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8
9 Counsel for Plaintiff

10 UNITED STATES DISTRICT COURT
11 NORTHERN DISTRICT OF CALIFORNIA

12 _____, Individually and on behalf
13 of all others similarly situated,

14 Plaintiff,

15 v.

16 SAGE THERAPEUTICS, INC.,
17 JEFFREY M. JONAS, AND KIMI
18 IGUCHI,

19 Defendants.

Case No:

**CLASS ACTION COMPLAINT FOR
VIOLATIONS OF THE FEDERAL
SECURITIES LAWS**

JURY TRIAL DEMANDED

20
21 Plaintiff _____ (“Plaintiff”), individually and on behalf of all other persons
22 similarly situated, by Plaintiff’s undersigned attorneys, for Plaintiff’s Complaint against
23 Defendants (defined below), alleges the following based upon personal knowledge as to
24 Plaintiff and Plaintiff’s own acts, and upon information and belief as to all other matters
25 based on the investigation conducted by and through Plaintiff’s attorneys, which
26 included, among other things, a review of U.S. Securities and Exchange Commission
27 (“SEC”) filings by Sage Therapeutics, Inc. (“Sage” or the “Company”), as well as media
28 and analyst reports about the Company. Plaintiff believes that substantial evidentiary

1 support will exist for the allegations set forth herein after a reasonable opportunity for
2 discovery.

3 **NATURE OF THE ACTION**

4 1. This is a federal securities class action on behalf of a class consisting of all
5 persons other than Defendants who purchased the securities of Sage between July 18,
6 2014 and March 22, 2016, inclusive, (the “Class Period”) seeking to recover
7 compensable damages caused by Defendants’ violations of federal securities laws and
8 pursue remedies under the Securities Exchange Act of 1934 (the “Exchange Act”).

9 **JURISDICTION AND VENUE**

10 2. The claims asserted herein arise under and pursuant to Sections 10(b) and
11 20(a) of the Exchange Act, (15 U.S.C. §78j (b) and 78t (a)), and Rule 10b-5 promulgated
12 thereunder (17 C.F.R. §240.10b-5).

13 3. This Court has jurisdiction over the subject matter of this action pursuant to
14 §27 of the Exchange Act (15 U.S.C. §78aa) and 28 U.S.C. § 1331.

15 4. Venue is proper in this District pursuant to §27 of the Exchange Act and 28
16 U.S.C. §1391(b) as Defendants conducts business in this district and a significant portion
17 of the Defendants’ actions and the subsequent damages took place within this District.

18 5. In connection with the acts, conduct and other wrongs alleged in this
19 Complaint, Defendants, directly or indirectly, used the means and instrumentalities of
20 interstate commerce, including but not limited to, the United States mails, interstate
21 telephone communications and the facilities of the national securities exchange.

22 **PARTIES**

23 6. Plaintiff, as set forth in the accompanying certification, incorporated by
24 reference herein, purchased Sage securities at artificially inflated prices during the Class
25 Period and has been damaged thereby.

26 7. Defendant Sage is a company incorporated under the laws of Delaware and
27 headquartered in Cambridge, Massachusetts. Defendant Sage is a clinical stage
28 biopharmaceutical company focused on developing and commercializing novel

1 medicines to treat life-threatening and rare central nervous system disorders. Its
2 securities trade on NASDAQ under the ticker symbol "SAGE." In October 2013, Sage
3 entered into a license agreement with the Regents of the University of California. The
4 active pharmaceutical ingredient, treatment Investigational New Drug Application and
5 support for emergency-use patients for the development of SAGE-547 have been
6 contributed under the agreement by the Regents of the University of California and the
7 University of California Davis.

8 8. Defendant Jeffrey M. Jonas ("Jonas") has served as the Company's Chief
9 Executive Officer and Director throughout the Class Period.

10 9. Defendant Kimi Iguchi ("Iguchi") has served as the Company's Chief
11 Financial Officer throughout the Class Period.

12 10. The defendants referenced above in ¶¶ 8 – 9 are sometimes referred to
13 herein as the "Individual Defendants."

14 11. Defendant Sage and the Individual Defendants are referred to herein,
15 collectively, as the "Defendants."

16 12. Each of the Individual Defendants:

- 17 (a) directly participated in the management of the Company;
- 18 (b) was directly involved in the day-to-day operations of the Company at
19 the highest levels;
- 20 (c) was privy to confidential proprietary information concerning the
21 Company and its business and operations;
- 22 (d) was involved in drafting, producing, reviewing and/or disseminating
23 the false and misleading statements and information alleged herein;
- 24 (e) was aware of or recklessly disregarded the fact that the false and
25 misleading statements were being issued concerning the Company; and
- 26 (f) approved or ratified these statements in violation of the federal
27 securities laws.

1 13. As officers, directors, and controlling persons of a publicly-held company
2 whose securities are and were registered with the SEC pursuant to the Exchange Act, and
3 was traded on NASDAQ and governed by the provisions of the federal securities laws,
4 the Individual Defendants each had a duty to disseminate accurate and truthful
5 information promptly with respect to the Company's business prospects and operations,
6 and to correct any previously-issued statements that had become materially misleading
7 or untrue to allow the market price of the Company's publicly-traded stock to reflect
8 truthful and accurate information.

9 14. Sage is liable for the acts of the Individual Defendants and its employees
10 under the doctrine of respondeat superior and common law principles of agency as all of
11 the wrongful acts complained of herein were carried out within the scope of their
12 employment with authorization.

13 15. The scienter of the Individual Defendants and other employees and agents
14 of the Company is similarly imputed to Sage under respondeat superior and agency
15 principles.

