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Sage Therapeutics Announces Third Quarter 2016 Financial Results and Provides SRSE European Update

SAGE THERAPEUTICS ANNOUNCES THIRD QUARTER 2016 FINANCIAL RESULTS AND PROVIDES SRSE EUROPEAN UPDATE

Positive Scientific Advice From European Medicines Agency on Development of SAGE-547 in SRSE Provides Regulatory Path in E.U.

Ongoing Phase 3 STATUS Trial Expected to be Sufficient to Support a European Marketing Authorization Application for SAGE-547 in SRSE

Eight Clinical Trials Across Pipeline Expected to Generate Top-Line Data in 2017

Moving into Next Strategic Phase - a Multi-Product, Neuropsych Development Portfolio

Conference Call Today at 8:00 AM ET

CAMBRIDGE, Mass.--(BUSINESS WIRE) -- Sage Therapeutics, Inc. (NASDAQ: SAGE) today reported financial results for the third quarter ended September 30, 2016 and an update on its corporate strategy. Sage recently received positive Scientific Advice from the European Medicines Agency (EMA) on the development of SAGE-547 in the treatment of patients with super-refractory status epilepticus (SRSE). Based on the Scientific Advice from the EMA, Sage believes its current Phase 3 program, if successful, will be sufficient to support a European Marketing Authorization Application (MAA) to the EMA for the SRSE indication. Scientific Advice is a procedure offered by the EMA to stakeholders for clarification of questions arising during development of medicinal products and focuses on development strategies rather than pre-evaluation of data to support an MAA.

"The recent EMA Scientific Advice provides Sage with a clear regulatory path forward in SRSE in the E.U. and is important for Sage as we plan for top-line results from the Phase 3 STATUS Trial in SRSE, expected in the first half of next year, while continuing to lay the groundwork for a potential near-term commercial launch of SAGE-547," said Jeff Jonas, M.D., Chief Executive Officer of Sage. "Building on our recent clinical and regulatory accomplishments, including FDA Breakthrough Therapy Designation for SAGE-547 in postpartum depression (PPD), we continue to transform Sage. We are now poised to drive our strategy to the next phase - a multi-product, neuropsych development portfolio across three distinct disease areas: neurology with SRSE, mood disorders with PPD and major depressive disorder (MDD), and movement disorders with essential tremor and Parkinson's. As we continue to explore the potential applications of our novel compounds through deliberate and stepwise development, Sage is now well-positioned to produce eight important data readouts throughout 2017."

Pipeline Update

Sage is advancing a portfolio of multiple, novel central nervous system (CNS) product candidates targeting the $GABA_A$ and NMDA receptor systems. Dysfunction in these systems are known to be at the core of numerous psychiatric and neurological disorders. Sage is employing an innovative development approach focused on indications where patient populations are easily identified, clinical endpoints are well-defined, and development pathways are feasible.

- **SAGE-547:** Sage is currently developing SAGE-547 in separate clinical programs for the treatment of SRSE and PPD:
  - **SRSE:** Sage is enrolling the Phase 3 STATUS Trial, a global, randomized, double-blind, placebo-controlled trial, designed to evaluate the efficacy and safety of SAGE-547 as a treatment for SRSE.
  - **PPD:** Based on positive results from the placebo-controlled 202A clinical trial in severe PPD, Sage expanded its development program evaluating SAGE-547 for PPD with the initiation of two additional multi-center, placebo-controlled trials, one of which is a dose-ranging study of SAGE-547 in severe PPD patients (202B) and the other is studying the efficacy of SAGE-547 in moderate PPD patients (202C). Both clinical trials are currently enrolling. In September, the U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy Designation to SAGE-547 for the treatment of PPD. Sage is currently in discussions with the FDA regarding the

design of the program to support a possible New Drug Application (NDA) approval.

