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): October 29, 2024

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.)**

55 Cambridge Parkway **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 October 29, 2024, Sage Therapeutics, Inc. announced its financial results for the quarter ended September 30, 2024. 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 October 29, 2024, 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: October 29, 2024

SAGE THERAPEUTICS, INC.

By: /s/ Barry E. Greene
Barry E. Greene
President and Chief Executive Officer

Exhibit 99.1

Sage Therapeutics Announces Third Quarter 2024 Financial Results and Highlights Pipeline and Business Updates

Achieved $11 million in ZURZUVAE® (zuranolone) collaboration revenue during the third quarter of 2024 (50% of the net revenue recorded by Biogen), representing 49% growth from the second quarter

Sage and Biogen will not pursue further development of zuranolone in major depressive disorder (MDD) in the U.S.

Topline data from the DIMENSION Study in Huntington's Disease (HD) expected late 2024

Cash, cash equivalents and marketable securities of $569 million as of September 30, 2024

CAMBRIDGE, Mass. – October 29, 2024 – Sage Therapeutics, Inc. (Nasdaq: SAGE), today reported business highlights and financial results for the third quarter ended September 30, 2024.

"We are committed to harnessing the full potential of ZURZUVAE as a transformative treatment for women with postpartum depression. Our encouraging third quarter results, highlighted by continued growth in revenue and shipments, brings us one step closer to our goal of establishing ZURZUVAE as the standard of care to help more women suffering from this debilitating condition," said Barry Greene. "Looking forward, we believe that our strategic decisions, including the recent reorganization, will best-position Sage to foster long-term growth and support our mission of better brain health for patients."

Third Quarter 2024 Portfolio Updates

ZURZUVAE

Sage and its collaborator, Biogen, are focused on the goal of establishing ZURZUVAE as the first line therapy and standard of care for women with postpartum depression (PPD). As of the third quarter ended September 30, 2024, the following results had been achieved:

- $11 million in collaboration revenue from ZURZUVAE in the third quarter of 2024, representing a 49% increase from the second quarter. Collaboration revenues represent 50% of the net revenues recorded when Biogen ships ZURZUVAE to the distributors.
- Approximately 2,000 prescriptions were shipped and delivered in the third quarter, representing an approximately 40% increase from the second quarter.
- Sage's expanded sales force is in the field as of the start of the fourth quarter.

Related to payor coverage, as of September 30, 2024:

- Over 90% of commercial and Medicaid lives are covered by payor policies in PPD, with the majority having no step therapy or complex prior authorizations.
- All three national PBMs have developed favorable coverage policies for ZURZUVAE in the treatment of women with PPD.

In terms of prescriber trends:

- ZURZUVAE is being prescribed across a breadth of HCPs who treat PPD. OBGYNs account for 70% of all prescribers.
- Prescribers and repeat writers continue to increase quarter over quarter with most new prescribers initiating after an interaction with a sales representative.
- Of those HCPs prescribing ZURZUVAE, the majority are using ZURZUVAE as a first-line PPD treatment.

- Company data suggests 90% aided brand awareness for ZURZUVAE among OBGYNs and psychiatrists.

Zuranolone Business Update

In August 2023, the FDA issued a Complete Response Letter for the New Drug Application for zuranolone in the treatment of adults with MDD. Sage and Biogen will not pursue further development of zuranolone as a treatment for MDD in the U.S. based on the significant new investment and time we expect would be needed to conduct additional studies. Sage plans to prioritize its resources on supporting the PPD patient community.

ZULRESSO

Sage plans to sunset ZULRESSO® (brexanolone) as a part of its strategic shift to further focus on the commercialization of ZURZUVAE for the treatment of women with PPD. ZULRESSO will be commercially available until December 31, 2024.