16 **SUBSTANTIVE ALLEGATIONS**

17 **Background**

18 16. Sage's primary drug candidate is SAGE-547 which is supposed to treat
19 super-refractory status epilepticus ("SRSE"). SRSE is a rare and life-threatening
20 condition where a patient is in a state of continuous seizure called status epilepticus
21 ("SE"). According to the Neurocritical Care Society, SE is one continuous unremitting
22 seizure lasting longer than five minutes, or recurrent seizures without regaining
23 consciousness between seizures for greater than five minutes. SRSE is when SE is lasts
24 for more than 24 hours.

25 17. Sage has been touting SAGE-547 as a novel approach to treat SRSE for it is
26 an intravenous formulation of allopregnanolone, a naturally occurring neurosteroid that
27 acts as a synaptic and extrasynaptic modulator of the GABA receptor. GABA is the
28

1 major inhibitory neurotransmitter in the CNS, and mediates downstream neurologic and
2 bodily function via activation of GABA_A receptors.

3 **Materially False And Misleading Statements**

4
5 18. On June 17, 2014, the Company filed a Registration Statement on Form S-
6 1 (the “Registration Statement”). The Registration Statement was signed by both
7 Defendants Jonas and Iguchi. The Registration Statement touted SAGE-547 as a novel
8 breakthrough, stating in relevant part:

9 *Allosteric modulation of extrasynaptic GABA_A receptors to treat SE*

10 *Our current near-term product candidates are allosteric modulators*
11 *of both synaptic and extrasynaptic, or existing outside of the synapse,*
12 *GABA_A receptors, a characteristic important in distinguishing our*
13 *approach from current therapies.* While altering the level of synaptic
14 GABA_A receptor activity can be beneficial in stopping seizures, this
15 approach has limitations for the treatment of SE. As SE progresses in many
16 patients, select synaptic GABA_A receptors are down-regulated, or removed
17 from the neuronal synaptic surface. As a result, drugs that target down-
18 regulated receptors, such as BDZs, often are not effective in stopping SE. *In*
19 *contrast, our product candidates work at both the synaptic and*
20 *extrasynaptic GABA_A receptors.* Non-clinical studies suggest that these
21 extrasynaptic GABA_A receptors remain fully active during SE, offering the
22 potential for drugs that impact GABA via the extrasynaptic GABA_A receptor
23 to alter GABA activity and abate seizure. We believe that by creating
24 compounds that target both these receptors, we may be successful in treating
25 seizures that do not respond to BDZ therapy.

22 * * *

23 **Our Strategy**

24 *Our goal is to become a leading biopharmaceutical company focused on*
25 *development and commercialization of novel proprietary therapies* for the
26 treatment of life-threatening, rare CNS disorders. Key elements of our
27 strategy are to:

27 *• Rapidly advance SAGE-547 as a treatment for SRSE.*

28 * * *

1 *Our current near-term product candidates are allosteric modulators of*
2 *both synaptic and extrasynaptic, or existing outside of the synapse,*
3 *GABA_A receptors, a characteristic important in distinguishing our*
4 *approach from current therapies.* While altering the level of synaptic
5 GABA_A receptor activity can be beneficial in stopping seizures, this
6 approach has limitations for the treatment of SE. As SE progresses in many
7 patients, select synaptic GABA_A receptors are down-regulated, or removed
8 from the neuronal synaptic surface. *As a result, drugs that target down-*
9 *regulated receptors, such as benzodiazepines, or BDZs, often are not*
10 *effective in stopping SE. In contrast, our product candidates work at both*
11 *the synaptic and extrasynaptic GABA_A receptors. Non-clinical studies*
12 *suggest that these extrasynaptic GABA_A receptors remain fully active*
13 *during SE, offering the potential for drugs that impact GABA via the*
14 *extrasynaptic GABA_A receptor to alter GABA activity and abate seizure.*
15 We believe that by creating compounds that target both these receptors, we
16 may be successful in treating seizures that do not respond to BDZ therapy.

17 (Emphasis added).

18 19. The Registration Statement discussed the addressable market for SAGE-
19 547, stating in relevant part:

20 *Status Epilepticus*

21 SE is a medical emergency and is treated with aggressive pharmacological
22 approaches. SE is diagnosed when a patient has a seizure lasting longer than
23 five minutes, and is associated with substantial morbidity and mortality. *We*
24 *estimate that in the United States each year there are up to 150,000 cases*
25 *of SE, of which 30,000 SE patients die. We estimate that there are 35,000*
26 *patients with SE in the United States that are hospitalized in the intensive*
27 *care unit, or ICU, each year.*

28 * * *

We estimate that the annual incidence of SE, RSE and SRSE in the
United States is up to 150,000, 35,000 and 25,000 patients, respectively.

(Emphasis added).

1 20. On July 17, 2014, the Company filed the third amendment to the
2 Registration Statement on Form S-1/A with the SEC, which was signed by Defendants
3 Jonas and Iguchi.

4 21. On July 18, 2014 the SEC declared the Registration Statement effective.

