# UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

DARREN KORVER, Individually and on Behalf of All Others Similarly Situated,

Case No.

Plaintiff,

**CLASS ACTION COMPLAINT** 

v.

٧.

JURY TRIAL DEMANDED

SAGE THERAPEUTICS, INC., BARRY E. GREENE, and KIMI IGUCHI,

Defendants.

Plaintiff Darren Korver ("Plaintiff"), individually and on behalf of all others similarly situated, by Plaintiff's undersigned attorneys, for Plaintiff's complaint against Defendants, alleges the following based upon personal knowledge as to Plaintiff and Plaintiff's own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiff's attorneys, which included, among other things, a review of the Defendants' public documents, conference calls and announcements made by Defendants, United States ("U.S.") Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Sage Therapeutics, Inc. ("Sage" or the "Company"), analysts' reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiff believes that substantial, additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

#### **NATURE OF THE ACTION**

1. This is a federal securities class action on behalf of a class consisting of all persons and entities other than Defendants that purchased or otherwise acquired Sage securities between April 12, 2021 and July 23, 2024, both dates inclusive (the "Class Period"), seeking to recover

damages caused by Defendants' violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder, against the Company and certain of its top officials.

- 2. Sage is a biopharmaceutical company that develops and commercializes brain health medicines. The Company is developing, *inter alia*, zuranolone (SAGE-217/BIIB125), a neuroactive steroid for the treatment of postpartum depression ("PPD") and major depressive disorder ("MDD"), in collaboration with Biogen Inc. ("Biogen"); SAGE-718 (dalzanemdor), an oral, oxysterol-based positive allosteric modulator of the N-methyl-D-aspartate ("NMDA") receptor for the treatment of, *inter alia*, mild cognitive impairment ("MCI") due to Parkinson's Disease ("PD"); and SAGE-324 (BIIB124), an oral investigational drug for the treatment of essential tremor ("ET"), also in collaboration with Biogen.
- 3. In May 2022, Sage announced that it had initiated a rolling submission of a New Drug Application ("NDA") to the U.S. Food and Drug Administration ("FDA") for zuranolone in the treatment of MDD. In June 2022, Sage announced that, rather than filing separate NDAs for zuranolone in the treatment of MDD and PPD, as originally intended, it would instead submit a single NDA seeking approval of zuranolone for the treatment of both MDD and PPD (the "Zuranolone NDA"). In December 2022, Sage announced the completion of the rolling submission of the Zuranolone NDA to the FDA.
- 4. Throughout the Class Period, Defendants made materially false and misleading statements regarding the Company's business, operations, and prospects. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) zuranolone was less effective in treating MDD than Defendants had led investors to believe; (ii) accordingly, the FDA was unlikely to approve the Zuranolone NDA for the treatment of MDD in its present form, and

zuranolone's clinical results for MDD, as well as its overall regulatory and commercial prospects, were overstated; (iii) SAGE-718 was less effective in treating MCI due to PD than Defendants had led investors to believe; (iv) accordingly, SAGE-718's clinical, regulatory, and commercial prospects as a treatment for MCI due to PD were overstated; (v) SAGE-324 was less effective in treating ET than Defendants had led investors to believe; (vi) accordingly, SAGE-324's clinical, regulatory, and commercial prospects as a treatment for ET were overstated; and (vii) as a result of all the foregoing, the Company's public statements were materially false and misleading at all relevant times.

- 5. On August 4, 2023, Sage issued a press release disclosing that the FDA had only approved the Zuranolone NDA insofar as it sought zuranolone as a treatment for adults with PPD and had "issued a Complete Response Letter (CRL) for the [NDA] for zuranolone in the treatment of adults with MDD" because "the application did not provide substantial evidence of effectiveness to support the approval of zuranolone for the treatment of MDD," advising that "an additional study or studies will be needed" for that additional indication.
- 6. On this news, Sage's stock price fell \$19.35 per share, or 53.6%, to close at \$16.75 per share on August 7, 2023.
- 7. On April 17, 2024, Sage issued a press release disclosing that a Phase 2 study of SAGE-718 as a treatment for MCI due to PD "did not meet its primary endpoint of demonstrating statistically significant difference from baseline in participants treated with once-daily dalzanemdor [SAGE-718] versus placebo on the Wechsler Adult Intelligence Scale Fourth Edition-IV (WAIS-IV) Coding Test score at Day 42," and that, "[b]ased on the data, the Company does not plan any further development of [SAGE-718] in PD."

- 8. On this news, Sage's stock price fell \$3.06 per share, or 19.58%, to close at \$12.57 per share on April 17, 2024.
- 9. Then, on July 24, 2024, Sage issued a press release disclosing that a Phase 2 study of SAGE-324 as a treatment for ET "did not demonstrate a statistically significant dose-response relationship in change from baseline to Day 91 based on the primary endpoint, The Essential Tremor Rating Assessment Scale (TETRAS) Performance Subscale (PS) Item 4 (upper limb) total score, in participants with ET"; that "there were no statistically significant differences demonstrated for any dose of SAGE-324 versus placebo in the change from baseline to Day 91 on the TETRAS PS Item 4 Total Score or the TETRAS Activities of Daily Living (ADL) Composite Score"; and that, "[g]iven these results, Sage and Biogen will close the ongoing open label safety study of SAGE-324 in ET and do not plan to conduct further clinical development of SAGE-324 in ET."
- 10. On this news, Sage's stock price fell \$2.70 per share, or 20.64%, to close at \$10.38 per share on July 24, 2024.
- 11. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

# **JURISDICTION AND VENUE**

- 12. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).
- 13. This Court has jurisdiction over the subject matter of this action pursuant to 28U.S.C. § 1331 and Section 27 of the Exchange Act.

