Sage Therapeutics Implements Strategic Reorganization to Support Plans for ZURZUVAE™ Commercial Launch and Pipeline Advancement

August 31, 2023

Potential growth catalysts include planned 4Q 2023 launch of ZURZUVAE (zuranolone) and expected data read-outs for SAGE-718 and SAGE-324 in 2024

Approximately 40% workforce reduction supports focus on agile execution of business priorities

Strengthened financial position with expected annualized net savings of approximately $240 million anticipated to extend cash runway into 2026

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Aug. 31, 2023-- Sage Therapeutics, Inc. (Nasdaq: SAGE), today announced plans to reorganize its business operations and pipeline priorities to support goals for long-term business growth, including the planned commercial launch of ZURZUVAE for women with postpartum depression (PPD) in late 2023.

“Our goal is to think big, start small and scale fast as we look to launch ZURZUVAE and help women suffering with PPD. Executing on launch and our potential long-term growth catalysts requires us to allocate resources strategically,” said Barry Greene, Chief Executive Officer at Sage Therapeutics. “Part of our efforts to become a leaner and stronger company means having to reorganize our workforce. The departing employees contributed so much to our mission and I’m grateful for their incredible dedication to helping patients. Our business fundamentals are strong, we are well capitalized, and our goal is to put Sage in a solid position to optimize commercial execution and develop our pipeline with the goal of significant value creation.”

Following a strategic review, the company will:

- Refine pipeline development efforts to advance SAGE-718 and SAGE-324, as well as pause certain earlier-stage programs, with the goal of making evidence-driven investments
- Implement a ~40% workforce reduction designed to right-size the organization as the company works to achieve sustained growth and allow for commercial hires to support the goal of a successful launch of ZURZUVAE to treat women with PPD
- Align its leadership team structure to scale with pipeline and commercial priorities

The changes to Sage’s leadership team are designed to help support the company’s future priorities. Al Robichaud, Sage’s Chief Scientific Officer since its founding in 2011, has decided to depart Sage. Al will remain as a scientific consultant and member of Sage’s Medicinal Chemistry and Pre-Clinical Scientific Advisory Boards. Mike Quirk will be promoted from SVP of Discovery Research to Chief Scientific Officer. In his new role, Dr. Quirk will lead Sage’s Research and Non-Clinical Development organizations. Jim Doherty, Chief Development Officer, also a founding member of Sage, will leave the company to pursue new opportunities. Both Dr. Robichaud and Dr. Doherty were pivotal in the development of the scientific platforms that established the company’s robust brain health pipeline. Both leaders played key roles in helping move the company’s two approved compounds from early discovery through approval. Laura Gault, Chief Medical Officer, will assume Dr. Doherty’s responsibilities.

Chris Benecchi, Chief Business Officer, will oversee Medical Affairs following the departure of Mark Pollack, SVP of Medical Affairs who is leaving to pursue new opportunities. Dr. Pollack is a recognized thought leader in the psychiatric field and made significant contributions to Sage’s medical thought leader engagement strategy since joining Sage over a year ago.

“Our new Chief Scientific Officer, Mike, has been with Sage for almost a decade and will apply his deep knowledge of our science and relentless commitment to innovation on behalf of patients,” added Mr. Greene. “I also want to express my sincere gratitude for the exceptional impact that Al, Jim, and Mark have made for the company and for patients. Al and Jim have been with us from the very beginning and have inspired us all to push forward in some of the most challenging and rewarding areas of drug discovery and development.”