Pipeline

Dalzanemdor (SAGE-718)

Sage recently announced results from the Phase 2 LIGHTWAVE Study in the treatment of mild cognitive impairment and mild dementia in Alzheimer's Disease (AD). The LIGHTWAVE Study did not demonstrate a statistically significant difference from baseline in participants treated with dalzanemdor versus placebo on the Wechsler Adult Intelligence Scale Fourth Edition (WAIS-IV) Coding Test at Day 84, the primary endpoint. Dalzanemdor was generally well-tolerated and no new safety signals were observed. The majority of treatment emergent adverse events were mild to moderate in severity. Based on these data, the Company does not plan further clinical development of dalzanemdor in AD.

Ongoing studies in the dalzanemdor clinical program include:

- DIMENSION (CIH-201) Study: The DIMENSION Study is a double-blind, placebo-controlled Phase 2 study in participants with cognitive impairment associated with HD. The study is designed to evaluate the efficacy and safety of once-daily dalzanemdor dosed over three months.
- PURVIEW (CIH-301) Study: The PURVIEW Study is an open-label Phase 3 safety study designed to evaluate the long-term safety and tolerability of dalzanemdor in participants with HD.

The Company expects to report topline data from the Phase 2 DIMENSION Study of dalzanemdor in cognitive impairment associated with HD later this year.

SAGE-324

In September, Sage announced that Biogen terminated its rights under the collaboration and license agreement with Sage specific to the SAGE-324 program. The companies previously announced negative results from the Phase 2 KINETIC 2 Study of investigational SAGE-324 for the chronic treatment of essential tremor (ET) and discontinued further clinical development of SAGE-324 in ET. Under the terms of the collaboration and license agreement, the termination will be effective on February 17, 2025, and Sage will resume full ownership of SAGE-324 at that time. Sage is continuing to evaluate other potential indications, if any, for SAGE-324.

Recent Period Business Update

In October, Sage announced a strategic reorganization of its business operations to support the ongoing launch of ZURZUVAE in PPD and focus pipeline development efforts ahead of the clinical study readout for dalzanemdor in HD expected later this year. The reorganization is intended to enable Sage to strengthen its balance sheet, extend cash runway, and position the company for long-term growth potential and is planned to be substantially completed by the end of the fourth quarter of 2024.

FINANCIAL RESULTS FOR THE THIRD QUARTER 2024

- **Cash Position:** Cash, cash equivalents and marketable securities as of September 30, 2024 were $569 million compared to $647 million at June 30, 2024.
- **Revenue:** Collaboration revenue from sales of ZURZUVAE was $11 million in the third quarter of 2024, representing a 49% increase compared to the second quarter of 2024. Reported collaboration revenue is 50% of the net revenues Biogen records for ZURZUVAE in the U.S. Net revenue from sales of ZULRESSO was $0.8 million in the third quarter of 2024, compared to $2.7 million in the same period of 2023.
- **Cost of Revenues:** Cost of revenues were $5.3 million in the third quarter of 2024 compared to $0.9 million for the same period in 2023. The third quarter 2024 expenses included $3.6 million of one-time excess inventory write-offs and intangible asset impairment costs related to the planned discontinuation of ZULRESSO commercial availability.
- **R&D Expenses:** Research and development expenses were $54.6 million, including $5.5 million of non-cash stock-based compensation expense, in the third quarter of 2024 compared to $101.9 million, including $6.9 million of non-cash stock-based compensation expense, for the same period in 2023. The decrease in R&D expenses as compared to the same period in 2023 was primarily related to the 2023 reorganization cost savings measures, including reduced headcount, budgeted expenditures and reprioritization of early-stage pipeline programs. The reimbursement from Biogen to Sage for R&D expenses pursuant to the Sage/Biogen Collaboration and License Agreement was $5.4 million in the third quarter of 2024 compared to $28.2 million in the same period of 2023.
- **SG&A Expenses:** Selling, general and administrative expenses were $53.2 million, including $8.7 million of non-cash stock-based compensation expense, in the third quarter of 2024, compared to $78.1 million, including $21.0 million of non-cash stock-based compensation expense, for the same period in 2023. The decrease in SG&A expenses as compared to the same period in 2023 was primarily related to stock-based compensation expense related to one-time vesting events in the third quarter of 2023 and the 2023 reorganization cost savings measures, including reduced headcount and budgeted expenditures. The reimbursement from Sage to Biogen for SG&A expenses pursuant to the Sage/Biogen Collaboration and License Agreement was $2.4 million in the third quarter of 2024 compared to $5.8 million in the same period of 2023.
- **Net Loss:** Net loss was $93.6 million for the third quarter of 2024 compared to $201.6 million for the same period in 2023.

