

**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): February 24, 2021**

**Sage Therapeutics, Inc.**

(Exact name of registrant as specified in its charter)

**DELAWARE**  
(State or other jurisdiction  
of incorporation)

**001-36544**  
(Commission  
File Number)

**27-4486580**  
(I.R.S. Employer  
Identification No.)

**215 First Street**  
**Cambridge, MA**  
(Address of principal executive offices)

**02142**  
(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.

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**Item 2.02 Results of Operations and Financial Condition**

On February 24, 2021, Sage Therapeutics, Inc. announced its financial results for the quarter and full year ended December 31, 2020. 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

<b>Exhibit No.</b>	<b>Description</b>
99.1	<a href="#">Press release issued by Sage Therapeutics, Inc. on February 24, 2021, furnished herewith.</a>
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: February 24, 2021

**SAGE THERAPEUTICS, INC.**

By: /s/ Jennifer Fitzpatrick  
Jennifer Fitzpatrick



**Sage Therapeutics Announces Fourth Quarter and Full Year 2020 Financial Results and Highlights Pipeline and Business Progress**

*Reported positive interim data from Phase 3 open-label SHORELINE Study showing that more than 70% of patients successfully treated with zuranolone 30 mg needed two or fewer treatment courses over one year*

*Progressed WATERFALL Study – now closed to enrollment - investigating zuranolone for as needed treatment of major depressive disorder with data anticipated in the first half of 2021*

*Entered into global collaboration with Biogen worth up to \$3.1 billion, enabling planned expansion and acceleration of the Sage pipeline and increasing the potential patient reach to more than 450 million, if successful*

*Initiated six late-stage clinical trials in 2020, including four Phase 3 trials*

*Ended 2020 with cash balance of \$2.1 billion*

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

**CAMBRIDGE, Mass. – Feb. 24, 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 fourth quarter and full year ended December 31, 2020.

“Although 2020 was a challenging year, Sage’s commitment to rigorous science, innovation and disciplined execution resulted in significant progress across all of our brain health franchises, strongly positioning us in our efforts to deliver revolutionary medicines to millions of patients,” said Barry Greene, chief executive officer at Sage Therapeutics. “Our collaboration with Biogen enhances our strategic, financial, and operational flexibility, enabling our plans to expand and accelerate our pipeline and extending the potential impact of our product candidates, if we’re successful, to more than 450 million patients worldwide. In the first months of 2021, we’ve already begun to realize this expansion and acceleration with the progression of multiple early-stage programs. I believe 2021, with 10 expected data readouts, will be a transformational year for Sage in our mission to become the leading brain health company in the next five years.”

**KEY 2020 UPDATES**

**Collaboration with Biogen:** In November 2020, Sage and Biogen entered into a global collaboration and license agreement to jointly develop and commercialize zuranolone (SAGE-217) for major depressive disorder (MDD), postpartum depression (PPD) and other disorders, and SAGE-324 for essential tremor (ET) and other disorders.

- Total potential value of the collaboration is \$3.1 billion, including \$1.5 billion received at closing on December 31, 2020, comprised of an upfront payment of \$875 million and a \$650 million equity investment, and \$1.6 billion in potential milestone payments.
- Transaction included purchase by Biogen of 6,241,473 shares of Sage common stock at a 40% premium.
- Sage and Biogen are jointly developing, and, if successful, will jointly commercialize, zuranolone and SAGE-324 in the U.S. Biogen has an exclusive license to develop and commercialize zuranolone and SAGE-324 outside of the U.S., excluding rights to zuranolone in Japan, Taiwan and South Korea.

**Zuranolone SHORELINE Study data:** In October 2020, Sage reported positive, interim topline results from a July data cut of the ongoing Phase 3 open-label SHORELINE Study of zuranolone in MDD. The SHORELINE Study is designed to evaluate the safety and tolerability of zuranolone in adults for up to one year.

