Sage Therapeutics Announces Fourth Quarter and Full Year 2017 Financial Results and Provides Pipeline Update

February 22, 2018

On track to submit New Drug Application for brexanolone for postpartum depression in 1H 2018 following pre-NDA meeting; buildout of commercial infrastructure underway for potential 1H 2019 launch

Breakthrough Therapy designation for SAGE-217 offers potential for expedited development of major depressive disorder program

Strong balance sheet of more than $1.0 billion in cash supports expected pipeline advancement in 2018

Conference call today at 8:00 AM ET

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Feb. 22, 2018-- 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 fourth quarter and full year ended December 31, 2017.

“By thinking differently about CNS, Sage has accelerated innovation across the development cycle, from discovery through development, and is now progressing toward potential commercial operations and patient care,” said Jeff Jonas, M.D., chief executive officer of Sage. “While our 2017 achievements demonstrate the strength of our R&D organization, successful execution against our 2018 goals will drive our planned transition to a commercial company with the opportunity to create a new standard of care for women with postpartum depression. In addition, our broad portfolio of fully-owned, internally developed molecules creates further opportunity to transform the lives of patients with life-altering CNS disorders and the potential to drive near and long-term value.”

Pipeline Updates

Sage is advancing a portfolio of novel CNS product candidates targeting the GABA and NMDA receptor systems. Dysfunction in these systems is known to be at the core of numerous psychiatric and neurological disorders.

GABA Programs

Sage is developing its proprietary intravenous (IV) formulation of brexanolone and a pipeline of novel, next-generation positive allosteric modulators of synaptic and extra-synaptic $GABA_A$ receptors.

- Brexanolone IV in Postpartum Depression (PPD):
  - Following a pre-NDA meeting with the U.S. Food and Drug Administration (FDA), Sage remains on track to file a New Drug Application (NDA) with the FDA in 1H 2018.
  - Sage anticipates presenting detailed study results from the Phase 3 program of brexanolone IV in PPD at upcoming medical meetings and through publication.
- SAGE-217 in Major Depressive Disorder (MDD):
  - The FDA recently granted Breakthrough Therapy designation to SAGE-217 for the treatment of MDD based on the positive results from the Phase 2, placebo-controlled trial of SAGE-217 in 89 adult patients with moderate to severe MDD.
  - Sage plans to initiate additional clinical trials of SAGE-217 in MDD in 2018.
- SAGE-217 in Postpartum Depression:
  - Sage is currently conducting a multi-center, double-blind, placebo-controlled, randomized Phase 2 clinical trial of SAGE-217 in severe PPD.
  - Sage believes the positive Phase 2 trial of SAGE-217 in MDD and positive Phase 3 trials of brexanolone in PPD support maximizing the utility of the ongoing Phase 2 trial of SAGE-217 in PPD. Sage increased the size of the ongoing trial and expects top-line results in 4Q 2018.
- SAGE-217 in Bipolar Depression, Parkinson’s Disease and Insomnia:
  - Sage plans to initiate clinical development of SAGE-217 in bipolar depression and continue further clinical development of SAGE-217 in Parkinson’s disease and disorders of sleep in 2018. Sage believes that available data from studies of MDD, Parkinson’s disease and a healthy volunteer insomnia model support further exploration in these indications.
- SAGE-324:
  - SAGE-324 is currently in IND-enabling studies and is intended to be developed with a focus on indications involving GABA hypofunction, such as essential tremor and epileptiform disorders.

- Sage expects to initiate a Phase 1 trial of SAGE-324 in 1H 2018.

- GABA Discovery Programs:
  - Sage is currently evaluating a series of novel $GABA_A$ receptor modulators in pre-clinical development, including SAGE-689, SAGE-105, and others.

NMDA Programs

Sage is developing novel, oral, first-in-class oxysterol-based positive allosteric modulators of the NMDA receptor, which may have potential in the treatment of a range of neurological disorders associated with a variety of cognitive, neurological and behavioral symptoms.

- SAGE-718:
  - Sage previously announced it completed a Phase 1 single-ascending dose study of SAGE-718 in healthy volunteers. SAGE-718 was generally well-tolerated with no severe adverse events. The pharmacokinetics of SAGE-718 were highly predictable with low variability.
  - Sage expects to initiate a Phase 1 multiple ascending dose program of SAGE-718 in 1H 2018.
- SAGE-904:
  - Sage recently announced it selected SAGE-904 as its second NMDA receptor positive allosteric modulator product candidate for development. SAGE-904 has a differentiated pharmacologic and pharmacokinetic profile from SAGE-718.
  - SAGE-904 is currently in IND-enabling studies.