- **SAGE-217:** Sage plans to focus clinical development of SAGE-217, a novel, orally-active next generation GABA modulator, on both mood and movement disorders, with four Phase 2 clinical programs expected to begin by the end of 2016.
  - **Mood Disorders:**
    - **PPD:** Sage plans to initiate a Phase 2 clinical program for SAGE-217 in PPD based on positive results to date from the SAGE-547 PPD clinical program. The Phase 2a multi-center, double-blind, placebo-controlled, randomized trial will evaluate the efficacy, safety, tolerability, and pharmacokinetics of SAGE-217 in the treatment of patients with PPD.
    - **MDD:** Sage plans to initiate a two-part Phase 2 clinical trial of SAGE-217 in MDD. Part A of the Phase 2 trial will be an open-label, proof-of-concept study which, if positive, may lead to a larger randomized, placebo-controlled Phase 2 trial.
  - **Movement Disorders:**
    - **Essential tremor:** Based on prior positive proof-of-concept data, Sage plans to initiate a Phase 2 clinical program for SAGE-217 in essential tremor. The Phase 2a multi-center, double-blind, placebo-controlled, randomized withdrawal trial will evaluate the efficacy, safety, tolerability, and pharmacokinetics of SAGE-217 in the treatment of patients with essential tremor.
    - **Parkinson's disease:** Sage plans to initiate a two-part Phase 2 clinical trial of SAGE-217 in Parkinson's disease. Part A of the Phase 2 trial will be an open-label, proof-of-concept study which, if positive, may lead to a larger randomized, placebo-controlled Phase 2 trial.
    - **Other GABA Programs:** Sage is currently evaluating a series of novel GABA modulators in pre-clinical development, including SAGE-105, SAGE-324 and SAGE-689. Sage is planning to initiate IND-enabling studies this year for a novel, orally active next generation GABA modulator, either SAGE-105 or SAGE-324, which is intended to be developed for GABA-related indications, such as orphan epilepsies.
    - **SAGE-718:** Sage is also studying novel compounds that target the NMDA receptor. The lead NMDA product candidate is SAGE-718, a novel NMDA positive allosteric modulator, currently being tested in IND-enabling studies. Sage expects to initiate Phase 1 clinical development for SAGE-718 in 2017.

Expected Near-Term Clinical Milestones

- **Trial Initiations:**
  - Phase 2 trial of SAGE-217 in essential tremor (Q4 2016)
  - Phase 2 trial of SAGE-217 in PPD (Q4 2016)
  - Phase 2 proof-of-concept trial of SAGE-217 in Parkinson's disease (Q4 2016)
  - Phase 2 proof-of-concept trial of SAGE-217 in MDD (Q4 2016)
  - Phase 1 program of first NMDA candidate, SAGE-718 (1H 2017)
- **Data Readouts:**
  - Phase 3 STATUS Trial of SAGE-547 in SRSE (1H 2017)
  - Phase 2 proof-of-concept trial of SAGE-217 in Parkinson's disease (1H 2017)
  - Phase 2 proof-of-concept trial of SAGE-217 in MDD (1H 2017)
  - 202B trial of SAGE-547 in PPD (2H 2017)
  - 202C trial of SAGE-547 in PPD (2H 2017)
  - Phase 2 trial of SAGE-217 in essential tremor (2H 2017)
  - Phase 2 trial of SAGE-217 in PPD (2H 2017)
  - Phase 1 SAD trial of SAGE-718 (2H 2017)

Financial Results for the Third Quarter of 2016

- **Cash Position:** Cash, cash equivalents and marketable securities as of September 30, 2016 were $431.3 million, compared with $186.8 million at December 31, 2015. The increase was primarily due to net proceeds of $189.2 million, after deducting commissions and underwriting discounts, from Sage's follow-on public offering completed in September 2016.

- **R&D Expenses:** Research and development expenses were $29.1 million, including $2.5 million of non-cash stock-based compensation expense, in the third quarter of 2016, compared to $17.5 million, including $1.5 million of non-cash stock-based compensation expense, for the same period of 2015. The increase in R&D expense was primarily due to the ongoing clinical development of SAGE-547 in SRSE and PPD, completion of Phase 1 development for SAGE-217 and preparation for initiation of the Phase 2 clinical programs, the ongoing IND-enabling studies for SAGE-718 and investments in R&D headcount to support the growth in Sage's pipeline and operations.
- **G&A Expenses:** General and administrative expenses were $9.0 million, including $2.2 million of non-cash stock-based compensation expense, in the third quarter of 2016, compared to $6.6 million, including $2.9 million of non-cash stock-based compensation expense, for the same period of 2015. The increase in G&A expenses was primarily due to the increase in personnel-related expenses and professional fees to support expanding operations, as well as early commercial planning.
- **Net Loss:** Net loss was $37.8 million for the third quarter of 2016 compared to net loss of $24.0 million for the same period of 2015.
- **Financial Guidance:** Sage expects that its existing cash, cash equivalents and marketable securities will fund operating expenses and capital expenditure requirements, based on its current operating plan, into the second quarter of 2018.