Interim topline data from the SHORELINE Study showed:

- Zuranolone was generally well-tolerated at the 30 mg dose and by the initial patients treated with the 50 mg dose with an adverse event profile consistent with that seen in earlier trials.
- Nearly half of trial participants with a positive response to the initial 14-day course of zuranolone 30 mg did not need an additional zuranolone treatment course and more than 70% needed two or fewer zuranolone treatment courses.
  - In the 30 mg cohort, the most common adverse events (reported <sup>3</sup>5%) were: somnolence (69; 9.5%), headache (63; 8.7%), and dizziness (39; 5.4%). Most adverse events were mild or moderate.
- At Day 15 of the first course of zuranolone in the initial group of patients who only received 50 mg in the study (n=52), ~75% achieved response (decrease in HAMD-17 baseline score of <sup>3</sup>50%) and ~48% achieved remission (HAM-D  $\leq$  7).
  - Safety data available from the 50 mg cohort was similar to that seen in patients who received 30 mg zuranolone. Events >5% of somnolence, dizziness, sedation, headache and tremor were observed to be more frequent in the 50 mg cohort, but were similar in severity to the events seen with 30 mg. Most adverse events were mild or moderate. In patients who received zuranolone 50 mg after having received 30 mg previously, higher rates and levels of intensity with AEs of >5% (sedation, somnolence) were noted.

**Corporate restructuring:** In April 2020, Sage completed a restructuring intended to enable the Company to advance its corporate strategy and pipeline throughout the COVID-19 pandemic and beyond.

## **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<sub>A</sub> 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<sub>A</sub> 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 PPD. Zuranolone has received breakthrough therapy designation from the FDA for the treatment of MDD.*

Zuranolone is being evaluating as a potential rapid-acting, short-course treatment for PPD and MDD in the NEST and LANDSCAPE clinical trial programs. Sage initiated three Phase 3 clinical studies in 2020. If successful, these studies, along with the rest of the program, may support paths to approval with three distinct opportunities to address patient needs: PPD, acute rapid response therapy (RRT) in MDD when co-initiated with a new standard antidepressant, and as-needed treatment of MDD.

The Company expects the following zuranolone data readouts in 2021:

- 1H 2021:
  - WATERFALL (MDD-301B) Study: A placebo-controlled Phase 3 trial evaluating a two-week course of zuranolone 50 mg in patients with MDD, with additional short-term follow-up. Today the Company announced the WATERFALL Study is closed to enrollment, with more than 525 patients expected to be randomized in the study. Data are anticipated in the first half of 2021.
- Mid-2021:
  - SHORELINE (MDD-303) Study 30 mg Cohort - Full Data: An open-label Phase 3 trial designed to naturalistically follow patients with MDD and evaluate the safety and tolerability of zuranolone 30 mg in adults for up to one year. The Company announced positive interim topline data from this cohort in October 2020.
- Late 2021:
  - SKYLARK (PPD-301) Study: A placebo-controlled Phase 3 trial evaluating a two-week course of zuranolone 50 mg in women with PPD, with additional short-term follow-up.
  - CORAL (MDD-305) Study: A placebo-controlled Phase 3 trial 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.
  - SHORELINE (MDD-303) Study 50 mg Cohort: An open-label Phase 3 trial designed to naturalistically follow patients with MDD and evaluate the safety and tolerability of zuranolone 50 mg in adults for up to one year.

Sage is also evaluating the ongoing zuranolone clinical pharmacology and safety program and plans to align with FDA on data to support a potential future new drug application (NDA) with the FDA. Additional development plans for zuranolone will be confirmed and announced as part of the Company's strategic collaboration with Biogen.

Additionally, Sage's collaboration with Shionogi & Co., Ltd. is progressing. In 2020, Shionogi initiated a Phase 2 trial with zuranolone in Japan for the treatment of MDD. Shionogi anticipates that this Phase 2 study will finish in the third quarter of 2021. Under the terms of the collaboration, Shionogi is responsible for all clinical development, regulatory filings and commercialization of zuranolone for MDD, and potentially other indications, in Japan, Taiwan and South Korea.

### Neurology Franchise

*SAGE-324, a next-generation PAM of GABA<sub>A</sub> receptors and Sage's lead neurology program, is in development as a potential oral therapy for neurological conditions, such as ET, epilepsy and Parkinson's disease (PD).*

The following milestones are expected for the neurology franchise in 2021:

- Early 2021:
  - KINETIC (324-ETD-201) Study: The Company expects topline data from the KINETIC Study, a placebo-controlled Phase 2 trial evaluating the safety and efficacy of SAGE-324 in patients with ET to readout in early 2021.

- Late 2021:
  - If data from the KINETIC Study support further development, Sage anticipates initiating a placebo-controlled Phase 2b trial with SAGE-324 in ET in late 2021 to explore dose and frequency, including potential formulations.

Additional development plans for SAGE-324 will be confirmed and announced as part of the Company's strategic collaboration with Biogen.

