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): November 2, 2021

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 November 2, 2021, Sage Therapeutics, Inc. announced its financial results for the quarter ended September 30, 2021. 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 November 2, 2021, 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: November 2, 2021

SAGE THERAPEUTICS, INC.

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

Sage Therapeutics Announces Third Quarter 2021 Financial Results and Highlights Pipeline and Business Progress

NDA submission for zuranolone for the treatment of MDD expected to be filed in the second half of 2022, with rolling submission planned to begin in early 2022

CORAL Study primary endpoint updated, in line with goal of study to demonstrate rapid reduction in depressive symptoms and benefits throughout treatment period when co-initiated with standard antidepressants

Continued pipeline progress demonstrated across brain health franchises, with plans to initiate three Phase 2 studies across SAGE-324 and SAGE-718 programs

Conference call today at 8:00 a.m. ET

CAMBRIDGE, Mass. – Nov. 2, 2021 – Today, Sage Therapeutics, Inc. (Nasdaq: SAGE), a biopharmaceutical company committed to developing novel therapies with the potential to transform the lives of people with debilitating disorders of the brain, reported business highlights and financial results for the third quarter ended September 30, 2021.

"I'm proud of the substantial progress we've made this quarter, including a successful pre-NDA meeting with the FDA for zuranolone. We're excited to have reached alignment with the Agency and to have what we believe is a clear, efficient path forward for zuranolone. We're now one step closer toward our goal of helping people living with MDD and PPD by bringing them a treatment that in clinical development to date has demonstrated rapid and sustained reductions in depressive symptoms with a well-tolerated safety profile," said Barry Greene, chief executive officer at Sage Therapeutics. "It is an exciting time here at Sage, and I look forward to sharing additional updates as we progress with our work on the NDA filing for zuranolone, as well as expected initiation of three new Phase 2 studies for SAGE-324 and SAGE-718."

Third Quarter 2021 and Recent Portfolio Updates

Sage is advancing a portfolio of clinical 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.

Depression Franchise

Sage's depression franchise features zuranolone, Sage's next-generation positive allosteric modulator (PAM) of $GABA_A$ receptors being evaluated in clinical development as a treatment for various affective disorders, and ZULRESSO® (brexanolone) CIV injection, approved by the U.S. Food and Drug Administration (FDA) as the first treatment specifically indicated for postpartum depression (PPD). Zuranolone has received breakthrough therapy designation from the FDA for the treatment of major depressive disorder (MDD).

Zuranolone is being evaluated as a potential rapid-acting, durable, once-daily, two-week treatment for MDD and PPD in the LANDSCAPE and NEST clinical development programs, respectively. Sage and Biogen recently announced their plan to submit a New Drug Application (NDA) to the FDA for zuranolone in the second half of 2022. The planned initial submission package will seek approval of zuranolone for the treatment of MDD and an additional filing for PPD is anticipated in the first half of 2023. The decision to submit the application follows recent discussions with the FDA, including a pre-NDA meeting held this fall.

The meeting reinforced Sage's belief that data from the MDD-201, ROBIN, and WATERFALL Studies and the Shionogi Phase 2 study along with supportive data from the MOUNTAIN Study will be sufficient for Sage to file in MDD. The planned initial NDA will focus on MDD and will also include data from the ongoing pharmacology and clinical studies (CORAL and SHORELINE Studies). An additional associated NDA for PPD is expected to be filed following the SKYLARK Study readout. If planned efforts are successful and zuranolone is approved, Sage and its collaboration partner, Biogen, plan to commence marketing for the approved indications as soon as possible. The review cycles may potentially allow commercialization of both indications simultaneously, if approved.

