Sage Therapeutics Inc Logo

Sage Therapeutics Announces First Quarter 2020 Financial Results and Highlights Pipeline and Business Progress

May 7, 2020

Expected initiation of three new short-term zuranolone clinical studies in 2020, with the potential for three distinct indications

April restructuring to advance corporate strategy and pipeline expected to result in approximate annualized cost savings of $170M, with significant portion related to ZULRESSO commercial and G&A support

Progress continues in neurology and neuropsychiatry franchises with planned initiation of Phase 2 clinical trials of SAGE-324 in 1H and SAGE-718 in 2H, 2020

Mike Cloonan elevated to chief operating officer

Conference call today at 4:30 p.m. ET

CAMBRIDGE, Mass.--(BUSINESS WIRE)--May 7, 2020-- Today, Sage Therapeutics, Inc. (NASDAQ:SAGE), a biopharmaceutical company committed to developing novel therapies with the potential to transform the lives of people with debilitating disorders of the brain, reported business highlights and financial results for the first quarter ended March 31, 2020. The Company also announced the promotion of Mike Cloonan to chief operating officer; he will continue to report into Jeff Jonas, Sage's chief executive officer. In the newly created role, Mr. Cloonan will strategically align the business functions to support the ongoing development and commercialization of Sage's brain health portfolio.

"I want to take a moment to acknowledge the challenges resulting from the global COVID-19 pandemic. I'm proud of the way our employees, partners, and the community have responded in this unprecedented time," said Jeff Jonas, M.D., chief executive officer at Sage Therapeutics. "The teams at Sage are handling virtual work well, and progress across our pipeline remains strong. Our mission is more important than ever as mental health issues are coming to the forefront and will continue to have significant impact even after the current phase of the COVID-19 pandemic is over. The strategic decisions we made in the first quarter, and the promotion of Mike to chief operating officer, have us on the right track, we believe, to continue developing medicines that matter for people with brain health disorders."

Portfolio Updates
Sage is advancing a portfolio of novel and differentiated product candidates designed to improve brain health by targeting the $GABA_A$ and NMDA receptor systems. Dysfunction in these systems is thought to be at the core of numerous neurological and neuropsychiatric disorders.

Depression Franchise
The Depression Franchise includes zuranolone (SAGE-217), Sage's next-generation positive allosteric modulator (PAM) of $GABA_A$ receptors, being evaluated in clinical development as a treatment for various affective disorders, and ZULRESSO™ (brexanolone) CIV injection, the first treatment approved by the U.S. Food and Drug Administration (FDA) specifically for postpartum depression (PPD). Zuranolone has received breakthrough therapy designation from the FDA for the treatment of major depressive disorder (MDD).

- **Zuranolone:** Sage is evaluating the potential of zuranolone as a rapid-acting, short-course treatment for PPD and MDD. Following discussions with the FDA, Sage plans to initiate three new short-term clinical studies in 2020, with the potential, if successful, for three distinct indications: PPD, acute rapid response therapy (RRT) in MDD when co-initiated with a newly administered standard antidepressant, and episodic treatment of MDD. These planned studies include:

- Oral therapy in women with PPD: Placebo-controlled trial evaluating a two-week course of zuranolone 50 mg in women with PPD, with additional short-term follow-up.
    - Topline data from this study is anticipated in 2021.
- RRT in patients with MDD when co-initiated with a newly administered standard antidepressant therapy: Placebo-controlled trial evaluating a two-week course of zuranolone 50 mg, when co-initiated with an open-label SSRI, in patients with MDD, with additional short-term follow-up.
    - Topline data from this study is anticipated in 2021.
- Episodic therapy in patients with MDD: Placebo-controlled trial evaluating a two-week course of zuranolone 50 mg in patients with MDD, with additional short-term follow-up.
    - Topline data from this study is anticipated in 2021.
    - Long-term safety data, including data from REDWOOD (MDD-302), are expected to be required to support a new drug application (NDA) filing for episodic treatment of depression.
- Ongoing study updates:
- SHORELINE Study (MDD-303): The Company is on track to report topline data in 2020 from patients with MDD who received zuranolone 30 mg in the SHORELINE Study.
    - The protocol has been amended to allow currently enrolled patients to receive retreatment with zuranolone 50 mg.
    - The Company expects to enroll a new cohort of patients with MDD who will receive zuranolone 50 mg.
- REDWOOD Study (MDD-302) and RAINFOREST Study (MDD-304): The Company has paused enrollment in the REDWOOD and RAINFOREST Studies, and is in the process of closing active sites, to focus resources and activities on enrollment in the three new planned Phase 3 clinical studies. The Company plans to reevaluate whether and when to reinitiate the REDWOOD and RAINFOREST studies at a later date.