### 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), PD and Alzheimer's disease (AD).*

Positive data with SAGE-718 to date include results from a Phase 1 open-label study evaluating the safety and pharmacokinetics of SAGE-718 in a cohort of patients with early HD. In that study, SAGE-718 was well tolerated with no serious adverse events or adverse events leading to treatment discontinuation and patients demonstrated improved performance, compared to baseline, on assessments of executive functioning, a core feature of early HD.

Ongoing trials with SAGE-718:

- **PARADIGM Study:** Phase 2a open-label trial evaluating SAGE-718 in patients with PD cognitive dysfunction. The Company initiated enrollment and dosing in September 2020.
- **LUMINARY Study:** Phase 2a open-label trial evaluating SAGE-718 in patients with AD mild cognitive impairment and mild dementia. The Company initiated enrollment and dosing in early 2021.

The following milestones are expected for the neuropsychiatry franchise in 2021:

- Early 2021:
  - **PARADIGM (718-CNP-201) Study:** The Company anticipates topline data from the PARADIGM Study in early 2021.
- Late 2021:
  - **LUMINARY (718-CNA-201) Study:** The Company anticipates topline data from the LUMINARY Study in late 2021.

Additionally, the Company expects to initiate a placebo-controlled Phase 2 trial with SAGE-718 in late 2021. Details of this trial will be informed by results from the Phase 2a studies and earlier work.

### Early Development

Sage expects to complete certain Phase 1 clinical studies for two programs in its early development pipeline in 2021, SAGE-689 (single ascending dose) and SAGE-904 (single ascending dose and multiple ascending dose).

- **SAGE-689:** is an intramuscular GABA<sub>A</sub> receptor PAM in development as a potential therapy for disorders associated with acute GABA hypofunction.
- **SAGE-904:** is Sage's second NMDA receptor PAM product candidate in development as a potential oral therapy for disorders associated with NMDA hypofunction.

Results from the Phase 1 studies will inform further development of these programs.

Additionally, the Company recently announced plans to advance SAGE-319 and SAGE-421 to preclinical studies.

- **SAGE-319:** is an oral, extrasynaptic GABA<sub>A</sub> receptor preferring PAM that Sage plans to study for potential use in disorders of social interaction.
- **SAGE-421:** is an oral, NMDA receptor PAM that Sage plans to study for potential use in neurodevelopmental disorders and cognitive recovery and rehabilitation.

### **Other Development Opportunities**

Sage initiated a Phase 3 trial with brexanolone in patients with advanced COVID-19 related acute respiratory distress syndrome (ARDS) in the fourth quarter of 2020 under the Coronavirus Treatment Acceleration Program (CTAP). The Company expects topline data from this trial in 2021.

### **ANTICIPATED 2021 MILESTONES**

#### Early 2021:

- SAGE-324:
  - Report topline data from Phase 2 placebo-controlled KINETIC Study in ET
- SAGE-718:
  - Report topline data from Phase 2a PARADIGM open-label, signal finding study in patients with PD cognitive dysfunction

#### Mid-2021:

- Zuranolone:
  - Report topline data from Phase 3 WATERFALL Study (1H21)
  - Report full data from Phase 3 SHORELINE Study 30mg cohort

#### Late 2021:

- Zuranolone:
  - Report topline data from Phase 3 SKYLARK Study
  - Report topline data from Phase 3 CORAL Study
  - Report topline data from Phase 3 SHORELINE Study 50mg cohort
- SAGE-324:
  - Initiate Phase 2b 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
- Brexanolone:
  - Report topline data from Phase 3 study in patients with advanced COVID-19 related ARDS
- SAGE-689 & SAGE-904:
  - Complete planned Phase 1 studies (SAD for SAGE-689 and SAD/MAD for SAGE-904)

### **FINANCIAL RESULTS FOR THE FOURTH QUARTER AND FULL YEAR 2020**

- **Cash Position:** Cash, cash equivalents, restricted cash, and marketable securities as of December 31, 2020 were \$2.1 billion compared to \$0.7 billion at September 30, 2020. The increase is from the receipt of cash from Biogen for the upfront under the collaboration and license agreement of \$875 million and the stock purchase of \$650 million.



