Sage Therapeutics Announces First Quarter 2024 Financial Results and Highlights Pipeline and Business Progress

April 25, 2024

Achieved $6.2 million in ZURZUVAE™ (zuranolone) collaboration revenue during the first quarter of 2024, representing 50% of the net revenues reported by Biogen

Encouraging initial demand for ZURZUVAE; More than 700 prescriptions shipped and delivered in the first quarter of 2024

Payor coverage now in place for a majority of commercially covered lives for ZURZUVAE in the treatment of women with postpartum depression (PPD) without step therapy or complex prior authorizations, including coverage from two national Pharmacy Benefit Managers (PBMs)

Phase 2 PRECEDENT Study did not show statistically significant differences versus placebo on primary endpoint in patients with mild cognitive impairment in Parkinson's Disease; Topline data expected for dalzanemdor (SAGE-718) in Huntington's Disease and Alzheimer's Disease in 2024

Cash, cash equivalents and marketable securities of $717 million as of March 31, 2024

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Apr. 25, 2024-- Sage Therapeutics, Inc. (Nasdaq: SAGE), a biopharmaceutical company leading the way to create a world with better brain health, today reported business highlights and financial results for the first quarter ended March 31, 2024.

"The launch of ZURZUVAE is off to an encouraging start, reflected in the strong performance in the first full quarter of the launch. We are seeing increasing demand among HCPs, particularly OBGYNs, and hearing inspiring success stories from women with PPD treated with ZURZUVAE. Importantly, momentum in commercial and government payor coverage is helping to support our goal of broad and equitable access for women with PPD," said Barry Greene, Chief Executive Officer at Sage Therapeutics. "In parallel, we are working with urgency to advance efforts across our pipeline. While we are disappointed by the results of the Phase 2 PRECEDENT study given the significant burden of mild cognitive impairment on people and families affected by Parkinson's Disease, we look forward to the other data readouts for dalzanemdor and SAGE-324 expected in 2024."

First Quarter 2024 Portfolio Updates

Sage is advancing a portfolio of clinical-stage programs featuring internally discovered novel chemical entities with the potential to become differentiated products designed to improve brain health by targeting the $GABA_A$ and NMDA receptor systems. Dysfunction in these systems is thought to be at the core of numerous neurological and neuropsychiatric disorders.

Postpartum Depression Commercial Products

ZURZUVAE was approved by the FDA in August 2023 as the first-and-only oral treatment specifically indicated for adults with PPD. ZURZUVAE was made commercially available in the U.S. in December 2023. ZURZUVAE is being developed and commercialized in collaboration with Biogen Inc. Sage also commercializes ZULRESSO® (brexanolone) CIV injection in the U.S. in the treatment of PPD.

ZURZUVAE

Sage and its collaborator, Biogen, are focused on the goal of establishing ZURZUVAE as the first line therapy and standard of care in the U.S. for women with PPD. ZURZUVAE was made commercially available in the U.S. in December 2023. The companies are utilizing a specialty pharmacy distribution model by which ZURZUVAE is shipped directly to those who are prescribed the treatment.

As of the first quarter ended March 31, 2024, the following results had been achieved:

- $6.2 million in collaboration revenue from ZURZUVAE, representing 50% of the net revenues recorded when Biogen shipped ZURZUVAE to the wholesalers. ZURZUVAE net revenues for the first quarter can be attributed to a combination of wholesalers purchasing ZURZUVAE to fill orders as well as building inventory in anticipation of increasing demand for ZURZUVAE in the treatment of women with PPD.
- Over 1,200 prescriptions written across a wide breadth of physician types who treat PPD, including psychiatrists, OBGYNs and primary care physicians (PCPs).
- In the first quarter of 2024, more than 700 prescriptions were shipped and delivered.