- The Company is also currently evaluating the ongoing zuranolone clinical pharmacology and safety program and plans to finalize requirements to support a potential future NDA with the FDA.

- **ZULRESSO™ (brexanolone) CIV injection:**
    - Revenue for Q1 2020 was $2.3 million, a 17% increase over Q4 2019. The Company continued focusing its efforts on navigating the barriers to treatment with ZULRESSO. The number of patients infused in the first quarter increased by more than 20% compared to the previous quarter. The Company received approximately 320 start forms and 12 new treating sites of care were added in the first quarter, increasing the total number of sites that have treated patients with ZULRESSO to 41 since launch.
    - The recent rapid spread of COVID-19 in the U.S. has resulted in a significant reduction in patient demand as well as sites of care starting to pause treatment of new patients with ZULRESSO during March 2020, and in increasing numbers since then. As a result of the pandemic only approximately 15% of sites active in the first quarter remained active in April. Concerns about exposure to the virus have also caused a reduction in the number of women with PPD seeking treatment with ZULRESSO, as evidenced by the approximately 75% decline in the monthly start form volume in April compared to the average monthly volume for the first quarter of 2020.
    - Sage recently executed a corporate restructuring. As a part of the restructuring, Sage downsized commercial efforts, including elimination of its entire salesforce. The Company now has a small account management field-based team with a primary focus on working with healthcare providers and supporting women with PPD in geographies with active, ZULRESSO treating sites.
    - Given the ongoing impact of the COVID-19 pandemic in the U.S., the Company expects de minimis revenues from sales of ZULRESSO in the second quarter of 2020. The Company does not plan to provide revenue guidance for the balance of 2020. The Company anticipates,

however, that the COVID-19 pandemic will continue to have an adverse impact on sales of ZULRESSO even after pandemic-related restrictions are eased as sites of care adjust to new processes and address ongoing concerns as the situation evolves.

Neurology Franchise
SAGE-324, a next-generation PAM of $GABA_A$ receptors and Sage's lead neurology asset, is in development as a potential oral therapy for neurological conditions, such as essential tremor (ET), epilepsy and Parkinson's disease.

- **SAGE-324:** The Company plans to initiate a placebo-controlled Phase 2 study evaluating the safety and efficacy of SAGE-324 in patients with ET in the first half of 2020. Patients will receive a once-daily, four-week course of SAGE-324 60 mg or placebo.
  – The planned progression of SAGE-324 in ET is based on results from a Phase 1 open-label study evaluating the safety and pharmacokinetics of SAGE-324 in patients with ET. Data from the study will be presented in 2020.

Neuropsychiatry Franchise
SAGE-718, Sage's first-in-class NMDA receptor PAM and lead neuropsychiatric drug candidate, is in development as a potential oral therapy for cognitive disorders associated with NMDA receptor dysfunction, including Huntington's disease (HD).

- **SAGE-718:** The Company plans to initiate one or more Phase 2a open-label studies in 2020 evaluating SAGE-718 in patients with impaired cognitive function, which may include Parkinson's disease, Alzheimer's disease, and other neuropsychiatric disorders. Results from these studies will inform potential advancement of SAGE-718 into further Phase 2 development.
  – The planned progression of SAGE-718 in disorders associated with impaired cognitive function is based on results from a Phase 1 open-label study evaluating the safety and pharmacokinetics of SAGE-718 in a cohort of patients with early HD. Results from the study were presented at the CHDI Foundation annual meeting in February 2020.

Anticipated Upcoming Milestones and Potential Impact of COVID-19
Sage has implemented business continuity policies and practices intended to safeguard employees and help reduce the spread of COVID-19, including initiating a work from home policy for all employees. Sage is working closely with clinical development teams to develop strategies to help mitigate potential disruptions caused by COVID-19 and at this time the Company does not anticipate there will be a significant impact to timelines for its planned or ongoing clinical programs.