- 14. Venue is proper in this District pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b). Sage's common stock trades on the Nasdaq Global Market ("NASDAQ"), which is located in this District.
- 15. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

# **PARTIES**

- 16. Plaintiff, as set forth in the attached Certification, acquired Sage securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures.
- 17. Defendant Sage is a Delaware corporation with principal executive offices located at 215 First Street, Cambridge, Massachusetts 02142. Sage's common stock trades in an efficient market on the NASDAQ under the ticker symbol "SAGE."
- 18. Defendant Barry E. Greene ("Greene") has served as Sage's Chief Executive Officer ("CEO"), President, and a Director of the Company at all relevant times.
- 19. Defendant Kimi Iguchi ("Iguchi") has served as Sage's Chief Financial Officer at all relevant times.
- 20. Defendants Greene and Iguchi are collectively referred to herein as the "Individual Defendants."
- 21. The Individual Defendants possessed the power and authority to control the contents of Sage's SEC filings, press releases, and other market communications. The Individual Defendants were provided with copies of Sage's SEC filings and press releases alleged herein to

be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or to cause them to be corrected. Because of their positions with Sage, and their access to material information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public, and that the positive representations being made were then materially false and misleading. The Individual Defendants are liable for the false statements and omissions pleaded herein.

22. Sage and the Individual Defendants are collectively referred to herein as "Defendants."

#### SUBSTANTIVE ALLEGATIONS

#### **Background**

23. Sage is a biopharmaceutical company that develops and commercializes brain health medicines. The Company is developing, *inter alia*, zuranolone (SAGE-217/BIIB125), a neuroactive steroid for the treatment of PPD and MDD, in collaboration with Biogen; SAGE-718 (dalzanemdor), an oral, oxysterol-based positive allosteric modulator of the NMDA receptor for the treatment of, *inter alia*, MCI due to PD; and SAGE-324 (BIIB124), an oral investigational drug for the treatment of ET, also in collaboration with Biogen.

## Materially False and Misleading Statements Issued During the Class Period

24. The Class Period begins on April 12, 2021, when Sage issued a press release during pre-market hours announcing topline results from a Phase 2 study, called the "KINETIC Study," evaluating SAGE-324 as a treatment for ET (the "April 12 Press Release"). The April 12 Press Release stated, *inter alia*:

The study (n=67 full analysis set) achieved its primary endpoint of a statistically significant reduction from baseline compared to placebo in The Essential Tremor

Rating Assessment Scale (TETRAS) Performance Subscale Item 4 upper limb tremor score on Day 29 (P=0.049), which corresponded to a 36% reduction from baseline in upper limb tremor amplitude in patients receiving SAGE-324 compared to a 21% reduction in patients receiving placebo. Activities of daily living (ADL) scores showed a statistically significant correlation with upper limb tremor score at all timepoints.

\* \* \*

In the KINETIC Study, patients (n=47) with a more severe tremor at baseline (at or above the median TETRAS Performance Subscale upper limb tremor Item 4 score of 12) who received SAGE-324, demonstrated a statistically significant reduction (P=0.007) from baseline in TETRAS Performance Subscale Item 4 upper limb tremor score compared to placebo at Day 29, corresponding to a 41% reduction from baseline in upper limb tremor amplitude in patients receiving SAGE-324 compared to an 18% reduction for placebo. Study patients were not taking other medications for ET during the 28-day treatment period.

25. In addition, the April 12 Press Release quoted Defendant Greene as stating, in relevant part:

In the design of the KINETIC Study, we set a high bar and believe we exceeded it. SAGE-324 met the primary endpoint in the trial . . . . The strong correlation observed in this study between TETRAS performance scale – measuring reduction of upper limb tremor, a disabling symptom experienced by more than 90% of people suffering from essential tremor -- and improvement on the ADL score provides suggestive evidence that these findings have the potential to be truly impactful for people with [ET] . . . . We believe the data announced today provide clear support and insights for the continued development of SAGE-324 in an area of significant unmet medical need.

26. On May 4, 2021, Sage issued a press release announcing its first quarter 2021 results (the "1Q21 Press Release"). The 1Q21 Press Release quoted Defendant Greene as stating, in relevant part:

Sage started 2021 with significant advances across our depression, neurology and neuropsychiatry franchises, and the progress we've made so far this year sets us up for near-, medium- and long-term value creation opportunities as we further advance our deep organic pipeline . . . . In the first quarter alone, we demonstrated the significant potential of our innovative development-stage therapeutics that modulate the GABA and NMDA pathways, through the positive clinical data demonstrated in studies of zuranolone, SAGE-324 and now SAGE-718. We are making great progress toward our goal of becoming the leading brain health

company and a top-tier biopharmaceutical company, with multiple upcoming catalysts that I believe represent important steps on our mission of delivering medicines that matter to address the ongoing crisis in brain health.

27. In addition, the 1Q21 Press Release discussed SAGE-718's purported efficacy observed in a Phase 2a open-label study, called the "PARADIGM Study," evaluating SAGE-718 as a treatment for patients with MCI due to PD, stating, in relevant part:

In the Phase 2a open-label PARADIGM Study, eight patients aged 50 to 75 years old with [MCI] due to PD received SAGE-718 3 mg daily for two-weeks.

- Patients showed performance improvements from baseline on multiple tests in the cognitive domain of executive function during the 14 days of treatment.
- Emerging signals on several measures also suggested improved performance from baseline on additional cognitive tests in the domains of learning and memory over a similar timeframe.

\* \* \*

Findings from the PARADIGM Study extend Sage's understanding of the potential impact of SAGE-718 on multiple domains of cognition. To date, SAGE-718 has demonstrated improvements in executive function in phase 1 and phase 2a studies and these findings add to the Company's confidence in the potential for SAGE-718 to become an important treatment for disorders associated with cognitive dysfunction, including . . . PD[.]

