November 11, 2014

SAGE Therapeutics Reports Third Quarter 2014 Results

SAGE-547 Phase 1/2 Study Meets Primary Efficacy and Safety Endpoints

CAMBRIDGE, Mass., Nov. 11, 2014 (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 pipeline updates and reported business and financial results for the quarter ended Sept. 30, 2014.

"So far this year, we have made great progress towards our mission to improve the lives of patients living with rare and severe CNS disorders," said Jeff Jonas, M.D., chief executive officer of SAGE. "Financial results were in line with expectations, and we recently announced that we met both the primary efficacy and safety endpoints for our Phase 1/2 clinical trial of SAGE-547 in patients with super-refractory status epilepticus. Based on the activity of SAGE-547 in this trial combined with the observed ability of SAGE-547 to halt status epilepticus in emergency-use cases, we are focusing our efforts on initiating our pivotal trial for treatment of this disorder in the first half of 2015, pending our discussions with the FDA. We are excited about the potential for SAGE-547, as well as our earlier-stage programs, to treat multiple orphan genetic epilepsies and other rare disorders for which there are few to no approved treatment options."

Pipeline Updates

- **Primary Efficacy and Safety Endpoints Met in Phase 1/2 Trial of SAGE-547 in Super-Refractory Status Epilepticus (SRSE):** Top-line data reported from 12 patients enrolled in the trial show that all 12 patients met the primary endpoint, safety and tolerability. Of the 11 patients evaluable for efficacy, eight patients met the key efficacy endpoint of being successfully weaned off their anesthetic agents while SAGE-547 was being administered, and eight patients were successfully weaned off SAGE-547 without recurrence of SRSE. SAGE-547 was generally well tolerated and no drug-related serious adverse events, as determined by the Safety Review Committee, were reported in treated patients. SAGE is continuing to enroll patients in this trial in an expansion cohort. This expansion will include pediatric patients as young as two years old and enable increased dosing of SAGE-547 per a recently approved protocol amendment.

- **Emergency-use Experience with SAGE-547 Consistent with Clinical Data:** To date, seven patients have been treated with SAGE-547 by independent centers under emergency-use Investigational New Drug Applications. Five of these patients treated with SAGE-547 achieved resolution of SRSE either during the course of or soon after SAGE-547 treatment.

- **Phase 2a Trial of SAGE-547 for the Treatment of Essential Tremor Initiated:** SAGE recently began patient enrollment in an exploratory, single-center Phase 2a clinical trial of SAGE-547 in patients with essential tremor, a debilitating neurological disorder that causes involuntary, rhythmic shaking with no known cause. This trial is designed to evaluate the safety, tolerability, pharmacokinetics and activity of SAGE-547 in patients with essential tremor. The company plans to use data from this exploratory study to help guide the design of a second-generation molecule for the chronic treatment of this disease.

- **SAGE-217 Non-clinical Data Suggest Improved Clinical Profile of Second-Generation Neuroactive Steroids**: At the Twelfth Eilat Conference on New Anti-Epileptic Drugs, SAGE presented non-clinical data on its second-generation neuroactive steroid, SAGE-217. The data suggest improved activity for SAGE-217 versus other first-generation neuroactive steroids in development, as well as favorable selectivity and pharmacokinetic profile, of the drug candidate. SAGE-217 is designed to be administered orally, in addition to intramuscular and intravenous dosing. This may make the compound suitable as a maintenance or chronic treatment for status epilepticus, as well as for other orphan genetic seizure disorders.

- **SAGE-217 Advanced to be Second Development Program:** Based on the non-clinical data and pharmacokinetic profile observed with SAGE-217, combined with the potential for multiple routes of administration, the company has elected to prioritize the development of SAGE-217 as its second clinical candidate. The company intends to file an IND for SAGE-217 in late 2015 and initiate Phase 1 development thereafter, which would be followed by clinical development of SAGE-689.

In addition, in September, SAGE strengthened its leadership team with the addition of Michael F. Cola to its Board of Directors.

Financial Results

- Cash Position: Cash, cash equivalents and marketable securities as of Sept. 30, 2014, were $136.7 million compared with $8.1 million at Dec. 31, 2013. The increase was primarily driven by net proceeds of $94.0 million from the company's initial public offering completed in July, offset by cash used to fund its operations.

- R&D Expenses: Research and development expenses were $6.6 million in the third quarter of 2014 compared to $3.4 million in the third quarter of 2013. The increase in R&D expenses 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 to support the advancement of SAGE's pipeline of programs, and expenses associated with the non-clinical development of SAGE-689 and SAGE-217.

- G&A Expenses: General and administrative expenses were $2.9 million in the third quarter of 2014 compared to $1.1 million for the third quarter of 2013. The increase in G&A expenses was largely due to personnel-related costs to support the activities associated with becoming a public company.

- Net Loss: Net loss was $9.5 million for the third quarter of 2014 compared to net loss of $4.5 million for the third quarter of 2013.

About SAGE Therapeutics

SAGE Therapeutics (Nasdaq:SAGE) 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, or 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 Statement

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 and essential tremor, 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 the final prospectus related to SAGE's initial public offering filed with the Securities and Exchange Commission pursuant to Rule 424(b) of the Securities Act of 1933, as amended, 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.

Balance Sheets

(in thousands, except share and per share data)

(Unaudited)

	September 30, 2014	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	$ 136,727	$ 8,066
Prepaid expenses and other current assets	1,063	341
Total current assets	137,790	8,407
Property and equipment, net	134	86
Restricted cash	39	39
Total assets	$ 137,963	$ 8,532
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 2,157	$ 1,988
Accrued expenses	2,853	327
Total current liabilities	5,010	2,315
Other liabilities:	34	44
Total liabilities	5,044	2,359
Redeemable convertible preferred stock (Series A, B and C), $0.0001 par value; 0 and 37,750,000 shares authorized at September 30, 2014 and December 31, 2013, respectively; 0 and 37,750,000 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively; liquidation preference of $0 and $40,663 at September 30, 2014 and December 31, 2013, respectively	--	37,709
Stockholders' equity (deficit):		
Common stock, $0.0001 par value; 70,623,905 and 66,000,000 shares authorized at September 30, 2014 and December 31, 2013, respectively; 25,586,295 and 1,622,761 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively	3	--
Additional paid-in capital	187,400	139
Accumulated deficit	(54,484)	(31,675)
Total stockholders' equity (deficit)	132,919	(31,536)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$ 137,963	$ 8,532

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

SAGE Therapeutics, Inc.

Statements of Operations and Comprehensive Loss

(in thousands, except share and per share data)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Operating expenses:				
Research and development	$ 6,601	$ 3,408	$ 15,155	$ 9,845
General and administrative	2,869	1,111	6,294	2,719

Total operating expenses	9,470	4,519	21,449	12,564
Loss from operations	(9,470)	(4,519)	(21,449)	(12,564)
Interest income (expense), net	3	--	4	--
Other income (expense), net	(1)	--	(5)	1
Net loss and comprehensive loss	(9,468)	(4,519)	(21,450)	(12,563)
Accretion of redeemable convertible preferred stock to redemption value	(391)	--	(2,294)	--
Net loss attributable to common stockholders	$ (9,859)	$ (4,519)	$ (23,744)	$ (12,563)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.50)	$ (2.98)	$ (3.08)	$ (8.56)
Weighted average number of common shares used in net loss per share attributable to common stockholders—basic and diluted	19,581,624	1,514,838	7,711,038	1,467,387

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

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