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): May 2, 2019

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))

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. ☐

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

Item 2.02 Results of Operations and Financial Condition

On May 2, 2019, Sage Therapeutics, Inc. announced its financial results for the quarter ended March 31, 2019. A copy of the press release is being furnished as Exhibit 99.1 to this Report on Form 8-K.

The information in this 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 (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 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 May 2, 2019, furnished herewith.

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: May 2, 2019

SAGE THERAPEUTICS, INC.

By: /s/ Anne Marie Cook
Anne Marie Cook
Senior Vice President, General Counsel

Exhibit 99.1

Sage Therapeutics Announces First Quarter 2019 Financial Results and Highlights Pipeline and Business Progress

ZULRESSO™ (brexanolone) injection approved by U.S. FDA and on track for launch in late June

Commercial team is launch ready; field teams focusing on payer engagement and identifying pathways to care

Strong financial position with ~$1.4B in cash

Milestones anticipated throughout 2019 in clinical studies across all three franchises: depression, neurology and neuropsychiatry

Conference call today at 8:00 A.M. ET

CAMBRIDGE, Mass. — May 2, 2019 — Sage Therapeutics, Inc. (NASDAQ: SAGE), a biopharmaceutical company developing novel medicines to treat life-altering central nervous system (CNS) disorders, today reported business highlights and financial results for the first quarter ended March 31, 2019.

"We started 2019 with positive data from a Phase 3 clinical trial of our lead oral compound SAGE-217 in postpartum depression and this was quickly followed by the FDA approval of ZULRESSO in PPD," said Jeff Jonas, M.D., chief executive officer at Sage. "It was gratifying that our first drug approval generated extensive media coverage of a disorder that for too long has been shrouded by stigma and shame. We anticipate additional momentum in our development efforts during the remainder of the year across our three franchises in depression, neurology and neuropsychiatry and believe the depth and breadth of our novel portfolio of compounds in these areas is unrivaled in the industry. We are confident in our potential to create a paradigm shift in the way brain health is thought about and treated."

Depression Franchise:

Led by ZULRESSO™ (brexanolone) injection, approved by the U.S. Food and Drug Administration (FDA) in March 2019 as the first treatment specifically indicated for postpartum depression (PPD), and SAGE-217, which is being evaluated in clinical studies as a treatment for major depressive disorder (MDD), PPD, bipolar depression as well as comorbid MDD and insomnia. SAGE-217 has received breakthrough therapy designation from the FDA in the treatment of MDD.

- ZULRESSO: Launch in the U.S. is on track for late June 2019 following scheduling by the U.S. Drug Enforcement Administration (DEA). ZULRESSO will only be available under a Risk Evaluation and Mitigation Strategy (REMS) program called the ZULRESSO REMS. Prior to launch, Sage continues executing against its go-to-market strategy with a focus on activating REMS-certified Centers of Excellence (COEs) and alternate sites of care, with the goal of ensuring broad access for women with PPD.
    - Sage has identified a targeted list of COEs that the Company believes are capable of providing ZULRESSO to patients at launch and in subsequent periods. These COEs are sites of care that have a PPD healthcare provider champion, ability to secure appropriate payer reimbursement for ZULRESSSO, and the capabilities to operate under the REMS. The commercial field teams are continuing to educate medical and administrative leaders at these COEs on the ZULRESSO REMS, as permitted, and we have been able to initiate the process of REMS-certification at some of these COEs.

- The Sage field market access team has completed more than 500 payer engagement meetings during the past several months, as permitted, including meetings with the majority of commercial and Medicaid payers. Since approval, these teams have conducted productive meetings with payers representing 90 percent of covered lives in the U.S.
- The Sage patient support organization is launch ready and will provide a range of patient support resources to assist women with PPD and their families, including: dedicated case managers who can provide information to help navigate the treatment journey; personalized support to assist with understanding insurance and coverage options; financial assistance programs for eligible patients; and access to educational resources and assistance through connections to local resources.
- Sage is continuing to use digital health technology in its efforts to raise awareness and reduce the stigma of PPD. Initiatives include:
  - Support of digital PPD education modules, reaching nearly 50,000 healthcare providers in the U.S. through the Medscape platform;
  - Support of digital health solutions to pregnant women and new moms, resulting in more than 100,000 digital screenings for PPD.
- A U.S. patent, exclusively licensed to the Company, was recently issued covering the method of treating PPD using brexanolone injection; this patent will expire in 2033.