- **Revenue:** Sage recorded \$1.1 billion in net revenue in the fourth quarter of 2020, comprised of \$1.1 billion of collaboration revenue from Biogen and \$1.7 million from sales of ZULRESSO, compared to \$2.0 million for the same period in 2019, which consisted of revenue from sales of ZULRESSO. For the year ended December 31, 2020, Sage recorded \$1.1 billion in net revenue comprised of \$1.1 billion of collaboration revenue from Biogen and \$6.7 million from sales of ZULRESSO, compared to \$6.9 million for the same period in 2019, which consisted of \$4.0 million in revenue from sales of ZULRESSO and \$2.9 million of collaboration revenue from Shionogi. The collaboration revenue of \$1.1 billion from Biogen recorded in the fourth quarter of 2020 consisted of an upfront payment of \$875 million plus \$232.5 million in excess proceeds from the equity investment under the stock purchase agreement.
- **R&D Expenses:** Research and development expenses were \$81.7 million, including \$10.1 million of non-cash stock-based compensation expense, in the fourth quarter of 2020 compared to \$91.3 million, including \$11.4 million of non-cash stock-based compensation expense, for the same period in 2019. For the year ended December 31, 2020, R&D expenses were \$292.7 million, including \$42.4 million of non-cash stock-based compensation expense, compared to \$368.8 million, including \$62.9 million of non-cash stock-based compensation expense, for the same period in 2019. The decreases in R&D expenses were primarily due to a decrease of \$30.2 million in expenses for zuranolone, primarily as a result of completion of the MOUNTAIN Study and decreased spending for clinical pharmacology studies, partially offset by an increase in spending for the WATERFALL Study and the SKYLARK Study. For the year, non-cash stock-based compensation expense decreased because the Company incurred no expense in 2020 for performance-based grants, and incurred \$14.0 million of expense for such grants as R&D expenses in 2019.
- **SG&A Expenses:** Selling, general and administrative expenses were \$53.5 million, including \$10.6 million of non-cash stock-based compensation expense, in the fourth quarter of 2020 compared to \$85.1 million, including \$19.3 million of non-cash stock-based compensation expense, for the same period in 2019. For the year ended December 31, 2020, SG&A expenses were \$197.0 million, including \$51.8 million of non-cash stock-based compensation expense, compared to \$345.8 million, including \$90.3 million of non-cash stock-based compensation expense, for the same period in 2019. The decreases in SG&A expenses were primarily due to the restructuring that the Company announced during the second quarter of 2020. For the year, non-cash stock-based compensation expense decreased because the Company incurred no expense in 2020 for performance-based grants, and incurred \$13.2 million of expense for such grants as SG&A expenses in 2019.
- **Net Income (loss):** Net income was \$974.9 million for the fourth quarter of 2020, compared a net loss of \$168.7 million for the same period in 2019. For the year ended December 31, 2020, net income was \$606.1 million, compared to a net loss of \$680.2 million for the same period in 2019. In both periods, the increase was due to the collaboration revenue from Biogen.

## **FINANCIAL GUIDANCE**

- Sage anticipates cash, cash equivalents, restricted cash, and marketable securities of more than \$1.7 billion at 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, Wednesday, February 24, at 8:00 am ET to discuss its fourth quarter and full year 2020 financial results and recent corporate updates. The live webcast can be accessed on the investor page of Sage's website at [investor.sagerx.com](http://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](http://www.sagerx.com).

## **Forward-Looking Statements**

*Various statements in this release concern Sage's future expectations, plans and prospects, including without limitation: our views and expectations regarding our planned research and development activities and related timelines, including plans for reporting data, initiation of new activities, and acceleration and expansion of our pipeline; our belief in the potential profile and benefit of our product candidates, and the opportunity to help patients, in various indications; the potential benefit and success of our collaborations; our goal to deliver medicines that we hope will help patients and the number of patients we hope our medicines will help; our mission to become the leading brain health company; our statements regarding the vision, opportunity and potential for our business; 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: success in non-clinical studies or in earlier clinical trials or at interim time periods 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 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 different or more severe adverse events at the higher doses we are studying in our ongoing trials; we may encounter issues with the efficacy or durability of short-term treatment, or co-initiated treatment with zuranolone or safety and efficacy concerns with respect to retreatment that require additional studies be conducted; the impact of the COVID-19 pandemic on our clinical development timelines may be more significant than we expect and may negatively impact expected site initiation, enrollment or conduct in our clinical trials, or cause us to pause trials or not be able to use data, in each case which may significantly impact our ability to meet our expected timelines or may significantly impact the integrity or sufficiency of the data from our*