Additionally, Sage today announced that the primary endpoint for the CORAL Study (HAMD-17 change from baseline) will be measured at Day 3. The CORAL Study is an adjunctive use study in MDD designed to demonstrate the benefit of zuranolone when co-initiated with a new antidepressant therapy, including rapid reduction in depressive symptoms as well as benefits across the treatment period with a well-tolerated safety profile. The Company believes that, if successful, the Day 3 primary endpoint and key secondary endpoints, including other timepoints, will provide additional data that may be important to inform real world use in MDD if zuranolone is approved.

In October, Sage and Biogen announced that data presented at the 34th European College of Neuropsychopharmacology (ECNP) Congress further support the differentiated profile seen to date with zuranolone in clinical development, including a rapid and sustained reduction in depressive symptoms and a unique and well-tolerated safety profile. Further, in a pooled analysis from the LANDSCAPE and NEST programs, zuranolone treatment led to rapid and sustained improvement in quality of life and overall health and well-being at Day 15 that continued to increase through Day 42, as measured by SF-36v2, a patient self-reported measure of general health. Sage also presented data at the 34th Psych Congress showing that zuranolone demonstrated rapid improvements across HAMD-17 subscales measuring the core symptoms of depression as well as symptoms of anxiety in the WATERFALL Study. These findings are consistent with the totality of data across the LANDSCAPE and NEST clinical programs. As a complement, Sage presented analyses demonstrating that zuranolone treatment led to rapid improvements in functional impairment and improvements in depressive symptoms across patient populations (e.g., age, gender, body mass index) at Day 15 and regardless of whether patients were receiving zuranolone as monotherapy or concomitantly with a standard of care antidepressant.

Sage also announced that it plans to initiate an open-label study designed to demonstrate the safe-use administration of ZULRESSO in a patient's home in the treatment of PPD. The study is expected to enroll an estimated 50 patients and is anticipated to be completed in 2022.

The Company expects the following milestones across the depression franchise in 2021 and 2022:

- Late 2021:
  - SHORELINE (MDD-303) Study 50 mg Cohort (1-year data cut): An open-label Phase 3 study designed to naturalistically follow patients with MDD and evaluate the safety and tolerability of zuranolone 50 mg in adults for up to one year. Topline results from the 1-year data cut of a 50 mg cohort are expected in late 2021. The SHORELINE Study is expected to remain open as patients may enroll following their completion of the CORAL Study.
- Early 2022
  - CORAL (MDD-305) Study: A placebo-controlled Phase 3 study evaluating a two-week course of zuranolone 50 mg, when co-initiated with a new antidepressant, in patients with MDD, with additional short-term follow-up. Sage expects to report topline data in early 2022.
- Mid-2022:
  - SKYLARK (PPD-301) Study: Sage expects to report topline data from the placebo-controlled Phase 3 study evaluating a two-week course of zuranolone 50 mg in women with PPD, with additional short-term follow-up, in mid-2022.

Neurology Franchise

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 neurological conditions, such as essential tremor (ET), epilepsy and Parkinson's disease (PD).

In the third quarter, Sage and Biogen advanced plans to initiate a Phase 2 dose-ranging study for SAGE-324 in ET in late 2021 with the goal of optimizing dosing to maintain plasma concentrations intended to translate into sustained tremor symptom control. In the KINETIC Phase 2 placebo-controlled study, SAGE-324 demonstrated a statistically significant reduction from baseline in the TETRAS Item 4 upper limb tremor score at Day 29 in the total studied population compared to placebo and a statistically significant correlation between TETRAS tremor score and activities of daily living at all measured time points.

The Company expects the following milestones across the neurology franchise in 2021:

- Late 2021:
    - Phase 2 Study in ET: Sage and Biogen anticipate initiating a placebo-controlled Phase 2 dose-ranging study in SAGE-324 for ET designed to optimize the dose and frequency in late 2021.

Neuropsychiatry Franchise

SAGE-718, Sage'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, potentially including Huntington's disease (HD), Parkinson's disease (PD) and Alzheimer's disease (AD).

