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

July 31, 2024

Achieved $7.4 million in ZURZUVAE™ (zuranolone) collaboration revenue during the second quarter of 2024 (50% of the net revenues recorded by Biogen), representing 19% growth from the first quarter

More than 1,400 prescriptions shipped and delivered during the second quarter of 2024, nearly doubling from the first quarter

Dalzanemdor (SAGE-718) topline data from the LIGHTWAVE (Alzheimer's Disease) and DIMENSION (Huntington's Disease) Studies expected in late 2024; primary endpoint for DIMENSION Study adjusted from HD-CAB composite to the Symbol Digit Modalities Test (SDMT)

SAGE-324 did not meet the primary endpoint in participants with essential tremor (ET); Sage and Biogen terminated clinical development for the ET program

Cash, cash equivalents and marketable securities of $647 million as of June 30, 2024

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jul. 31, 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 second quarter ended June 30, 2024.

"We are pleased with the strength of ZURZUVAE's early commercial launch performance and its positive, real-world impact on women suffering from PPD. Supported by several tailwinds, including increasing demand among a mix of providers, particularly OBGYNs, we believe ZURZUVAE is well-positioned to become the first line therapy and standard of care for women with PPD," said Barry Greene, Chief Executive Officer at Sage Therapeutics. "While we are deeply disappointed by the results from the KINETIC 2 study and for the essential tremor community, we remain focused on progressing our pipeline and look forward to additional clinical data readouts expected in late 2024."

Second Quarter 2024 Portfolio Updates

Sage is advancing a portfolio of 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 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 postpartum depression (PPD). ZURZUVAE was made commercially available in December 2023. ZURZUVAE is being developed and commercialized in collaboration with Biogen Inc. Sage also commercializes ZULRESSO® (brexanolone) CIV injection 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 for women with PPD. The companies are utilizing a specialty pharmacy distribution model by which ZURZUVAE is shipped directly to women with PPD who are prescribed the treatment.

As of the second quarter ended June 30, 2024, the following results had been achieved:

- $7.4 million in collaboration revenue from ZURZUVAE in the second quarter of 2024, representing a 19% increase from the first quarter. Collaboration revenues represent 50% of the net revenues recorded when Biogen ships ZURZUVAE to the distributors.
- Approximately 2,000 prescriptions written in the second quarter, representing a greater than 60% increase from the first quarter.
- More than 1,400 prescriptions were shipped and delivered in the second quarter, representing a greater than 95% increase from the first quarter.

Sage and Biogen field sales teams are engaging in promotional dialogues with HCPs who actively identify and treat women with PPD. In the second quarter of 2024, OBGYNs accounted for more than 70% of prescriptions written, followed by psychiatrists and PCPs. The number of new and repeat ZURZUVAE prescribers grew during the second 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.

- As of late July 2024, approximately 80% 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 women with PPD. Conversations with the third national PBM continue to progress.
- Medicaid reviews are ongoing, with additional states, including several of the largest states, completing reviews during the second quarter of 2024. The majority of Medicaid coverage decisions have already been made and the Company expects the remainder of decisions to occur in the second half of 2024.
- In the second quarter of 2024, the majority of prescriptions shipped were covered by commercial or government payors.

Sage and Biogen's patient support program for women with PPD, ZURZUVAE For You, provides educational resources, help with understanding insurance coverage and assistance navigating the prescription fulfillment process. The program also includes financial assistance, such as a copay assistance program and product at no cost, for eligible patients. In the second quarter of 2024, the vast 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 analyses of real-world evidence for ZURZUVAE including health economics and patient reported outcomes

Pipeline

Dalzanemdor (SAGE-718)
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 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 HD and entry into the Innovative Licensing and Access Pathway (ILAP) by the U.K. Medicines and Healthcare products Regulatory Agency (MHRA).

Sage is advancing a clinical program for dalzanemdor with ongoing Phase 2 studies, including the DIMENSION study 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).

In June, Sage announced topline results from the SURVEYOR Study. The SURVEYOR Study met its primary endpoint demonstrating a statistically significant difference as measured by the HD-Cognitive Assessment Battery (HD-CAB) composite score at baseline between healthy participants and participants with Huntington's Disease (HD) prior to any treatment with dalzanemdor (SAGE-718) or placebo, further underscoring the cognitive impact of HD. For participants with HD that received dalzanemdor or placebo, dalzanemdor was generally well-tolerated with no new safety signals observed. There was a small numerical difference observed between dalzanemdor and placebo on the HD-CAB composite score at Day 28. Other prespecified analyses suggested the potential for directionally positive signals in a number of individual component tests of the HD-CAB and in some functional assessments.

Based on the review of data from the SURVEYOR Study and other relevant information, the Company has decided to adjust the primary endpoint in the ongoing placebo-controlled DIMENSION Study in HD from the HD-CAB composite to the Symbol Digit Modalities Test (SDMT), one of the cognitive tests included in the composite. Other secondary endpoints include additional measures of cognition, functioning and safety. Topline data from the DIMENSION Study are expected in late 2024.

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 and safety of once-daily dalzanemdor dosed over three months.
- PURVIEW (CIH-301) Study: The PURVIEW Study is an open-label Phase 3 safety study designed to evaluate the long-term safety and tolerability of dalzanemdor in participants with HD.
- 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:

- 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 the clinical development program as well as disease state and burden of disease research in HD and/or AD

SAGE-324
SAGE-324 is a $GABA_A$ receptor PAM, being developed as a potential oral therapy in collaboration with Biogen Inc.