FINANCIAL GUIDANCE

- Based upon the Company's current operating plan, Sage anticipates that its existing cash, cash equivalents and marketable securities as of September 30, 2024, anticipated funding from ongoing collaborations and estimated revenues, excluding any potential savings resulting from its October 2024 reorganization, will support its operations into 2026. The Company plans to update cash runway guidance in the near future.

- The Company does not anticipate receipt of any milestone payments from collaborations in the remainder of 2024.
- The Company anticipates operating expenses will decrease in 2025 relative to 2024.
- With the uptake of ZURZUVAE as an oral treatment for women with PPD, the Company anticipates ZULRESSO use will continue to decrease and has decided to no longer make ZULRESSO commercially available as of December 31, 2024.

Conference Call Information

Sage will host a conference call and webcast today, October 29, 2024, at 4:30 p.m. ET to review its third quarter 2024 financial results and discuss recent corporate updates. The live webcast can be accessed on the investor page of Sage's website at investor.sagerx.com. A replay of the webcast will be available on Sage's website following the completion of the event and will be archived for up to 30 days.

About Sage Therapeutics

Sage Therapeutics (Nasdaq: SAGE) is a biopharmaceutical company committed to our mission of pioneering solutions to deliver life-changing brain health medicines, so every person can thrive. Sage developed the only two FDA-approved treatments indicated for postpartum depression and is advancing a robust pipeline to target unmet needs in brain health. Sage was founded in 2010 and is headquartered in Cambridge, Mass. Find out more at www.sagerx.com or engage with us on Facebook, LinkedIn, Instagram, and X.

Forward-Looking Statements

Various statements in this release concern Sage's future expectations, plans and prospects, including without limitation our statements regarding: our plans, expectations and goals for commercialization of ZURZUVAE as a treatment for women with PPD, including our goal to establish ZURZUVAE as the first line therapy and standard of care in this indication; our beliefs that our strategic decisions, including implementation of the October 2024 reorganization, will reduce our operating expenses, foster long-term growth and support our mission; our belief in the potential for ZURZUVAE and that ZURZUVAE will be successful as a transformative treatment in helping women with PPD; anticipated timelines for completion of enrollment in clinical trials and reporting of results with respect to certain of our other programs, including the expected timing of readout of the DIMENSION Study of dalzanemdor in HD; our plans to not pursue further development of zuranolone as a treatment for MDD and discontinue commercial availability of ZULRESSO as of December 31, 2024, and our strategic shift to further focus on commercialization of ZURZUVAE for the treatment of women with PPD; our expectations regarding expenses and our cash runway, including our plans to update our cash runway guidance in the near future; our plans to evaluate next steps, if any, for the SAGE-324 program; our expectations related to the October 2024 reorganization, including timing, cost savings, and our goals to position the company for long-term growth and focus pipeline development efforts; our belief in the potential profile and benefit of our product candidates, potential indications for our product candidates, the potential for success of our programs, and the opportunity to help patients in various indications; our belief as to the key catalysts for our business and potential value creation; and the mission and goals for our business. These statements constitute forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. These forward-looking statements are neither promises nor guarantees of future performance, and are subject to a variety of risks and uncertainties, many of which are beyond our control, which could cause actual results to differ materially from those contemplated in these forward-looking statements, including the risks that: we may not realize cost savings from the October 2024 reorganization at the levels we expect, and as a result, the reorganization may not strengthen our balance sheet, foster long-term growth, or enable us to extend our cash runway; our launch and