SAGE-718 is currently being studied in the 4-week dosing cohort, or part B, of the PARADIGM Study, a Phase 2a open-label study in patients aged 50 to 75 years old with mild cognitive impairment due to PD and the LUMINARY Study, a Phase 2a open-label study evaluating SAGE-718 in patients with AD mild cognitive impairment and mild dementia.

In the third quarter, SAGE-718 received Fast Track Designation for development as a potential treatment for HD. The Company plans to initiate a placebo-controlled Phase 2 study of SAGE-718 in patients with early to moderate HD in late 2021. Also, Sage today announced plans to initiate a second placebo-controlled Phase 2 Study with SAGE-718 in patients with PD mild cognitive impairment in 2022.

The Company expects the following milestones across the neuropsychiatry franchise in 2021 and 2022:

- Late 2021:
    - LUMINARY (718-CNA-201) Study**:** The LUMINARY Study is fully enrolled, and the Company anticipates topline data from the study in late 2021.
    - Phase 2 Study in HD: The Company is on track to initiate a placebo-controlled Phase 2 study with SAGE-718 in early to moderate HD in late 2021.
- 2022:
    - Phase 2 Study in PD: The Company plans to initiate a placebo-controlled Phase 2 Study with SAGE-718 in PD mild cognitive impairment in 2022.

Early Development

Sage expects to complete certain ongoing Phase 1 clinical studies for two programs in its early development pipeline in late 2021, SAGE-689 (single ascending dose) and SAGE-904 (single ascending dose). The multiple ascending dose study for SAGE-904 is also ongoing. Results from the Phase 1 studies will inform further development of these programs.

- **SAGE-689:** an intramuscular $GABA_A$ receptor PAM in development as a potential therapy for disorders associated with acute GABA hypofunction. The first patient was dosed in the SAGE-689 Phase 1 single ascending dose study earlier this year.

- **SAGE-904:** Sage's second NMDA receptor PAM product candidate in development as a potential oral therapy for disorders associated with NMDA hypofunction. The first patient was dosed in the continued SAGE-904 Phase 1 studies earlier this year.

Additionally, IND-enabling work is underway for SAGE-319.

- **SAGE-319**: an oral, extrasynaptic $GABA_A$ receptor preferring PAM that Sage plans to study for potential use in disorders of social interaction.

The Company now plans to advance SAGE-421 to preclinical studies in 2022.

- **SAGE-421:** an oral, NMDA receptor PAM that Sage plans to study for potential use in neurodevelopmental disorders and cognitive recovery and rehabilitation.

Business Updates

During the third quarter, the Company strengthened its leadership with key changes:

- Chris Benecchi, MBA, joined Sage as Chief Commercial Officer. Chris will lead Sage's global commercial efforts across all Sage programs, new product planning, strategy, and competitive intelligence.
- Jim Doherty, Ph.D., assumed the role of Chief Development Officer. Jim will continue to drive expansion and acceleration of Sage's development programs and lead the Research and Development Leadership Team.
- Mike Quirk, Ph.D., promoted to Senior Vice President of Discovery Research. As part of his new role, Mike will continue to build the necessary research expertise to position Sage to deliver on the Company's goal of delivering two IND enabling programs per year by 2023. Mike brings more than 20 years of experience in biopharmaceutical drug discovery and development solving biological and translational science problems in psychiatry, neurology, and pain.
- Vanessa Procter promoted to Senior Vice President, External Affairs and joined the executive leadership team. As part of her new role, Vanessa will build and lead a new external affairs capability within Sage. Vanessa has more than 20 years of experience navigating corporate policy, advocacy, and political spheres to deliver tangible business results.
- Steve Kanes, M.D., resigned as Sage's Chief Medical Officer. Steve is pursuing a new opportunity as a Chief Executive Officer at a private biotechnology company.