- 28. On June 15, 2021, Sage issued a press release announcing purported positive pivotal Phase 3 results for zuranolone in treating MDD (the "June 15 Press Release"). The June 15 Press Release stated, *inter alia*, "that the WATERFALL Study in patients with MDD met its primary endpoint with zuranolone (SAGE-217/BIIB125) 50 mg showing statistically significant improvement in depressive symptoms compared with placebo at Day 15 as assessed by the 17-item Hamilton Rating Scale for Depression (HAMD-17) total score."
- 29. The June 15 Press Release also quoted Defendant Greene as stating, in relevant part, that "Sage's expertise in the modulation of the GABA receptor pathway in the brain, coupled with insights on the treatment wants and needs of clinicians and patients, has resulted in our

targeting a unique benefit/risk profile with the development of zuranolone supported to date by the data generated in the WATERFALL Study and the broader Landscape and NEST programs[.]"

30. On October 4, 2021, Sage issued a press release "announc[ing] new data from the LANDSCAPE and NEST clinical development programs evaluating the efficacy and safety of zuranolone for the treatment of [MDD] and [PPD] presented at the 34th European College of Neuropsychopharmacology (ECNP) Congress," stating, in relevant part:

The Presentations include data from the WATERFALL Study, a Phase 3 placebo-controlled trial evaluating the efficacy and safety of zuranolone 50 mg in adults 18 to 64 years old with MDD as well as the open-label SHORELINE Study in MDD and cross-study analyses from across the LANDSCAPE and NEST programs. Collectively, the studies show reductions in depressive symptoms with zuranolone-treated patients such as consistent improvements in depressive mood, as well as rapid onset of significant effect by Day 3 . . . In pooled analyses from the LANDSCAPE and NEST programs of SF-36v2, a patient self-reported measure of general health, zuranolone treatment led to rapid improvement in quality of life and overall health across all functioning and well-being domains at Day 15 and across all domains at Day 42 (Day 45 in ROBIN Study).

31. On October 19, 2021, Sage issued a press release announcing that the Company and Biogen planned to submit an NDA for zuranolone to the FDA in the second half of 2022, with a rolling submission expected to start in early 2022 (the "October 19 Press Release"). The October 19 Press Release stated, *inter alia*:

Sage . . . and Biogen . . . plan to submit a[n NDA] to the [FDA] for zuranolone . . . in the second half of 2022. The planned initial submission package will seek approval of zuranolone for the treatment of [MDD] . . . . The decision to submit the application follows recent discussions with the FDA, including a pre-NDA meeting held this fall. Data from completed studies in the LANDSCAPE and NEST programs, as well as data from the ongoing clinical and pharmacology studies, are planned to be included as part of the submission packages.

32. In addition, the October 19 Press Release quoted Defendant Greene as stating, in relevant part:

In the pre-NDA meeting, the FDA's response on the regulatory pathway for zuranolone continued to be consistent with previous discussions. In the clinical

development programs, zuranolone has shown remarkably consistent, rapid, and sustained reductions in depressive symptoms, including anxiety and sleep loss . . . . We believe we have a solid filing package with four adequate and well controlled trials now in hand and, if approved, zuranolone will fill a real unmet need and be welcomed by people living with depression . . . . We have identified what we believe is the most efficient path forward for an FDA filing and potential approval.

33. On November 2, 2021, Sage issued a press release announcing its third quarter 2021 results (the "3Q21 Press Release"). The 3Q21 Press Release quoted Defendant Greene as stating, in relevant part:

I'm proud of the substantial progress we've made this quarter, including a successful pre-NDA meeting with the FDA for zuranolone. We're excited to have reached alignment with the Agency and to have what we believe is a clear, efficient path forward for zuranolone. We're now one step closer toward our goal of helping people living with MDD . . . by bringing them a treatment that in clinical development to date has demonstrated rapid and sustained reductions in depressive symptoms[.]

34. With respect to zuranolone as a treatment for MDD, the 3Q21 Press Release stated, *inter alia*:

The [pre-NDA] meeting reinforced Sage's belief that data from the MDD-201, ROBIN, and WATERFALL Studies and the Shionogi Phase 2 study along with supportive data from the MOUNTAIN Study will be sufficient for Sage to file in MDD. The planned initial NDA will focus on MDD and will also include data from the ongoing pharmacology and clinical studies (CORAL and SHORELINE Studies).

35. On December 8, 2021, Sage issued a press release announcing new analyses from the LANDSCAPE clinical development program of zuranolone in MDD presented at the American College of Neuropsychopharmacology (ACNP) Congress (the "December 8 Press Release"). The December 8 Press Release stated, in relevant part:

Data from the SHORELINE and WATERFALL Studies in the LANDSCAPE clinical program further the understanding of the potential efficacy . . . profile of zuranolone for the treatment of MDD. Across the studies, zuranolone treatment led to improvements in depressive symptoms as well as in symptoms of elevated anxiety as assessed by multiple scales (HAMD-17, MADRS and HAM-A, respectively). In the WATERFALL Study, a rapid onset of effect in HAMD-17 was

observed compared to placebo as early as Day 3, reaching statistical significance, followed by a stabilization of depressive symptoms through the follow-up period.

\* \* \*

In an analysis of a subgroup of patients (N=96) over the age of 65 in the SHORELINE Study, zuranolone efficacy . . . results for the initial 2-week dose treatment course were similar to that of the general study population. At the time of the analysis, retreatment data were only available for the zuranolone 30 mg cohort of the SHORELINE Study. In a subgroup of patients 65 years and older who responded to the initial 2-week treatment course of zuranolone 30 mg, and were followed for up to one year in the SHORELINE Study, more than half did not receive a second course of treatment during their time in the study.

