



February 24, 2016

Sage Therapeutics Announces Fourth Quarter and Full Year 2015 Financial Results

Top-line Results of Phase 3 STATUS Trial for SAGE-547 in SRSE Expected in 2H 2016

Robust, Wholly-Owned Pipeline Includes 6 Novel Compounds in Evaluation across Multiple CNS Indications

3 Clinical Data Readouts and Multiple Trial Initiations Anticipated Across Pipeline in 2016

Conference Call Today at 8:30 AM ET

CAMBRIDGE, Mass., Feb. 24, 2016 (GLOBE NEWSWIRE) -- Sage Therapeutics, Inc. (NASDAQ:SAGE) today reported business highlights and financial results for the fourth quarter and full year ended December 31, 2015.

"2015 was a year of significant achievement for Sage and this success serves as the foundation for a potentially transformative year ahead. We are now poised to execute across a broad pipeline of innovative CNS therapies as we evolve into a fully-integrated biopharmaceutical company," said Jeff Jonas, M.D., Chief Executive Officer of Sage. "Sage is preparing for several important corporate milestones that we believe will provide major forward momentum in 2016, including top-line results from our Phase 3 STATUS Trial and multiple data announcements and trial initiations. Our strong financial position enables us to continue investment in our pipeline, establish a commercial infrastructure and expand our industry-leading team, as we aggressively pursue our mission of delivering important treatments for patients with few or inadequate treatment options."

2015 Key Achievements and Recent Corporate Highlights

- | Reported positive results from Phase 1/2 clinical trial of SAGE-547 in super-refractory status epilepticus (SRSE), initiated Phase 3 STATUS Trial in SRSE and secured Special Protocol Assessment (SPA) with the U.S. Food and Drug Administration (FDA)
- | Reported promising early clinical proof-of-concept results of SAGE-547 in severe postpartum depression (PPD) and essential tremor, and initiated Phase 2 placebo-controlled clinical trial of SAGE-547 in severe PPD
- | Initiated Phase 1 development program evaluating SAGE-217 in healthy volunteers
- | Selected three next generation development candidates, including NMDA modulator SAGE-718 and GABA modulators SAGE-105 and SAGE-324
- | Continue to strengthen organizational infrastructure and expanded leadership team with key development, research, technical operations and medical affairs appointments
- | Ended 2015 with a strong balance sheet including cash and cash equivalents as of December 31, 2015 of \$186.8 million. In January 2016, Sage completed an underwritten public offering resulting in net proceeds of approximately \$140.4 million.

Upcoming 2016 Pipeline Milestones

- | **Top-line data for Phase 3 STATUS Trial of SAGE-547 in SRSE expected in second half of 2016:** The STATUS Trial is a global, Phase 3, randomized, double-blind, placebo-controlled clinical trial evaluating SAGE-547 as a treatment for patients with SRSE, and is expected to enroll approximately 140 patients to achieve 126 evaluable patients with SRSE, ages two years or older.
- | **Top-line data for SAGE-547 in severe PPD expected during first half of 2016:** Sage is conducting a Phase 2 placebo-controlled clinical trial of SAGE-547 in patients with severe PPD. The multi-center study is planned to enroll up to 32 patients diagnosed with severe PPD and is intended to validate the activity signal observed in an initial open-label clinical trial.
- | **Top-line data for Phase 1 clinical program of SAGE-217 expected during first half of 2016:** Sage is currently dosing subjects in the Phase 1 clinical development program evaluating the safety, tolerability, pharmacokinetics and pharmacodynamic effects of SAGE-217 in healthy adult volunteers. SAGE-217 is a next generation positive allosteric modulator that has been optimized for selectivity of synaptic and extrasynaptic GABA_A receptors and for a pharmacokinetic profile allowing once-daily oral dosing.

- | **Potential Phase 2 clinical trial initiations for SAGE-217 in multiple indications during the second half of 2016:** If data from the ongoing Phase 1 clinical development program of SAGE-217 support further development, Sage plans to initiate up to three separate Phase 2 clinical trials with SAGE-217 in essential tremor, orphan epilepsies and potentially severe PPD, subject to positive results from the placebo-controlled clinical trial of SAGE-547 in severe PPD.
- | **Initiation of Phase 1 clinical development program for SAGE-689 during the second half of 2016:** Sage anticipates beginning Phase 1 clinical development for SAGE-689, a next generation positive allosteric modulator of GABA_A receptors that is being developed as an acute parenteral therapy for the treatment of indications where a high degree of anti-seizure activity and sedation are desirable prior to the introduction of general anesthesia, such as status epilepticus. Planned commencement of the trial is tied to satisfaction of a request from the U.S. Food and Drug Administration (FDA) for additional non-clinical study data.
- | **NMDA Program:** In November 2015, Sage announced the selection of SAGE-718 as its first NMDA development candidate. SAGE-718 is currently in IND-enabling studies and is being developed as a first-in-class, oxysterol-based positive allosteric modulator of NMDA receptors, a critical excitatory receptor system implicated in a broad range of CNS disorders. The initial indications selected by Sage for development are two NMDA-related orphan disorders - Smith-Lemli-Opitz Syndrome and Anti-NMDA Receptor Encephalitis, for which there are currently no approved treatments. Sage expects that SAGE-718 will begin clinical development in 2017.