5 22. On July 18, 2014, the Company filed the Prospectus with the SEC. The
6 Prospectus touted SAGE-547 as a novel breakthrough, stating in relevant part:

7 *Allosteric modulation of extrasynaptic GABA_A receptors to treat SE*

8 *Our current near-term product candidates are allosteric modulators of*
9 *both synaptic and extrasynaptic, or existing outside of the synapse,*
10 *GABA_A receptors, a characteristic important in distinguishing our*
11 *approach from current therapies.* While altering the level of synaptic
12 GABA_A receptor activity can be beneficial in stopping seizures, this
13 approach has limitations for the treatment of SE. As SE progresses in many
14 patients, select synaptic GABA_A receptors are down-regulated, or removed
15 from the neuronal synaptic surface. As a result, drugs that target down-
16 regulated receptors, such as BDZs, often are not effective in stopping SE. In
17 contrast, our product candidates work at both the synaptic and extrasynaptic
18 GABA_A receptors. Non-clinical studies suggest that these extrasynaptic
19 GABA_A receptors remain fully active during SE, offering the potential for
20 drugs that impact GABA via the extrasynaptic GABA_A receptor to alter
21 GABA activity and abate seizure. *We believe that by creating compounds*
22 *that target both these receptors, we may be successful in treating seizures*
23 *that do not respond to BDZ therapy.*

24 * * *

25 **Our Strategy**

26 *Our goal is to become a leading biopharmaceutical company focused on*
27 *development and commercialization of novel proprietary therapies* for the
28 treatment of life-threatening, rare CNS disorders. Key elements of our
strategy are to:

• *Rapidly advance SAGE-547 as a treatment for SRSE.*

* * *

1 **SAGE-547**

2 SAGE-547, a proprietary formulation of allopregnanolone, is a known
3 metabolite of progesterone formed in the CNS in humans through the actions
4 of two enzymes. SAGE-547 is being developed as an IV adjunctive therapy
5 in conjunction with underlying anesthesia as a treatment for SRSE. SAGE-
6 547 is currently in Phase 1/2 clinical development. In April 2014, the FDA
7 granted us orphan drug designation for SAGE-547 as a treatment for SE.

8 We believe SAGE-547 has an optimal profile for the treatment of SRSE.
9 SAGE-547 has a wide therapeutic window that allows for allosteric
10 modulation of the GABA_A receptor both synaptically and extrasynaptically
11 without inducing deep anesthesia. The pharmacological properties of SAGE-
12 547, including a short half-life of one hour, allows for continuous IV
13 administration. The ability to titrate SAGE-547 creates the opportunity to
14 tailor therapy to a specific SRSE patient's needs as well as to efficiently
15 administer and withdraw the compound.

16 * * *

17 *Currently, there are no therapies that have been specifically approved for*
18 *treatment of RSE or SRSE.* However, many products approved for other
19 indications, for example, general anesthetics and anti-seizure drugs, are used
20 off-label for various stages of SE therapy. Additionally, though not
21 indicated, acupuncture, hypothermia, and electroconvulsive therapy are
22 sometimes used prior to withdrawal of care for patients with SRSE.

23 (Emphasis added).

24 23. The Prospectus discussed the addressable market for SAGE-547, stating in
25 relevant part:

26 ***Status Epilepticus***

27 SE is a medical emergency and is treated with aggressive pharmacological
28 approaches. SE is diagnosed when a patient has a seizure lasting longer than
five minutes, and is associated with substantial morbidity and mortality. *We
estimate that in the United States each year there are up to 150,000 cases
of SE, of which 30,000 SE patients die. We estimate that there are 35,000
patients with SE in the United States that are hospitalized in the intensive
care unit, or ICU, each year.* This results in an overall inpatient cost of \$3.8
billion to \$7.0 billion per year in the United States. An SE patient is first

1 treated with benzodiazepines, or BDZs, and if no response then treated with
2 other, second-line, anti-seizure drugs. If the seizure persists after second-line
3 therapy the patient is diagnosed as having refractory SE, or RSE, admitted to
4 the ICU and placed into a medically induced coma. Currently, there are no
5 therapies that have been specifically approved for RSE; however, physicians
6 typically use anesthetic agents to induce the coma and stop the seizure
7 immediately. After a period of 24 hours, an attempt is made to wean the
8 patient from the anesthetic agents to evaluate whether or not the seizure
9 condition has resolved. Unfortunately, not all patients respond to weaning
10 attempts, in which case the patient must be maintained in the medically
11 induced coma. At this point, the patient is diagnosed as having SRSE.

12 * * *

13 SE is diagnosed when a patient has a seizure lasting longer than five
14 minutes, and is associated with substantial morbidity and mortality. *We*
15 *estimate that in the United States each year there are up to 150,000 cases*
16 *of SE, of which 30,000 SE patients die. We estimate that there are 35,000*
17 *patients with SE in the United States that are hospitalized in the intensive*
18 *care unit, or ICU, each year.* An SE patient is first treated with
19 benzodiazepines, or BDZs, and if no response then treated with other,
20 second-line, anti-seizure drugs. If the seizure persists after second-line
21 therapy the patient is diagnosed as having refractory SE, or RSE, admitted to
22 the ICU and placed into a medically induced coma. Currently, there are no
23 therapies that have been specifically approved for refractory SE, or RSE;
24 however, physicians typically use anesthetic agents to induce the coma and
25 stop the seizure immediately. After a period of 24 hours, an attempt is made
26 to wean the patient from the anesthetic agents to evaluate whether or not the
27 seizure condition has resolved. Unfortunately, not all patients respond to
28 weaning attempts, in which case the patient must be maintained in the
medically induced coma. At this point, the patient is diagnosed as having
SRSE.

(Emphasis added).

24. On March 6, 2015, the Company filed its annual report on Form 10-K for
the year ending December 31, 2014 (the “2014 10-K”) with the SEC, which contained
the Company’s financial results for the year ending December 31, 2014. The 2014 10-K

1 was signed by Defendants Jonas and Iguchi. The 2014 10-K contained signed
2 certifications pursuant to the Sarbanes-Oxley Act of 2002 (“SOX”) by Defendants Jonas
3 and Iguchi attesting to the accuracy of the 2014 10-K.

