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 19, 2021

Sage Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

DELAWARE	001-36544	27-4486580
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

215 First Street Cambridge, MA	02142
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code (617) 299-8380

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	**SAGE**	**The Nasdaq Global Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events.

On October 19, 2021, Sage Therapeutics, Inc. issued a press release titled “Sage Therapeutics and Biogen Announce Plans to Submit a New Drug Application (NDA) for Zuranolone to the U.S. Food & Drug Administration in the Second Half of 2022 with Rolling Submission Expected to Start in Early 2022.” A copy of the press release is filed as Exhibit 99.1 hereto and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by Sage Therapeutics, Inc. on October 19, 2021.
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 19, 2021

SAGE THERAPEUTICS, INC.

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

Sage Therapeutics and Biogen Announce Plans to Submit a New Drug Application (NDA) for Zuranolone to the U.S. Food & Drug Administration in the Second Half of 2022 with Rolling Submission Expected to Start in Early 2022

Following the pre-NDA meeting, the companies confirmed the current efficacy and safety databases are expected to be adequate for filing with confirmed pathways for MDD and PPD

The planned initial submission package will be for the treatment of MDD with an anticipated PPD filing thereafter

CAMBRIDGE, Mass. – October 19, 2021 – Sage Therapeutics, Inc. (Nasdaq: SAGE) and Biogen Inc. (Nasdaq: BIIB) today announced their plan to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for zuranolone, an investigational two-week, once-daily therapeutic in the second half of 2022. The planned initial submission package will seek approval of zuranolone for the treatment of major depressive disorder (MDD) and an additional filing for postpartum depression (PPD) is anticipated in the first half of 2023. The decision to submit the application follows recent discussions with the FDA, including a pre-NDA meeting held this fall. Data from completed studies in the LANDSCAPE and NEST programs, as well as data from the ongoing clinical and pharmacology studies are planned to be included as part of the submission packages.

“In the pre-NDA meeting, the FDA’s response on the regulatory pathway for zuranolone continued to be consistent with previous discussions. In the clinical development programs, zuranolone has shown remarkably consistent, rapid, and sustained reductions in depressive symptoms, including anxiety and sleep loss, in addition to a well-tolerated safety profile. We believe we have a solid filing package with four adequate and well controlled trials now in hand and, if approved, zuranolone will fill a real unmet need and be welcomed by people living with depression,” said Barry Greene, chief executive officer at Sage Therapeutics. “We have identified what we believe is the most efficient path forward for an FDA filing and potential approval.”

Sage and Biogen also announced the CORAL Study is fully enrolled and closed to further screening, with topline data expected in early 2022. The CORAL Study is designed to demonstrate a rapid onset of depression relief when zuranolone is co-initiated with a standard antidepressant therapy.

“We are pleased to share what we believe is an efficient filing pathway for zuranolone, with the goal of bringing a new treatment option to the millions of people who suffer from depression worldwide,” said Alfred Sandrock, Jr., M.D., Ph.D., Head of Research and Development at Biogen. “The efficacy and safety data planned for FDA submission support our vision of zuranolone being an as-needed, two-week once-daily treatment option for MDD and PPD that produces rapid relief from symptoms within days.”

Sage and Biogen plan to submit a separate and distinct filing for PPD once the ongoing PPD 301-SKYLARK Study completes so as not to affect the MDD review timeline. The companies plan to commence marketing for the approved indications as soon as possible pending the FDA’s approval. The review cycles may allow commercialization of both indications simultaneously, if approved.

About Major Depressive Disorder (MDD)

Major depressive disorder (MDD) is a common but serious mood disorder in which people experience depressive symptoms that impair their social, occupational, educational, or other important functioning, such as a depressed mood or loss of interest or pleasure in daily activities, consistently for at least a two-week period. It is estimated that approximately 19 million people in the U.S. and more than 250 million people worldwide suffer from MDD each year. While antidepressants are widely used to treat MDD, large-scale studies have demonstrated the need for additional therapies with a differentiated profile.