- SAGE-217: The pivotal program evaluating the potential of SAGE-217 as a short-course episodic, rapidly-acting oral treatment for MDD and PPD is progressing on target. This program includes two completed, positive pivotal studies, one in MDD and one in PPD.
  - In January 2019, Sage announced statistically significant topline results in primary and secondary endpoints from the Phase 3 ROBIN Study of SAGE-217 in women with severe PPD. These results demonstrated a rapid, stable, and clinically meaningful improvement in depressive symptoms in the SAGE-217 treatment group compared to the placebo group after two weeks of treatment. The effect was maintained through the end of the four-week follow-up period. The most common adverse events in the treatment group were somnolence, headache, dizziness, upper respiratory tract infection, diarrhea, and sedation. Two subjects experienced serious adverse events, one in each treatment group.
  - Ongoing or planned studies in the program include:
    - *MOUNTAIN Study:* Evaluates a dosing regimen of two weeks of 20mg or 30mg SAGE-217 treatment compared to placebo in approximately 450 patients with MDD, with four weeks of blinded follow-up. Top-line data from the study are expected in Q4 2019 or Q1 2020. As a separate observational phase, the Company will continue to follow patients for up to 6 months.
    - *Retreatment studies*: These studies are designed to provide longer-term retreatment and follow-up safety and tolerability data.
      - MDD-302 will evaluate fixed interval SAGE-217 monotherapy maintenance (treatment without traditional antidepressants) for up to a year. This placebo-controlled trial is expected to commence in 3Q 2019 and, if successful, is intended to help meet the expected requirements for a New Drug Application for SAGE-217, and enable inclusion of maintenance dosing as part of the label.

- The SHORELINE Study evaluates 30mg SAGE-217 open-label treatment, treatment-free intervals and as-needed retreatment for return of major depressive episodes over the course of up to a year. Patients will receive an initial two-week course of SAGE-217 therapy and will be assessed every eight weeks for potential relapse of depressive symptoms. Data are expected in 2020.

- *RAINFOREST Study*: Evaluates two weeks of 30mg SAGE-217 treatment compared to placebo in approximately 100 patients with MDD and co-morbid insomnia. Top-line data are expected in 2020.

- The Company is also evaluating SAGE-217 in the Phase 2 open-label ARCHWAY Study in approximately 30 patients with bipolar I/II disorder with a current major depressive episode. Primary endpoints are safety and tolerability; secondary endpoints will measure improvements in depressive symptoms and sleep. Sage plans to announce top-line data from this study in July 2019.

- The Company is also evaluating the potential for development of SAGE-217 in additional affective disorders and expects to provide an update on those plans in July 2019.

Neurology Franchise:

Led by SAGE-324, a next-generation positive allosteric modulator (PAM) of $GABA_A$ receptors, in development as a potential therapy for neurological conditions, such as essential tremor (ET) and epileptiform disorders.

- SAGE-324: In a Phase 1 single ascending dose study (SAD), SAGE-324 was generally well-tolerated with no serious adverse events and demonstrated a pharmacokinetic profile consistent with once-daily dosing.

  - Sage is continuing to evaluate SAGE-324 in a Phase 1 multiple ascending dose (MAD) study in healthy volunteers and a Phase 1 single dose open-label study in patients with ET. These studies are designed to evaluate the safety, tolerability and pharmacokinetics of the compound. Target engagement using pharmaco-EEG (ß-band power) was observed in the SAD study and will continue to be evaluated in the MAD study. Results from these trials are expected to be announced in 2H 2019.

Neuropsychiatry Franchise:

Led by SAGE-718, a first-in-class NMDA receptor PAM, in development as a potential therapy for certain cognition-related disorders impacted by NMDA receptor dysfunction.

- SAGE-718: The completed Phase 1 single and multiple ascending dose studies in healthy volunteers demonstrated a pharmacokinetic profile consistent with once-daily dosing. SAGE-718 was generally well-tolerated in the studies with no serious adverse events.

  - Results from ongoing Phase 1 target engagement biomarker studies in healthy volunteers, focusing on electrophysiology and imaging, are expected to be announced in July 2019.

  - Results from an ongoing Phase 1 study to determine the safety, tolerability and pharmacokinetics in patients with early Huntington's disease are expected to be announced in 2H 2019.