*trials or increase our costs or cause us to have to change our plans; we may encounter other 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; the FDA may ultimately decide that the design or results of our completed and planned clinical trials for any of our product candidates, even if positive, are not sufficient for regulatory approval in the indications that are the focus of our development plan; other 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; the anticipated benefits of our ongoing collaborations may never be achieved; 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; 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; 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; the number of patients with the diseases or disorders for which our products are developed or the unmet need for additional treatment options 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 which may delay our timing or change our plans or increase our costs; as well as those risks more fully discussed in the section entitled "Risk Factors" in our most recent Annual Report on Form 10-K, 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 December 31,		Year Ended December 31,	
	2020	2019	2020	2019
Product revenue, net	\$ 1,686	\$ 1,960	\$ 6,700	\$ 3,957
Collaboration revenue	1,107,500	—	1,107,500	2,911
Total revenue	1,109,186	1,960	1,114,200	6,868
Operating costs and expenses:				
Cost of goods sold	136	219	565	400
Research and development	81,706	91,250	292,714	368,815
Selling, general and administrative	53,498	85,129	196,952	345,777
Restructuring	(130)	—	27,743	—
Total operating costs and expenses	135,210	176,598	517,974	714,992
Income (loss) from operations	973,976	(174,638)	596,226	(708,124)
Interest income, net	834	5,915	9,597	27,804
Other income, net	85	70	250	82
Net income (loss)	\$ 974,895	\$ (168,653)	\$ 606,073	\$ (680,238)
Net loss per share - basic	\$ 18.71	\$ (3.25)	\$ 11.66	\$ (13.38)
Net loss per share - diluted	\$ 18.19	\$ (3.25)	\$ 11.43	\$ (13.38)
Weighted average shares outstanding - basic	52,115,022	51,834,880	51,983,188	50,833,837
Weighted average shares outstanding - diluted	53,594,637	51,834,880	53,003,115	50,833,837

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

	December 31, 2020	December 31, 2019
Cash, cash equivalents, restricted cash and investments	\$ 2,101,265	\$ 1,010,760
Total assets	\$ 2,159,246	\$ 1,084,150
Total liabilities	\$ 86,912	\$ 139,495
Total stockholders' equity	\$ 2,072,334	\$ 944,655

**ZULRESSO can cause serious side effects, including:**

- Excessive sedation and sudden loss of consciousness. ZULRESSO may cause you to feel very sleepy (excessive sedation) or pass out (loss of consciousness). Your healthcare provider should check you for symptoms of excessive sleepiness every 2 hours while you are awake.
  - During your infusion, tell your healthcare provider right away if you feel like you cannot stay awake during the time you are normally awake or if you feel like you are going to pass out. Your healthcare provider may lower your dose or stop the infusion until symptoms go away
  - You must have a caregiver or family member with you to help care for your child(ren) during your infusion

- Because of the risk of serious harm resulting from excessive sedation or sudden loss of consciousness, ZULRESSO is only available through a restricted program called the ZULRESSO REMS.

**ZULRESSO can cause other serious side effects, including:**

- **Increased risk of suicidal thoughts or actions.** ZULRESSO and other antidepressant medicines may increase suicidal thoughts and actions in some people 24 years of age and younger. **Pay close attention to and 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, other unusual or sudden changes in behavior or mood
  - Keep all follow-up visits and call your healthcare provider between visits as needed, especially if you have concerns about symptoms.

**The most common side effects of ZULRESSO include:**

- Sleepiness, dry mouth, passing out, flushing of the skin or face.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**Before receiving ZULRESSO, tell your healthcare provider about all your medical conditions** including if you drink alcohol, have kidney problems, are pregnant or think you may be pregnant, or are breastfeeding or plan to breastfeed. It is not known if ZULRESSO will harm your unborn baby. If you become pregnant during treatment, talk with your healthcare provider about enrolling with the National Pregnancy Registry for Antidepressants at 1-844-405-6185.

**While receiving ZULRESSO, avoid the following:**

- Driving a car or doing other dangerous activities after your ZULRESSO infusion until your feeling of sleepiness has completely gone away
- Do not drink alcohol

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

**Especially tell your healthcare provider if you take** other antidepressants, opioids, or Central Nervous System (CNS) depressants (such as benzodiazepines).

**Please see the patient Medication Guide, including information about serious side effects, for Zulresso in the full Prescribing Information.**

**Investor Contact**

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