On July 24, 2024, Sage and Biogen announced topline results from the Phase 2 KINETIC 2 study of SAGE-324 as a potential treatment in ET. The

KINETIC 2 Study did not demonstrate a statistically significant dose-response relationship in change from baseline to Day 91 based on the primary endpoint, The Essential Tremor Rating Assessment Scale (TETRAS) Performance Subscale (PS) Item 4 (upper limb) Total Score, in participants with ET. In addition, there were no statistically significant differences demonstrated for any dose of SAGE-324 versus placebo in the change from baseline to Day 91 on the TETRAS PS Item 4 Total Score or the TETRAS Activities of Daily Living (ADL) Composite Score. Given these results, Sage and Biogen do not plan to conduct further clinical development of SAGE-324 in ET and will close the ongoing open label safety study. The companies are evaluating next steps, if any, for other potential indications.

FINANCIAL RESULTS FOR THE SECOND QUARTER 2024

- **Cash Position:** Cash, cash equivalents and marketable securities as of June 30, 2024 were $647 million compared to $717 million at March 31, 2024.
- **Revenue:** Collaboration revenue from sales of ZURZUVAE was $7.4 million in the second quarter of 2024, representing a 19% increase compared to the first quarter of 2024. Reported collaboration revenue is 50% of the net revenues Biogen records for ZURZUVAE in the U.S. A key factor impacting revenue in the second quarter of 2024 was wholesalers bringing down initial inventory levels. Net revenue from sales of ZULRESSO was $0.6 million in the second quarter of 2024, compared to $2.5 million in the same period of 2023.
- **R&D Expenses:** Research and development expenses were $62.6 million, including $6.1 million of non-cash stock-based compensation expense, in the second quarter of 2024 compared to $97.2 million, including $4.5 million of non-cash stock-based compensation expense, for the same period in 2023. The decrease in R&D expenses as compared to the same period in 2023 was related to the Q3 2023 restructuring which reduced headcount, and decreased spend on the early stage pipeline, zuranolone clinical development, and manufacturing. The reimbursement from Biogen to Sage for R&D expenses pursuant to the Sage/Biogen Collaboration and License Agreement was $3.3 million in the second quarter of 2024 compared to $22.4 million in the same period of 2023, the reduction is a result of the lower spend on zuranolone clinical development and manufacturing.
- **SG&A Expenses:** Selling, general and administrative expenses were $56.0 million, including $11.0 million of non-cash stock-based compensation expense, in the second quarter of 2024, compared to $75.6 million, including $7.2 million of non-cash stock-based compensation expense, for the same period in 2023. The decrease in SG&A expenses as compared to the same period in 2023 was primarily due 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 $1.0 million in the second quarter of 2024 as compared to $7.5 million in the same period of 2023.
- **Net Loss:** Net loss was $102.9 million for the second quarter of 2024 compared to $160.3 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 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 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, July 31, 2024, at 4:30 p.m. ET to review its second 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 ongoing clinical trials of dalzanemdor and other planned activities; plans to evaluate other potential indications for SAGE-324; 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 reporting of data with respect to any of our ongoing clinical trials, including as a result of changes in the trials, 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 or cause us to discontinue 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 previously announced from the PRECEDENT study in MCI in Parkinson's Disease; potentially directionally positive signals in certain measures of the treatment phase of the SURVEYOR study of dalzanemdor may not prove to be actual signals or meaningful to the development program; we do not know if adjusting the primary endpoint of the DIMENSION Study will increase the probability of success, and it may not; unexpected concerns may arise from additional data, analysis or results from any of our completed studies; we and our collaborator, Biogen, may jointly or individually determine not to proceed with further development of SAGE-324 in any indication or at all; decisions or actions of the FDA or the timing of meetings with the FDA may affect the timing, design, size, progress and cost of ongoing or future clinical trials of our current or future product candidates, 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 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)

	June 30, 2024	December 31, 2023
Cash, cash equivalents and marketable securities	$ 646,793	$ 753,184
Total assets	697,105	882,277
Total liabilities	69,043	82,747
Total stockholders' equity	628,062	799,530

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023

Product revenue, net	$ 600	$ 2,460	$ 2,289	$ 5,754
Collaboration revenue - related party	7,420	-	13,633	-
Other collaboration revenue	634	14	634	14
Total revenues	8,654	2,474	16,556	5,768
Operating costs and expenses:				
Cost of revenues	1,407	205	2,676	435
Research and development	62,564	97,161	134,297	189,987
Selling, general and administrative	55,983	75,565	108,556	141,273
Total operating costs and expenses	119,954	172,931	245,529	331,695
Loss from operations	(111,300)	(170,457)	(228,973)	(325,927)
Interest income, net	8,431	10,173	17,634	19,003
Other income (expense), net	15	(41)	2	(229)
Net loss	$ (102,854)	$ (160,325)	$ (211,337)	$ (307,153)
Net loss per share - basic and diluted	$ (1.70)	$ (2.68)	$ (3.50)	$ (5.14)
Weighted average shares outstanding - basic and diluted	60,538,319	59,769,640	60,337,258	59,722,147

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/20240731771837/en/

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