Sage and Biogen field sales teams are engaging in promotional dialogues with HCPs who actively identify and treat women with PPD. In the first quarter of 2024, OBGYNs accounted for the largest share of prescriptions, followed by psychiatrists and PCPs. The number of new ZURZUVAE prescribers grew each month during the first quarter of 2024.

The companies continue to advance discussions with national, regional and government payors to advocate for broad and equitable access to ZURZUVAE for women with PPD with minimal restrictions and expect formulary discussions to continue over the course of 2024.

- In the first quarter of 2024, the majority of prescriptions were covered by payors.

- As of mid-April 2024, over 65% of all commercial lives are covered by payor policies in PPD, with the majority having no step therapy or complex prior authorizations, including two of three national PBMs who have developed coverage policies for ZURZUVAE in the treatment of PPD. Conversations are progressing with the third national PBM.
- Medicaid reviews are ongoing with almost half of the states, including several of the largest states, completing reviews during the first quarter of 2024. The companies expect the majority of Medicaid coverage decisions in PPD by the end of 2024.

Sage and Biogen's patient support program, ZURZUVAE For You, provides educational resources, helps with understanding insurance coverage and assistance navigating the prescription fulfillment process for women with PPD who are prescribed treatment. The program also includes financial assistance, such as a copay assistance program and product at no cost, for eligible patients. In the first quarter of 2024, the majority of commercially-insured patients using the ZURZUVAE savings card paid no copay.

The Company expects the following milestones for ZURZUVAE in 2024:

- 2024:
  - Ongoing commercialization of ZURZUVAE in the treatment of women with PPD
  - Present additional analyses of data from NEST clinical program, including health economics and patient reported outcomes

Pipeline

Dalzanemdor (SAGE-718), the Company's first-in-class NMDA receptor positive allosteric modulator (PAM), is in development as a potential oral therapy for cognitive impairment associated with certain neurodegenerative disorders. Dalzanemdor has received Fast Track Designation and Orphan Drug Designation (ODD) from the FDA, and Orphan Drug Designation from the European Medicines Agency (EMA) for the potential treatment of Huntington's Disease. Dalzanemdor has also been awarded an Innovation Passport Designation for cognitive impairment associated with Huntington's Disease and entry into the Innovative Licensing and Access Pathway (ILAP) by the U.K. Medicines and Healthcare products Regulatory Agency (MHRA). SAGE-324, the Company's next-generation PAM of GABA $_A$ receptors, is in development as a potential oral therapy for essential tremor (ET). SAGE-324 is being developed in collaboration with Biogen Inc.

Dalzanemdor (SAGE-718)

Sage is advancing a robust clinical program for dalzanemdor with multiple ongoing Phase 2 studies, including the DIMENSION and SURVEYOR studies in people with cognitive impairment associated with Huntington's Disease (HD), the lead indication for dalzanemdor, and the LIGHTWAVE study in people with mild cognitive impairment (MCI) and mild dementia due to Alzheimer's Disease (AD).

On April 17, 2024, Sage announced topline results from PRECEDENT, a double-blind, placebo-controlled Phase 2 study of dalzanemdor in people with MCI in Parkinson's Disease. The PRECEDENT Study did not meet its primary endpoint of demonstrating statistically significant difference from baseline in participants treated with once-daily dalzanemdor versus placebo on the Wechsler Adult Intelligence Scale Fourth Edition-IV (WAIS-IV) Coding Test score at Day 42. Dalzanemdor was generally well-tolerated, and there were no new safety signals observed. Based on the data, the Company does not plan any further development of dalzanemdor in Parkinson's Disease.

