UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of The Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): August 7, 2023

Sage Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

DELAWARE	001-36544	27-4486580
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

215 First Street Cambridge, MA	02142
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code (617) 299-8380

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	SAGE	The Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition

On August 7, 2023, Sage Therapeutics, Inc. announced its financial results for the quarter ended June 30, 2023. A copy of the press release is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Current Report on Form 8-K and Exhibit 99.1 attached hereto is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by Sage Therapeutics, Inc. on August 7, 2023, furnished herewith.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: August 7, 2023

SAGE THERAPEUTICS, INC.

By: /s/ Jennifer Fitzpatrick
Jennifer Fitzpatrick
Vice President, Corporate Counsel

Exhibit 99.1

Sage Therapeutics Announces Second Quarter 2023 Financial Results and Highlights Pipeline and Business Progress

ZURZUVAE™ (zuranolone) approved as first-and-only oral treatment specifically indicated for adults with postpartum depression (PPD) and on-track for planned launch in the fourth quarter of 2023 shortly after DEA scheduling

Sage brain health pipeline provides potential for significant long-term value creation

Remain well capitalized with $1.0 billion of cash, cash equivalents and marketable securities as of June 30, 2023

CAMBRIDGE, Mass. – August 7, 2023 – 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, 2023.

“We are currently at a tipping point with the burden and prevalence of brain health conditions accelerating at an alarming rate. The need has never been greater than it is today and our team is singularly focused on changing the trajectory of these devastating diseases through our development efforts and novel pipeline,” said Barry Greene, Chief Executive Officer at Sage Therapeutics. “We were delighted to receive U.S. Food and Drug Administration (FDA) approval for ZURZUVAE as the first-and-only oral treatment specifically indicated for adults with postpartum depression (PPD), the most common medical complication of childbirth. We believe the need for new treatment options for women with PPD is a significant medical need and presents a strong business opportunity. While we were very disappointed by the recent Complete Response Letter (CRL) we received from the FDA regarding zuranolone in the treatment of major depressive disorder (MDD), we are reviewing the feedback from the FDA and evaluating next steps.”

“While we believe we are well capitalized, given the impact of the CRL for zuranolone in MDD on our plans, we are currently evaluating resource allocation, including pipeline prioritization and a workforce reorganization with a goal of extending our cash runway. With a right-sized organization and portfolio, we believe we have an opportunity to emerge as an even stronger company. We plan to provide greater detail and next steps before the end of the third quarter,” continued Mr. Greene.

Second Quarter 2023 Portfolio Updates

Sage is advancing a portfolio of clinical-stage programs with internally discovered novel chemical entities that have the potential to address urgent unmet needs in 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.

Depression Franchise

ZURZUVAE was approved by the FDA in August 2023 as the first-and-only oral treatment specifically indicated for adults with PPD. Zuranolone is a next-generation positive allosteric modulator (PAM) of $GABA_A$ receptors being evaluated as a treatment for various affective disorders in collaboration with Biogen Inc. Sage also commercializes ZULRESSO® (brexanolone) CIV injection in the treatment of PPD.

ZURZUVAE is expected to be commercially available for adults with PPD in the fourth quarter of 2023 shortly following scheduling by the U.S. Drug Enforcement Administration (DEA), which is expected to occur within 90 days.

Sage also announced that the FDA issued a CRL for the New Drug Application (NDA) seeking approval of zuranolone as a treatment for MDD.

In the CRL, the FDA stated that the application did not provide substantial evidence of effectiveness to support the approval of zuranolone for the treatment of MDD and that an additional study or studies will be needed. Sage and Biogen are reviewing the feedback from the FDA and are evaluating next steps.

Today, Sage also announced additional data from the open-label SHORELINE Study in MDD, specifically from the cohort of patients (n=277) that rolled over into the SHORELINE Study from the CORAL Study. In this cohort, the adverse event profile and the data generated on repeat treatments were similar to previously reported data from other cohorts of the SHORELINE Study, with no new safety signals identified. Sage plans to present further analyses from the SHORELINE Study at future medical congresses.