4 25. The 2014 10-K touted SAGE-547 as a novel breakthrough, stating in
5 relevant part:

6
7 The lead product candidate in our SE program, SAGE-547, is an
8 intravenous, or IV, agent in Phase 1/2 clinical development as an adjunctive
9 therapy, a therapy combined with current therapeutic approaches, for the
10 treatment of super-refractory SE, or SRSE. *The current standard of care for*
11 *SRSE is empiric, and there are no therapies at present that have been*
12 *specifically approved for this indication. We thus believe there is a*
13 *significant medical need for SAGE-547.*

14 * * *

15 **Our Strategy**

16 *Our goal is to become a leading biopharmaceutical company focused on*
17 *development and commercialization of novel proprietary therapies for the*
18 *treatment of life-threatening, rare CNS disorders.*

19 Key elements of our strategy are to:

- 20 • **Rapidly advance SAGE-547 as a treatment for SRSE.** We are
21 developing SAGE-547 as an adjunctive therapy for the treatment of
22 SRSE. Following the completion of our ongoing Phase 1/2 clinical
23 trial of SAGE-547, we intend to complete the additional clinical trials
24 required for approval of SAGE-547 as rapidly as possible. We believe
25 we may be able to expeditiously complete these clinical trials due to
26 the fact that the endpoints of such clinical trials will be measured
27 shortly after initiation of therapy and the relatively small number of
28 patients required to be enrolled in such clinical trials. We will also
provide mechanisms for access to SAGE-547 for emergency use to
patients who experience SRSE but do not meet the inclusion criteria of
our ongoing trial, so that they can receive the potential benefit from
this product candidate.

* * *

1 ***Our proprietary chemistry platform***

2 ***Our proprietary chemistry platform is centered on novel chemical***
3 ***scaffolds of endogenous or chemically modified synthetic neuroactive***
4 ***steroid compounds that are allosteric modulators of GABA_A or NMDA***
5 ***receptors.*** We have leveraged this platform to assemble a chemistry
6 portfolio of greater than 1,400 compounds. We believe our proprietary
7 chemistry platform allows us to:

- 8 • optimize the properties of neuroactive steroid compounds to develop
9 proprietary, new chemical entities, with the potential to be used as
10 oral, IV or intramuscular therapies;
- 11 • control important properties such as half-life, brain penetration and
12 the types of receptors our drugs act upon, thereby modulating either
13 inhibition or excitation either acutely or chronically; and
- 14 • create drugs that exert control over the intensity of receptor activation
15 or deactivation, with the potential to hit targets in the brain with more
16 precision, increased safety and tolerability and fewer off-target side
17 effects than current CNS therapies.

18 * * *

19 **SAGE-547**

20 SAGE-547, a proprietary formulation of allopregnanolone, is a known
21 metabolite of progesterone formed in the CNS in humans through the actions
22 of two enzymes. SAGE-547 is being developed as an IV adjunctive therapy
23 in conjunction with underlying anesthesia as a treatment for SRSE. SAGE-
24 547 is currently in Phase 1/2 clinical trial for SE and in exploratory Phase 2a
25 clinical trials for essential tremor and severe PPD. In April 2014, the FDA
26 granted us orphan drug designation for SAGE-547 as a treatment for SE. In
27 July 2014, the FDA granted us fast track designation for the SAGE-547
28 development program.

We believe SAGE-547 has an optimal profile for the treatment of SRSE. SAGE-547 has a wide therapeutic window that allows for allosteric modulation of the GABA_A receptor both synaptically and extrasynaptically without inducing deep anesthesia. The pharmacological properties of SAGE-547, including a short half-life of one hour, allows for continuous IV administration. The ability to titrate SAGE-547 creates the opportunity to tailor therapy to a specific SRSE patient's needs as well as to efficiently administer and withdraw the compound.

1 (Emphasis added).

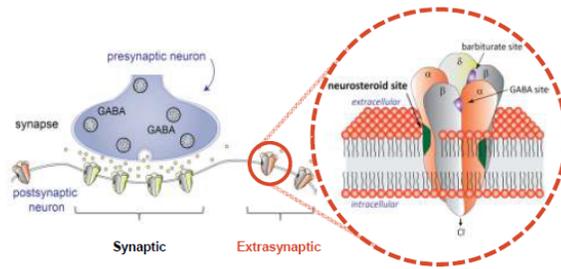
2 26. The 2014 10-K discussed the addressable market for SAGE-547, stating in
3 relevant part:

4 SE is diagnosed when a patient has a seizure lasting longer than five
5 minutes, and is associated with substantial morbidity and mortality. *We*
6 *estimate that in the United States each year there are up to 150,000 cases*
7 *of SE, of which 30,000 SE patients die. We estimate that there are 35,000*
8 *patients with SE in the United States that are hospitalized in the intensive*
9 *care unit, or ICU, each year.* An SE patient is first treated with
10 benzodiazepines, or BDZs, and if no response, then treated with other,
11 second-line, anti-seizure drugs. If the seizure persists after second-line
12 therapy, the patient is diagnosed as having refractory SE, or RSE, admitted
13 to the ICU and placed into a medically induced coma. Currently, there are no
14 therapies that have been specifically approved for refractory SE, or RSE;
15 however, physicians typically use anesthetic agents to induce the coma and
16 stop the seizure immediately. After a period of 24 hours, an attempt is made
17 to wean the patient from, the anesthetic agents to evaluate whether or not the
18 seizure condition has resolved. Unfortunately, not all patients respond to
19 weaning attempts, in which case the patient must be maintained in the
20 medically induced coma. At this point, the patient is diagnosed as having
21 SRSE.

17 (Emphasis added).