Anticipated Upcoming Milestones

- **Top-line data readouts:**
    - SAGE-217 Phase 2 ARCHWAY Study in bipolar depression (July 2019)
    - SAGE-324 Phase 1 MAD study; cohorts 1-4 (July 2019)
    - SAGE-718 Phase 1 biomarker data (July 2019)
    - SAGE-718 early Huntington's disease Phase 1 cohort data (2H 2019)
    - SAGE-324 essential tremor Phase 1 topline data (2H 2019)
    - SAGE-217 MDD Phase 3 MOUNTAIN Study (Q4 2019/Q1 2020)
    - SAGE-217 MDD Phase 3 RAINFOREST and SHORELINE studies (2020)
- **Regulatory and commercial:**
    - ZULRESSO commercial launch in the U.S., pending DEA scheduling (late June 2019)

Financial Results for the First Quarter of 2019

- **Cash Position:** Cash, cash equivalents, and marketable securities as of March 31, 2019 were approximately $1.4 billion, compared to $922.8 million at December 31, 2018. The increase was primarily due to proceeds from Sage's follow-on public offering completed in February 2019.
- **R&D Expenses:** Research and development expenses were $86.4 million, including $20.7 million of non-cash stock-based compensation expense, in the first quarter of 2019, compared to $49.3 million, including $8.9 million of non-cash stock-based compensation expense, for the same period of 2018. The increase in R&D expenses year-over-year was primarily due to advancement of the pivotal program for SAGE-217 in depression; continued research efforts across our early-stage clinical and discovery pipeline; and investments in R&D headcount to support the growth in Sage's pipeline and operations.
- **G&A Expenses:** General and administrative expenses were $83.9 million, including $23.4 million of non-cash stock-based compensation expense, in the first quarter of 2019, compared to $28.8 million, including $6.9 million of non-cash stock-based compensation expense, for the same period of 2018. The increase in G&A expenses was primarily due to the increase in personnel-related expenses, professional fees to support expanding operations, costs related to continued preparations for the anticipated commercial launch of ZULRESSO, and facilities-related costs to support expanding operations.
- **Net Loss:** Net loss was $163.4 million for the first quarter of 2019 compared to a net loss of $74.6 million, for the comparable period of 2018.

Financial Guidance

- Based on its current operating plan, Sage now anticipates that its balance of cash, cash equivalents and marketable securities will be at least $950 million at the end of 2019.
- Sage expects that its operating expenses will increase year-over-year in 2019 to support continued pipeline advancement and anticipated commercialization of ZULRESSO in PPD.

Conference Call Information

Sage will host a conference call and webcast today at 8:00 A.M. ET to discuss its first quarter 2019 financial results and recent corporate updates. The live webcast can be accessed on the investor page of Sage's website at investor.sagerx.com. The conference call can be accessed by dialing 1-866-450-8683 (toll-free domestic) or 1-281-542-4847 (international) and using the conference ID 5968036. 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 medicines to transform the lives of patients with life-altering central nervous system (CNS) disorders. Sage's portfolio of novel compounds targets critical receptor systems in the brain and includes the first treatment specifically approved by the U.S. Food and Drug Administration for postpartum depression as well as compounds being developed as potential treatments for diseases such as major depressive disorder, insomnia, bipolar disorder and essential tremor. 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 expectations regarding the timing of scheduling and launch of ZULRESSO in the treatment of PPD; our plans regarding anticipated future commercial and patient support activities; our expectations regarding availability of REMS-certified sites of care for the administration of ZULRESSO and access to treatment for women with PPD; our statements regarding the potential for reimbursement of ZULRESSO; our view as to the potential for us to change the way brain health is treated; our statements regarding the target product profiles, plans and timelines for development of our product candidates, including planned clinical activities and reporting of results; our views as to the depth and breadth of our portfolio and the opportunity represented by our programs and business; and our expectations regarding our cash position at year-end and increases in operating expense. 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: scheduling and launch of ZULRESSO may not occur on the timelines we expect; we may encounter issues or other challenges in launching and commercializing ZULRESSO, including issues related to market acceptance by healthcare providers, healthcare settings and women with PPD, challenges with reimbursement, issues related to limitations on the site of administration of ZULRESSO to REMS-certified supervised healthcare settings and the other requirements of the REMS, and challenges associated with execution of our sales and patient support activities, which in each case could limit the potential of ZULRESSO; results achieved with use of ZULRESSO in the treatment of PPD once we have launched the product may be different than observed in clinical trials, and may vary among patients; the number of women with PPD or the unmet need for additional treatment options may be significantly smaller than we expect; we may encounter unexpected safety or tolerability issues with ZULRESSO or any of our product candidates; we may not be successful in our development of any of our current or future product candidates in any indication we are currently pursuing or may in the future pursue; success in early stage clinical trials may not be repeated or observed in ongoing or future studies of any of our product candidates; ongoing and future clinical results may not support further development or be sufficient to gain regulatory approval of our product candidates; we may decide that a development pathway for one of our product candidates in one or more indications is no longer feasible or advisable or that the unmet need no longer exists; the FDA may decide that the development program for any of our product candidates, even if positive, is not sufficient for a new drug application filing or approval; 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; we may experience slower than expected enrollment in ongoing or future clinical trials; the internal and external costs required for our anticipated launch and commercialization activities and ongoing and planned research and development efforts, and to build our organization in connection with such activities, and the resulting expense increases and use of cash, may be higher than expected, or we may conduct additional clinical trials or pre-clinical studies, or engage in new activities,