1H2020

- SAGE-324:
  – Initiate Phase 2 placebo-controlled study in ET

2H 2020

- Zuranolone:
  – Initiate Phase 3 trial evaluating a two-week course of zuranolone 50 mg in women with PPD
  – Initiate Phase 3 trial evaluating a two-week course of zuranolone 50 mg, when co-initiated with an open-label SSRI, as an acute rapid response therapy in patients with MDD
  – Initiate Phase 3 trial evaluating a two-week course of zuranolone 50 mg in patients with MDD (acute study intended to support episodic indication)
  – Report topline data from Phase 3 MDD SHORELINE Study (30 mg)

- SAGE-718:

– Initiate Phase 2a open-label study or studies in various disorders associated with cognitive dysfunction

2021

- Zuranolone:
  – Report topline data from Phase 3 trials in PPD, RRT, and MDD

- SAGE-324:
  – Report topline data from Phase 2 placebo-controlled study in ET

- SAGE-718:
  – Report topline data from Phase 2a open-label study or studies in various disorders associated with cognitive dysfunction

Financial Results for the First Quarter 2020

- **Revenues**: Sage recorded $2.3 million in net revenues in the first quarter of 2020 from sales of ZULRESSO. Sage recorded $0.5 million in collaboration revenues from Shionogi & Co., Ltd. related to reimbursement of product expense for the same period of 2019.
- **Cash Position**: Cash, cash equivalents, restricted cash, and marketable securities as of March 31, 2020 were approximately $0.9 billion compared to $1.0 billion at December 31, 2019.
- **R&D Expenses**: Research and development expenses were $63.6 million, including $12.2 million of non-cash stock-based compensation expense, in the first quarter of 2020, compared to $86.4 million, including $20.7 million of non-cash stock-based compensation expense, for the same period of 2019. The decrease in R&D expenses was primarily related to pauses in enrollment of certain Phase 3 clinical trials of zuranolone in MDD and the completion of the MOUNTAIN Study, a Phase 3 clinical trial of zuranolone in MDD.
- **SG&A Expenses**: Selling, general and administrative expenses were $70.1 million, including $18.9 million of non-cash stock-based compensation expense, in the first quarter of 2020, compared to $83.9 million, including $23.4 million of non-cash stock-based compensation expense, for the same period in 2019. The decrease in SG&A expenses was primarily due to a decrease in professional fees, primarily due to costs incurred in the three months ended March 31, 2019, related to preparations for the commercial launch of ZULRESSO in the U.S., which commenced on June 24, 2019.
- **Net Loss:** Net loss was $126.7 million for the first quarter of 2020, compared to a net loss of $163.4 million for the comparable period of 2019.

Financial Guidance

- Sage anticipates a cash balance of at least $550 million at end of 2020, which the Company anticipates will support operations into 2022 based on current operating plans.

Conference Call Information
Sage will host a conference call and webcast today, Thursday, May 7, 2020, at 4:30 p.m. ET to discuss its first quarter 2020 financial results and recent corporate updates. The live webcast can be accessed on the investor page of Sage's website at investor.sagerx.com. A replay of the webcast will be available on Sage's website approximately two hours after the completion of the event and will be archived for up to 30 days.

About Sage Therapeutics
Sage Therapeutics is a biopharmaceutical company committed to developing novel therapies with the potential to transform the lives of people with debilitating disorders of the brain. We are pursuing new pathways with the goal of improving brain health, and our depression, neurology and neuropsychiatry franchise programs aim to change how brain disorders are thought about and treated. Our mission is to

make medicines that matter so people can get better, sooner. For more information, please visit www.sagerx.com.