18 27. On November 5, 2015, the Company published a presentation with its third
19 quarter of 2015 financial results. Included in the presentation was a PowerPoint slide
20 about SAGE-547's novelty:

SAGE-547: Novel GABA_A Receptor Modulator



- Synaptic and extrasynaptic allosteric modulator
- Foundational molecule validating GABA_A modulator mechanism of action
- Granted orphan drug for status epilepticus, including SRSE, and Fast Track designation in U.S.
- FDA agreement on SPA for Phase 3 trial in SRSE



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28. On November 10, 2015, the Company gave a presentation at the 24th Annual Credit Suisse Healthcare Conference. Included in the Company's presentation were slides stating the number of people with SRSE:

SRSE: Rare and Life-Threatening Seizure Disorder with No Approved Treatment

Super-Refractory Status Epilepticus (SRSE)

- Rare, life-threatening condition with high morbidity and mortality rates
- Severe form of status epilepticus that continues for >24 hours despite multiple therapeutic interventions

25,000

Estimated annual SRSE cases in U.S.

>60%

Patients die or remain severely disabled

0

Approved treatments



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8

Sources: DeLorenzo et al. *J Clin Neuro* 1995; 12(4): 316-325.
Claassen et al. *Epilepsia* 2002; 43(2): 146-153.
Novy et al. *Epilepsia* 2010; 51(2): 251-256.

29. On February 29, 2016, the Company filed its annual report on Form 10-K for the year ending December 31, 2015 (the "2015 10-K") with the SEC, which

1 contained the Company's financial results for the year ending December 31, 2015. The
2 2015 10-K was signed by Jonas and Iguchi. The 2015 10-K contained signed SOX
3 certifications by Defendant Jonas and Iguchi attesting to the accuracy of the 2015 10-K.

4 30. The 2015 10-K touted SAGE-547 as a novel breakthrough, stating in
5 relevant part:

6
7 *We are a clinical-stage biopharmaceutical company committed to*
8 *developing and commercializing novel medicines to treat life-threatening*
9 *central nervous system, or CNS, disorders, where there are inadequate or*
10 *no approved existing therapies.* We are targeting CNS indications where
11 patient populations are easily identified, clinical endpoints are well-defined,
and development pathways are feasible.

12 Our lead product candidate is SAGE-547, a proprietary intravenous
13 formulation of allopregnanolone, a naturally occurring neurosteroid that acts
14 as a synaptic and extrasynaptic modulator of the GABA_A receptor. GABA is
15 the major inhibitory neurotransmitter in the CNS, and mediates downstream
16 neurologic and bodily function via activation of GABA_A receptors. *We*
17 *believe that allosteric modulation of the GABA_A receptor has the potential*
18 *to be well-suited for the treatment of seizures and certain other CNS*
19 *disorders because it allows for the fine-tuning of neuronal signals rather*
20 *than complete activation or complete inhibition.* SAGE-547 is in Phase 3
21 clinical development as an adjunctive therapy for the treatment of super-
22 refractory status epilepticus, or SRSE. SRSE is a rare and life-threatening
23 condition where a patient is in a state of continuous seizure called status
24 epilepticus, or SE, and all of the standard treatment regimens normally
25 sufficient to stop the seizure activity have failed. We expect to report top-
line results from the global, randomized, double-blind, placebo-controlled
Phase 3 trial of SAGE-547 in SRSE in the second half of 2016. If successful,
we believe the results of the Phase 3 clinical trial, together with other
clinical data obtained from the SAGE-547 clinical program, and results of
ongoing non-clinical studies, could form the basis of a New Drug
Application, or NDA submission, in the U.S. for SAGE-547.

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Our Strategy

Our goal is to become a leading biopharmaceutical company focused on development and commercialization of novel proprietary therapies for the treatment of life-threatening CNS disorders. Key elements of our strategy are to:

- Rapidly advance SAGE-547 as a treatment for SRSE.
- Utilize SAGE-547 in exploratory trials in certain diseases of interest to help guide the development of second-generation GABA_A receptor modulators for those diseases.

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Our proprietary chemistry platform

Our proprietary chemistry platform is centered on novel chemical scaffolds of endogenous or chemically modified synthetic neuroactive steroid compounds that are allosteric modulators of GABA_A or NMDA receptors. We have leveraged this platform to assemble a chemistry portfolio of greater than 2,000 compounds. We believe our proprietary chemistry platform allows us to:

- optimize the properties of neuroactive steroid compounds to develop proprietary, new chemical entities, with the potential to be used as oral, intravenous, or IV, or intramuscular therapies;
- control important properties such as half-life, brain penetration and the types of receptors our drugs act upon, thereby modulating either inhibition or excitation either acutely or chronically; and
- create drugs that are designed to exert control over the intensity of receptor activation or deactivation, with the potential to hit targets in the brain with more precision, with the goal of increased tolerability and fewer off-target side effects than current CNS therapies.

* * *

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SAGE-547

Overview

SAGE-547 is a proprietary IV formulation of allopregnanolone, a naturally occurring neurosteroid that acts as a synaptic and extrasynaptic modulator of the GABA_A receptor. SAGE-547 is being developed as an

1 adjunctive therapy in conjunction with underlying anesthesia, as a treatment
2 for SRSE. In the third quarter of 2015, we initiated the STATUS Trial
3 (SAGE-547 Treatment as Adjunctive Therapy Utilized in Status
4 Epilepticus), a global, randomized, double-blind, placebo-controlled Phase 3
5 clinical trial to evaluate SAGE-547 as a treatment for patients with SRSE.
6 We expect to announce top-line results for the Phase 3 clinical trial in the
7 second half of 2016. If successful, we believe the results from this Phase 3
8 clinical trial, together with other clinical data obtained from the SAGE-547
9 development program and results of completed and ongoing non-clinical
10 studies, could form the basis of an NDA submission for SAGE-547 in the
11 U.S. The FDA granted us orphan drug designation for SAGE-547 in the
12 treatment of SE including SRSE, and Fast Track designation for our
13 investigational new drug application for SAGE-547 as a treatment for SRSE

14 (Emphasis added).