Ongoing studies in the dalzanemdor clinical program include:

- DIMENSION (CIH-201) Study: The DIMENSION Study is a double-blind, placebo-controlled Phase 2 study in people with cognitive impairment associated with HD. The study is designed to evaluate the efficacy of dalzanemdor dosed over a 12-week period, with a target enrollment of approximately 178 people. The DIMENSION Study is enrolling across 40 clinical sites.
- SURVEYOR (CIH-202) Study: The SURVEYOR Study is a double-blind, placebo-controlled Phase 2 study in people with cognitive impairment associated with HD. The SURVEYOR Study is designed to generate evidence linking changes in cognition to functioning, and is not designed or powered to demonstrate a statistically significant difference between dalzanemdor and placebo.
- PURVIEW (CIH-301) Study: The PURVIEW Study is an open-label Phase 3 safety study of dalzanemdor in people with cognitive impairment associated with HD. The study is designed to evaluate the long-term safety profile and long-term functioning compared to HD natural history of those treated for one year or more.
- LIGHTWAVE (CNA-202) Study: The LIGHTWAVE Study is a double-blind, placebo-controlled Phase 2 study of dalzanemdor in people with MCI and mild dementia due to AD. The study is designed to evaluate the safety and efficacy of dalzanemdor dosed over a 12-week period.

The Company expects the following milestones for dalzanemdor in 2024:

- Mid-2024:
  - Report topline data from SURVEYOR Study in people with HD cognitive impairment
- Late 2024:
  - Report topline data from LIGHTWAVE Study in people with MCI and mild dementia due to AD
  - Report topline data from DIMENSION Study in people with HD cognitive impairment
- 2024:
  - Present additional analyses of data from clinical development program as well as disease state and burden of

disease research in HD and/or AD

SAGE-324

Sage and its collaborator, Biogen, have completed enrollment in the Phase 2b KINETIC 2 placebo-controlled study of SAGE-324 in ET, which follows positive results from the completed KINETIC Study of SAGE-324 in ET. KINETIC 2 is a Phase 2b dose-ranging study with the primary goal of defining the dose for SAGE-324 with an efficacy and tolerability profile that maintains plasma concentrations needed for sustained tremor symptom control in treating ET. Topline data from the KINETIC 2 Study are expected in mid-2024.

Sage is also enrolling patients in a Phase 2 long-term open-label safety study to evaluate the long-term safety and tolerability of SAGE-324 in ET. The primary endpoint is incidence of treatment-emergent adverse events.

The Company expects the following milestones for SAGE-324 in 2024:

- Mid-2024:
  - Report topline data from Phase 2b KINETIC 2 Study in people with ET
- 2024:
  - Present additional analyses of data from clinical development program as well as disease state and burden of disease research in ET

FINANCIAL RESULTS FOR THE FIRST QUARTER 2024

- **Cash Position:** Cash, cash equivalents and marketable securities as of March 31, 2024 were $717 million compared to $753 million at December 31, 2023.
- **Revenue:** Collaboration revenue from sales of ZURZUVAE was $6.2 million in the first quarter of 2024, the first full quarter of sales. Reported collaboration revenue is 50% of the net revenues Biogen reports for ZURZUVAE in the U.S. ZURZUVAE net revenues for the first quarter can be attributed to a combination of wholesalers purchasing ZURZUVAE to fill orders as well as building inventory in anticipation of increasing demand for ZURZUVAE in the treatment of women with PPD. A $75.0 million milestone payment was earned in the fourth quarter of 2023 upon the first commercial sale of ZURZUVAE in PPD and was received from Biogen in January 2024. Net revenue from sales of ZULRESSO was $1.7 million in the first quarter of 2024, compared to $3.3 million in the same period of 2023.
- **R&D Expenses:** Research and development expenses were $71.7 million, including $5.0 million of non-cash stock-based compensation expense, in the first quarter of 2024 compared to $92.8 million, including $8.8 million of non-cash stock-based compensation expense, for the same period in 2023. The decrease in R&D expenses was primarily due to decreased headcount, decreased spend on early-stage pipeline, decreased zuranolone clinical trials and manufacturing as result of the Q3 2023 restructuring, partially offset by higher spend on dalzanemdor trials. The reimbursement from Biogen to Sage for R&D expenses pursuant to the Sage/Biogen Collaboration and License Agreement was $5.7 million in the first quarter of 2024 compared to $17.3 million in the same period of 2023, the reduction a result of the lower spend on zuranolone clinical development and manufacturing.
- **SG&A Expenses:** Selling, general and administrative expenses were $52.6 million, including $8.7 million of non-cash stock-based compensation expense, in the first quarter of 2024, compared to $65.7 million, including $11.3 million of non-cash stock-based compensation expense, for the same period in 2023. The decrease in SG&A expenses was primarily due to decreased headcount, overhead and technology spend as a result of the Q3 2023 restructuring. The reimbursement from Sage to Biogen for SG&A expenses pursuant to the Sage/Biogen Collaboration and License Agreement was $2.3 million in the first quarter of 2024 as compared to $3.0 million in the same period of 2023.
- **Net Loss:** Net loss was $108.5 million for the first quarter of 2024 compared to $146.8 million for the same period in 2023.