commercialization efforts in the U.S. with respect to ZURZUVAE for the treatment of women with PPD may not be successful, and we may be unable to generate revenues from sales of ZURZUVAE at the levels or on the timing we expect or at levels or on the timing necessary to support our goals; early positive signs from launch or from our engagements with healthcare professionals, patients and payors related to ZURZUVAE may not be a signal of the potential for future success; the number of women with PPD, the unmet need for additional treatment options, and the potential market for ZURZUVAE in women with PPD, may be significantly smaller than we expect; ZURZUVAE may not achieve the clinical benefit, clinical use or level of market acceptance from healthcare professionals, patients or payors in the treatment of PPD we expect or we may encounter reimbursement-related or other market-related issues, including competition in the market, or issues with our distribution network that impact the success of our commercialization efforts, including our ability to achieve access goals; ZURZUVAE may never become the first line treatment and standard of care for women with PPD; we may encounter delays in initiation, conduct, completion of enrollment or completion and reporting of data with respect to any of our ongoing clinical trials, such as our plans disclose the results of the DIMENSION Study, 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 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 or the timing of meetings with the FDA may affect the timing, design, size, progress and cost of clinical trials or the timing of data read-outs or our ability to proceed with further development or may impair the potential for successful development or the timing or success of filing for and gaining regulatory approval; we may encounter adverse events at any stage that negatively impact further development and the potential for approval of our product candidates or the potential for successful commercialization of any our products or that require additional nonclinical and clinical work, which may not yield positive results; the need to align with our collaborators may hamper or delay our development and commercialization efforts for the products or product candidates that are part of the collaboration or increase our costs; the anticipated benefits of our ongoing collaborations, including the receipt of payments or the successful development or commercialization of products and generation of revenue, may never be achieved at the levels or timing we expect or at all; our business may be adversely affected and our costs may increase if any of our key collaborators fails to perform its obligations or terminates our collaboration; the internal and external costs required for our ongoing and planned activities, and the resulting impact on expense and use of cash, may be higher than expected, which may cause us to change or curtail some of our plans or both; we may not be successful in our efforts to gain regulatory approval of products beyond ZURZUVAE and ZULRESSO; we may not achieve revenues from our products that may be successfully developed in the future, at levels we expect; additional funding may not be available on acceptable terms when we need it, which could hamper our development and commercialization activities; any of the foregoing events could impair the value creation opportunities for our business; and we may encounter technical and other unexpected hurdles in the development and manufacture of our product candidates or the commercialization of any current or future marketed product, which may delay our timing or change our plans, increase our costs or otherwise negatively impact our business; as well as those risks more fully discussed in the section entitled "Risk Factors" in our most recent annual or quarterly report filed with the Securities and Exchange Commission, as well as discussions of potential risks, uncertainties, and other important factors in our subsequent filings with the Securities and Exchange Commission. In addition, any forward-looking statements represent our views only as of today and should not be relied upon as representing our views as of any subsequent date. We explicitly disclaim any obligation to update any forward-looking statements.

Financial Tables

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

	September 30, 2024	December 31, 2023
Cash, cash equivalents and marketable securities	$ 569,155	$ 753,184
Total assets	622,432	882,277
Total liabilities	70,597	82,747
Total stockholder's equity	551,835	799,530

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,	
	2024	2023	2024	2023
Product revenue, net	$ 843	$ 2,716	$ 3,132	$ 8,469
Collaboration revenue - related party	11,028	—	24,661	—
Other collaboration revenue	—	—	634	14
Total revenues	11,871	2,716	28,427	8,483
Operating costs and expenses:				
Cost of revenues	5,278	905	7,955	1,339
Research and development	54,576	101,919	188,873	291,905
Selling, general and administrative	53,219	78,142	161,775	219,415
Restructuring	—	33,599	—	33,599
Total operating costs and expenses	113,073	214,565	358,603	546,258
Loss from operations	(101,202)	(211,849)	(330,176)	(537,775)
Interest income, net	7,642	10,274	25,277	29,276
Other income (expense), net	9	(55)	11	(284)
Net loss	$ (93,551)	$ (201,630)	$ (304,888)	$ (508,783)
Net loss per share - basic and diluted	$ (1.53)	$ (3.37)	$ (5.03)	(8.51)
Weighted average shares outstanding - basic and diluted	61,116,524	59,912,378	60,598,909	59,786,254

SELECT IMPORTANT SAFETY INFORMATION FOR ZURZUVAE

ZURZUVAE (zuranolone) CIV, is a neuroactive steroid gamma-aminobutyric acid (GABA) A receptor positive modulator indicated for the treatment of postpartum depression in adults.

