Sage Therapeutics Inc Logo

Sage Therapeutics Announces Third Quarter 2019 Financial Results and Highlights Pipeline and Business Progress

November 12, 2019

ZULRESSO™ (brexanolone) CIV injection revenues of $1.5M in third quarter

Enrollment completed in SAGE-217 Phase 3 MOUNTAIN and SHORELINE studies with topline data expected in 4Q 2019 and 2020, respectively

Planning to expand pipeline with two new GABA and NMDA clinical-stage assets

Conference call today at 8:00 a.m. EST

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Nov. 12, 2019-- Today, Sage Therapeutics (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 third quarter ended September 30, 2019.

“Sage’s approach to drug discovery and development has led to the significant progress we have made during the third quarter,” said Jeff Jonas, M.D., chief executive officer of Sage Therapeutics. “We are pleased with the execution by our teams at Sage. Our Depression Franchise continues to advance, our SAGE-217 studies are progressing well, and the launch of ZULRESSO in postpartum depression is yet another step towards upending conventional wisdom about treating psychiatric disorders. On top of this, our early stage pipeline continues to expand. We are looking forward to the upcoming data readout for SAGE-217, and we are excited by the possibilities in front of us.”

Portfolio Updates

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

Depression Franchise

Sage’s Depression Franchise includes ZULRESSO™ (brexanolone) CIV injection, the first treatment specifically approved by the U.S. Food and Drug Administration (FDA) for postpartum depression (PPD), and SAGE-217, Sage’s investigational oral neuroactive steroid GABA $_A$ receptor positive allosteric modulator (PAM), that is being evaluated as a treatment for various affective disorders. SAGE-217 received breakthrough therapy designation from the FDA for the treatment of major depressive disorder (MDD).

- **ZULRESSO:** Following the U.S. commercial launch of ZULRESSO on June 24, 2019, Sage remains focused on enabling broad access to ZULRESSO for women with PPD and establishing treatment-ready sites of care. The Company is encouraged by positive indicators in the first few months that suggest the long-term potential of ZULRESSO, including patient demand, interest from HCPs, and favorable payer coverage.
    - Sites of Care
        - Sage continues to focus on helping sites of care advance through the actions required to be treatment-ready to ensure women with PPD have access to a healthcare setting capable of administering ZULRESSO. Sage continues to expect the majority of healthcare sites will take an estimated six to nine months or more to complete the actions required to be treatment-ready, which include:

        - establishing protocols for administering ZULRESSO;
        - certifying under the ZULRESSO REMS (Risk Evaluation and Mitigation Strategy);
        - achieving formulary approval; and
        - securing satisfactory reimbursement from payers.
    - Sage expects some treatment-ready sites to wait to gain familiarity with the clinical profile of ZULRESSO and to secure direct experience with reimbursement prior to increasing patient intake. As a result, Sage expects that revenue momentum may lag the expected increase in site of care activation.
    - As of September 30, 2019, more than 140 healthcare facilities, including hospitals, infusion centers, wellness centers, and fertility centers were ZULRESSO REMS certified across 66 of the top 140 Metropolitan Statistical Areas in the U.S. Of these healthcare facilities, 11 sites were able to accelerate the activation process for treatment-readiness and infused patients with ZULRESSO in the third quarter of 2019.
  - Payer Coverage & Reimbursement
    - As of September 30, 2019, plans representing in aggregate more than 75 percent of all covered lives have committed to favorable coverage with either light or no restrictions.
    - The Company has made progress with coverage and reimbursement across national commercial payers and several state Medicaid plans.
  - Patient Support
    - Sage Central, Sage's patient support center, continues to provide a range of patient resources to assist women with PPD and their families in the treatment journey. In the third quarter of 2019, more than 90% of referred patients have used Sage Central's resources.
- **SAGE-217:** The clinical program evaluating the potential of SAGE-217 as a rapid-acting, durable, short-course treatment for MDD and PPD is progressing. In addition to the two completed positive pivotal studies, one in MDD (MDD-201) and one in PPD (ROBIN Study), ongoing or planned Phase 3 studies include:
  - MOUNTAIN Study (MDD-301): Placebo-controlled pivotal trial evaluating the safety and efficacy of SAGE-217 in patients with MDD. Patients received a two-week course of SAGE-217, 20mg or 30mg, or placebo, with four weeks of blinded follow-up and will have up to six months of open-label follow-up.
    - Enrollment completed in September 2019. The Company anticipates reporting topline data in 4Q 2019.
  - REDWOOD Study (MDD-302): Placebo-controlled pivotal trial evaluating the efficacy – time to first relapse – and long-term safety of fixed interval SAGE-217 monotherapy maintenance treatment. Randomized patients receive a two-week course of SAGE-217 or placebo every two months until the first relapse for up to one year.
    - Dosing in the study commenced in 3Q 2019.
  - SHORELINE Study (MDD-303): Open-label, long-term pivotal trial evaluating the safety of as needed repeat treatment with SAGE-217. Patients receive an initial two-week course of therapy and as needed retreatment and are assessed for potential relapse of depressive symptoms for up to one year.
    - Enrollment completed in October 2019. The Company anticipates reporting topline data in 2020.
  - RAINFOREST Study (MDD-304): Placebo-controlled pivotal trial evaluating SAGE-217 in patients with comorbid MDD and insomnia. The study will evaluate the effects on sleep as measured by polysomnography.
    - The Company anticipates reporting topline data in 2020.
  - Treatment-resistant depression (TRD): Planned placebo-controlled pivotal trial evaluating SAGE-217 as a potential therapy for TRD.
    - The Company is in the process of evaluating the design and timing of the study.

