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SAGE Therapeutics Reports Fourth Quarter and Full Year 2014 Financial Results

Multiple Clinical and Scientific Milestones Anticipated in 2015

CAMBRIDGE, Mass., Feb. 27, 2015 (GLOBE NEWSWIRE) -- SAGE Therapeutics (Nasdaq:SAGE), a clinical-stage biopharmaceutical company developing novel medicines to treat life-threatening, rare central nervous system (CNS) disorders, today reported business highlights and financial results for the fourth quarter and full year ended December 31, 2014.

"SAGE had a remarkable year in 2014 with the achievement of several clinical and corporate milestones, including significant progress in the development of our lead molecule, SAGE-547, successful completion of our initial public offering, and essential additions to our leadership team and board," said Jeff Jonas, M.D., chief executive officer of SAGE. "Importantly, SAGE-547 has demonstrated a strong and consistent safety and activity profile in two distinct groups of patients with super-refractory status epilepticus, a rare and life-threatening seizure disorder that is devastating for patients and their families and for which treatment options are limited. Positive data from both our ongoing Phase 1/2 clinical trial and the emergency-use setting give us confidence in the therapeutic potential for SAGE-547."

"Looking ahead, 2015 will be a year rich with milestones. We expect to report final results from our ongoing Phase 1/2 trial of SAGE-547 before initiating a registration trial by mid-year. We are on track to report proof of principle data from exploratory Phase 2a studies of SAGE-547 in essential tremor and severe postpartum depression in mid-2015. Further, we expect to broaden our clinical program with the initiation of Phase 1 trials for both SAGE-217 and SAGE-689 by year-end. We believe 2015 is poised to be a transformative year for SAGE," said Kimi Iguchi, chief financial officer of SAGE.

Pipeline Updates and Upcoming Milestones

- **Phase 1/2 Trial of SAGE-547 in Super-Refractory Status Epilepticus (SRSE) Continues to Enroll:** The Phase 1/2 open-label trial is continuing to enroll patients in an expansion cohort under a protocol amendment, allowing treatment of pediatric patients as young as two years old and enabling increased dosing of SAGE-547. SAGE expects to initiate a registration trial of SAGE-547 for the treatment of SRSE by mid-2015.

  Earlier this year, SAGE reported updated data from the Phase 1/2 trial of SAGE-547 as an adjunctive therapy for the treatment of SRSE, a critical condition in which the brain is in a state of persistent seizure, where patients are placed in a medically induced coma in an attempt to stabilize them, and where conventional and approved therapies fail to resolve their status epilepticus. The primary endpoint, safety and tolerability, was achieved in all patients. Of 17 patients evaluable for efficacy, 71 percent met the key efficacy endpoints of being successfully weaned off their anesthetic agents while SAGE-547 was being administered and being weaned off SAGE-547 without recurrence of SRSE. Final data from this trial are expected to be reported by mid-year.

- **SAGE-547 Emergency-Use Program Consistent with Clinical Activity and Safety Profile:** Earlier this year, SAGE reported that ten patients have been treated with SAGE-547 by independent centers under emergency use Investigational New Drug applications. Seven of nine evaluable patients treated with SAGE-547 achieved resolution of SRSE either during or soon after SAGE-547 treatment, resulting in an overall response rate of 78 percent, similar to the observed response rate in the Phase 1/2 clinical trial.

- **Exploratory Phase 2a Trials of SAGE-547 Continue to Enroll:** SAGE is using SAGE-547 to establish proof of principle in clinical trials for additional CNS disorders, including essential tremor and severe postpartum depression. These trials are designed to evaluate the safety, tolerability, pharmacokinetics and activity of SAGE-547, and to help guide the design of second-generation molecules for the chronic treatment of these diseases. SAGE expects to report data from both exploratory studies by mid-2015.

