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

FORM 8-K

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

Date of Report (Date of Earliest Event Reported): August 7, 2018

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. ☐

Item 2.02 Results of Operations and Financial Condition

On August 7, 2018, Sage Therapeutics, Inc. announced its financial results for the quarter ended June 30, 2018. 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 August 7, 2018, 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.

SAGE THERAPEUTICS, INC.

Date: August 7, 2018

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

Exhibit 99.1

Sage Therapeutics Announces Second Quarter 2018 Financial Results and Highlights Pipeline and Business Progress

Conditional acceptance granted by U.S. Food and Drug Administration (FDA) for the proprietary name ZULRESSO™ for Sage's intravenous formulation of brexanolone

Continuing to execute commercial build and launch readiness for ZULRESSO™ (brexanolone injection) in postpartum depression ahead of PDUFA target date of December 19, 2018

Accelerating breakthrough pivotal program for SAGE-217 in depression with key trial milestones expected in 4Q 2018

Progressed clinical pipeline with SAGE-718 Phase 1 multiple ascending dose and SAGE-324 Phase 1 single ascending dose trial initiations and planned SAGE-217 Phase 2 trial initiation in bipolar depression

Conference call today at 8:00 AM ET

CAMBRIDGE, Mass., August 7, 2018 – Sage Therapeutics, Inc. (NASDAQ: SAGE), a clinical-stage biopharmaceutical company developing novel medicines to treat life-altering central nervous system (CNS) disorders, today reported business highlights and financial results for the second quarter ended June 30, 2018.

"This quarter we continued to make great progress on our journey to become a multinational biotech company," said Jeff Jonas, M.D., chief executive officer of Sage. "This was underscored by the regulatory milestones and commercial launch readiness activities in support of ZULRESSO™ (brexanolone injection), the initiation of our strategic collaboration with Shionogi on the development and commercialization of SAGE-217 in key Asian markets, and the ongoing advancement of our early stage drug candidates, SAGE-718 and SAGE-324, into new Phase 1 clinical studies. With the upcoming potential approval and launch of ZULRESSO, we remain focused in our approach to forge news paths for the treatments of CNS disorders."

ZULRESSO Regulatory, Commercial and Pre-Launch Activities Updates:

- The FDA has conditionally accepted the proprietary name ZULRESSO for Sage's intravenous (IV) formulation of brexanolone;
- Sage's New Drug Application for ZULRESSO for the treatment of PPD was accepted for Priority Review by the FDA. The FDA has assigned a Prescription Drug User Fee Act (PDUFA) target date of December 19, 2018, and is planning to hold an Advisory Committee meeting to discuss the ZULRESSO application on November 2, 2018, consistent with FDA's policy to seek advice on new medicines with a new mechanism of action for a new indication;
- Sage continues with preparations for a potential 1H 2019 commercial launch of ZULRESSO for the treatment of PPD, if the NDA is approved, including:
    - Advancing development of a family-centric site of care strategy for PPD patients with potential options ranging from the in-patient hospital setting, supervised home care, and alternate sites of care, subject to FDA approval of each option and agreement on the final ZULRESSO label;
    - Partnering with Lash Group, a part of AmerisourceBergen, to establish a robust patient support model leveraging innovative technologies coupled with Sage-led case management support for PPD patients, and completing preparations for the opening of Sage's National Patient Support Center in Raleigh, North Carolina this fall;

- Continuing expansion of the commercial organization, including considerable progress in the build of the field team;
- Engaging in permitted discussions with payers to raise awareness of PPD and on the value proposition of the ZULRESSO product profile, conducting over 100 customer meetings and having met with all National Payer Accounts.

- Sage presented a systematic literature review on the humanistic burden of PPD at the 23rd Annual International Society for Pharmacoeconomics and Outcomes Research (ISPOR) Meeting. The review concluded that there is a considerable body of literature suggesting that PPD has a substantial humanistic burden on affected mothers as well as their children and families, including impaired mother-infant bonding, lower rates of breastfeeding, and the potential for significant long-term impact on the physical and mental development of children. To further understand real-world burdens of PPD, Sage has partnered with the PatientsLikeMe patient network;
    - Sage is also working with top U.S. health economists on the value assessment of ZULRESSO as part of broader health economics and outcomes research initiatives.

Pipeline Updates:

Beyond ZULRESSO, Sage is advancing a portfolio of novel CNS product candidates targeting the GABA and NMDA receptor systems. Dysfunction in these systems is known to be at the core of numerous psychiatric and neurological disorders.