36. In addition, the December 8 Press Release quoted Defendant Greene as stating, in relevant part:

The data shared at ACNP continue to provide insight to help us better understand how zuranolone could impact the treatment of depression and potentially differentiate further from current antidepressants, if approved . . . . The analysis conducted evaluating zuranolone's effects on measures of anxiety in patients with MDD is critical. Symptoms of anxiety are highly present in patients with depression, which can pose unique challenges to care. We are also pleased with the data for those 65 and older, who can struggle with current therapies to treat their depression. Zuranolone has consistently demonstrated rapid and sustained improvements in depressive symptoms . . . in our clinical trials to date[.]

37. On February 16, 2022, Sage issued a press release announcing additional positive clinical results purportedly supporting zuranolone's efficacy in treating MDD (the "February 16 Press Release"). The February 16 Press Release stated, *inter alia*:

[T]he CORAL Study in people with [MDD] met the trial objectives, demonstrating a rapid and statistically significant reduction in depressive symptoms at Day 3 and over the 2-week treatment period, achieving the primary and key secondary endpoints. This significance was demonstrated at the first measured time point, Day 3, with zuranolone 50 mg co-initiated with an open-label standard of care antidepressant (ADT) as assessed by change from baseline in the 17-item Hamilton Rating Scale for Depression (HAMD-17). The CORAL Study also met its key secondary endpoint, with zuranolone co-initiated with a standard of care ADT demonstrating a statistically significant improvement in depressive symptoms compared to ADT co-initiated with placebo, over the 2-week treatment period . . . . In meeting its pre-defined objectives, the CORAL Study supports the potential of

zuranolone, when co-initiated with standard of care, to accelerate the benefit of depression treatment compared to treatment with ADTs alone.

38. The February 16 Press Release also quoted Defendant Greene as stating, in relevant part:

We believe the CORAL Study is clinically meaningful and with the addition of this data the LANDSCAPE program now demonstrates zuranolone has three potential real world uses for the treatment of MDD. The LANDSCAPE data support zuranolone as a monotherapy, and since many people in the previously completed studies were already on maintenance ADTs, we believe our data also support zuranolone as additive therapy. The CORAL Study further supports the use of zuranolone to accelerate the benefit of conventional ADTs in treating MDD with a well-tolerated safety profile . . . . Including the CORAL Study, zuranolone now has six positive clinical studies, and we remain on track to start the rolling submission for a[n NDA] in MDD early this year with completion targeted for the second half of 2022.

39. On February 24, 2022, Sage issued a press release announcing its fourth quarter and full year 2021 financial results (the "4Q/FY21 Press Release"). The 4Q/FY21 Press Release quoted Defendant Greene as stating:

2021 was a data rich year marked by important advancements in multiple disease areas across all of our brain health franchises . . . . I'm excited to build on this foundation, especially with the initiation of the rolling NDA submission for zuranolone in MDD planned for early this year. We believe the entirety of the development program to date supports zuranolone's potential to address substantial unmet needs in [MDD] and [PPD] and to be a differentiated treatment option for people with these brain health disorders.

40. With respect to the data that purportedly supported zuranolone's approval as a treatment for MDD, the 4Q/FY21 Press Release stated, in relevant part:

Positive topline data from the WATERFALL and SHORELINE Studies announced in 2021 and multiple data presentations supporting zuranolone efficacy and safety: Along with collaborator Biogen, Sage announced positive topline data from the WATERFALL and SHORELINE Studies in 2021. The Companies also presented multiple datasets from the LANDSCAPE and NEST clinical development programs that support the potential efficacy and safety of zuranolone for the treatment of [MDD] and [PPD], respectively.

- Positive results were shared from the WATERFALL Study, a Phase 3 placebocontrolled trial that evaluated the efficacy and safety of zuranolone 50 mg in adults 18 to 64 years of age with MDD.
- Positive results from the open-label SHORELINE Study in MDD showed the majority of people who responded to an initial zuranolone 50 mg treatment course received only one treatment and 80% received only 1 or 2 treatment courses during their time in this year-long study.
- Shionogi presented positive results from a Phase 2 study of zuranolone in MDD in Japan.
- In clinical trials, zuranolone has consistently demonstrated rapid and sustained improvements in depressive symptoms, with rapid onset of significant effect as early as Day 3.

# (Emphasis in original.)

41. With respect to SAGE-718's purported efficacy in treating MCI due to PD, the 4Q/FY21 Press Release stated, in relevant part:

# **Topline data from PARADIGM and LUMINARY Studies with SAGE-718:** SAGE-718 demonstrated improvements across multiple domains of cognition in Phase 1 and Phase 2a studies of people with cognitive impairment across several indications, including . . . [PD] . . . . These findings support the Company's belief in the potential for SAGE-718 to be an important treatment for disorders associated with cognitive dysfunction.

The open-label PARADIGM Study evaluated SAGE-718 in people with [MCI] due to PD. Data from the study showed that SAGE-718 had a positive impact on multiple domains of cognition, including executive function and learning and memory, while leaving domains altering simple attention or reaction time unaffected.

# (Emphasis in original.)

42. With respect to SAGE-324's purported efficacy in treating ET, the 4Q/FY21 Press Release stated, in relevant part:

#### **Topline data from the KINETIC Study with SAGE-324:**

• Sage and Biogen announced that the KINETIC Study, a Phase 2 multicenter, randomized, double-blind, placebo-controlled study of SAGE-324 in [ET], met its primary endpoint. In the study, SAGE-324 demonstrated a statistically significant reduction from baseline in The Essential Tremor Rating Assessment Scale (TETRAS) Performance Subscale Item 4 upper limb tremor score at Day 29 in the total studied population compared to placebo.

• SAGE-324 also demonstrated a statistically significant correlation between TETRAS upper limb tremor score and activities of daily living at all measured time points.

(Emphasis in original.)