The Company expects the following milestones in its Depression franchise in late 2023:

- Commercial availability of ZURZUVAE in the treatment of adults with PPD in the fourth quarter of 2023 shortly following DEA scheduling
- Present additional analyses of data from LANDSCAPE and NEST clinical programs, including health economics and patient reported outcomes

Neuropsychiatry Franchise

SAGE-718, the Company's first-in-class NMDA receptor PAM and lead neuropsychiatric drug candidate, is in development as a potential oral therapy for cognitive disorders associated with NMDA receptor dysfunction, including Huntington's disease (HD), Parkinson's disease (PD) and Alzheimer's disease (AD). SAGE-718 has received Fast Track Designation from the FDA and Orphan Drug Designation from the European Medicines Agency (EMA) for the potential treatment of HD.

Sage is advancing a robust clinical program for SAGE-718 and is currently enrolling in the following studies with data read-outs expected to begin in 2024:

- DIMENSION (CIH-201) Study: The DIMENSION Study is a double-blind, placebo-controlled Phase 2 study in people with HD cognitive impairment. The study is designed to evaluate the efficacy of once-daily SAGE-718 dosed over three months, with a target enrollment of approximately 178 people. Sage expects the DIMENSION Study to include more than 40 clinical sites.
- SURVEYOR (CIH-202) Study: The SURVEYOR Study is a double-blind, placebo-controlled Phase 2 study in people with HD cognitive impairment and healthy volunteers, with the goal of generating evidence linking efficacy signals on cognitive performance to domains of real-world functioning.
- PURVIEW (CIH-301) Study: The PURVIEW Study is an open-label Phase 3 safety study of SAGE-718 in people with HD cognitive impairment. The study is designed to evaluate the long-term safety profile and benchmark performance against HD natural history studies.
- PRECEDENT (CNP-202) Study: The PRECEDENT Study is a double-blind, placebo-controlled Phase 2 study in people with mild cognitive impairment due to PD. The study is designed to evaluate the safety and efficacy of SAGE-718 dosed over 42 days, followed by a controlled follow-up period.
- LIGHTWAVE (can-202) Study: The LIGHTWAVE Study is a double-blind, placebo-controlled Phase 2 study of SAGE-718 in people with MCI and mild dementia due to AD. The study is designed to evaluate the safety and efficacy of SAGE-718 dosed over an 84-day period, followed by a controlled follow-up period.

The Company expects the following milestones in neuropsychiatry in 2023:

- Progress recruitment in the ongoing DIMENSION, SURVEYOR, PURVIEW, PRECEDENT, and LIGHTWAVE Studies
- Present additional analyses of data on disease state and burden of disease research in Huntington's, Parkinson's and Alzheimer's diseases

Neurology Franchise

Sage's lead neurology drug candidates include SAGE-324 and SAGE-689. SAGE-324, a next-generation PAM of $GABA_A$ receptors and Sage's lead neurology program, is in development as a potential oral therapy for movement disorders, such as essential tremor (ET), epilepsy and PD. SAGE-689, a Sage wholly-owned program, is an intramuscular balanced $GABA_A$ receptor PAM in development as a potential therapy for disorders associated with GABA hypofunction.

Sage and its collaborator, Biogen, are actively enrolling participants in the Phase 2b KINETIC 2 placebo-controlled study of SAGE-324 in ET following positive results from the KINETIC Study. The KINETIC 2 Study is a Phase 2b dose-ranging study with the primary goal of defining the dose for SAGE-324 in ET with a good tolerability profile and a dosing schedule to maintain plasma concentrations needed for sustained tremor symptom control in treating ET. Enrollment in the KINETIC 2 Study is targeted for completion in late 2023.

Sage is also currently 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 of the open-label study is incidence of treatment-emergent adverse events.

SAGE-689 continues in Phase 1 development.

The Company expects the following milestones in neurology in 2023:

Late 2023:

- Targeted completion of enrollment in the Phase 2b KINETIC 2 Study
- Present additional analyses of data from clinical development program as well as disease state and burden of disease research in ET

Early Development

Sage continues to progress its early development programs, SAGE-319 and SAGE-421. SAGE-319 is currently in Phase 1 studies and IND-enabling work is underway for SAGE-421.

