Sage Therapeutics Announces First Quarter 2018 Financial Results and Provides Update on Pipeline and Progress toward Launch Readiness

May 3, 2018

New Drug Application for intravenous (IV) formulation of brexanolone as a treatment for postpartum depression submitted to U.S. Food and Drug Administration

Significant progress achieved in launch readiness preparations in anticipation of potential 1H 2019 brexanolone IV launch

Broad pipeline of drug candidates to treat central nervous system disorders continues to advance, with at least 7 clinical trial programs expected to be ongoing in 2018

Conference call today at 8:00 AM ET

CAMBRIDGE, Mass.--(BUSINESS WIRE)--May 3, 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 first quarter ended March 31, 2018.

“At Sage, we are focused on improving patient care through innovation. In the first half of 2018, we made great progress toward achieving that mission by accelerating launch preparation activities and R&D efforts across our portfolio,” said Jeff Jonas, M.D., chief executive officer of Sage. “We have taken important steps to further Sage’s planned transition to a commercial stage company, starting with the submission of our New Drug Application (NDA) for brexanolone IV, expansion of our commercial leadership, and the build-out of our patient support organization in advance of a potential approval. At the same time, we look forward to moving three additional drug candidates forward through 7 clinical programs, several of which we expect to initiate in the coming months. The commercial and development milestones we hope to achieve this year are focused on our goal of making a positive impact on the lives of patients suffering with serious CNS conditions and their caregivers.”

Launch Readiness Updates:

- Sage has made significant recent progress in preparing for a potential 1H 2019 commercial launch of brexanolone IV for the treatment of PPD, if the NDA is approved, including:
    - Expanding the commercial organization, including the addition of senior leaders across Marketing, Sales, Market Access and Patient Support Services; initiating the field team build with the addition of the national sales directors, and national and regional payer account directors;
    - Advancing our strategy to deliver a family-centric support model with varied potential site of care options for patients with PPD, including progressing work towards the development of a national network intended to support home infusion;
    - Creating a robust patient support model, including plans for in-house case management support, with headquarters expected to be located in North Carolina; and
    - Engaging in permitted discussions with payers to raise awareness of PPD and on the value proposition of the brexanolone IV product profile.

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 IV formulation of brexanolone and a pipeline of novel, next-generation, positive allosteric GABA modulators, including SAGE-217 and SAGE-324.

- Brexanolone IV in Postpartum Depression (PPD):
    - Sage recently submitted an NDA to the U.S. Food and Drug Administration (FDA) for brexanolone for the treatment of PPD. Sage is preparing for a potential commercial launch of brexanolone IV in PPD in the U.S. in the first half of 2019, if the product is approved by the FDA.
    - Sage presented detailed clinical results from Phase 2 and Phase 3 programs of brexanolone IV in PPD at the North American Society for Psychosocial Obstetrics and Gynecology (NASPOG) and American College of Obstetricians and Gynecologists (ACOG) 2018 annual meetings. Sage plans to also present these study results at upcoming medical meetings and through publication.

- SAGE-217 in Major Depressive Disorder (MDD), Bipolar Depression, and Sleep Disorders:

    - Earlier this year, the FDA granted Breakthrough Therapy designation to SAGE-217 for the treatment of MDD, offering the potential for an expedited development path that may include increased interaction and guidance from the agency. Sage anticipates meeting with the FDA to discuss the design of additional clinical trials of SAGE-217 in depression. Sage expects to initiate further MDD trials in 2018.
    - Sage plans to further explore SAGE-217 as a potential treatment in sleep disorders with a Phase 2 clinical trial expected to begin later this year.
- SAGE-217 in PPD:
    - Sage is currently conducting a multi-center, double-blind, placebo-controlled, randomized Phase 2 clinical trial of SAGE-217 in 140 patients with PPD and expects to report top-line results in 4Q 2018.
- SAGE-217 in Parkinson's Disease:
    - Sage plans to initiate a randomized, placebo-controlled Phase 2 clinical trial in Parkinson's disease patients with residual tremor in 2H 2018.
- SAGE-324:
    - Sage expects to initiate a Phase 1 single-ascending dose study of SAGE-324 in 3Q 2018. SAGE-324 is being developed as a potential treatment for chronic conditions involving GABA hypofunction, such as essential tremor and epileptiform disorders.
- 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:
    - Given the pharmacokinetics of SAGE-718 observed in a Phase 1 single ascending dose study, Sage expects to further evaluate the safety, tolerability, pharmacokinetic and pharmacodynamic profile of the compound in a Phase 1 multiple ascending dose trial in healthy volunteers that is expected to start in 2Q 2018.
    - If the Phase 1 program is successful, Sage plans to advance SAGE-718 into clinical trials of certain CNS disorders characterized by NMDA receptor hypofunction.

- SAGE-904:
    - SAGE-904, Sage's second NMDA positive allosteric modulator candidate, is currently in IND-enabling studies.

Disease Education Initiatives:

- Sage has advanced a variety of efforts to increase awareness of PPD and the need for screening, through initiatives led by Sage's Medical Affairs organization:
    - Establishing support of digital and live medical education programs on screening and current management of PPD;
    - Conducting ongoing broad multi-channel disease awareness efforts via digital women's health apps, web-based adaptive education, and advocacy partnerships to reduce stigma of PPD and help patients and families discuss symptoms of PPD with healthcare providers; and
    - Initiating ongoing collaborations on educational initiatives with top academic societies, including ACOG.