FINANCIAL GUIDANCE

- Based upon the Company's current operating plan, Sage anticipates that its existing cash, cash equivalents and marketable securities, anticipated funding from ongoing collaborations, and estimated revenues, will support its operations into 2026.
- The Company does not anticipate receipt of any additional milestone payments from collaborations in the remainder of 2024.
- The Company anticipates operating expenses will decrease in 2024 relative to 2023.
- With the availability of ZURZUVAE in the U.S. as an additional treatment for women with PPD, the Company anticipates ZULRESSO revenues will continue to decrease over time.

Conference Call Information

Sage will host a conference call and webcast today, Thursday, April 25, at 8:00 a.m. ET to review its first quarter 2024 financial results and discuss recent corporate updates. The live webcast can be accessed on the investor page of Sage's website at investor.sagerx.com. A replay of the webcast will be available on Sage's website following the completion of the event and will be archived for up to 30 days.

About Sage Therapeutics

Sage Therapeutics (Nasdaq: SAGE) is a biopharmaceutical company committed to our mission of pioneering solutions to deliver life-changing brain health medicines, so every person can thrive. Sage developed the only two FDA-approved treatments indicated for postpartum depression and is advancing a robust pipeline to target unmet needs in brain health. Sage was founded in 2010 and is headquartered in Cambridge, Mass. Find out more at www.sagerx.com or engage with us on Facebook, LinkedIn, Instagram, and X.