- SAGE-217 in Major Depressive Disorder (MDD) and PPD:
    - In June, Sage received support from the FDA on an expedited pivotal development plan evaluating the novel concept of episodic dosing using a short course treatment of SAGE-217 in both MDD and PPD.
    - Sage plans to initiate a Phase 3 placebo-controlled trial of SAGE-217 in MDD in 4Q 2018. The trial will evaluate two weeks of 20mg or 30mg SAGE-217 treatment compared to placebo in 450 patients with MDD, with four weeks of additional follow-up.
    - Sage is also evaluating SAGE-217 in a Phase 3 placebo-controlled trial in 140 patients with PPD, and plans to announce top-line results in 4Q 2018.
    - Additional data regarding patient safety and potential treatment of recurrent or new major depressive episodes will be acquired through a long-term open-label study program in which approximately 300 patients will be followed for six months and 100 patients will be followed for a year after initial SAGE-217 treatment and episodic retreatment as needed.
    - In June, Sage entered into a strategic collaboration with Shionogi & Co., Ltd. for the clinical development and commercialization of SAGE-217 for the treatment of MDD and other indications in Japan, Taiwan and South Korea.
- SAGE-217 in Other Psychiatric Indications:
    - Bipolar depression: Sage plans to initiate a two-part Phase 2 trial initially evaluating four weeks of open-label SAGE-217 treatment in up to 30 patients with bipolar I/II disorder with a current major depressive episode. If warranted, the study will progress to a randomized, placebo-controlled study. The trial is intended to evaluate the safety and tolerability of SAGE-217 (primary endpoint) and secondary endpoints, including efficacy in improving depressive symptoms and sleep. Sage plans to initiate this study in 4Q 2018.

- Sleep disorders: Sage recently announced additional data on key secondary endpoints from a placebo-controlled trial in a model of insomnia demonstrating an encouraging impact of SAGE-217 on sleep architecture and that treatment did not impact next-day cognitive performance. These data are being planned for presentation at an upcoming medical meeting. Sage plans to initiate a Phase 3 placebo-controlled polysomnography trial in MDD patients with co-morbid insomnia in 4Q 2018, and also plans to seek feedback later this year from the FDA on potential development plans for SAGE-217 for the treatment of sleep disorders.

- SAGE-324 in Neurological Indications:
  - Sage recently received IND clearance to initiate a Phase 1 single-ascending dose trial of SAGE-324 in healthy volunteers. Based on its pre-clinical pharmacokinetic/pharmacodynamic profile, SAGE-324 may be suitable for chronic oral dosing, and is being developed as a potential treatment for patients impacted by neurological conditions, such as epileptiform disorders, essential tremor, and Parkinson's disease. Sage plans to release top-line results from the study, which is intended to evaluate the safety, tolerability, pharmacokinetic and pharmacodynamic profile of SAGE-324, in 4Q 2018.
- GABA Discovery Programs:
  - Sage continues to evaluate additional novel $GABA_A$ receptor modulators that are currently in pre-clinical development, including SAGE-689, SAGE-105 and others.
- NMDA Programs:
  - SAGE-718: Sage recently initiated a Phase 1 multiple ascending dose trial of SAGE-718 in healthy volunteers. Sage plans to release top-line results from the study, which is intended to further evaluate the safety, tolerability, pharmacokinetic and pharmacodynamic profile of SAGE-718, in 4Q 2018. If the Phase 1 program is successful, Sage expects to advance SAGE-718 into clinical trials of certain CNS disorders characterized by NMDA receptor hypofunction.
  - SAGE-904: Sage's second NMDA positive allosteric modulator candidate, SAGE-904, is in IND-enabling studies.

Disease Education Initiatives:

- Sage is continuing to advance multiple PPD disease awareness and screening efforts, through initiatives led by Sage's Medical Affairs organization. Sage is seeing tangible signs of progress on these efforts to improve the urgency to manage PPD, including the American Congress of Obstetricians and Gynecologists' (ACOG) Committee Opinion on Redefining the Postpartum Visit and recommendation on comprehensive maternal mental care support by Obstetricians/Gynecologists throughout the fourth trimester of pregnancy. The following initiatives were led by the Sage Medical Affairs team in the second quarter:
  - Launched broad digital disease awareness campaign and knowppd.com website for healthcare providers to improve screening and care for PPD patients.
  - Conducted live PPD educational symposia at ACOG, American Psychiatric Association (APA), and Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN) Annual Meetings to increase physician and nurse understanding of PPD.
  - Supported development and launch of independent digital medical education programs on screening and current management of PPD via Medscape and WebMD.
  - Continued collaboration with national and local patient advocacy groups during maternal mental health month to help reduce stigma of PPD and help patients and families navigate to care.

- Ongoing, permitted engagement with a broad number of maternal and psychiatric health centers across the U.S. to develop in-depth profiles on their respective PPD healthcare providers, unique management pathways, and unmet needs.