About Postpartum Depression (PPD)

Postpartum depression (PPD) is one of the most common medical complications during and after pregnancy. PPD can have a serious negative impact on a woman, including significant functional impairment, depressed mood and/or loss of interest in her newborn, and associated symptoms of depression such as loss of appetite, difficulty sleeping, motor challenges, lack of concentration, loss of energy and poor self-esteem. PPD is estimated to affect approximately one in eight women who have given birth in the U.S. or approximately over 500,000 women annually.

About Zuranolone

Zuranolone (SAGE-217/BIIB125) is a once-daily, two-week, investigational drug in development for the treatment of major depressive disorder (MDD) and postpartum depression (PPD). Zuranolone is an investigational oral neuroactive steroid (NAS) GABA-A receptor positive allosteric modulator (PAM). The GABA system is the major inhibitory signaling pathway of the brain and central nervous system and contributes to regulating brain function. Zuranolone has been granted Breakthrough Therapy Designation by the U.S. Food & Drug Administration.

Zuranolone is being evaluated in the NEST and LANDSCAPE clinical trial programs. The two development programs include multiple studies examining use of zuranolone in several thousand patients with a variety of dosing, clinical endpoints, and treatment paradigms. The LANDSCAPE program includes five studies of zuranolone in patients with MDD (MDD-201B, MOUNTAIN, SHORELINE, WATERFALL, and CORAL Studies). The NEST program includes two placebo-controlled studies of zuranolone in patients with PPD (ROBIN and SKYLARK Studies). Additionally, Shionogi recently completed a Phase 2 study of zuranolone in Japan.

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.

About Biogen

At Biogen, our mission is clear: we are pioneers in neuroscience. Biogen discovers, develops and delivers worldwide innovative therapies for people living with serious neurological and neurodegenerative diseases as well as related therapeutic adjacencies. One of the world’s first global biotechnology companies, Biogen was founded in 1978 by Charles Weissmann, Heinz Schaller, Kenneth Murray and Nobel Prize winners Walter Gilbert and Phillip Sharp. Today Biogen has the leading portfolio of medicines to treat multiple sclerosis, has introduced the first approved treatment for spinal muscular atrophy, commercializes biosimilars of advanced biologics and is focused on advancing research programs in multiple sclerosis and neuroimmunology, Alzheimer’s disease and dementia, neuromuscular disorders, movement disorders, ophthalmology, neuropsychiatry, immunology, acute neurology and neuropathic pain.

We routinely post information that may be important to investors on our website at www.biogen.com. Follow us on social media - Twitter, LinkedIn, Facebook, YouTube.