Forward-Looking Statements

Various statements in this release concern Sage's future expectations, plans and prospects, including without limitation our statements regarding: our plans, expectations and goals for commercialization of ZURZUVAE as a treatment for women with PPD, including our goal for ZURZUVAE to become the first line treatment and standard of care in this indication; our expectations as to coverage decisions related to ZURZUVAE in PPD and our goal of broad and equitable access to ZURZUVAE for women with PPD who are prescribed treatment; our belief in the commercial potential and profile for ZURZUVAE in the treatment of women with PPD and our expectations as launch progresses; anticipated timelines for reporting of results with respect to certain of our other programs; our belief in the potential profile and benefit of our product candidates; potential indications for our product candidates; the potential for success of our programs, and the opportunity to help patients in various indications; our expectations as to our cash runway, future expense levels and other financial guidance and statements as to the mission and goals for our business. These statements constitute forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. 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: our launch and commercialization efforts in the U.S. with respect to ZURZUVAE for the treatment of women with PPD may not be successful, and we may be unable to generate revenues from sales of ZURZUVAE at the levels or on the timing we expect or at levels or on the timing necessary to support our goals; early positive signs from launch or from our engagements with healthcare professionals, patients and payors related to ZURZUVAE may not be a signal of the potential for future success; the number of women with PPD, the unmet need for additional treatment options, and the potential market for ZURZUVAE in women with PPD, may be significantly smaller than we expect; ZURZUVAE may not achieve the clinical benefit, clinical use or level of market acceptance from healthcare professionals, patients or payors in the treatment of PPD we expect or we may encounter reimbursement-related or other market-related issues or issues with our distribution network that impact the success of our commercialization efforts, including our ability to achieve access goals; ZURZUVAE may never become the first line treatment and standard of care for women with PPD; we may encounter delays in completion of enrollment or completion and reporting of data with respect to any of our ongoing clinical trials, including as a result of slower than expected site initiation, slower than expected enrollment, the need or decision to expand the trials or other changes, that may impact our ability to meet our expected timelines and may increase our costs; success in earlier clinical trials of any of our product candidates may not be repeated or observed in ongoing or future studies, and ongoing and future clinical trials may not meet their primary or key secondary endpoints which may substantially impair development; in particular with respect to dalzanemdor, the results of our ongoing clinical studies of dalzanemdor in HD and AD may be negative like the results we recently announced from the PRECEDENT study in MCI in PD; unexpected concerns may arise from additional data, analysis or results from any of our completed studies; decisions or actions of the FDA or the timing of meetings with the FDA may affect the timing, design, size, progress and cost of clinical trials, the timing of data read-outs, the planned regulatory pathway or our ability to proceed with further development or may impair the potential for successful development or the timing or success of filing for and gaining regulatory approval; we may encounter adverse events at any stage that negatively impact further development and the potential for approval of our product candidates or the potential for successful commercialization of any our approved products or that require additional nonclinical and clinical work which may not yield positive results; the need to align with our collaborators may hamper or delay our development and commercialization efforts for the products or product candidates that are part of the collaboration or increase our costs; the anticipated benefits of our ongoing collaborations, including the future receipt of payments or the successful development or commercialization of products and generation of revenue, may never be achieved at the levels or timing we expect or at all; our business may be adversely affected and our costs may increase if any of our key collaborators fails to perform its obligations or terminates our collaboration; the internal and external costs required for our ongoing and planned activities, and the resulting impact on expense and use of cash, may be higher than expected which may cause us to not meet our cash runway or expense expectations or we may change or curtail some of our plans or both; we may not be successful in our efforts to gain regulatory approval of products beyond ZURZUVAE and ZULRESSO; we may not achieve revenues from our currently marketed products or any potential future products, at levels we expect; if we do not achieve revenues at the levels we expect from our currently marketed products, we may not achieve our expected cash runway; additional funding may not be available on acceptable terms when we need it which could hamper our development and commercialization activities; any of the foregoing events could impair the value creation opportunities for our business; and we may encounter technical and other unexpected hurdles in the development and manufacture of our product candidates or the commercialization of any current or future marketed product which may delay our timing or change our plans, increase our costs or otherwise negatively impact our business; as well as those risks more fully discussed in the section entitled "Risk Factors" in our most recent quarterly report filed with the Securities and Exchange Commission, 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.

Financial Tables

Sage Therapeutics, Inc. and Subsidiaries
Condensed Consolidated Balance Sheets
(in thousands)
(unaudited)

	March 31, 2024	December 31, 2023
Cash, cash equivalents and marketable securities	$ 717,013	$ 753,184
Total assets	767,600	882,277
Total liabilities	61,799	82,747
Total stockholders' equity	705,801	799,530

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

	Three Months Ended March 31,	
	2024	**2023**
Product revenue, net	$ 1,690	$ 3,294
Collaboration revenue - related party	6,212	-
Total revenue	7,902	3,294
Operating costs and expenses:		
Cost of revenues	1,269	230
Research and development	71,734	92,826
Selling, general and administrative	52,574	65,708
Total operating costs and expenses	125,577	158,764
Loss from operations	(117,675)	(155,470)
Interest income, net	9,204	8,830
Other expense, net	(12)	(188)
Net loss	$ (108,483)	$ (146,828)
Net loss per share - basic and diluted	$ (1.80)	$ (2.46)
Weighted average shares outstanding - basic and diluted	60,136,198	59,674,127

SELECT IMPORTANT SAFETY INFORMATION FOR ZURZUVAE

ZURZUVAE (zuranolone) CIV, is a neuroactive steroid gamma-aminobutyric acid (GABA) A receptor positive modulator indicated for the treatment of postpartum depression in adults.