43. Also on February 24, 2022, Sage filed an annual report on Form 10-K with the SEC, reporting the Company's financial and operating results for the quarter and year ended December 31, 2021 (the "2021 10-K"). With respect to zuranolone's purported efficacy in treating MDD, the 2021 10-K stated, *inter alia*:

On February 16, 2022, we announced results from the CORAL Study, a placebo-controlled Phase 3 clinical trial evaluating a two-week course of zuranolone 50 mg, when co-initiated with a newly administered open-label standard antidepressant therapy, or ADT, compared with open-label standard of care ADT co-initiated with placebo, as an acute rapid response treatment in patients with MDD . . . . In the CORAL Study, zuranolone 50 mg co-initiated with an ADT met the primary endpoint of statistically significant reduction in depressive symptoms at Day 3 and met the key secondary endpoint of a statistically significant improvement in depressive symptoms over the two-week treatment period, in each case as compared to ADT co-initiated with placebo.

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In June 2021, we announced that the WATERFALL Study, a pivotal, Phase 3, double-blind, randomized, placebo-controlled clinical trial evaluating the efficacy and safety of zuranolone 50 mg in adults aged 18 to 64 years with MDD, met its primary endpoint.

44. With respect to SAGE-718's purported efficacy in treating MCI due to PD, the 2021 10-K stated, *inter alia*:

In May 2021, we announced results from the first part of a Phase 2a open-label study of SAGE-718 evaluating patients with [MCI] due to [PD], known as the PARADIGM Study. Data from the PARADIGM Study showed that SAGE-718 had a positive impact on multiple domains of cognition, including executive function and learning and memory, while leaving domains altering simple attention or reaction time unaffected.

45. With respect to SAGE-324's purported efficacy in treating ET, the 2021 10-K stated, *inter alia*:

The Phase 2 KINETIC Study evaluating SAGE-324 for the treatment of adults with [ET] (n=67 full analysis set) achieved its primary endpoint of a statistically significant reduction from baseline compared to placebo in The Essential Tremor Rating Assessment Scale, or TETRAS, Performance Subscale Item 4 upper limb tremor score on Day 29 (p-value=0.049), which corresponded to a 36% reduction from baseline in upper limb tremor amplitude in patients receiving SAGE-324 compared to a 21% reduction in patients receiving placebo . . . . The trial evaluated treatment of SAGE-324 at the higher end of the dose range and the daily dose could be down-titrated to 45 mg or 30 mg. Activities of daily living, or ADL, scores showed a statistically significant correlation with upper limb tremor score at all timepoints. Although the clinical trial was not powered to fully examine TETRAS ADL, SAGE-324 was numerically superior to placebo at all time points during treatment . . . . In the KINETIC Study, patients with a more severe tremor at baseline (at or above the median TETRAS Performance Subscale upper limb tremor Item 4 score of 12) (n=47) who received SAGE-324 demonstrated a statistically significant reduction (p-value=0.007) from baseline in TETRAS Performance Subscale Item 4 upper limb tremor score compared to placebo at Day 29, corresponding to a 41% reduction from baseline in upper limb tremor amplitude in patients receiving SAGE-324 compared to an 18% reduction for placebo.

- 46. Appended as exhibits to the 2021 10-K were signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX"), wherein the Individual Defendants certified that the 2021 10-K "does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;" and that "the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the [Company] as of, and for, the periods presented in this report[.]"
- 47. On March 15, 2022, Sage issued a press release announcing the presentation of purported "Encouraging results from the Phase 2 PARADIGM Study (Part A) of SAGE-718 in Patients with [MCI] due to [PD]," stating, in relevant part:

The PARADIGM Study is a Phase 2, open-label study evaluating the . . . efficacy of SAGE-718 once daily in individuals with [MCI] due to [PD]

Patients who received SAGE-718 in the study experienced improvement in performance of cognitive tests of executive functioning and learning and memory

\* \* \*

SAGE-718, a first-in-class, oral, positive allosteric modulator of the NMDA receptor, was associated with improvements on multiple tests of executive functioning and learning and memory in patients with [MCI] due to [PD] in the open label Phase 2 PARADIGM Study.

(Emphases in original.)

48. On May 2, 2022, Sage issued a press release announcing that the Company and Biogen had initiated the rolling submission of an NDA with the FDA for zuranolone in the treatment of MDD (the "May 2 Press Release"). The May 2 Press Release stated, in relevant part:

Sage . . . and Biogen . . . initiated a rolling submission of a[n NDA] to the [FDA] for zuranolone in the treatment of [MDD] . . . . The companies have submitted the nonclinical module of the NDA to the FDA and plan to submit the remaining components for the MDD filing in the second half of 2022.

Data from the completed studies of zuranolone in the LANDSCAPE and NEST clinical development programs, including data from the ongoing open-label SHORELINE Study in MDD, as well as data from the completed clinical pharmacology studies, will comprise the full submission package. The rolling submission process allows completed sections of an NDA to be submitted to the FDA for review on an ongoing basis.

49. In addition, the May 2 Press Release quoted Defendant Greene as stating:

There are millions of people living with depression and the initiation of the rolling NDA submission brings us one step closer to our goal of offering zuranolone as a potential new treatment option . . . . We believe the results from the LANDSCAPE and NEST programs, in which zuranolone demonstrated rapid and sustained effects . . . support zuranolone as a potential novel treatment option for MDD, if approved. We look forward to providing an update when the rolling submission for zuranolone in MDD is complete, which we expect to occur in the second half of this year.