- **SAGE-319:** an oral, extra-synaptic preferring $GABA_A$ receptor PAM that Sage plans to study for potential use in disorders of social interaction.
- **SAGE-421:** an oral, NMDA receptor PAM that Sage plans to study for potential use in neurodevelopmental disorders and cognitive recovery and rehabilitation.

FINANCIAL RESULTS FOR THE SECOND QUARTER 2023

- **Cash Position:** Cash, cash equivalents and marketable securities as of June 30, 2023, were $1.0 billion compared to $1.1 billion at March 31, 2023.
- **Revenue:** Net revenue from sales of ZULRESSO was $2.5 million in the second quarter of 2023 compared to $1.5 million in the same period of 2022.
- **R&D Expenses:** Research and development expenses were $97.2 million, including $4.5 million of non-cash stock-based compensation expense, in the second quarter of 2023 compared to $77.3 million, including $6.5 million of non-cash stock-based compensation expense, in the same period of 2022. The increase in spending was primarily due to an increase in the hiring of employees and corporate infrastructure costs, such as information technology costs, to support

the growth in our research and development operations. The reimbursement from Biogen to Sage for R&D expenses pursuant to the Sage/Biogen Collaboration and License Agreement was $22.4 million in the second quarter of 2023 compared to $21.0 million in the same period of 2022.

- **SG&A Expenses:** Selling, general and administrative expenses were $75.6 million, including $7.2 million of non-cash stock-based compensation expense, in the second quarter of 2023 compared to $52.4 million, including $8.2 million of non-cash stock-based compensation expense, in the same period of 2022. The increase in SG&A expenses was primarily due to hiring employees to support ongoing activities in anticipation of the potential launch of zuranolone. The reimbursement from Sage to Biogen for SG&A expenses pursuant to the Sage/Biogen Collaboration and License Agreement was $7.5 million in the second quarter of 2023 compared to $2.8 million of reimbursement from Biogen to Sage in the same period of 2022. The primary reason for the decrease in net reimbursement was an increase in the collaboration costs incurred by Biogen in anticipation of a potential commercialization of zuranolone.
- **Net Loss:** Net loss was $160.3 million in the second quarter of 2023 compared to $126.3 million in the same period of 2022.

FINANCIAL GUIDANCE

- Based upon Sage's current estimates, Sage expects that its current cash, cash equivalents and marketable securities, along with anticipated funding from ongoing collaborations and potential revenue, will support its operations into 2025.
- Additionally, Sage is evaluating resource allocation, including pipeline prioritization and a workforce reorganization, with a goal of extending its cash runway and anticipates operating expenses will decrease in 2024.
- We have the potential to earn a milestone payment of $75.0 million from Biogen related to the first commercial sale of ZURZUVAE for the treatment of PPD.

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 http://www.sagerx.com.