This does not include all the information needed to use ZURZUVAE safely and effectively. See full prescribing information for ZURZUVAE.

ZURZUVAE may cause serious side effects, including decreased awareness and alertness, which can affect your ability to drive safely or safely do other dangerous activities. Do not drive, operate machinery, or do other dangerous activities until at least 12 hours after taking each dose. You may not be able to tell on your own if you can drive safely or tell how much ZURZUVAE is affecting you. ZURZUVAE may cause central nervous system (CNS) depressant effects including sleepiness, drowsiness, slow thinking, dizziness, confusion, and trouble walking. Taking alcohol, other medicines that cause CNS depressant

effects such as benzodiazepines, or opioids while taking ZURZUVAE can make these symptoms worse and may also cause trouble breathing. ZURZUVAE is a federally controlled substance schedule IV because it contains zuranolone, which can be abused or lead to dependence. Tell your healthcare provider right away if you become pregnant or plan to become pregnant during treatment with ZURZUVAE. You should use effective birth control (contraception) during treatment with ZURZUVAE and for 1 week after the final dose. ZURZUVAE and other antidepressant medicines may increase the risk of suicidal thoughts and actions in people 24 years of age and younger. ZURZUVAE is not for use in children. The most common side effects of ZURZUVAE include sleepiness or drowsiness, dizziness, common cold, diarrhea, feeling tired, weak, or having no energy, and urinary tract infection.

SELECT IMPORTANT SAFETY INFORMATION for ZULRESSO

ZULRESSO (brexanolone) CIV, is a neuroactive steroid gamma-aminobutyric acid (GABA) A receptor positive modulator indicated for the treatment of postpartum depression in individuals 15 years and older.

This does not include all the information needed to use ZULRESSO safely and effectively. See full prescribing information for ZULRESSO.

WARNING: EXCESSIVE SEDATION AND SUDDEN LOSS OF CONSCIOUSNESS

See full prescribing information for complete boxed warning

Patients are at risk of excessive sedation or sudden loss of consciousness during administration of ZULRESSO.

Because of the risk of serious harm, patients must be monitored for excessive sedation and sudden loss of consciousness and have continuous pulse oximetry monitoring. Patients must be accompanied during interactions with their child(ren).

ZULRESSO is available only through a restricted program called the ZULRESSO REMS.

WARNINGS AND PRECAUTIONS

Suicidal Thoughts and Behaviors: Consider changing the therapeutic regimen, including discontinuing ZULRESSO, in patients whose PPD becomes worse or who experience emergent suicidal thoughts and behavior.

ADVERSE REACTIONS: Most common adverse reactions (incidence ≥5% and at least twice the rate of placebo) were sedation/somnolence, dry mouth, loss of consciousness, and flushing/hot flush.

USE IN SPECIFIC POPULATIONS

- **Pregnancy:** ZULRESSO may cause fetal harm. Healthcare providers are encouraged to register patients by calling the National Pregnancy Registry for Antidepressants at 1-844-405-6185 or visiting online at https://womensmentalhealth.org/clinical-and-researchprograms/pregnancyregistry/antidepressants/
- **Renal Impairment:** Avoid use of ZULRESSO in patients with end stage renal disease (ESRD)

To report SUSPECTED ADVERSE REACTIONS, contact Sage Therapeutics, Inc. at 1-844-4-SAGERX (1-844-472-4379) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. **Please see accompanying full Prescribing Information including Boxed Warning.**

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