- 50. On May 3, 2022, Sage issued a press release announcing its first quarter 2022 results (the "1Q22 Press Release"). The 1Q22 Press Release quoted Defendant Greene as stating, in relevant part:
  - [A]t Sage, we've made a strong start to 2022 with the initiation of our rolling regulatory submission for zuranolone in [MDD] and meaningful progress across our entire pipeline . . . . We are currently executing four Phase 2 studies across our neuropsychiatry and neurology franchises, and we recently presented encouraging data from our SAGE-718 program in patients with[, *inter alia*, MCI] due to [PD] . . . at key scientific forums.
- 51. With further respect to SAGE-718's purported efficacy in treating MCI due to PD, the 1Q22 Press Release stated, *inter alia*:

Data from the Company's Phase 2 open label PARADIGM Study presented at the AD/PD 2022 Advances in Science & Therapy International Conference on Alzheimer's and Parkinson's Diseases and Related Neurological Disorders, showed that SAGE-718 given once daily for 14 days was associated with improvements in executive function and learning and memory at Day 14 in patients with MCI due to PD. Additionally, sustained effects and improving trends were seen out to Day 28.

52. On June 13, 2022, Sage filed a current report on Form 8-K with the SEC, reporting that, rather than filing separate NDAs for zuranolone in the treatment of MDD and PPD, as originally intended, it would instead submit a single NDA seeking approval of zuranolone for the treatment of both MDD and PPD, stating, in relevant part:

The Company is reporting that, in lieu of separate NDA filings, the Company and Biogen have decided to submit a single NDA seeking approval of zuranolone for the treatment of both MDD and PPD. The Company has informed the FDA of this update, and the FDA raised no objections and stated it looked forward to continuing discussions with the Company. The Company and Biogen expect to complete the submission of this single NDA in the second half of 2022, and to seek priority review of the filing. This represents an acceleration of the planned PPD timelines. If the Company meets its planned filing timelines and the NDA receives priority review, the Company expects the PDUFA target action date for zuranolone to be in the third quarter of 2023.

53. On August 2, 2022, Sage issued a press release announcing its second quarter 2022 results. The press release quoted Defendant Greene as stating, in relevant part:

The first half of 2022 has been marked by important clinical and regulatory achievements across our entire pipeline, paving the way for continued focused execution throughout the remainder of the year . . . . We are making progress on the NDA submission for zuranolone and building our organization to support a potential launch. Based on the consistent clinical profile of zuranolone, we believe it has the potential, if approved, to address the significant unmet need for people suffering from MDD . . . and we are working with a sense of urgency toward our goal of bringing zuranolone to them. Beyond zuranolone, we are continuing to advance our pipeline, with the presentation of multiple data sets at key upcoming scientific congresses. I believe our progress this year, combined with the strong foundation we've built, supports our growth as a leader in brain health and a toptier biopharmaceutical company.

54. On November 8, 2022, Sage issued a press release announcing its third quarter 2022 results. The press release quoted Defendant Greene as stating, in relevant part:

This has been an important year for Sage, marked by the execution of significant milestones across our franchises. Looking ahead, we remain focused on the completion of the NDA submission for zuranolone in MDD and PPD, and are well into commercialization preparations to support a potential launch . . . . We believe zuranolone, if approved, has the potential to deliver a new treatment option for patients[.]

55. On December 6, 2022, Sage issued a press release announcing the completion of the rolling submission of the Zuranolone NDA, stating, in relevant part:

Sage . . . and Biogen . . . announced the completion of the rolling submission of a[n NDA] to the [FDA] for zuranolone in the treatment of [MDD] and [PPD] . . . . The submission completes the NDA filing that was initiated earlier this year.

In the clinical development program to date, zuranolone showed rapid and sustained improvement of depressive symptoms . . . Zuranolone . . . has a novel mechanism of action as a positive allosteric modulator of GABA-A receptors. In people with depression, it may help to rapidly rebalance dysregulated neuronal networks to help restore brain function. Zuranolone targets brain networks responsible for functions such as mood, arousal, behavior, and cognition.

\* \* \*

The NDA submission includes data from the LANDSCAPE and NEST development programs for zuranolone. The LANDSCAPE program includes five studies of zuranolone in adults with MDD (MDD-201B, MOUNTAIN, SHORELINE, WATERFALL, and CORAL Studies).

56. On February 16, 2023, Sage issued a press release announcing its fourth quarter and full year 2022 results (the "4Q/FY22 Press Release"). The 4Q/FY22 Press Release quoted Defendant Greene as stating:

We set out in 2022 to deliver on a bold agenda; starting with the goal of transforming the treatment of depression. We have been laser focused on the opportunity to help millions of people who are desperate for new treatment options and the recent acceptance of the NDA filing for zuranolone in MDD and PPD puts us one step closer to that goal . . . . We are also progressing a promising and targeted pipeline with the goal of being able to launch new drugs or indications for years to come. This momentum puts us in a position of strength as we kick off 2023 and progress in our plan to become the leader in brain health and a top tier biopharmaceutical company.

57. With respect to SAGE-718's purported efficacy in treating MCI due to PD, the 4Q/FY22 Press Release stated, in relevant part:

Presented Encouraging Data from Phase 2 Open Label LUMINARY and Open Label PARADIGM Studies of SAGE-718: SAGE-718 demonstrated improvements across multiple domains of cognition, including executive performance and learning and memory, . . . [including] in patients with [MCI] due to [PD] in the Phase 2 open-label PARADIGM Study.

- Data from the Phase 2 open-label PARADIGM Study (Part A, 14 days of dosing) presented at the AD/PD 2022 Advances in Science & Therapy International Conference on Alzheimer's and Parkinson's Diseases and Related Neurological Disorders, showed that SAGE-718 was associated with improvements in executive function and learning and memory at Day 14 in patients with MCI due to PD. Additionally, sustained effects and improving trends were observed at 14 days post-treatment.
- Additional results from the Phase 2 open-label PARADIGM Study (Part B, 28 days of dosing) were presented at ECNP and showed that improvements in executive function could be sustained through 28 days of dosing.

(Emphasis in original.)