Expected Milestones

- **Medical Meeting Presentations:**
    - American Psychiatric Association (APA) 2018 Annual Meeting, May 5 – May 9, 2018 in New York, NY
    - Society of Biological Psychiatry (SOBP) 73rd Annual Meeting, May 10 – May 12, 2018 in New York, NY
    - International Society for Pharmacoeconomics and Outcomes Research (ISPOR) 2018 Annual International Meeting, May 19 – May 23, 2018 in Baltimore, MD
    - American Society of Clinical Psychopharmacology (ASCP) 2018 Annual Meeting, May 29 – June 1, 2018 in Miami, FL
    - Postpartum Support International (PSI) Annual Conference, July 13 – July 15, 2018 in Houston, TX

- **Trial Initiations:**
    - Phase 1 multiple ascending dose trial for SAGE-718 (2Q 2018)
    - Phase 1 single ascending dose trial for SAGE-324 (3Q 2018)
    - Phase 2 clinical trial for SAGE-217 in Parkinson's disease (2H 2018)
    - SAGE-217 programs in MDD, bipolar depression, and sleep disorders (2018)

- **Data Readouts:**
    - Results from Phase 2 trial of SAGE-217 in PPD (4Q 2018)

- Results from Phase 1 multiple ascending dose trial for SAGE-718 (2H 2018)
- Results from clinical trials of SAGE-217 in MDD, bipolar disorder, Parkinson's disease and sleep disorders expected to be initiated in 2018 (2019)

- **Regulatory and Commercial:**
  - Acceptance of NDA filing submission in U.S. for brexanolone IV in PPD (2Q 2018)
  - EMA Scientific Advice for brexanolone IV in PPD (2H 2018)
  - Brexanolone IV commercial launch in PPD, if approved (1H 2019)

Financial Results for the First Quarter of 2018

"We continue to be very strategic in the investments we make across the organization to ensure our ability to maximize the potential of our development-stage and pre-commercial assets," said Kimi Iguchi, chief financial officer of Sage. "With over $1 billion in cash, we are confident in the strength of our balance sheet to continue to support advancement of the pipeline and ongoing launch preparation."

- **Cash Position:** Cash, cash equivalents, and marketable securities as of March 31, 2018 were $1.1 billion, compared with $518.8 million at December 31, 2017. The increase was primarily due to net proceeds of $632.2 million from Sage's follow-on public offering completed in February 2018.
- **R&D Expenses:** Research and development expenses were $49.3 million, including $8.9 million of non-cash stock-based compensation expense, in the first quarter of 2018, compared to $45.2 million, including $3.6 million of non-cash stock-based compensation expense, for the same period of 2017. The increase in R&D expenses year-over-year was primarily due to increases in ongoing R&D programs and discovery efforts focused on identifying new clinical candidates and additional indications of interest and investments in R&D headcount to support the growth in Sage's pipeline and operations, offset by decreases in expenses due to the completion of Phase 3 clinical development of brexanolone IV, and completion of certain Phase 2 clinical trials of SAGE-217.
- **G&A Expenses:** General and administrative expenses were $28.8 million, including $6.9 million of non-cash stock-based compensation expense, in the first quarter of 2018, compared to $12.3 million, including $2.6 million of non-cash stock-based compensation expense, for the same period of 2017. 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 $74.6 million for the first quarter of 2018 compared to a net loss of $56.8 million, for the comparable period of 2017.

Financial Guidance:

- Based on its current operating plan, Sage anticipates that its existing cash, cash equivalents and marketable securities 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 preparations for potential commercialization of brexanolone IV in PPD, if approved.

Conference Call Information

Sage will host a conference call and webcast today at 8:00 AM ET to discuss its first quarter 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 (866) 450-8683 (toll-free domestic) or (281) 542-4847 (international) and using the conference ID 1675388. 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 acceptance by the FDA for filing and review of our NDA submission seeking approval of brexanolone IV in the treatment of PPD, and the potential for approval of the NDA; our expectations regarding our possible transition to a commercial-stage company, including the timing of a potential launch of brexanolone IV in PPD; our plans and expectations regarding our future commercial activities, if brexanolone IV is approved, including our expectations regarding the availability of home infusion and other potential sites of care and the nature of our planned patient support model; 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 regarding the strength of our balance sheet, the potential for future revenue 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: the FDA may decide not to accept for filing our NDA for brexanolone IV in PPD; 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; even if brexanolone IV is approved in PPD, we may encounter issues, delays or other challenges in launching or commercializing the product, including issues related to market acceptance and reimbursement, regulatory and other challenges or restrictions related to enabling home infusion and other venues as options for site of administration of brexanolone IV, and challenges associated with the build of our sales and patient support organizations and their activities; 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, manufacture and potential future commercialization 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 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, 2018	December 31, 2017
Assets		
Current Assets:		
Cash and cash equivalents	$ 557,555	$ 306,235
Marketable securities	525,958	212,613
Prepaid expenses and other current assets	11,575	6,227
Total current assets	1,095,088	525,075
Property and equipment and other long-term assets	5,564	4,862
Total assets	$ 1,100,652	$ 529,937
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 8,350	$ 9,350
Accrued expenses	29,522	42,601
Total current liabilities	37,872	51,951
Other liabilities	3,504	2,511
Total liabilities	41,376	54,462
Total stockholders' equity	1,059,276	475,475
Total liabilities and stockholders' equity	$ 1,100,652	$ 529,937

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

(Unaudited)

	Three Months Ended March 31,	
	2018	2017
Operating expenses:		
Research and development	$ 49,270	$ 45,200
General and administrative	28,849	12,280
Total operating expenses	78,119	57,480
Loss from operations	(78,119)	(57,480)
Interest income, net	3,529	707

Other expense, net	(8)	(5)
Net loss	$ (74,598)	$ (56,778)
Net loss per share - basic and diluted	$ (1.68)	$ (1.52)
Weighted average shares outstanding - basic and diluted	44,325,371	37,269,148

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Source: Sage Therapeutics, Inc.

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