requiring additional expenditures and using cash more quickly than anticipated and we may encounter technical and other unexpected hurdles in the commercialization of ZULRESSO or in the development of our product candidates; as well as those risks more fully discussed in the section entitled "Risk Factors" in our most recent report filed with the Securities and Exchange Commission (SEC), and discussions of potential risks, uncertainties, and other important factors in our subsequent filings with the SEC. 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 March 31,	
	2019	2018
Collaboration revenue	$ 465	$ —
Operating expenses:		
Research and development	86,398	49,270
General and administrative	83,919	28,849
Total operating expenses	170,317	78,119
Loss from operations	(169,852)	(78,119)
Interest income, net	6,442	3,529
Other income (expense), net	4	(8)
Net loss	$ (163,406)	$ (74,598)
Net loss per share — basic and diluted	$ (3.37)	$ (1.68)
Weighted average shares outstanding — basic and diluted	48,491,834	44,325,371

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

	March 31, 2019	December 31, 2018
Cash, cash equivalents, restricted cash and investments	$1,353,618	$ 925,143
Total assets	$1,422,914	$ 952,705
Total liabilities	$ 103,380	$ 89,734
Total stockholders' equity	$1,319,534	$ 862,971

Important Safety Information:

What is ZULRESSO™?

ZULRESSO is a prescription medicine used in adults to treat a certain type of depression called Postpartum Depression.

IMPORTANT SAFETY INFORMATION

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

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 ZULRESSO 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 ZULRESSO 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.

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. It is not known if ZULRESSO will harm your unborn baby.
  - There is a pregnancy registry for females who are exposed to ZULRESSO during pregnancy. The purpose of the registry is to collect information about the health of females exposed to ZULRESSO and their baby. If you become pregnant during treatment with ZULRESSO, talk to your healthcare provider about registering with the National Pregnancy Registry for Antidepressants at 1-844-405-6185 or visit https://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/antidepressants/
- are breastfeeding or plan to breastfeed. ZULRESSO passes into breast milk. Talk to your healthcare provider about the risks and benefits of breastfeeding and about the best way to feed your baby while receiving ZULRESSO.

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).

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine. Your healthcare provider will decide if other medicines can be taken with ZULRESSO.

How will I receive ZULRESSO?

ZULRESSO is given to you by continuous intravenous (IV) infusion into your vein. The infusion will last for a total of 60 hours (2.5 days).

What should I avoid while receiving ZULRESSO?

- ZULRESSO may make you feel dizzy and sleepy. Do not drive a car or do other dangerous activities after your ZULRESSO infusion until your feeling of sleepiness has completely gone away. See "**What is the most important information I should know about ZULRESSO?**"
- Do not drink alcohol while receiving ZULRESSO.

What are the possible side effects of ZULRESSO?

ZULRESSO can cause serious side effects, including:

- See "**What is the most important information I should know about ZULRESSO?**"
- **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. Depression or other serious mental illnesses are the most important causes of suicidal thoughts or actions.

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.
  – 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, other unusual changes in behavior or mood

The most common side effects of ZULRESSO include:

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

These are not all the side effects of ZULRESSO.

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

Please see full Prescribing Information, including Boxed WARNING, and Medication Guide for ZULRESSO™ and discuss any questions you may have with your healthcare provider.

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