This does not include all the information needed to use ZURZUVAE safely and effectively. See full prescribing information for ZURZUVAE.

ZURZUVAE may cause serious side effects, including decreased awareness and alertness, which can affect your ability to drive safely or safely do other dangerous activities. Do not drive, operate machinery, or do other dangerous activities until at least 12 hours after taking each dose. You may not be able to tell on your own if you can drive safely or tell how much ZURZUVAE is affecting you. ZURZUVAE may cause central nervous system (CNS) depressant effects including sleepiness, drowsiness, slow thinking, dizziness, confusion, and trouble walking. Taking alcohol, other medicines that cause CNS depressant effects such as benzodiazepines, or opioids while taking ZURZUVAE can make these symptoms worse and may also cause trouble breathing. ZURZUVAE is a federally controlled substance schedule IV because it contains zuranolone, which can be abused or lead to dependence. Tell your healthcare provider right away if you become pregnant or plan to become pregnant during treatment with ZURZUVAE. You should use effective birth control (contraception) during treatment with ZURZUVAE and for 1 week after the final dose. ZURZUVAE and other antidepressant medicines may increase the risk of suicidal thoughts and actions in people 24 years of age and younger. ZURZUVAE is not for use in children. The most common side effects of ZURZUVAE include sleepiness or drowsiness, dizziness, common cold, diarrhea, feeling tired, weak, or having no energy, and urinary tract infection.

SELECT IMPORTANT SAFETY INFORMATION for ZULRESSO

ZULRESSO (brexanolone) CIV, is a neuroactive steroid gamma-aminobutyric acid (GABA) A receptor positive modulator indicated for the treatment of postpartum depression in individuals 15 years and older.

This does not include all the information needed to use ZULRESSO safely and effectively. See full prescribing information for ZULRESSO.

WARNING: EXCESSIVE SEDATION AND SUDDEN LOSS OF CONSCIOUSNESS
See full prescribing information for complete boxed warning
Patients are at risk of excessive sedation or sudden loss of consciousness during administration of ZULRESSO.

Because of the risk of serious harm, patients must be monitored for excessive sedation and sudden loss of consciousness and have continuous pulse oximetry monitoring. Patients must be accompanied during interactions with their child(ren).

ZULRESSO is available only through a restricted program called the ZULRESSO REMS.

WARNINGS AND PRECAUTIONS
Suicidal Thoughts and Behaviors: Consider changing the therapeutic regimen, including discontinuing ZULRESSO, in patients whose PPD becomes worse or who experience emergent suicidal thoughts and behavior.

ADVERSE REACTIONS: Most common adverse reactions (incidence ≥5% and at least twice the rate of placebo) were sedation/somnolence, dry

mouth, loss of consciousness, and flushing/hot flush.

USE IN SPECIFIC POPULATIONS

- **Pregnancy:** ZULRESSO may cause fetal harm. Healthcare providers are encouraged to register patients by calling the National Pregnancy Registry for Antidepressants at 1-844-405-6185 or visiting online at https://womensmentalhealth.org/clinical-and-researchprograms/pregnancyregistry/antidepressants/
- **Renal Impairment:** Avoid use of ZULRESSO in patients with end stage renal disease (ESRD)

To report SUSPECTED ADVERSE REACTIONS, contact Sage Therapeutics, Inc. at 1-844-4-SAGERX (1-844-472-4379) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.
Please see accompanying full Prescribing Information including Boxed Warning.

View source version on businesswire.com: https://www.businesswire.com/news/home/20240425567718/en/

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