ANTICIPATED 2021 AND 2022 MILESTONES

Late 2021:

- Zuranolone:
  - Report topline data cut from Phase 3 SHORELINE Study 50 mg cohort in MDD
- SAGE-324:
  - Initiate Phase 2 dose-ranging study in ET
- SAGE-718:
  - Report topline data from Phase 2a LUMINARY open-label, signal finding study in patients with AD mild cognitive impairment and mild dementia
  - Initiate placebo-controlled Phase 2 study in early to moderate HD

2022:

- Zuranolone:
  - Report topline data from the CORAL Study (early 2022)
  - Report topline data from the SKYLARK Study (mid-2022)
  - Submit NDA filing package for zuranolone for the treatment of MDD (2H 2022) with rolling submission starting early 2022
- SAGE-718:
  - Initiate placebo-controlled Phase 2 study in PD

FINANCIAL RESULTS FOR THE THIRD QUARTER OF 2021

- **Cash Position:** Cash, cash equivalents and marketable securities as of September 30, 2021 were $1.8 billion compared to $1.9 billion at June 30, 2021.
- **Revenue:** Net revenue from sales of ZULRESSO was $1.4 million in the third quarter of 2021 compared to $1.6 million in the same period of 2020.
- **R&D Expenses:** Research and development expenses were $83.5 million, including $17.9 million of non-cash stock-based compensation expense, in the third quarter of 2021 compared to $74.1 million, including $9.9 million of non-cash stock-based compensation expense, for the same period in 2020, an increase of $9.4 million. The amount for the third quarter of 2021 reflects an increase in expenses of $31.0 million and a reduction in expenses of $21.6 million due to reimbursement from Biogen pursuant to the Sage/Biogen Collaboration and License Agreement. The primary reasons for the increase in expenses were manufacturing-related activities for zuranolone, work on studies that began in 2021, work on research activities, an increase in hiring and non-cash stock-based compensation expense based on the determination that the achievement of a milestone for vesting of certain outstanding performance restricted stock units was considered probable.
- **SG&A Expenses:** Selling, general and administrative expenses were $48.7 million, including $16.5 million of non-cash stock-based compensation expense, in the third quarter of 2021 compared to $35.1 million, including $10.2 million of non-cash stock-based compensation expense, for the same period in 2020, an increase of $13.6 million. The amount for the third quarter of 2021 reflects an increase in expenses of $16.4 million and a reduction in expenses of $2.8 million due to reimbursement from Biogen pursuant to the Sage/Biogen Collaboration and License Agreement. The primary reasons for the increase in expenses were an increase in hiring and non-cash stock-based compensation expense based on the determination that the achievement of a milestone for vesting of certain outstanding performance restricted stock units was considered probable.
- **Net Loss:** Net loss was $130.2 million for the third quarter of 2021 compared to $105.7 million for the same period of 2020.

FINANCIAL GUIDANCE

- Sage anticipates cash, cash equivalents and marketable securities of more than $1.7 billion at the end of 2021.
- The Company does not anticipate receipt of any milestone payments from collaborations in 2021.

Conference Call Information

Sage will host a conference call and webcast today, Tuesday, November 2, at 8:00 a.m. ET to discuss its third quarter 2021 financial results and 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 approximately two hours after the completion of the event and will be archived for up to 30 days.

About Sage Therapeutics

Sage Therapeutics is a biopharmaceutical company committed to developing novel therapies with the potential to transform the lives of people with debilitating disorders of the brain. We are pursuing new pathways with the goal of improving brain health, and our depression, neurology and neuropsychiatry franchise programs aim to change how brain disorders are thought about and treated. Our mission is to make medicines that matter so people can get better, sooner. For more information, please visit www.sagerx.com.