Expected Milestones

- **Medical Meeting Presentations:**
  - 24th Congress of the European Sleep Research Society (ESRS), September 25 – September 28, 2018 in Basel, Switzerland
  - International Marce Society for Perinatal Health Biennial Scientific Meeting 2018, September 26 – September 28, 2018 in Bangalore, India
  - 31st European College of Neuropsychopharmacology Congress (ECNP), October 6 – October 9, 2018 in Barcelona, Spain
  - 48th Annual Meeting of the Society for Neuroscience (SfN), November 3 – November 7, 2018 in San Diego, CA
- **Trial Initiations:**
  - SAGE-217 Phase 3 placebo-controlled trial in MDD (4Q 2018)
  - SAGE-217 Phase 3 placebo-controlled polysomnography trial in MDD patients with co-morbid insomnia (4Q 2018)
  - SAGE-217 Phase 2 trial in bipolar depression (4Q 2018)
- **Data Readouts:**
  - SAGE-217 Phase 3 placebo-controlled trial in PPD (4Q 2018)
  - SAGE-718 Phase 1 multiple ascending dose trial (4Q 2018)
  - SAGE-324 Phase 1 single ascending dose trial (4Q 2018)
- **Regulatory and Commercial:**
  - EMA Scientific Advice for brexanolone in PPD (4Q 2018)
  - FDA planned Advisory Committee Meeting for ZULRESSO in PPD (November 2, 2018)
  - ZULRESSO in PPD PDUFA target date (December 19, 2018)
  - ZULRESSO in PPD commercial launch, if approved (1H 2019)

Financial Results for the Second Quarter of 2018

“We are excited to announce that our collaboration with Shionogi, in the second quarter, enabled Sage to book revenue for the first time,” said Kimi Iguchi, chief financial officer of Sage. “This capital further strengthens our financial position and provides us the ability to make aggressive investments in our late-stage assets, ZULRESSO and SAGE-217, as well as in earlier-stage assets, such as SAGE-324 and SAGE-718. Sage’s cost-efficient approach to drug development, our diverse pipeline, and our focus on larger markets with substantial patient populations, represents a unique value proposition with near, intermediate and long-term opportunities.”

- **Revenues:** Collaboration revenues were $90.0 million in the second quarter of 2018, compared with no revenues for the same period of 2017. All revenues for the second quarter of 2018 are attributable to an upfront payment from Sage’s strategic collaboration with Shionogi & Co., Ltd.
- **R&D Expenses:** Research and development expenses were $69.0 million, including $12.1 million of non-cash stock-based compensation expense, in the second quarter of 2018, compared to $55.9 million, including $5.2 million of non-cash stock-based compensation expense, for the same period of 2017. The increase in R&D expenses year-over-year was primarily due to increases in ongoing R&D programs and discovery efforts focused on identifying new clinical

candidates and additional indications of interest and investments in R&D headcount to support the growth in Sage's pipeline and operations, offset by decreases in expenses due to the completion of Phase 3 clinical development of ZULRESSO.

- **G&A Expenses:** General and administrative expenses were $43.2 million, including $16.9 million of non-cash stock-based compensation expense, in the second quarter of 2018, compared to $15.0 million, including $4.1 million of non-cash stock-based compensation expense, for the same period of 2017. 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 a potential commercial launch, and facilities-related costs to support expanding operations.
- **Net Loss:** Net loss was $17.0 million for the second quarter of 2018 compared to a net loss of $70.2 million for the comparable period of 2017.
- **Cash Position:** Cash, cash equivalents, and marketable securities as of June 30, 2018 were $1.1 billion, compared with $518.8 million at December 31, 2017. The increase was primarily due to net proceeds of $631.2 million from Sage's follow-on public offering completed in February 2018.

Financial Guidance:

- Based on its current operating plan, Sage anticipates that its existing cash, cash equivalents and marketable securities will enable Sage to fund its operating expenses and capital expenditure requirements into 2020.
- Sage expects that its operating expenses will increase year-over-year in 2018 to support continued pipeline advancement, including ongoing Phase 3 development of SAGE-217, and preparations for potential commercialization of ZULRESSO in PPD, if approved.

