedation or sudden loss of consciousness during administration of ZULRESSO.

Because of the risk of serious harm, patients must be monitored for excessive sedation and sudden loss of consciousness and have continuous pulse oximetry monitoring. Patients must be accompanied during interactions with their child(ren).

ZULRESSO is available only through a restricted program called the ZULRESSO REMS.

## WARNINGS AND PRECAUTIONS

Suicidal Thoughts and Behaviors: Consider changing the therapeutic regimen, including discontinuing ZULRESSO, in patients whose PPD becomes worse or who experience emergent suicidal thoughts and behavior.

ADVERSE REACTIONS: Most common adverse reactions (incidence ≥5% and at least twice the rate of placebo) were sedation/somnolence, dry mouth, loss of consciousness, and flushing/hot flush.

## USE IN SPECIFIC POPULATIONS

- Pregnancy: ZULRESSO may cause fetal harm. Healthcare providers are encouraged to register patients by calling the National Pregnancy Registry for Antidepressants at 1-844-405-6185 or visiting online at **https://womensmentalhealth.org/clinical-and-researchprograms/pregnancyregistry/antidepressants/**
- Renal Impairment: Avoid use of ZULRESSO in patients with end stage renal disease (ESRD)

To report SUSPECTED ADVERSE REACTIONS, contact Sage Therapeutics, Inc. at 1-844-4-SAGERX (1-844-472-4379) or FDA at 1-800-FDA-1088 or **www.fda.gov/medwatch**.

Please see accompanying full Prescribing Information including Boxed Warning.

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