Forward-Looking Statements

Various statements in this release concern Sage's future expectations, plans and prospects, including without limitation: our views and expectations regarding revenues from sales of ZULRESSO and factors that may impact revenues, including the expected impact of the COVID-19 pandemic on ZULRESSO revenues; our clinical development plans and expected timelines, including our belief as to our ability to mitigate the possible impact of the COVID-19 pandemic on our clinical development timelines; the amount of the expected one-time cost associated with our restructuring; expected reductions in external expenses; our expectations with respect to 2020 operating expenses and year-end cash; our belief that existing cash will support operations into 2022; our belief in the potential of our product candidates in various indications; the potential profile and benefit of our product candidates; and the goals, opportunity and potential for our business. These statements constitute forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. These forward-looking statements are neither promises nor guarantees of future performance, and are subject to a variety of risks and uncertainties, many of which are beyond our control, which could cause actual results to differ materially from those contemplated in these forward-looking statements, including the risks that: we may never be able to generate meaningful revenues from sales of ZULRESSO or to generate revenues at levels necessary to justify our investment; the impact of the COVID-19 pandemic on sales of ZULRESSO may last longer than we expect or may reoccur in waves; our post-restructuring focus on geographies where there are existing, active ZULRESSO treating sites may not be sufficient for us to achieve success from the sale of ZULRESSO or to generate revenues at meaningful levels or at levels necessary to justify our investment even after the impact of the COVID-19 pandemic lessens; we may not be able to overcome the barriers to treatment with ZULRESSO or we may continue to encounter other issues or challenges in commercializing ZULRESSO which could further limit the potential of ZULRESSO and the timing and amount of future revenues; results achieved with use of ZULRESSO in the treatment of PPD in commercial use may be different than observed in clinical trials, and may vary among patients; the number of women with PPD or the unmet need for additional treatment options may be significantly smaller than we expect; we may not realize expected cost savings from our restructuring, including the anticipated decrease in external spend, at the levels we expect; we may encounter delays in initiation or conduct of our planned clinical trials, including slower than expected site initiation or enrollment, that may impact our ability to meet our expected time-lines and increase our costs; we may not be able to mitigate the impact of COVID-19 on our clinical development timelines and the impact may be more significant than we expect and may negatively impact expected site initiation or enrollment in our clinical trials, or cause us to pause trials or not be able to use data, in each case which may significantly impact our ability to meet our expected time-lines or may significantly impact the integrity or sufficiency of the data from our trials or increase our costs or cause us to have to change our plans; the internal and external costs required for our ongoing and planned activities, and the resulting impact on expense and use of cash, may be higher than expected which may cause us to use cash more quickly than we expect or change or curtail some of our plans or both; our expectations as to expenses, year-end cash and cash needs may prove not to be correct for other reasons such as changes in plans or actual events being different than our assumptions; we may be opportunistic in our future financing plans even if available cash is sufficient; we may not be successful in our development of any of our product candidates in any indication we are currently pursuing or may in the future pursue; success in our non-clinical studies or in earlier clinical trials may not be repeated or observed in ongoing or future studies, and ongoing and future non-clinical and clinical results may not meet their primary or key secondary endpoints or be sufficient to file for or gain regulatory approval to market the product without further development work or may not support further development at all; we may encounter adverse events at any stage of development that negatively impact further development or that require additional nonclinical and clinical work which may not yield positive results; we may encounter different or more severe adverse events at the higher doses we are planning to study in new trials; we may encounter issues with the efficacy or durability of short-term treatment, or co-initiated treatment with

zuranolone or safety and efficacy concerns with respect to retreatment that require additional studies be conducted; the FDA may ultimately decide that the design or results of our completed and planned clinical trials for any of our product candidates, even if positive, are not sufficient for regulatory approval in the indications that are the focus of our development plan; other decisions or actions of the FDA or other regulatory agencies may affect the initiation, timing, design, size, progress and cost of clinical trials and our ability to proceed with further development; we may encounter technical and other unexpected hurdles in the development and manufacture of our product candidates which may delay our timing or change our plans or increase our costs; as well as those risks more fully discussed in the section entitled "Risk Factors" in our most recent Quarterly Report on Form 10-Q, as well as discussions of potential risks, uncertainties, and other important factors in our subsequent filings with the Securities and Exchange Commission. In addition, any forward-looking statements represent our views only as of today, and should not be relied upon as representing our views as of any subsequent date. We explicitly disclaim any obligation to update any forward-looking statements.

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

	Three Months Ended March 31,	
	2020	**2019**
Product revenue, net	$ 2,286	$ -
Collaboration revenue	-	465
Total revenue	2,286	465
Operating costs and expenses:		
Cost of goods sold	170	-
Research and development	63,610	86,398
Selling, general and administrative	70,130	83,919
Total operating costs and expenses	133,910	170,317
Loss from operations	(131,624)	(169,852)
Interest income, net	4,729	6,442

Other income, net	155	4
Net loss	$ (126,740)	$ (163,406)
Net loss per share - basic and diluted	$ (2.44)	$ (3.37)
Weighted average shares outstanding - basic and diluted	51,908,760	48,491,834

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

	March 31, 2020	December 31, 2019
Cash, cash equivalents, restricted cash and investments	$ 875,124	$ 1,010,760
Total assets	$ 944,973	$ 1,084,150
Total liabilities	$ 95,767	$ 139,495
Total stockholders' equity	$ 849,206	$ 944,655

About ZULRESSO™ (brexanolone) CIV injection
ZULRESSO, the first medicine specifically approved by the U.S. Food and Drug Administration (FDA) for the treatment of postpartum depression (PPD) in adults, is a positive allosteric modulator of both synaptic and extrasynaptic GABAA receptors. Allosteric modulation of neurotransmitter receptor activity results in varying degrees of desired activity rather than complete activation or inhibition of the receptor.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about ZULRESSO?