Forward-Looking Statements

Sage Therapeutics Safe Harbor

Various statements in this release concern Sage's future expectations, plans and prospects, including without limitation statements regarding: plans for an NDA filing for zuranolone in MDD and PPD, and the potential timing of such submissions; our belief in the adequacy of the data we plan to submit in the NDA; the potential for FDA acceptance of an NDA for zuranolone; the potential for regulatory approval and commencement of commercialization of zuranolone and our goals as to timing; our planned timing for reporting of data from ongoing clinical trials; the potential profile and benefit of zuranolone in MDD and PPD; our belief in the regulatory filing pathways and opportunities for zuranolone; other planned next steps for the program; our estimates as to the number of patients with MDD and PPD; and other statements regarding the goals, opportunity and potential for zuranolone and 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 experience delays or unexpected hurdles in our efforts to submit an NDA for zuranolone and we may not be able to submit the NDA on the timelines we expect or at all; the FDA may find inadequacies and deficiencies in our NDA for zuranolone, including in the data we submit, and may decide not to accept the NDA for filing; even if the FDA accepts the NDA for filing, the FDA may not meet expected review timelines and may ultimately decide not to approve zuranolone in MDD or PPD; the FDA may decide that the design, conduct or results of our completed and ongoing clinical trials for zuranolone, even if positive, are not sufficient for approval in MDD or PPD and may require additional trials or data which may significantly delay and put at risk our efforts to obtain approval and may not be successful; other decisions or actions of the FDA or other regulatory agencies may affect the zuranolone program and our plans, progress or results; we may experience negative results in ongoing or future studies of zuranolone that negatively affect our ability to obtain approval of zuranolone or that impair the potential profile of zuranolone; success in earlier clinical trials 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 or generate results sufficient to gain regulatory approval to market zuranolone without further development work; unexpected concerns may arise from additional data, analysis or results from any of our completed studies; we may encounter adverse results or adverse events at any stage of development that negatively impact further development or that require additional nonclinical and clinical work which may not yield positive results; we may encounter delays in conduct of our clinical trials, including slower than expected site initiation or enrollment, that may impact our ability to meet our expected time-lines; the actual size of the MDD and PPD patient populations may be significantly lower than our estimates and, even if zuranolone is approved, it may only be approved or used to treat a subset of the relevant patient populations; we may encounter technical and other unexpected hurdles in the development and manufacture of zuranolone or our other product candidates which may delay our timing or change our plans; as well as those risks more fully discussed in the section entitled "Risk Factors" in our most recent Quarterly Report on Form 10-Q, as well as discussions of potential risks, uncertainties, and other important factors in our subsequent filings with the Securities and Exchange Commission. In addition, any forward-looking statements represent our views only as of today, and should not be relied upon as representing our views as of any subsequent date. We explicitly disclaim any obligation to update any forward-looking statements.

Biogen Safe Harbor

This news release contains forward-looking statements, including statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, relating to the potential, benefits, safety and efficacy of zuranolone; the potential clinical effects of zuranolone; the clinical development program for zuranolone; clinical development programs, clinical trials and data readouts and presentations for zuranolone; the potential treatment of MDD and PPD; the potential of Biogen's commercial business and pipeline programs, including zuranolone; the anticipated benefits and potential of Biogen's collaboration arrangement with Sage; and risks and uncertainties associated with drug development and commercialization. These forward-looking statements may be accompanied by words such as "aim," "anticipate," "believe," "could," "estimate," "expect," "forecast," "intend," "may," "plan," "potential," "possible," "will," "would" and other words and terms of similar meaning. Drug development and commercialization involve a high degree of risk and only a small number of research and development programs result in commercialization of a product. Results in early-stage clinical trials may not be indicative of full results or results from later stage or larger scale clinical trials and do not ensure regulatory approval. You should not place undue reliance on these statements, or the scientific data presented.

These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements, including without limitation, uncertainty of success in the development and potential commercialization of zuranolone; unexpected concerns may arise from additional data, analysis or results of clinical studies of zuranolone; regulatory authorities may require additional information or further studies, or may fail or refuse to approve or may delay approval of Biogen's drug candidates, including zuranolone; the occurrence of adverse safety events; the risks of other unexpected hurdles, costs or delays; failure to protect and enforce data, intellectual property and other proprietary rights and uncertainties relating to intellectual property claims and challenges; product liability claims; third party collaboration risks; and the direct and indirect impacts of the ongoing COVID-19 pandemic on our business, results of operations and financial condition. The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from Biogen's expectations in any forward-looking statement. Investors should consider this cautionary statement as well as the risk factors identified in Biogen's most recent annual or quarterly report and in other reports Biogen has filed with the U.S. Securities and Exchange Commission. These statements are based on Biogen's current beliefs and expectations and speak only as of the date of this news release. Biogen does not undertake any obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise.

SAGE MEDIA CONTACT:
Maureen L. Suda
(617) 949-4289
Maureen.Suda@sagerx.com

SAGE INVESTOR CONTACT:
Helen Rubinstein
(315) 382-3979
Helen.Rubinstein@sagerx.com

BIOGEN MEDIA CONTACT:
Ashleigh Koss
Tel: +1 908-205-2572
public.affairs@biogen.com

BIOGEN INVESTOR CONTACT:
Mike Hencke
+1 781 464 2442
IR@biogen.com

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