Forward-Looking Statements

Various statements in this release concern Sage's future expectations, plans and prospects, including without limitation our statements regarding: the completion of DEA scheduling, plans for launch, availability and commercialization of ZURZUVAE as a treatment for women with PPD, and potential timing of such activities; our belief in the business case in PPD and our readiness for commercial launch of ZURZUVAE in this indication; our plans to review the CRL received with respect to zuranolone for the treatment of MDD and evaluation of next steps; the potential benefit of ZURZUVAE in the treatment of women with PPD; the number of women with PPD and the potential market for ZURZUVAE for the treatment of women with PPD; our belief in the potential of ZURZUVAE to be successful and to meet an unmet need in the treatment of women with PPD, anticipated timelines for commencement of trials, completion of enrollment, initiation of new activities and other plans for our other programs and early stage pipeline; 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; the potential for value creation opportunities; the mission and goals for our business; our anticipated cash runway and plans to evaluate resource allocation and a reorganization with a goal of extending the cash runway and becoming a stronger company; and our expectations with respect to potential receipt of milestones from collaborations, potential future revenue, funding of future operations, and a potential decrease in expenses. 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 at the levels or on the timing we expect or at levels or on the timing necessary to support our goals; the number of patients with the diseases or disorders for which our products are developed and approved, the unmet need for additional treatment options, and the potential market for ZURZUVAE in women with PPD, or for any other future products, if successfully developed, may be significantly smaller than we expect; ZURZUVAE or any other products that we may successfully develop in the future, may not achieve the clinical benefit, clinical use or market acceptance we expect 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 for zuranolone in MDD; the FDA has taken the position that one or more additional clinical trials of zuranolone are required to support approval in MDD, and even if we appeal this decision in the future, the FDA 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 our clinical trials for zuranolone, 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; even if we run additional clinical trials to try to obtain approval of zuranolone in MDD or with respect to clinical trials for our other product candidates, we may encounter delays in initiation, conduct, completion of enrollment or completion of any such 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 zuranolone or 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; unexpected concerns may arise from additional data, analysis or results from any of our completed studies; decisions or actions of the FDA may affect the initiation, timing, design, size, progress and cost of clinical trials 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; the anticipated benefits of our ongoing collaborations, including the receipt of milestone payments or the successful development or commercialization of products and generation of revenue, may never be achieved; 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; and 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 use cash more quickly than we expect or to change or curtail some of our plans or both; 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, and our plans to evaluate resource allocation with the goal of extending our cash runway may not be successful or actually extend our cash runway; we may never be able to generate meaningful revenues from sales of ZULRESSO or to generate revenues at levels we expect or at levels necessary to justify our investment; we may not be successful in our efforts to gain regulatory approval of products beyond ZURZUVAE and ZULRESSO; we may not achieve revenues from other of our products that may be successfully developed in the future, at levels we expect; our expectations as to cash runway, the sufficiency of cash to fund future operations and expense levels may prove not to be correct for these and 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; additional funding may not be available on acceptable terms when we need it; 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, 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, 2023	December 31, 2022
Cash, cash equivalents and marketable securities	$1,002,616	$ 1,272,494
Total assets	1,082,288	1,356,449
Total liabilities	97,912	103,850
Total stockholders' equity	984,376	1,252,599

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,	
	2023	2022	2023	2022
Product revenue, net	$ 2,460	$ 1,501	$ 5,754	$ 3,082
Collaboration revenue	14	—	14	—
Total revenue	2,474	1,501	5,768	3,082
Operating costs and expenses:				
Cost of goods sold	205	200	435	486
Research and development	97,161	77,297	189,987	155,315
Selling, general and administrative	75,565	52,411	141,273	98,888
Total operating costs and expenses	172,931	129,908	331,695	254,689
Loss from operations	(170,457)	(128,407)	(325,927)	(251,607)
Interest income, net	10,173	2,102	19,003	3,270
Other income (expense), net	(41)	45	(229)	22
Net loss	$ (160,325)	$ (126,260)	$ (307,153)	$ (248,315)
Net loss per share - basic and diluted	$ (2.68)	$ (2.13)	$ (5.14)	$ (4.20)
Weighted average shares outstanding - basic and diluted	59,769,640	59,266,322	59,722,147	59,148,246

ZURZUVAE (zuranolone) IMPORTANT SAFETY INFORMATION

What is the most important information I should know about ZURZUVAE?

ZURZUVAE may cause serious side effects, including:

- **Decreased ability to drive or do other dangerous activities.** ZURZUVAE may decrease your 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** during your 14-day treatment course of ZURZUVAE.
  - You may not be able to tell on your own if you can drive safely or tell how much ZURZUVAE is affecting you.

- **Decreased awareness and alertness [central nervous system (CNS) depressant effects].** ZURZUVAE may cause sleepiness, drowsiness, slow thinking, dizziness, confusion, and trouble walking.
    - Because of these symptoms, you may be at a higher risk for falls during treatment with ZURZUVAE.
    - Taking alcohol, other medicines that cause CNS depressant effects, or opioids while taking ZURZUVAE can make these symptoms worse and may also cause trouble breathing.
    - Tell your healthcare provider if you develop any of these symptoms, or if they get worse during treatment with ZURZUVAE. Your healthcare provider may decrease your dose or stop ZURZUVAE treatment if you develop these symptoms.

