May 5, 2016

Sage Therapeutics Announces First Quarter 2016 Financial Results

Five data presentations across two indications presented at AAN Annual Meeting

Multiple upcoming milestones and events planned for 2016

Conference call today at 4:30 PM ET

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Sage Therapeutics, Inc. (NASDAQ: SAGE), a clinical-stage biopharmaceutical company developing novel medicines to treat life-altering central nervous system (CNS) disorders, today reported business highlights and financial results for the first quarter ended March 31, 2016.

"We began 2016 with a clear focus on execution across our pipeline, and continued expansion of our expertise and infrastructure through strategic hires across key functions that support our goal of becoming a fully integrated biopharmaceutical company," said Jeff Jonas, M.D., Chief Executive Officer of Sage. "In the near-term, anticipated data readouts during the second quarter will inform our plans for Phase 2 trials of SAGE-217. These plans include potential trials in essential tremor and orphan epilepsies, assuming a positive readout from the Phase 1 clinical program, and a potential Phase 2 clinical trial of SAGE-217 in severe postpartum depression (PPD) if the ongoing SAGE-547 proof-of-concept trial in severe PPD validates the potential for the GABA mechanism of action in this indication. Later this year, we anticipate providing top-line results from the Phase 3 STATUS Trial of SAGE-547 in super-refractory status epilepticus (SRSE), and the groundwork is being laid for a potential commercial launch assuming positive data outcomes and regulatory approval."

Recent Highlights

- In January 2016, Sage raised approximately $140.4 million in net proceeds, after underwriters' discounts and commissions and offering expenses, through a follow-on public offering of 3,157,894 shares of its common stock at a price of $47.50 per share.
- Sage presented data from five abstracts at the 68th American Academy of Neurology (AAN) Annual Meeting on April 15-21, 2016 in Vancouver, Canada, including an oral platform presentation:
  - Presented detailed data regarding effects of underlying disorders, and treatment approaches from the open-label Phase 1/2 study of SAGE-547 in SRSE in a peer-reviewed setting for first time.
  - Demonstrated that the key efficacy endpoint response rate in the Phase 1/2 SRSE study was not related to age, gender, ethnicity, co-morbid medical condition, underlying medical condition, or previous antiepileptic or third line agent treatment; identified additional treatment characteristics subsequently incorporated into the Phase 3 STATUS Trial protocol.
  - Identified an exploratory pharmacodynamic biomarker that was significantly correlated with the plasma concentration of SAGE-547 during Phase 1/2 study.
  - Estimated the health economic burden of illness of SRSE in the U.S. through analysis of cases classified as SRSE using a treatment algorithm applied to a database of certain patient-level demographics and resource utilization data from 2012, highlighting significant morbidity, lengthy hospitalizations and significant utilization of ICU and overall hospital resources.
  - Presented data from a proof-of-concept study using SAGE-547 in 25 patients to evaluate the GABA mechanism as a potential treatment for essential tremor, and informing assessment and statistical methodology for the anticipated Phase 2 trial with next-generation $GABA_A$ modulator, SAGE-217, later this year.
- In April 2016, Sage was awarded Most Innovative Clinical Trial Design for the Phase 1/2 clinical trial of SAGE-547 in SRSE at Informa's 1st Annual Clinical & Research Excellence (CARE) Awards. Sage was a finalist in three award categories.
- Sage was announced as a finalist for the Most Valuable HCP or Healthcare Initiative for the Phase 3 STATUS Trial app at the 2nd Annual eyeforpharma Philadelphia Awards 2016.

Upcoming Milestones

- Upcoming data presentations at the Society of Biological Psychiatry (SOBP) 71st Annual Scientific Meeting on May 12-14 in Atlanta, GA.
- Detailed data from the open-label, proof-of-concept study for SAGE-547 in four PPD patients.
- Late-breaking abstract highlighting pre-clinical data from the first NMDA positive allosteric modulator candidate, SAGE-718, showing effects in established animal models of psychosis and cerebrosterol deficit disorders.
- Top-line results for the Phase 2 placebo-controlled, proof-of-concept clinical trial of SAGE-547 in severe PPD is expected during the second quarter of 2016.
- Top-line results for the Phase 1 clinical program of SAGE-217 is expected during the second quarter of 2016.
- Top-line results for the Phase 3 STATUS Trial of SAGE-547 in SRSE is expected during the second half of 2016.
- Phase 2 clinical trial initiations for SAGE-217 in at least two indications, among essential tremor, orphan epilepsies and possibly, severe PPD, planned for the second half of 2016, assuming successful completion of Phase 1 and, in the case of severe PPD, positive data from the ongoing SAGE-547 proof-of-concept trial.
- Initiation of the Phase 1 development program for SAGE-689, a next generation positive allosteric modulator of $GABA_A$ receptors, expected during the second half of 2016, assuming additional non-clinical data is satisfactory to the FDA.
- Clinical development with the first NMDA candidate, SAGE-718, planned to begin in 2017.