Expected Milestones

- **Trial Initiations:**
  - Phase 1 program for SAGE-324 (1H 2018)
  - Phase 1 multiple ascending dose program of SAGE-718 (1H 2018)
  - Trials of SAGE-217 in MDD, bipolar depression, Parkinson's disease, and sleep disorders (2018)
- **Data Readouts:**
  - Results from Phase 1 multiple ascending dose program of SAGE-718 (2H 2018)
  - Results from recently expanded Phase 2 trial of SAGE-217 in PPD (4Q 2018)
  - Results from trials of SAGE-217 in MDD, bipolar depression, Parkinson's disease, and sleep disorders (2018-2019)
- **Regulatory and Commercial:**
  - NDA filing in U.S. for brexanolone in PPD (1H 2018)
  - Brexanolone commercial launch in PPD, if approved (1H 2019)

Financial Results for the Fourth Quarter and Full Year 2017

"Sage has a track-record of executing with a very deliberate R&D strategy and a disciplined investment philosophy," said Kimi Iguchi, chief financial officer of Sage. "Our robust balance sheet and strategic approach to spending facilitate the continued expansion of our commercial, manufacturing, quality, and medical affairs capabilities as part of our planned transition to a fully integrated biopharmaceutical company and enable the continued development of Sage's broad CNS pipeline."

- **Cash Position:** Cash, cash equivalents, and marketable securities as of December 31, 2017 were $518.8 million, compared with $397.5 million at December 31, 2016. The increase was primarily due to net proceeds of $325.8 million from Sage's follow-on public offering completed in November 2017. In February 2018, Sage completed an underwritten public offering, which included the full exercise of the underwriters' option to purchase additional shares, resulting in net proceeds of approximately $631.1 million.
- **R&D Expenses:** Research and development expenses were $50.9 million, including $5.7 million of non-cash stock-based compensation expense, in the fourth quarter of 2017, compared to $42.0 million, including $5.0 million of non-cash stock-based compensation expense, for the same period of 2016. For the year ended December 31, 2017, research and development expenses were $210.3 million, including $19.9 million of non-cash stock-based compensation expense, compared to $120.8 million, including $11.2 million of non-cash stock-based compensation expense, for the same period of 2016. The increase in R&D expenses year-over-year was primarily due to Phase 3 clinical development of brexanolone and CMC work in preparation for a potential filing for regulatory approval; the ongoing Phase 2 development of SAGE-217; ongoing early-stage R&D programs and discovery efforts focused on identifying new development candidates and additional indications of interest; and investments in R&D headcount to support the growth in Sage's pipeline and operations.
- **G&A Expenses:** General and administrative expenses were $19.6 million, including $4.6 million of non-cash stock-based compensation expense, in the fourth quarter of 2017, compared to $14.4 million, including $5.1 million of non-cash stock-based compensation expense, for the same period of 2016. For the year ended December 31, 2017, G&A expenses were $62.9 million, including $15.6 million of non-cash stock-based compensation expense, compared to $39.4 million, including $11.8 million of non-cash stock-based compensation expense, for the same period of 2016. The increase in G&A

expenses was primarily due to the increase in personnel-related expenses, professional fees to support expanding operations, costs related to continued preparations for a potential commercial launch, and facilities-related costs to support expanding operations.

- **Net Loss:** Net loss was $69.4 million for the fourth quarter of 2017 and $270.1 million for the year ended December 31, 2017, compared to a net loss of $55.9 million and $159.0 million, respectively, for the comparable periods of 2016.

2018 Financial Guidance

- Based upon its current operating plan, Sage anticipates that its existing cash, cash equivalents and marketable securities, and estimated brexanolone product sales, if the product is approved, will enable Sage to fund its operating expenses and capital expenditure requirements into 2020.
- Sage expects that its operating expenses will increase year over year in 2018 to support continued pipeline advancement and potential product commercialization of brexanolone in PPD.