ZURZUVAE is a federally controlled substance (C-XX) because it contains zuranolone that can be abused or lead to dependence. Keep ZURZUVAE in a safe place to protect it from theft. Do not sell or give away ZURZUVAE because it may harm others and is against the law.

Before taking ZURZUVAE, tell your healthcare provider about all of your medical conditions, including if you:

- drink alcohol
- have abused or been dependent on prescription medicines, street drugs, or alcohol
- have liver or kidney problems
- are pregnant or plan to become pregnant. ZURZUVAE may harm your unborn baby.
- are breastfeeding or plan to breastfeed. ZURZUVAE passes into breast milk, and it is not known if it can harm your baby. Talk to your healthcare provider about the risks and benefits of breastfeeding and about the best way to feed your baby during treatment with ZURZUVAE.

Females who are able to become pregnant:

- Tell your healthcare provider right away if you 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.
- There is a pregnancy registry for females who are exposed to ZURZUVAE during pregnancy. The purpose of the registry is to collect information about the health of females exposed to ZURZUVAE and their baby. If you become pregnant during treatment with ZURZUVAE, talk to your healthcare provider about registering with the National Pregnancy Registry for Antidepressants at 1-844-405-6185 or visit online at https://womensmentalhealth.org/research/pregnancyregistry/antidepressants/.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. ZURZUVAE and some medicines may interact with each other and cause serious side effects. ZURZUVAE may affect the way other medicines work and other medicines may affect the way ZURZUVAE works.

Especially tell your healthcare provider if you take antidepressants, opioids, or CNS depressants such as benzodiazepines.

What should I avoid while taking ZURZUVAE?

- **Do not** drive a car, operate machinery, or do other dangerous activities **until at least 12 hours after taking each dose of ZURZUVAE** because ZURZUVAE may make you feel sleepy, confused, or dizzy.
- **Do not** drink alcohol or take other medicines that make you sleepy or dizzy while taking ZURZUVAE without talking to your healthcare provider.

See “**What is the most important information I should know about ZURZUVAE?”**

ZURZUVAE may cause serious side effects, including:

- See "**What is the most important information I should know about ZURZUVAE?**"
- **Increased risk of suicidal thoughts or actions.** 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.**

How can I watch for and try to prevent suicidal thoughts and actions?

- Pay close attention to any changes, especially sudden changes in mood, behavior, thoughts, or feelings, or if you develop suicidal thoughts or actions. This is very important when an antidepressant medicine is started or when the dose is changed.
- Tell your healthcare provider right away if you have any new or sudden changes in mood, behavior, thoughts, or feelings.
- Keep all follow-up visits with your healthcare provider as scheduled. Call your healthcare provider between visits as needed, especially if you have concerns about symptoms.

Tell your healthcare provider right away if you have any of the following symptoms, especially if they are new, worse, or worry you:

- attempts to commit suicide
- thoughts about suicide or dying
- new or worse depression
- feeling very agitated or restless
- trouble sleeping (insomnia)
- new or worse anxiety
- panic attacks
- new or worse irritability
- acting aggressive, being angry, or violent
- an extreme increase in activity and talking (mania)
- acting on dangerous impulses
- other unusual changes in behavior or mood

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

These are not all of the possible side effects of ZURZUVAE. Call your doctor for medical advice about side effects. You can report side effects to FDA at 1-800-FDA-1088 or. www.fda.gov/medwatch.

Please see the Full Prescribing Information, including Boxed WARNING, and Medication Guide for ZURZUVAE.

ZULRESSO (brexanolone) SELECT IMPORTANT SAFETY INFORMATION

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)

Controlled Substance: ZULRESSO contains brexanolone, a Schedule IV controlled substance under the Controlled Substances Act.

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.

Investor Contact
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