- **Advancing Portfolio of Proprietary Molecules:** SAGE continues to advance its pipeline of second-generation molecules. SAGE-217 is being developed as an oral therapy for orphan genetic epilepsies, and SAGE-689 is being developed as an adjunctive intravenous second-line therapy for the treatment of refractory status epilepticus. Both compounds are progressing through preclinical development and SAGE plans to initiate Phase 1 clinical trials of these molecules in late 2015.

Fourth Quarter and Full Year 2014 Financial Results

- **Cash Position:** Cash and cash equivalents as of December 31, 2014 were $127.8 million, compared with $8.1 million at December 31, 2013. The increase was primarily due to net proceeds of $94.0 million from the company's initial public offering completed in July 2014, partially offset by cash used to fund its operations.

- **R&D Expenses:** Research and development expenses were $8.9 million in the fourth quarter of 2014 and $24.1 million for the year ended December 31, 2014, compared to $4.5 million and $14.4 million in the comparable periods in 2013. The increase in R&D expense was primarily due to increased spending on clinical activities as SAGE-547 continued enrollment in its Phase 1/2 trial, increased personnel-related R&D expenses supporting the advancement of SAGE's pipeline of programs, and accrued expenses associated with the preclinical development of SAGE-217 and SAGE-689.

- **G&A Expenses:** General and administrative expenses were $3.4 million in the fourth quarter of 2014 and $9.7 million in the year ended December 31, 2014, compared to $1.2 million and $3.9 million in the comparable periods in 2013. The increase in G&A expenses was largely due to personnel-related costs and professional fees to support public company operations.

- **Net Loss:** Net loss was $12.4 million for the fourth quarter and $33.8 million for the year ended December 31, 2014, compared to net loss of $5.7 million and $18.3 million for the comparable periods of 2013.

About SAGE-547

SAGE-547 is an allosteric modulator of both synaptic and extra-synaptic $GABA_A$ receptors. $GABA_A$ receptors are widely regarded as validated drug targets for a variety of disorders, with decades of research and multiple approved drugs targeting these receptor systems. SAGE-547 is an intravenous agent in Phase 1/2 clinical development as an adjunctive therapy, a therapy combined with current therapeutic approaches, for the treatment of super-refractory status epilepticus (SRSE), as well as in exploratory Phase 2a clinical trials for the treatment of essential tremor and as an adjunctive therapy for the treatment of severe postpartum depression (PPD). In 2014, the U.S. Food and Drug Administration (FDA) granted both Fast Track and orphan drug designation to SAGE-547 for the treatment of SRSE.

About SAGE Therapeutics

SAGE Therapeutics is a clinical-stage biopharmaceutical company committed to developing and commercializing novel medicines to treat life-threatening, rare central nervous system, or CNS, disorders. SAGE's lead program, SAGE-547, is in clinical development for super-refractory status epilepticus (SRSE) and is the first of several compounds the company is developing in its portfolio of potential seizure medicines. The active pharmaceutical ingredient, treatment IND and support for emergency-use patients have been contributed under agreement by the Regents of the University of California and the University of California Davis. SAGE's proprietary chemistry platform has generated multiple new compounds that target $GABA_A$ and NMDA receptors, which are broadly accepted as impacting many psychiatric and neurological disorders. For more information, please visit www.sagerx.com.