15 31. The 2015 10-K discussed the addressable market for SAGE-547, stating in
16 relevant part:

17 At this point, patients are considered to be in a state of SRSE. *The current
18 standard of care for SRSE is empiric, and there are no therapies at present
19 that have been specifically approved for this indication. We estimate that
20 there are approximately 150,000 cases of SE each year in the United
21 States, of which approximately 25,000 progress to SRSE.*

22 (Emphasis added).

23 32. The statements referenced in ¶¶18 – 31 above were materially false and/or
24 misleading because they misrepresented and failed to disclose the following adverse
25 facts pertaining to the Company’s business, operational and financial results, which were
26 known to Defendants or recklessly disregarded by them. Specifically, Defendants made
27 false and/or misleading statements and/or failed to disclose that: (1) SAGE-547 is not a
28 novel breakthrough treatment for SRSE; (2) the addressable market for SAGE-547 is
smaller than Defendants suggested; and (3) as a result, Defendants’ statements about

1 Sage’s business, operations and prospects were materially false and misleading and/or
2 lacked a reasonable basis at all relevant times.

3 **The Truth Emerges**

4 33. On March 23, 2016, analyst firm Kerrisdale Capital issued a report (the
5 “Kerrisdale Report”) about Sage asserting, among other things, that: (1) SAGE-547 was
6 not a novel drug to treat SRSE as Defendants had been touting and (2) Defendants had
7 been multiplying the market for SAGE-547 by a factor of six. The Kerrisdale Report
8 stated in relevant part:

9
10 *Sage’s drug, a proprietary formulation of the neurosteroid*
11 *allopregnanolone that the company calls SAGE-547, is little more than a*
12 *Band-Aid, achieving, at best, a temporary reduction in brain activity – very*
13 *similar to many other treatments that doctors already use. But SAGE-547*
14 *leaves the underlying causes of SRSE untouched. We believe that, in Phase*
15 *3, SAGE-547 will fail to outperform placebo to a statistically significant*
16 *degree, throwing Sage’s future into question. Moreover, a thorough*
17 *analysis of the scientific literature suggests that Sage’s estimates of the*
18 *size of the SRSE market are inflated by a factor of 6; thus, even if SAGE-*
19 *547 does manage to produce passable data, its commercial prospects are*
20 *far murkier than the market appreciates. As a result, Sage is worth little*
21 *more than its cash balance, 70% below the current stock price.*

22
23 *While Sage touts SAGE-547 as a novel breakthrough, its high-level*
24 *mechanism of action – tipping the balance of brain activity from excitation*
25 *toward inhibition – is exactly the same as that of standard drugs like*
26 *benzodiazepines, anti-epileptics, and anesthetics that already form the*
27 *standard of care for status epilepticus. Sage argues that its compound is*
28 *special because it can affect a specific category of receptors (extrasynaptic*
GABA_A receptors) and thereby influence a different form of inhibition (tonic
rather than phasic). However, a large body of scientific research clearly
shows that many other drugs used in SRSE, including the anesthetics
midazolam and propofol, also bind to extrasynaptic GABA_A receptors.
SAGE-547 is not special.

* * *

1 *But, while it's true that most benzodiazepines, which constitute the first*
2 *line of treatment in SRSE, don't bind to most extrasynaptic*
3 *GABA_A receptors, many other standard drugs for treating*
4 *SRSE do, especially general anesthetics.* In Sage's Phase 1/2 trial, the most
5 common anesthetics used were midazolam, propofol, pentobarbital, and
6 ketamine; *every one of these drugs has been shown to bind to extrasynaptic*
7 *GABA_A receptors and strengthen tonic inhibition,[1]* just like SAGE-547
8 aims to do. It's just not that special.

9 * * *

10 Not only does Sage exaggerate the strength of the hypothesis that
11 extrasynaptic receptors are crucial in treating SRSE; it also fails to mention
12 that many drugs besides SAGE-547 also bind to extrasynaptic receptors. In
13 the words of one review:

14 During the past decade, the emergence of tonic inhibitory
15 conductance in extrasynaptic GABA_ARs has coincided with
16 evidence showing that these receptors are **highly sensitive to**
17 **the sedatives and hypnotics used in anesthesia.** (12)

18 * * *

19 *In light of all this evidence, it's clear that, far from having a "unique*
20 *mechanism," SAGE-547 and its active ingredient, allopregnanolone, are*
21 *more of the same.* In fact, the anesthetic midazolam even appears to increase
22 the synthesis of *endogenous* allopregnanolone, making the subsequent
23 introduction of *foreign* allopregnanolone even less likely to matter (20; 21).
24 By definition, patients with super-refractory status epilepticus have already
25 received general anesthetics. As a result, their extrasynaptic GABA_A
26 receptors have already been modulated. If strengthening the effects of these
27 receptors were enough to fix their seizures, they would already be fixed. *The*
28 *notion that SAGE-547 is so novel that it can do significantly more than*
ordinary anesthetics makes no sense.

* * *

In sum, we believe that SAGE-547's physiological effects, though real, are
temporary and add little to no value to existing treatments for SRSE.

(Emphasis added).