58. Also on February 16, 2023, Sage filed an annual report on Form 10-K with the SEC, reporting the Company's financial and operating results for the quarter and year ended December 31, 2022 (the "2022 10-K"). With respect to zuranolone's purported efficacy in treating MDD, the 2022 10-K stated, *inter alia*:

To date, we have completed six pivotal clinical trials of zuranolone, four in MDD . . . . [T]hree of the four completed pivotal trials evaluating zuranolone for the treatment of MDD met their primary endpoints.

59. With respect to SAGE-718's purported efficacy in treating MCI due to PD, the 2022 10-K stated, *inter alia*:

In May 2021, we announced results from the 14-day dosing cohort, or Cohort A, of a Phase 2a open-label clinical trial of SAGE-718 evaluating patients with [MCI] due to [PD], known as the PARADIGM Study. In Cohort A of the clinical trial, eight patients aged 50 to 75 years with [MCI] due to [PD] received 3 mg of SAGE-718 daily for 14 days. Patients showed performance improvements from baseline on multiple tests in the cognitive domain of executive function during the 14 days of treatment. Emerging signals on several measures also suggested improved performance from baseline on cognitive tests in the domains of learning and memory over a similar timeframe.

In October 2022, we presented additional results from the 28-day cohort, or Cohort B, of the open-label PARADIGM Study. In Cohort B of the clinical trial, seven patients aged 50 to 75 years with mild cognitive impairment due to Parkinson's disease received 3 mg of SAGE-718 daily for 28 days. Patients showed performance improvements from baseline on multiple tests in the cognitive domain of executive function during the 28 days of treatment, as well as during the 14 day follow-up period.

- 60. In addition, the 2022 10-K contained the same statements as referenced in ¶ 45, *supra*, regarding SAGE-324's purported efficacy in treating ET, as observed in the Phase 2 KINETIC Study.
- 61. Appended as exhibits to the 2022 10-K were substantively the same SOX certifications as referenced in ¶ 46, *supra*, signed by the Individual Defendants.

62. On May 2, 2023, Sage issued a press release announcing its first quarter 2023 results. The press release quoted Defendant Greene as stating:

The first quarter was marked by important advancements across our brain health pipeline and product engine, which lay the groundwork for continued execution and the potential for long-term value creation, particularly as we approach the PDUFA target action date for zuranolone in MDD and PPD . . . . We are laser focused on progressing launch readiness activities in collaboration with Biogen and we believe that our planned strategic approach to the commercialization of zuranolone, if approved, will help us to achieve our vision of transforming the way depression is treated.

- Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) zuranolone was less effective in treating MDD than Defendants had led investors to believe; (ii) accordingly, the FDA was unlikely to approve the Zuranolone NDA for the treatment of MDD in its present form, and zuranolone's clinical results for MDD, as well as its overall regulatory and commercial prospects, were overstated; (iii) SAGE-718 was less effective in treating MCI due to PD than Defendants had led investors to believe; (iv) accordingly, SAGE-718's clinical, regulatory, and commercial prospects as a treatment for MCI due to PD were overstated; (v) SAGE-324 was less effective in treating ET than Defendants had led investors to believe; (vi) accordingly, SAGE-324's clinical, regulatory, and commercial prospects as a treatment for ET were overstated; and (vii) as a result of all the foregoing, the Company's public statements were materially false and misleading at all relevant times.
- 64. In addition, Defendants violated Item 303 of SEC Regulation S-K, 17 C.F.R. § 229.303(b)(2)(ii) ("Item 303"), which required Sage to "[d]escribe any known trends or uncertainties that have had or that are reasonably likely to have a material favorable or unfavorable

impact on net sales or revenues or income from continuing operations." Defendants' failure to disclose that zuranolone, SAGE-718, and SAGE-324 were not as effective as they had led investors to believe violated Item 303 because this issue represented a known trend or uncertainty that was likely to have a material unfavorable impact on the Company's business and financial results.

# The Truth Begins to Emerge

65. On August 4, 2023, during after-market hours, Sage issued a press release disclosing that the FDA had only approved the Zuranolone NDA insofar as it sought zuranolone as a treatment for adults with PPD and had rejected the Zuranolone NDA for the treatment of MDD, stating, in relevant part:

[T]he FDA issued a Complete Response Letter (CRL) for the [NDA] for zuranolone in the treatment of adults with [MDD]. The CRL stated that the application did not provide substantial evidence of effectiveness to support the approval of zuranolone for the treatment of MDD and that an additional study or studies will be needed. Sage and Biogen are reviewing the feedback and evaluating next steps.

- 66. On this news, Sage's stock price fell \$19.35 per share, or 53.6%, to close at \$16.75 per share on August 7, 2023. Despite this decline in Sage's stock price, the Company's securities continued trading at artificially inflated prices throughout the remainder of the Class Period because of Defendants' continued misstatements and omissions regarding SAGE-718's effectiveness in treating MCI due to PD, SAGE-324's effectiveness in treating ET, and both drug's clinical, regulatory, and commercial prospects for these respective indications.
- 67. For example, on February 14, 2024, Sage filed an annual report on Form 10-K with the SEC, reporting the Company's financial and operating results for the quarter and year ended December 31, 2023 (the "2023 10-K"). The 2023 10-K contained substantively the same

statements as referenced in ¶ 59, *supra*, regarding SAGE-718's purported efficacy in treating MCI due to PD, as observed in the PARADIGM Study.