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 study-related activities for a Phase 2 study evaluating SAGE-324 as a potential therapy for ET in 4Q 2019.

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. SAGE-718 represents a new and complementary set of opportunities for the Sage portfolio.

- **SAGE-718:** The Company expects to report data from a Phase 1 clinical trial evaluating the safety and pharmacokinetics of SAGE-718 in a cohort of patients with early Huntington's Disease in 4Q 2019.

Early Development

- **SAGE-904:** Sage's second NMDA receptor PAM product-candidate is in development as a potential oral therapy for disorders associated with NMDA hypofunction. Dosing in a Phase 1 clinical trial of SAGE-904 in healthy volunteers commenced in 3Q 2019.
- **SAGE-689:** Sage is developing an intramuscular $GABA_A$ receptor PAM, SAGE-689, as a potential therapy for disorders associated with GABA hypofunction. The IND for SAGE-689 was cleared by the FDA and the Company expects to commence dosing in a Phase 1 clinical trial in healthy volunteers in 2020.

Anticipated Upcoming Milestones

- **Top-line Data Readouts:**
  - SAGE-217 Phase 3 MDD MOUNTAIN Study (4Q 2019)
  - SAGE-718 Phase 1 cohort data in early Huntington's disease (4Q 2019)
  - SAGE-217 Phase 3 MDD SHORELINE Study (2020)
  - SAGE-217 Phase 3 MDD and Comorbid Insomnia RAINFOREST Study (2020)
- **Planned Clinical Trial Initiations:**
  - SAGE-324 Phase 2 placebo-controlled study in ET (4Q 2019 for study-related activities; 1H 2020 for dosing)
  - SAGE-689 Phase 1 study in healthy volunteers (2020)

Financial Results for the Third Quarter of 2019

- **Revenues**: Sage recorded $3.6 million in revenues in the third quarter of 2019, including $1.5 million of net revenues from sales of ZULRESSO and $2.1 million in collaboration revenues from Shionogi & Co., Ltd. related to reimbursement of product expense. Sage recorded no revenue for the same period in 2018.
- **Cash Position**: Cash, cash equivalents, restricted cash, and marketable securities as of September 30, 2019 were approximately $1.1 billion compared to $925.1 million at December 31, 2018. The increase was primarily due to proceeds from Sage's follow-on public offering completed in February 2019.
- **R&D Expenses**: Research and development expenses were $102.1 million, including $17.1 million of non-cash stock-based compensation expense in the third quarter of 2019, compared to $75.1 million, including $14.0 million of non-cash stock-based compensation expense, for the same period in 2018.

The increase in R&D expenses was primarily due to advancement of the pivotal program for SAGE-217 in MDD and continued research efforts across the Company's early-stage clinical and discovery pipeline.

- **SG&A Expenses**: Selling, general and administrative expenses were $88.5 million, including $26.6 million of non-cash stock-based compensation expense in the third quarter of 2019, compared to $53.7 million, including $11.5 million of non-cash stock-based compensation expense, for the same period in 2018. The increase in SG&A expenses was primarily due to an increase in personnel-related expenses, along with facilities and corporate infrastructure costs to support expanding operations and the ZULRESSO commercial launch.
- **Net Loss:** Net loss was $180.0 million for the third quarter of 2019 compared to a net loss of $122.9 million for the same period in 2018.