1 34. The Kerrisdale Report discussed Defendants’ overestimation of SAGE-
2 547’s addressable market, stating in relevant part:

3
4 **SAGE-547’s addressable market may be dramatically smaller than the**
5 **market realizes.** Sage management contends that there are 25,000 annual
6 cases of SRSE in the US, and the sell side has dutifully accepted this claim
7 at face value. *When we attempted to reconcile this figure with the scientific*
8 *literature, however, we came up with a much lower estimate – just 4,000*
9 *cases.* Sage’s lofty estimate draws primarily on a single epidemiological
10 study of a single small city from 1996 – a study clearly regarded as an
11 unrepresentative outlier by other researchers in the field. Thus, even if
12 SAGE-547 does manage to outperform placebo in Phase 3, its commercial
13 prospects look dim. Making matters worse, Marinus Pharmaceuticals – a
14 sort of sister company for Sage, whose scientific founder has been heavily
15 involved in Sage’s research and whose main drug is a synthetic version of
16 Sage’s – plans to enter the status-epilepticus market with its own extremely
17 similar treatment.

18 * * *

19 *Sage management asserts that about 25,000 patients per year in the US*
20 *develop SRSE. Our analysis of the scientific literature, however, points to*
21 *a far lower number – just 4,000. It is thus quite possible that, even if*
22 *SAGE-547 wins approval, its sales will disappoint investors on a massive*
23 *scale.*

24 (Emphasis added).

25 35. On this news, share of Sage fell \$4.30 per share or approximately 12.8%
26 from its previous closing price to close at \$29.10 per share on March 23, 2016, damaging
27 investors.

28 36. 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

37 37. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil
38 Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or

1 otherwise acquired Sage securities during the Class Period (the “Class”); and were
2 damaged upon the revelation of the alleged corrective disclosure. Excluded from the
3 Class are Defendants herein, the officers and directors of the Company, at all relevant
4 times, members of their immediate families and their legal representatives, heirs,
5 successors or assigns and any entity in which Defendants have or had a controlling
6 interest.

7 38. The members of the Class are so numerous that joinder of all members is
8 impracticable. Throughout the Class Period, Sage securities were actively traded on
9 NASDAQ. While the exact number of Class members is unknown to Plaintiff at this
10 time and can be ascertained only through appropriate discovery, Plaintiff believes that
11 there are hundreds or thousands of members in the proposed Class. Record owners and
12 other members of the Class may be identified from records maintained by Sage or its
13 transfer agent and may be notified of the pendency of this action by mail, using the form
14 of notice similar to that customarily used in securities class actions.

15 39. Plaintiff’s claims are typical of the claims of the members of the Class as all
16 members of the Class are similarly affected by Defendants’ wrongful conduct in
17 violation of federal law that is complained of herein.

18 40. Plaintiff will fairly and adequately protect the interests of the members of
19 the Class and has retained counsel competent and experienced in class and securities
20 litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

21 41. Common questions of law and fact exist as to all members of the Class and
22 predominate over any questions solely affecting individual members of the Class.
23 Among the questions of law and fact common to the Class are:

- 24 • whether the federal securities laws were violated by Defendants’ acts as
25 alleged herein;
- 26 • whether statements made by Defendants to the investing public during the
27 Class Period misrepresented material facts about the business, operations
28 and management of Sage;

- 1 • whether the Individual Defendants caused Sage to issue false and
- 2 misleading financial statements during the Class Period;
- 3 • whether Defendants acted knowingly or recklessly in issuing false and
- 4 misleading financial statements;
- 5 • whether the prices of Sage securities during the Class Period were
- 6 artificially inflated because of the Defendants' conduct complained of
- 7 herein; and
- 8 • whether the members of the Class have sustained damages and, if so, what
- 9 is the proper measure of damages.

10 42. A class action is superior to all other available methods for the fair and
11 efficient adjudication of this controversy since joinder of all members is impracticable.
12 Furthermore, as the damages suffered by individual Class members may be relatively
13 small, the expense and burden of individual litigation make it impossible for members of
14 the Class to individually redress the wrongs done to them. There will be no difficulty in
15 the management of this action as a class action.

16 43. Plaintiff will rely, in part, upon the presumption of reliance established by
17 the fraud-on-the-market doctrine in that:

- 18 • Defendants made public misrepresentations or failed to disclose material
- 19 facts during the Class Period;
- 20 • the omissions and misrepresentations were material;
- 21 • Sage securities are traded in an efficient market;
- 22 • the Company's shares were liquid and traded with moderate to heavy
- 23 volume during the Class Period;
- 24 • the Company traded on NASDAQ and was covered by multiple analysts;
- 25 • the misrepresentations and omissions alleged would tend to induce a
- 26 reasonable investor to misjudge the value of the Company's securities; and
- 27 • Plaintiff and members of the Class purchased, acquired and/or sold Sage
- 28 securities between the time the Defendants failed to disclose or

1 securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and
2 course of conduct, Defendants, and each of them, took the actions set forth herein.

3 49. Pursuant to the above plan, scheme, conspiracy and course of conduct, each
4 of the Defendants participated directly or indirectly in the preparation and/or issuance of
5 the annual reports, SEC filings, press releases and other statements and documents
6 described above, including statements made to securities analysts and the media that
7 were designed to influence the market for Sage securities. Such reports, filings, releases
8 and statements were materially false and misleading in that they failed to disclose
9 material adverse information and misrepresented the truth about Sage's disclosure
10 controls and procedures.