Upcoming Events and Presentations

- **Society of Biological Psychiatry 71st Annual Scientific Meeting,** Atlanta, May 12-14
- **2nd Congress of the European Academy of Neurology (EAN),** Copenhagen, May 28-May 31
- **American Society of Clinical Psychopharmacology (ASCP) 2016 Annual Meeting,** Scottsdale, May 30-June 3
- **Goldman Sachs Global Healthcare Conference,** Rancho Palos Verdes, June 7-9
- **Eilat Conference on New Antiepileptic Drugs (Eilat XIII),** Madrid, June 26-29

First Quarter 2016 Financial Results

- **Cash Position:** Cash and cash equivalents as of March 31, 2016 were $299.7 million, compared with $186.8 million at December 31, 2015. In January 2016, Sage completed an underwritten public offering resulting in net proceeds of $140.4 million.
- **R&D Expenses:** Research and development expenses in the first quarter of 2016 were $23.6 million, including $1.6 million of non-cash stock-based compensation expense, compared to $12.9 million, including $0.5 million of non-cash stock-based compensation expense, for the same period of 2015. The increase in R&D expense was primarily due to increased spending on clinical activities related to the continued advancement of the SAGE-547 Phase 3 development program, the Phase 2 proof-of-concept trial of SAGE-547 in severe PPD, and the SAGE-217 Phase 1 development program; increased personnel-related R&D expenses supporting the advancement of Sage's pipeline of product candidates; and increased non-cash stock-based compensation expense.
- **G&A Expenses:** General and administrative expenses in the first quarter of 2016 were $7.1 million, including $2.1 million of non-cash stock-based compensation expense, compared to $4.0 million, including $0.8 million of non-cash stock-based compensation expense, for the same period of 2015. The increase in G&A expenses was primarily due to an increase in personnel-related costs to support general operations.
- **Net Loss:** Net loss was $30.5 million for the first quarter of 2016 compared to net loss of $16.9 million for the same period of 2015.
- **Financial Guidance:** Sage reiterates its expectation that its existing cash and cash equivalents will be sufficient to fund operations into the beginning of 2018 based on its current operating plans.

Conference Call Information

SAGE will host a conference call and webcast today at 4:30 PM ET to discuss its first 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 99951496. 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; estimates as to burden of illness of SRSE; and our expectations with respect to our use of cash and future 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 experience slower than planned clinical site initiation, slower than planned identification and enrollment of evaluable patients, 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 early 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; the actual size of the patient populations and healthcare costs associated with the diseases for which we are developing our product candidates may be significantly lower than our estimates; the internal and external costs required for our activities, and to build the organization in connection with such activities, may be higher than expected, or we may engage in new activities requiring additional expenditures; 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 Annual Report on Form 10-K, 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)

	March 31, 2016	December 31, 2015
Assets		
Current Assets:		
Cash and cash equivalents	$ 299,680	$ 186,753
Prepaid expenses and other current assets	2,926	1,738
Total current assets	302,606	188,491
Property and equipment and other long-term assets	904	525
Total assets	$ 303,510	$ 189,016
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 4,540	$ 5,159
Accrued expenses	11,430	10,148
Total current liabilities	15,970	15,307

Other liabilities	40	14
Total liabilities	16,010	15,321
Total Stockholders' Equity	287,500	173,695
Total liabilities and stockholders' equity	$ 303,510	$ 189,016

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

	Three Months Ended March 31,	
	2016	**2015**
Operating expenses:		
Research and development	$ 23,581	$ 12,900
General and administrative	7,133	3,997
Total operating expenses	30,714	16,897
Loss from operations	(30,714)	(16,897)
Interest income, net	175	21
Other income (expense), net	(4)	5
Net loss and comprehensive loss	$ (30,543)	$ (16,871)
Net loss per share - basic and diluted	$ (0.97)	$ (0.66)
Weighted-average shares outstanding - basic and diluted	31,643,216	25,655,883

View source version on businesswire.com: http://www.businesswire.com/news/home/20160505006414/en/

Investor Contact:
Sage Therapeutics
Paul Cox, 617-299-8377
paul.cox@sagerx.com
or
Media Contact:
Suda Communications LLC
Maureen L. Suda, 585-387-9248
maureen.suda@sagerx.com

Source: Sage Therapeutics, Inc.