- 68. The 2023 10-K also contained the same statements as referenced in ¶ 45, *supra*, regarding SAGE-324's purported efficacy in treating ET, as observed in the KINETIC Study.
- 69. Appended as exhibits to the 2023 10-K were substantively the same SOX certifications as referenced in ¶ 46, *supra*, signed by the Individual Defendants.
- 70. The statements referenced in ¶¶ 67-69 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) SAGE-718 was less effective in treating MCI due to PD than Defendants had led investors to believe; (ii) accordingly, SAGE-718's clinical, regulatory, and commercial prospects as a treatment for MCI due to PD were overstated; (iii) SAGE-324 was less effective in treating ET than Defendants had led investors to believe; (iv) accordingly, SAGE-324's clinical, regulatory, and commercial prospects as a treatment for ET were overstated; and (v) as a result of all the foregoing, the Company's public statements were materially false and misleading at all relevant times.
- 71. In addition, Defendants violated Item 303, which required Sage to "[d]escribe any known trends or uncertainties that have had or that are reasonably likely to have a material favorable or unfavorable impact on net sales or revenues or income from continuing operations." Defendants' failure to disclose that SAGE-718 and SAGE-324 were not as effective as Defendants had led investors to believe violated Item 303 because this issue represented a known trend or uncertainty that was likely to have a material unfavorable impact on the Company's business and financial results.

## **The Truth Fully Emerges**

- 72. On April 17, 2024, during pre-market hours, Sage issued a press release disclosing that a Phase 2 study of SAGE-718 as a treatment for MCI due to PD, referred to as the "PRECEDENT Study," failed to meet its primary endpoint and, accordingly, the Company would discontinue SAGE-718's development as a treatment for PD, stating, in relevant part:
  - The PRECEDENT Study did not meet its primary endpoint of demonstrating statistically significant difference from baseline in participants treated with once-daily dalzanemdor [SAGE-718] versus placebo on the Wechsler Adult Intelligence Scale Fourth Edition-IV (WAIS-IV) Coding Test score at Day 42.

\* \* \*

• Analyses did not suggest any meaningful differences versus placebo in the other exploratory endpoints such as SCOPA-Cog.

Based on the data, the Company does not plan any further development of dalzanemdor (SAGE-718) in PD.

- 73. On this news, Sage's stock price fell \$3.06 per share, or 19.58%, to close at \$12.57 per share on April 17, 2024.
- 74. Then, on July 24, 2024, during pre-market hours, Sage issued a press release announcing that it will no longer advance SAGE-324 as a treatment for ET following topline results from a Phase 2 study called the "KINETIC 2 Study," stating, in relevant part:

The KINETIC 2 Study did not demonstrate a statistically significant dose-response relationship in change from baseline to Day 91 based on the primary endpoint, The Essential Tremor Rating Assessment Scale (TETRAS) Performance Subscale (PS) Item 4 (upper limb) total score, in participants with ET. In addition, there were no statistically significant differences demonstrated for any dose of SAGE-324 versus placebo in the change from baseline to Day 91 on the TETRAS PS Item 4 Total Score or the TETRAS Activities of Daily Living (ADL) Composite Score. Given these results, Sage and Biogen will close the ongoing open label safety study of SAGE-324 in ET and do not plan to conduct further clinical development of SAGE-324 in ET. The companies are evaluating next steps, if any, for other potential indications.

- 75. On this news, Sage's stock price fell \$2.70 per share, or 20.64%, to close at \$10.38 per share on July 24, 2024.
- 76. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

# PLAINTIFF'S CLASS ACTION ALLEGATIONS

- 77. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired Sage securities during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosures. Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.
- 78. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Sage securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Sage or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

- 79. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.
- 80. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.
- 81. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:
  - whether the federal securities laws were violated by Defendants' acts as alleged herein;
  - whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Sage;
  - whether the Individual Defendants caused Sage to issue false and misleading financial statements during the Class Period;
  - whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;
  - whether the prices of Sage securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and
  - whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.
- 82. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

- 83. Plaintiff will rely, in part, upon the presumption of reliance established by the fraudon-the-market doctrine in that:
  - Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
  - the omissions and misrepresentations were material;
  - Sage securities are traded in an efficient market;
  - the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;
  - the Company traded on the NASDAQ and was covered by multiple analysts;
  - the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and
  - Plaintiff and members of the Class purchased, acquired and/or sold Sage securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.
- 84. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.
- 85. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

#### COUNT I

# (Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants)

86. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

- 87. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.
- During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Sage securities; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Sage securities and options at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.
- 89. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Sage securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Sage's finances and business prospects.
- 90. By virtue of their positions at Sage, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended

thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each Defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

- 91. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As the senior managers and/or directors of Sage, the Individual Defendants had knowledge of the details of Sage's internal affairs.
- 92. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of Sage. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Sage's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of Sage securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Sage's business and financial condition which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Sage securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by Defendants, and were damaged thereby.

- 93. During the Class Period, Sage securities were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Sage securities at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of Sage securities was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Sage securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.
- 94. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.
- 95. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's securities during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

#### **COUNT II**

#### (Violations of Section 20(a) of the Exchange Act Against the Individual Defendants)

96. Plaintiff repeats and re-alleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

- 97. During the Class Period, the Individual Defendants participated in the operation and management of Sage, and conducted and participated, directly and indirectly, in the conduct of Sage's business affairs. Because of their senior positions, they knew the adverse non-public information about Sage's misstatement of income and expenses and false financial statements.
- 98. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Sage's financial condition and results of operations, and to correct promptly any public statements issued by Sage which had become materially false or misleading.
- 99. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Sage disseminated in the marketplace during the Class Period concerning Sage's results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Sage to engage in the wrongful acts complained of herein. The Individual Defendants, therefore, were "controlling persons" of Sage within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Sage securities.
- By reason of their senior management positions and/or being directors of Sage, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, Sage to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Sage and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

101. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Sage.

# PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

- A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;
- B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;
- C. Awarding Plaintiff and the other members of the Class prejudgment and postjudgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and
  - D. Awarding such other and further relief as this Court may deem just and proper.

# **DEMAND FOR TRIAL BY JURY**

Plaintiff hereby demands a trial by jury.

Dated