11 50. By virtue of their positions at Sage, Defendants had actual knowledge of the
12 materially false and misleading statements and material omissions alleged herein and
13 intended thereby to deceive Plaintiff and the other members of the Class, or, in the
14 alternative, Defendants acted with reckless disregard for the truth in that they failed or
15 refused to ascertain and disclose such facts as would reveal the materially false and
16 misleading nature of the statements made, although such facts were readily available to
17 Defendants. Said acts and omissions of Defendants were committed willfully or with
18 reckless disregard for the truth. In addition, each defendant knew or recklessly
19 disregarded that material facts were being misrepresented or omitted as described above.

20 51. Information showing that Defendants acted knowingly or with reckless
21 disregard for the truth is peculiarly within Defendants' knowledge and control. As the
22 senior managers and/or directors of Sage, the Individual Defendants had knowledge of
23 the details of Sage's internal affairs.

24 52. The Individual Defendants are liable both directly and indirectly for the
25 wrongs complained of herein. Because of their positions of control and authority, the
26 Individual Defendants were able to and did, directly or indirectly, control the content of
27 the statements of Sage. As officers and/or directors of a publicly-held company, the
28 Individual Defendants had a duty to disseminate timely, accurate, and truthful

1 information with respect to Sage’s businesses, operations, future financial condition and
2 future prospects. As a result of the dissemination of the aforementioned false and
3 misleading reports, releases and public statements, the market price of Sage securities
4 was artificially inflated throughout the Class Period. In ignorance of the adverse facts
5 concerning Sage’s business and financial condition which were concealed by
6 Defendants, Plaintiff and the other members of the Class purchased or otherwise
7 acquired Sage securities at artificially inflated prices and relied upon the price of the
8 securities, the integrity of the market for the securities and/or upon statements
9 disseminated by Defendants, and were damaged thereby.

10 53. During the Class Period, Sage securities were traded on an active and
11 efficient market. Plaintiff and the other members of the Class, relying on the materially
12 false and misleading statements described herein, which the Defendants made, issued or
13 caused to be disseminated, or relying upon the integrity of the market, purchased or
14 otherwise acquired shares of Sage securities at prices artificially inflated by Defendants’
15 wrongful conduct. Had Plaintiff and the other members of the Class known the truth,
16 they would not have purchased or otherwise acquired said securities, or would not have
17 purchased or otherwise acquired them at the inflated prices that were paid. At the time of
18 the purchases and/or acquisitions by Plaintiff and the Class, the true value of Sage
19 securities was substantially lower than the prices paid by Plaintiff and the other members
20 of the Class. The market price of Sage securities declined sharply upon public disclosure
21 of the facts alleged herein to the injury of Plaintiff and Class members.

22 54. By reason of the conduct alleged herein, Defendants knowingly or
23 recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and
24 Rule 10b-5 promulgated thereunder.

25 55. As a direct and proximate result of Defendants’ wrongful conduct, Plaintiff
26 and the other members of the Class suffered damages in connection with their respective
27 purchases, acquisitions and sales of the Company’s securities during the Class Period,
28

1 upon the disclosure that the Company had been disseminating misrepresented financial
2 statements to the investing public.

3 **COUNT II**

4 **Violations of Section 20(a) of The Exchange Act**
5 **Against The Individual Defendants**

6 56. Plaintiff repeats and realleges each and every allegation contained in the
7 foregoing paragraphs as if fully set forth herein.

8 57. During the Class Period, the Individual Defendants participated in the
9 operation and management of Sage, and conducted and participated, directly and
10 indirectly, in the conduct of Sage's business affairs. Because of their senior positions,
11 they knew the adverse non-public information about Sage's operations, current financial
12 position and future business prospects.

13 58. As officers and/or directors of a publicly owned company, the Individual
14 Defendants had a duty to disseminate accurate and truthful information with respect to
15 Sage's business practices, and to correct promptly any public statements issued by Sage
16 which had become materially false or misleading.

17 59. Because of their positions of control and authority as senior officers, the
18 Individual Defendants were able to, and did, control the contents of the various reports,
19 press releases and public filings which Sage disseminated in the marketplace during the
20 Class Period concerning the Company's disclosure controls and procedures. Throughout
21 the Class Period, the Individual Defendants exercised their power and authority to cause
22 Sage to engage in the wrongful acts complained of herein. The Individual Defendants
23 therefore, were "controlling persons" of Sage within the meaning of Section 20(a) of the
24 Exchange Act. In this capacity, they participated in the unlawful conduct alleged which
25 artificially inflated the market price of Sage securities.

26 60. Each of the Individual Defendants, therefore, acted as a controlling person
27 of Sage. By reason of their senior management positions and/or being directors of Sage
28 each of the Individual Defendants had the power to direct the actions of, and exercised

1 the same to cause, Sage to engage in the unlawful acts and conduct complained of
2 herein. Each of the Individual Defendants exercised control over the general operations
3 of Sage and possessed the power to control the specific activities which comprise the
4 primary violations about which Plaintiff and the other members of the Class complain.

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

7
8 **PRAYER FOR RELIEF**

9 WHEREFORE, Plaintiff demands judgment against Defendants as follows:

10 A. Determining that the instant action may be maintained as a class action
11 under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the
12 Class representative;

13 B. Requiring Defendants to pay damages sustained by Plaintiff and the Class
14 by reason of the acts and transactions alleged herein;

15 C. Awarding Plaintiff and the other members of the Class prejudgment and
16 post-judgment interest, as well as her reasonable attorneys' fees, expert fees and other
17 costs; and

18 D. Awarding such other and further relief as this Court may deem just and
19 proper.

20 **DEMAND FOR TRIAL BY JURY**

21 Plaintiff hereby demands a trial by jury.

22
23 Dated: March __, 2016

Respectfully submitted,

24 **THE ROSEN LAW FIRM, P.A.**

25
26 _____
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