Forward-Looking Statements

Various statements in this release concern Sage's future expectations, plans and prospects, including without limitation our statements regarding: plans for an NDA filing and associated submission for zuranolone in MDD and PPD, and the potential timing of such submissions; our belief in the adequacy of the data we plan to include in the zuranolone NDA; the potential for FDA acceptance of an NDA for zuranolone; our belief in the regulatory filing pathways for zuranolone; the potential profile and benefit of zuranolone in MDD and PPD; the potential for regulatory approval and commencement of commercialization of zuranolone and our belief as to the potential to commence commercialization of both indications, if approved, in parallel; other planned next steps for the program; anticipated timelines for reporting clinical trial results, commencement of trials, and initiation of new activities; our plans for advancement of our 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 mission and goals for our business and potential value creation opportunities; and our expectations with respect to 2021 year-end cash. 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 experience delays or unexpected hurdles in our efforts to submit an NDA for zuranolone and we may not be able to submit the NDA on the timelines we expect or at all; the FDA may find inadequacies and deficiencies in our NDA for zuranolone, including in the data we submit, despite prior discussions, and may decide not to accept the NDA for filing; even if the FDA accepts the NDA for filing, the FDA may find that the data included in the NDA are not sufficient for approval and may not approve the NDA; the FDA may decide that the design, conduct or results of our completed and ongoing clinical trials for zuranolone, even if positive, are not sufficient for approval in MDD or PPD and may require additional trials or data which may significantly delay and put at risk our efforts to obtain approval and may not be successful; the FDA may not meet expected review timelines for our NDA; other decisions or actions of the FDA or other regulatory agencies may affect our efforts with respect to zuranolone and our plans, progress or results; we may experience negative results in ongoing or future studies of zuranolone that negatively affect our ability to obtain approval of zuranolone or that impair the potential profile of zuranolone; 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; unexpected concerns may arise from additional data, analysis or results from any of our completed studies; we may encounter adverse events at any stage of development that negatively impact further development or that require additional nonclinical and clinical work which may not yield positive results; we may encounter delays in initiation, conduct or completion of our ongoing and planned clinical trials, including as a result of slower than expected site initiation or enrollment, the need or decision to expand the trials or other changes, that may impact our ability to meet our expected timelines and increase our costs; decisions or actions of the FDA or other regulatory agencies may affect the initiation, timing, design, size, progress and cost of clinical trials and our ability to proceed with further development or may impair the potential for successful development; the anticipated benefits of our ongoing collaborations may never be achieved and the need to align with our collaborators may hamper or delay our development and commercialization efforts or increase our costs; 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 use cash more quickly than we expect or change or curtail some of our plans or both; 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; our expectations as to year-end cash 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; additional funding may not be available on acceptable terms when we need it; the number of patients with the diseases or disorders for which our products are developed, the unmet need for additional treatment options and the potential market for our current or future products may be significantly smaller than we expect; and we may encounter technical and other unexpected hurdles in the development and manufacture of our product candidates or the commercialization of our 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 on Form 10-Q, 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.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Product revenue, net	$ 1,440	$ 1,639	$ 4,666	$ 5,014
Operating costs and expenses:				
Cost of goods sold	131	149	466	429
Research and development	83,497	74,078	207,723	211,008
Selling, general and administrative	48,706	35,099	131,899	143,454
Restructuring	—	(529)	—	27,873
Total operating costs and expenses	132,334	108,797	340,088	382,764
Loss from operations	(130,894)	(107,158)	(335,422)	(377,750)
Interest income, net	692	1,347	2,132	8,763
Other income, net	31	76	110	165
Net loss	$ (130,171)	$ (105,735)	$ (333,180)	$ (368,822)
Net loss per share—basic and diluted	$ (2.21)	$ (2.03)	$ (5.69)	$ (7.10)
Weighted average shares outstanding—basic and diluted	58,819,548	51,981,468	58,593,743	51,938,923

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

	September 30, 2021	December 31, 2020
Cash, cash equivalents and marketable securities	$ 1,843,169	$ 2,099,549
Total assets	$ 1,927,180	$ 2,159,246
Total liabilities	$ 91,526	$ 86,912
Total stockholders' equity	$ 1,835,654	$ 2,072,334

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 ³5% 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.

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