Conference Call Information

Sage will host a conference call and webcast on Tuesday, August 7, 2018 at 8:00 A.M. ET to report its second quarter 2018 financial results and to discuss recent business 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 (866) 450-8683 (toll-free domestic) or (281) 542-4847 (international) and using the conference ID 5396188. 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 clinical-stage biopharmaceutical company committed to developing novel medicines to transform the lives of patients with life-altering CNS disorders. Sage's lead product candidate, ZULRESSO™ (brexanolone injection), has completed Phase 3 clinical development for postpartum depression and a New Drug Application is currently under review with the U.S. Food and Drug Administration. Sage is developing a portfolio of novel product candidates targeting critical CNS receptor systems, including SAGE-217, which is in Phase 3 development in major depressive disorder and postpartum depression. 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 potential for approval of our NDA for brexanolone IV in the treatment of PPD; our expectations regarding our possible transition to a commercial-stage company, including the timing of a potential decision by the FDA and potential launch of brexanolone IV

in PPD; our plans and expectations regarding our future commercial activities in the U.S., if brexanolone IV is approved, including the potential availability of home infusion and other potential sites of care and the nature of our planned patient support model; our statements regarding plans and timelines for further development of SAGE-217 and our other product candidates and planned clinical and regulatory activities; our expectations regarding the potential sufficiency of our planned SAGE-217 development program, if successful, to support regulatory filing and approval of SAGE-217 in MDD and PPD; our views as to the potential of SAGE-217 to represent a potential paradigm shift in the treatment of MDD; our views as to the opportunity represented by Sage's portfolio and business, and the potential for value creation; and our expectations regarding the strength of our balance sheet, the potential for future revenue and future cash needs. 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: the FDA may decide not to approve our NDA for brexanolone IV in PPD; the clinical and non-clinical data we have generated with our proprietary formulation of brexanolone to date may be determined by the FDA and other regulatory authorities, despite prior advice, to be insufficient to gain regulatory approval to launch and commercialize our product in PPD and regulatory authorities may determine that additional trials or data are necessary in order to obtain approval; regulatory authorities may find fault with the data generated at particular clinical site or sites or with the activities of our trial monitor or may disagree with our analyses of the results of our trials or identify issues with our manufacturing or quality systems, and any such findings or issues could require additional data or analyses or changes to our systems that could delay or prevent us from gaining approval of brexanolone IV; even if brexanolone IV is approved in PPD, regulatory authorities may impose significant restrictions or conditions on use or on administration, including on sites of care; we may encounter issues, delays or other challenges in launching or commercializing the product, including issues related to market acceptance and reimbursement, challenges associated with any restrictions or conditions that may be imposed by regulatory authorities, including any challenges or restrictions related to enabling home infusion and other venues as viable options for site of administration of brexanolone IV, and challenges associated with the build of our sales and patient support organizations and their activities, which in each case could limit the potential of our product; we may encounter unexpected safety or tolerability issues with brexanolone IV, SAGE-217 or any of our other product candidates in ongoing or future development; we may not achieve expedited development or review of SAGE-217; the FDA may ultimately decide that the design or results of our planned clinical trials for SAGE-217 even if positive are not sufficient for regulatory approval in MDD, PPD or any other indication or do not support episodic treatment of MDD which is the focus of our expedited development plan; we may not be successful in our development of SAGE-217 or in our development of any of our 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 SAGE-217 or any of our other 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; 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 clinical trials; the internal and external costs required for our activities, and to build our organization in connection with such activities, and the resulting 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 development, manufacture and potential future

commercialization of our product candidates; as well as those risks more fully discussed in the section entitled "Risk Factors" in our most recent Quarterly Report on Form 10-Q, and 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.

Investor Contact:
Paul Cox, 617-299-8377
paul.cox@sagerx.com

Media Contact:
Maureen L. Suda, 585-355-1134
maureen.suda@sagerx.com

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Collaboration revenue	$ 90,000	$ —	$ 90,000	$ —
Operating expenses:				
Research and development	68,980	55,900	118,250	101,100
General and administrative	43,167	14,954	72,016	27,234
Total operating expenses	112,147	70,854	190,266	128,334
Loss from operations	(22,147)	(70,854)	(100,266)	(128,334)
Interest income, net	5,137	672	8,666	1,379
Other expense, net	32	(20)	24	(24)
Net loss	$ (16,978)	$ (70,202)	$ (91,576)	$ (126,979)
Net loss per share – basic and diluted	$ (0.36)	$ (1.88)	$ (2.02)	$ (3.40)
Weighted average shares outstanding – basic and diluted	46,541,716	37,361,129	45,439,666	37,315,393

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

	June 30, 2018	December 31, 2017
Assets		
Current Assets:		
Cash and cash equivalents	$ 325,830	$ 306,235
Marketable securities	766,603	212,613
Prepaid expenses and other current assets	12,958	6,227
Receivable from collaborator	18,378	—
Total current assets	1,123,769	525,075
Property and equipment and other long-term assets	5,714	4,862
Total assets	$ 1,129,483	$ 529,937
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 8,338	$ 9,350
Accrued expenses	39,581	42,601
Total current liabilities	47,919	51,951
Other liabilities	3,801	2,511
Total liabilities	51,720	54,462
Total stockholders' equity	1,077,763	475,475
Total liabilities and stockholders' equity	$ 1,129,483	$ 529,937