Expected Upcoming Events and Presentations

- The Society of Neuroscience Annual Meeting, San Diego, November 12-16
- The Stifel Healthcare Conference, New York, November 16
- The American Epilepsy Society Annual Meeting, Houston, December 2-6
- Sage 2016 R&D Day, Boston, December 13

Conference Call Information

Sage will host a conference call and webcast today at 8:00 AM ET to discuss its third quarter 2016 financial results and recent business updates. The live webcast can be accessed on the investor page of Sage's website at investor.sagerx.com. The conference call can be accessed by dialing 1-866-450-8683 (toll-free domestic) or 1-281-542-4847 (international) and using the conference ID 4543484. 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 clinical-stage biopharmaceutical company committed to developing novel medicines to transform the lives of patients with life-altering central nervous system (CNS) disorders. Sage has a portfolio of novel product candidates targeting critical CNS receptor systems, GABA and NMDA. Sage's lead program, SAGE-547, is in Phase 3 clinical development for super-refractory status epilepticus, a rare and severe seizure disorder, and is being developed for postpartum depression. Sage is developing its next generation modulators, including SAGE-217 and SAGE-718, with a focus on acute and chronic CNS disorders. 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 expectations regarding development of our product candidates and their potential in the treatment of various CNS disorders; the expected timing of initiation and completion of clinical trials; the expected timing of IND-enabling activities; the anticipated availability and announcement of data and results from clinical trials of our product candidates; our plans for evaluation of new indications and new compounds; our expectations regarding the regulatory pathway for SAGE-547 in the treatment of SRSE in the E.U., and our belief that the results of the current development program for SAGE-547 in SRSE, if successful, will be sufficient for an MAA filing in the EU; our expectations regarding a potential future NDA filing and commercial launch of SAGE-547, if successfully developed and approved; and our expectations with respect to future cash use and cash needs. 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 continue to experience slower than expected enrollment and randomization of evaluable patients in the STATUS trial or slower than expected clinical site initiation and enrollment in our other clinical trials, or the potential need for additional analysis or data or the need to enroll additional patients, leading to possible delays in completion of trials or in the availability of data; we may not be able to generate supportive non-clinical data or to successfully demonstrate the efficacy and safety of our product candidates at each stage of development; success in our non-clinical studies or in earlier stage clinical trials may not be repeated or observed in ongoing or future studies involving the same compound or other product candidates, and ongoing and future pre-clinical and clinical results may not support further development of product candidates or be sufficient to gain regulatory approval to market any product; decisions or actions of regulatory agencies may affect the

initiation, timing, progress and cost of clinical trials, and our ability to proceed with further clinical studies of a product candidate or to obtain marketing approval, including the risk that the EMA may, despite scientific advice, decide that the data from our Phase 3 trial in SRSE are not sufficient to support approval; the internal and external costs required for our activities, and to build our organization in connection with such activities, and the resulting use of cash, may be higher than expected, or we may conduct additional clinical trials or pre-clinical studies or engage in new activities, requiring additional expenditures and using cash more quickly than anticipated; and we may encounter technical and other unexpected hurdles in the development and manufacture of our products which may delay our timing or increase our expenses and use of cash, 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 Balance Sheets
(in thousands)
(unaudited)

	September 30, 2016	December 31, 2015
Assets		
Current Assets:		
Cash and cash equivalents	$ 320,078	$ 186,753
Marketable securities	111,192	-
Prepaid expenses and other current assets	3,418	1,738
Total current assets	434,688	188,491
Property and equipment and other long-term assets	1,613	525
Total assets	$ 436,301	$ 189,016
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 5,237	$ 5,159
Accrued expenses	17,093	10,148
Total current liabilities	22,330	15,307
Other liabilities	234	14
Total liabilities	22,564	15,321
Total stockholders' equity	413,737	173,695
Total liabilities and stockholders' equity	$ 436,301	$ 189,016

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,	
	2016	2015	2016	2015
Operating expenses:				
Research and development	29,075	17,478	78,752	48,981
General and administrative	8,989	6,604	25,033	17,057
Total operating expenses	38,064	24,082	103,785	66,038
Loss from operations	(38,064)	(24,082)	(103,785)	(66,038)
Interest income, net	275	53	717	115
Other expense, net	(7)	(6)	(18)	(10)
Net loss	$ (37,796)	$ (24,035)	$ (103,086)	$ (65,933)
Net loss per share - basic and diluted	$ (1.15)	$ (0.84)	$ (3.20)	$ (2.40)

Weighted-average shares outstanding - basic and diluted	32,975,897	28,737,743	32,218,204	27,430,275

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