Conference Call Information

Sage will host a conference call and webcast today at 8:00 AM ET to discuss its fourth quarter and full year 2017 financial results and recent corporate 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 6272049. 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, a proprietary IV formulation of brexanolone (SAGE-547), has completed Phase 3 clinical development for postpartum depression. Sage is developing its next generation modulators, including SAGE-217 and SAGE-718, in various 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 the timing of a potential NDA filing and launch of our proprietary formulation of brexanolone in PPD, and the expected build of commercial infrastructure; our statements regarding plans and timelines for further development of SAGE-217 and our other product candidates and related activities and our view of the potential for successful development; our statements as to the potential for expedited development for SAGE-217 in MDD as a result of the Breakthrough Therapy designation; our views as to the opportunity represented by Sage's portfolio and business, and the potential for value creation; and our expectations with respect to future use of cash. 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: the clinical and non-clinical data we have generated with our proprietary formulation of brexanolone to date may be determined by regulatory authorities, despite prior advice, to be insufficient to file for or gain regulatory approval to launch and commercialize our product in PPD and regulatory authorities may determine that additional trials or data are necessary in order to file for or obtain approval; regulatory authorities may find fault with the data generated at particular clinical site or sites or with the activities of our trial monitor or may disagree with our analyses of the results of our trials or identify issues with our manufacturing or quality systems, and any such findings or issues could require additional data or analyses or changes to our systems that could delay or prevent us from gaining approval of brexanolone IV; we may encounter unexpected safety or tolerability issues with brexanolone IV, SAGE-217 or any of our other product candidates in ongoing or future development; we may not be able to successfully demonstrate the efficacy and safety of SAGE-217 or any of our other product candidates at each stage of development; success in early stage clinical trials may not be repeated or observed in ongoing or future studies of SAGE-217 or any of our other product candidates; ongoing and future clinical results may not support further development or be sufficient to gain regulatory approval to market SAGE-217 or any of our other product candidates; we may decide that a development pathway for one of our product candidates in one or more indications is no longer feasible or advisable or that the unmet need no longer exists; we may not achieve expedited development or review of SAGE-217 as a result of the Breakthrough Therapy designation; decisions or actions of the FDA or other regulatory agencies may affect the initiation, timing, design, size, progress and cost of clinical trials and our ability to proceed with further development; we may experience slower than expected enrollment in ongoing clinical trials; 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 product candidates; as well as those risks more fully discussed in the section entitled "Risk Factors" in our most recent Quarterly Report on Form 10-Q and Annual Report on Form 10-K, and 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)

	December 31, 2017	December 31, 2016

Assets

Current Assets:		
Cash and cash equivalents	$ 306,235	$ 168,517
Marketable securities	212,613	228,962
Prepaid expenses and other current assets	6,227	5,100
Total current assets	525,075	402,579
Property and equipment and other long-term assets	4,862	1,952
Total assets	$ 529,937	$ 404,531

Liabilities and Stockholders' Equity

Current Liabilities:		
Accounts payable	$ 9,350	$ 12,817
Accrued expenses	42,601	22,352
Total current liabilities	51,951	35,169
Other liabilities	2,511	845
Total liabilities	54,462	36,014
Total stockholders' equity	475,475	368,517
Total liabilities and stockholders' equity	$ 529,937	$ 404,531

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

	Three Months Ended December 31,		Year Ended December 31,	
	2017	**2016**	**2017**	**2016**
Operating expenses:				
Research and development	$ 50,890	$ 42,004	$ 210,277	$ 120,756
General and administrative	19,558	14,375	62,878	39,407
Total operating expenses	70,448	56,379	273,155	160,163
Loss from operations	(70,448)	(56,379)	(273,155)	(160,163)
Interest income, net	1,042	494	3,099	1,211
Other expense, net	(15)	(16)	(64)	(35)
Net loss	$ (69,421)	$ (55,901)	$ (270,120)	$ (158,987)
Net loss per share - basic and diluted	$ (1.75)	$ (1.50)	$ (7.09)	$ (4.75)
Weighted average shares outstanding - basic and diluted	39,583,004	37,198,631	38,113,678	33,492,795

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Source: Sage Therapeutics

Sage Therapeutics
Investor Contact:
Paul Cox, 617-299-8377
paul.cox@sagerx.com
or
Media Contact:
Maureen L. Suda, 585-355-1134
maureen.suda@sagerx.com