Forward-Looking Statements

This release contains forward-looking statements and information. The use of words such as "may," "might," "will," "should," "expect," "plan," "anticipate," "believe," "estimate," "project," "intend," "future," "potential," or "continue," and other similar expressions are intended to identify forward looking statements. For example SAGE's future expectations, plans and prospects, including without limitation, SAGE's expectations regarding the potential safety, pharmacological effect and efficacy of SAGE-547 as a treatment for SRSE, essential tremor and postpartum depression, the expected development pathway for its other product candidates and its expectations with respect to the timing and success of its clinical trials, in particular a new clinical trial for SAGE-547 as a treatment for SRSE and whether such trial will be deemed by FDA to be a pivotal trial, constitute forward-looking statements for the purposes of the safe harbor provisions under The Private Securities Litigation Reform Act of 1995 and other federal securities laws. In particular, it should be noted that the initial data reported from the ongoing Phase 1/2 clinical trial of SAGE-547 are preliminary in nature and that the SAGE-547 clinical trial has not been completed. The preliminary data may change as additional data is released and such preliminary data may not be repeated or observed in ongoing or future studies involving SAGE-547 or our other product candidates. Actual results may differ materially from those indicated by these forward-looking statements as a result of various important factors, including, without limitation, SAGE's ability to successfully demonstrate the efficacy and safety of its product candidates, the pre-clinical and clinical results for its product candidates, which may not support further development of product candidates, actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials, obtaining, maintaining and protecting intellectual property, SAGE's ability to enforce its patents against infringers and defend its patent portfolio against challenges from third parties, competition from others developing products for similar uses, SAGE's ability to manage operating expenses, SAGE's ability to obtain additional funding to support its business activities and establish and maintain strategic business alliances and new business initiatives, SAGE's dependence on third parties for development, manufacture, marketing, sales and distribution of products, the outcome of litigation, and unexpected expenditures, as well as those risks more fully discussed in the section entitled "Risk Factors" in SAGE's latest Quarterly Report on Form 10-Q, as well as discussions of potential risks, uncertainties, and other important factors in SAGE's subsequent filings with the Securities and Exchange Commission. In addition, any forward-looking statements

represent SAGE's views only as of today and should not be relied upon as representing its views as of any subsequent date. SAGE explicitly disclaims any obligation to update any forward-looking statements.

Sage Therapeutics, Inc. and Subsidiary

Consolidated Balance Sheets

(in thousands, except share and per share data)

	December 31, 2014	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	$ 127,766	$ 8,066
Prepaid expenses and other current assets	1,056	341
Total current assets	128,822	8,407
Property and equipment, net	163	86
Restricted cash	39	39
Deferred tax assets, long-term	641	--
Total assets	$ 129,665	$ 8,532
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 2,429	$ 1,988
Accrued expenses	4,687	327
Deferred tax liability, current portion	641	--
Total current liabilities	7,757	2,315
Other liabilities	23	44
Total liabilities	7,780	2,359
Commitments and Contingencies		
Redeemable convertible preferred stock (Series A, B and C), $0.0001 par value; 5,000,000 and 37,750,000 shares authorized at December 31, 2014 and 2013, respectively; 0 and 37,750,000 shares issued and outstanding at December 31, 2014 and 2013, respectively; liquidation preference of $0 and $40,663 at December 31, 2014 and 2013, respectively	--	37,709
Stockholders' equity (deficit):		
Common stock, $0.0001 par value; 120,000,000 and 66,000,000 shares authorized at December 31, 2014 and 2013, respectively; 25,621,791 and 1,622,761 shares issued and outstanding at December 31, 2014 and 2013, respectively	3	--
Additional paid-in capital	188,727	139
Accumulated deficit	(66,845)	(31,675)
Total stockholders' equity (deficit)	121,885	(31,536)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$ 129,665	$ 8,532

The accompanying notes are an integral part of these consolidated financial statements.

Sage Therapeutics, Inc. and Subsidiary

Consolidated Statements of Operations and Comprehensive Loss

(in thousands, except share and per share data)

	2014	2013
Operating expenses:		
Research and development	$ 24,100	$ 14,357
General and administrative	9,710	3,922
Total operating expenses	33,810	18,279
Loss from operations	(33,810)	(18,279)
Interest income (expense), net	8	1
Other income (expense), net	(9)	(3)
Net loss and comprehensive loss	(33,811)	(18,281)
Accretion of redeemable convertible preferred stock to redemption value	(2,294)	(7)
Net loss attributable to common stockholders	$ (36,105)	$ (18,288)
Net loss per share attributable to common stockholders—basic and diluted	$ (1.67)	$ (12.26)
Weighted average number of common shares used in net loss per share attributable to common stockholders—basic and diluted	21,574,347	1,492,288

The accompanying notes are an integral part of these consolidated financial statements.

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