Financial Guidance

- Based on its current operating plan, Sage anticipates that its balance of cash, cash equivalents, restricted cash, and marketable securities will be at least $950 million at the end of 2019.
- Sage expects ZULRESSO revenue growth will be modest over the next few quarters and anticipates a meaningful increase in ZULRESSO revenue in the second half of 2020.

Conference Call Information

Sage will host a conference call and webcast today, Tuesday, November 12, 2019, at 8:00 a.m. EST to discuss its third quarter 2019 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 our commercial launch of ZULRESSO and its long-term potential, including the potential timing for sites to become ready to administer ZULRESSO and expectations regarding an increase in the number of activated sites, the potential timing of revenue momentum and the potential for favorable reimbursement of ZULRESSO; our development plans, goals and strategy and the potential timing and results of our development efforts; our belief in the potential of our product candidates in various indications; the potential profile and benefit of our product candidates; the goals, opportunity and potential for our business; and our expectations regarding our cash position at year-end and increases in operating expense. 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 encounter issues or other challenges in commercializing ZULRESSO, including issues related to market acceptance by healthcare providers, healthcare settings and women with PPD, issues related to the willingness of sites to

administer ZULRESSO, issues related to reimbursement, issues related to the requirements of the REMS, and challenges associated with execution of our sales and patient support activities, which in each case could 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 encounter unexpected safety or tolerability issues with ZULRESSO or any of our product candidates; we may not be successful in our development of any of our current or future product candidates in any indication we are currently pursuing or may in the future pursue; success in prior clinical trials or nonclinical studies may not be repeated or observed in ongoing or future studies of any of our product candidates; ongoing and future clinical or nonclinical results may generate results that are different than we expect or may not support further development or be sufficient to gain regulatory approval of our product candidates; we may decide that a development pathway for one of our product candidates in one or more indications is no longer feasible or advisable or that the unmet need no longer exists; the FDA may decide that the development program for any of our product candidates, even if positive, is not sufficient for a new drug application filing or approval; 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 experience slower than expected initiation or enrollment in ongoing or future clinical trials; we may encounter unexpected safety or tolerability issues with our product candidates; the internal and external costs required for our ongoing and planned research and development efforts, and to build our organization in connection with such activities, and the resulting expense increases and use of cash, may be higher than expected which may cause us to change or curtail some of our plans; we may change our plans for other business reasons; and we may encounter technical and other unexpected hurdles in the development of our product candidates; as well as those risks more fully discussed in the section entitled "Risk Factors" in our most recent quarterly report filed with the Securities and Exchange Commission (SEC), and discussions of potential risks, uncertainties, and other important factors in our subsequent filings with the SEC. 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 September 30,		Nine Months Ended September 30,	
	2019	**2018**	**2019**	**2018**
Product revenue, net	$ 1,478	$ -	$ 1,997	$ -
Collaboration revenue	2,092	-	2,911	90,000
Total revenue	3,570	-	4,908	90,000
Operating costs and expenses:				

Cost of goods sold	137	-	181	-
Research and development	102,108	75,052	277,565	193,302
Selling, general and administrative	88,502	53,693	260,648	125,709
Total operating costs and expenses	190,747	128,745	538,394	319,011
Loss from operations	(187,177)	(128,745)	(533,486)	(229,011)
Interest income, net	7,227	5,817	21,889	14,483
Other income (expense), net	(8)	10	12	34
Net loss	$ (179,958)	$ (122,918)	$ (511,585)	$ (214,494)
Net loss per share - basic and diluted	$ (3.48)	$ (2.63)	$ (10.13)	$ (4.68)
Weighted average shares outstanding - basic and diluted	51,704,687	46,706,770	50,496,489	45,866,676

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

	September 30, 2019	December 31, 2018
Cash, cash equivalents, restricted cash and investments	$ 1,124,617	$ 925,143
Total assets	$ 1,203,727	$ 952,705
Total liabilities	$ 122,656	$ 89,734
Total stockholders' equity	$ 1,081,071	$ 862,971

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

What is ZULRESSO?
ZULRESSO™ (brexanolone) CIV is a prescription medicine used in adults to treat a certain type of depression called Postpartum Depression.

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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20191112005558/en/

Source: Sage Therapeutics

Investor Contact
Matt Calistri
617-914-2635
matthew.calistri@sagerx.com

Media Contact
Alexis Smith
617-588-3740
alexis.smith@sagerx.com