ZULRESSO can cause serious side effects, including:

- **Excessive sedation and sudden loss of consciousness.** ZULRESSO may cause you to feel very sleepy (excessive sedation) or pass out (loss of consciousness). Your healthcare provider should check you for symptoms of excessive sleepiness every 2 hours while you are awake.
  - During your ZULRESSO infusion, tell your healthcare provider right away if you feel like you cannot stay awake during the time you are normally awake or if you feel like you are going to pass out. Your healthcare provider may lower your dose or stop the infusion until symptoms go away.
  - You must have a caregiver or family member with you to help care for your child(ren) during your ZULRESSO infusion.
- Because of the risk of serious harm resulting from excessive sedation or sudden loss of consciousness, ZULRESSO is only available through a restricted program called the ZULRESSO REMS.

Before receiving ZULRESSO, tell your healthcare provider about all your medical conditions, including if you:

- drink alcohol
- have kidney problems
- are pregnant or think you may be pregnant. It is not known if ZULRESSO will harm your unborn baby. - There is a pregnancy registry for females who are exposed to ZULRESSO during pregnancy. The purpose of the registry is to collect information about the health of females exposed to ZULRESSO and their baby. If you become pregnant during treatment with ZULRESSO, talk to your healthcare provider about registering with the National Pregnancy Registry for Antidepressants at 1-844-405-6185 or visit https://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/antidepressants/
- are breastfeeding or plan to breastfeed. ZULRESSO passes into breast milk. Talk to your healthcare provider about the risks and benefits of breastfeeding and about the best way to feed your baby while receiving ZULRESSO.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

ZULRESSO and some medicines may interact with each other and cause serious side effects.

Especially tell your healthcare provider if you take other antidepressants, opioids, or Central Nervous System (CNS) depressants (such as benzodiazepines).

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine. Your healthcare provider will decide if other medicines can be taken with ZULRESSO.

How will I receive ZULRESSO?
ZULRESSO is given to you by continuous intravenous (IV) infusion into your vein. The infusion will last for a total of 60 hours (2.5 days).

What should I avoid while receiving ZULRESSO?

- ZULRESSO may make you feel dizzy and sleepy. Do not drive a car or do other dangerous activities after your ZULRESSO infusion until your feeling of sleepiness has completely gone away. See "**What is the most important information I should know about ZULRESSO?**"
- Do not drink alcohol while receiving ZULRESSO.

What are the possible side effects of ZULRESSO?

ZULRESSO can cause serious side effects, including:

- See "**What is the most important information I should know about ZULRESSO?**"
- **Increased risk of suicidal thoughts or actions.** ZULRESSO and other antidepressant medicines may increase suicidal thoughts and actions in some people 24 years of age and younger. Depression or other serious mental illnesses are the most important causes of suicidal thoughts or actions.

How can I watch for and try to prevent suicidal thoughts and actions?

- Pay close attention to any changes, especially sudden changes in mood, behavior, thoughts, or feelings, or if you develop suicidal thoughts or actions.
- Tell your healthcare provider right away if you have any new or sudden changes in mood, behavior, thoughts, or feelings.

- Keep all follow-up visits with your healthcare provider as scheduled. Call your healthcare provider between visits as needed, especially if you have concerns about symptoms.

Tell your healthcare provider right away if you have any of the following symptoms, especially if they are new, worse, or worry you:
- Attempts to commit suicide, thoughts about suicide or dying, new or worse depression, other unusual changes in behavior or mood

The most common side effects of ZULRESSO include:

- Sleepiness, dry mouth, passing out, flushing of the skin or face.

These are not all the side effects of ZULRESSO.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Please see **Full Prescribing Information including Boxed Warning** and **Medication Guide** for ZULRESSO and discuss any questions you may have with your healthcare provider.

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