Upcoming Events and Presentations

- | **Epilepsy Foundation Pipeline Conference**, San Francisco, February 26th
- | **Cowen and Company 36th Annual Health Care Conference**, Boston, March 7th
- | **American Chemical Society National Meeting & Exposition**, San Diego, March 13th-17th
- | **American Academy of Neurology 68th Annual Meeting**, Vancouver, April 15th-21st

Fourth Quarter and Full Year 2015 Financial Results

- | **Cash Position:** Cash and cash equivalents as of December 31, 2015 were \$186.8 million, compared with \$127.8 million at December 31, 2014. In January 2016, Sage completed an underwritten public offering resulting in net proceeds of approximately \$140.4 million.
- | **R&D Expenses:** Research and development expenses were \$20.4 million in the fourth quarter of 2015 and \$69.4 million for the year ended December 31, 2015, compared to \$8.9 million and \$24.1 million in the comparable periods in 2014. The increase in R&D expense was primarily due to increased spending on clinical activities and the advancement of SAGE-547 into Phase 3 development and SAGE-217 into Phase 1 development, increased personnel-related R&D expenses supporting the advancement of SAGE's pipeline of programs, and increased non-cash stock-based compensation expense.
- | **G&A Expenses:** General and administrative expenses were \$8.2 million in the fourth quarter of 2015 and \$25.3 million in the year ended December 31, 2015, compared to \$3.4 million and \$9.7 million in the comparable periods in 2014. The increase in G&A expenses was primarily due to personnel-related costs, and professional fees associated with operating as a public company and costs related to general operations.
- | **Net Loss:** Net loss was \$28.6 million for the fourth quarter and \$94.5 million for the year ended December 31, 2015, compared to net loss of \$12.4 million and \$36.1 million for the comparable periods of 2014.
- | **Financial Guidance:** Based on its current operating plan, Sage expects that its existing cash and cash equivalents will be sufficient to fund its current operations into the beginning of 2018.

Conference Call Information

SAGE will host a conference call and webcast today at 8:30 AM ET to report its fourth quarter and full year 2015 financial results and discuss 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 49865237. 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. Sage is developing its next generation modulators, including SAGE-217, SAGE-689 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 concerning 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 clinical activities; the anticipated availability and announcement of data and results from clinical trials of our product candidates; the expected drivers and evolution of our business; and our expectations regarding the sufficiency of its cash position to fund operations. 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 experience slower than expected clinical site initiation, slower than expected identification and enrollment of evaluable patients, or 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 early stage clinical trials may not be repeated or observed in ongoing or future studies involving the same compound or other product candidates, 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; the internal and external costs required for our activities, and to build the organization in connection with such activities, may be higher than expected; and we may encounter technical and other unexpected hurdles in the development and manufacture of our products, 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
Consolidated Balance Sheets
(in thousands, except share and per share data)
(unaudited)

	December 31, 2015	December 31, 2014
Assets		
Current Assets:		
Cash and cash equivalents	\$ 186,753	\$ 127,766
Prepaid expenses and other current assets	1,738	1,056
Total current assets	188,491	128,822
Property and equipment, net	286	163
Restricted cash	39	39
Deferred offering costs	200	-
Deferred tax assets	-	641
Total assets	\$ 189,016	\$ 129,665
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	\$ 5,159	\$ 2,429
Accrued expenses	10,148	4,687
Deferred tax liabilities	-	641
Total current liabilities	15,307	7,757
Other liabilities	14	23
Total liabilities	15,321	7,780
Commitments and contingencies		
Stockholders' Equity		
Preferred stock, \$0.0001 par value; 5,000,000 shares authorized at December 31, 2015 and December 31, 2014, respectively; no shares		

issued or outstanding at December 31, 2015 and December 31, 2014, respectively	-	-
Common stock, \$0.0001 par value; 120,000,000 shares authorized at December 31, 2015 and December 31, 2014, respectively; 28,823,549 and 25,621,791 shares issued and outstanding at December 31, 2015 and December 31, 2014, respectively	3	3
Additional paid-in capital	335,032	188,727
Accumulated deficit	(161,340)	(66,845)
Total stockholders' equity	173,695	121,885
Total liabilities and stockholders' equity	\$ 189,016	\$ 129,665

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2015	2014	2015	2014
Operating expenses:				
Research and development	20,376	8,945	69,357	24,100
General and administrative	8,236	3,416	25,293	9,710
Total operating expenses	<u>28,612</u>	<u>12,361</u>	<u>94,650</u>	<u>33,810</u>
Loss from operations	(28,612)	(12,361)	(94,650)	(33,810)
Interest income, net	63	4	178	8
Other expense, net	(13)	(4)	(23)	(9)
Net loss and comprehensive loss	<u>(28,562)</u>	<u>(12,361)</u>	<u>(94,495)</u>	<u>(33,811)</u>
Accretion of redeemable convertible preferred stock to redemption value	-	-	-	(2,294)
Net loss attributable to common stockholders	<u>\$ (28,562)</u>	<u>\$ (12,361)</u>	<u>\$ (94,495)</u>	<u>\$ (36,105)</u>
Net loss attributable to common stockholders per common share - basic and diluted	<u>\$ (0.99)</u>	<u>\$ (0.48)</u>	<u>\$ (3.40)</u>	<u>\$ (1.67)</u>
Weighted-average shares outstanding - basic and diluted	<u>28,810,565</u>	<u>25,605,622</u>	<u>27,778,288</u>	<u>21,574,347</u>

Investor Contact:

Paul Cox, Sage Therapeutics

paul.cox@sagerx.com

617-299-8377

Media Contact:

Maureen L. Suda, Suda Communications LLC

maureen.suda@sagerx.com

585-387-9248

 Primary Logo

Source: SAGE Therapeutics

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