The reorganization plan is intended to enable Sage to strengthen its balance sheet and position the company for long-term growth potential. Based on the post-reorganization operating plan which includes Sage’s pipeline prioritization, workforce reduction, and additional incremental commercial hires, the company expects:

- Annualized net savings of approximately $240 million, of which 60% is related to R&D
- A non-recurring charge of approximately $36 million to $38 million associated with the reorganization, primarily incurred in the third quarter of 2023
- The potential to earn a milestone payment of $75 million from Biogen related to the first commercial sale of ZURZUVAE for the treatment of PPD
- Cash, cash equivalents, and marketable securities of approximately $1.0 billion as of June 30, 2023 along with anticipated funding from ongoing collaborations and potential revenue will support operations into 2026

About Sage Therapeutics

Sage Therapeutics is a biopharmaceutical company fearlessly leading the way to create a world with better brain health. Our mission is to pioneer solutions to deliver life-changing brain health medicines, so every person can thrive. For more information, please visit www.sagerx.com.

Sage Therapeutics Safe Harbor

Various statements in this release concern Sage's future expectations, plans and prospects, including without limitation our statements regarding: the potential cost savings from our reorganization; the amount and timing of the expected non-recurring charge associated with our reorganization; our expectations that the cost savings from the restructuring will help support commercial launch, advance our late-stage pipeline and strengthen our financial position; our expectations regarding our cash runway; our expectations as to the timing of planned launch of ZURZUVAE in the treatment of women with PPD; the potential for a milestone payment related to first commercial sale; our goals for the launch and the potential for success; potential growth catalysts for our business and the potential for sustainable long-term growth; and 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: we may not realize expected cost savings from the reorganization, including the anticipated decrease in spend, at the levels we expect; we may realize additional charges or expenses associated with the reorganization; the internal and external costs required for our ongoing, planned and other future activities, and the resulting impact on expense and use of cash, may be higher than expected which may cause us to use cash more quickly than we expect or change or curtail some of our plans, or both; our expectations as to expenses, cash usage, potential revenue, funding from collaborations, including milestones, cash runway and cash needs may prove not to be correct for other reasons such as changes in plans or actual events being different than our assumptions; we may be opportunistic in our future financing plans even if available cash is sufficient; 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 at the levels or on the timing we expect or at levels or on the timing necessary to support our goals; the number of women with PPD, the unmet need for additional treatment options, and the potential market for ZURZUVAE in this indication may be significantly smaller than we expect; ZURZUVAE may not achieve the clinical benefit, clinical use or market acceptance we expect in the treatment of women with PPD or we may encounter reimbursement-related or other market-related issues that impact the success of our commercialization efforts; we may never achieve regulatory approval of zuranolone in MDD; the FDA has taken the position that an additional clinical trial or clinical trials of zuranolone are required to support approval in MDD and may not change that position; such trial or trials could be time-consuming, significantly increase our expenses, and may not be feasible; even if we conduct such clinical trials, they may not be successful; the FDA may decide that the design, conduct or results of such clinical trials, even if positive, are not sufficient for approval in MDD or may find other deficiencies in our development program, data, processes, or manufacturing sites; even if we receive regulatory approval of zuranolone for the treatment of MDD, the FDA may approve zuranolone for only a subset of MDD patients or with limitations or restrictions; we may not be successful in our development of any of our product candidates in any indication we are currently pursuing or may in the future pursue; success in our non-clinical studies or in earlier clinical trials may not be repeated or observed in ongoing or future studies, and ongoing and future non-clinical and clinical results may not meet their primary or key secondary endpoints or be sufficient to file for or gain regulatory approval to market the product without further development work or may not support further development at all; we may encounter delays in conduct of our ongoing clinical trials, including slower than expected site initiation or enrollment, that may impact our ability to meet our expected time-lines and increase our costs; we may encounter adverse events for ZURZUVAE at any stage that negatively impact commercialization in women with PPD; we may encounter adverse events for any of our product candidates that impact further development or the potential for future regulatory approval; decisions or actions of the FDA may affect the initiation, timing, design, size, progress, cost and potential for success of clinical trials of our product candidates and our ability to proceed with further development or may impair the potential for successful development; the need to align with our collaborators may hamper or delay our development and commercialization efforts or increase our costs; and 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; as well as those risks more fully discussed in the section entitled "Risk Factors" in our most recent quarterly report, 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.

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