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): December 19, 2022

CEREVEL THERAPEUTICS HOLDINGS, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-39311**	**85-3911080**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

222 Jacobs Street **Suite 200** **Cambridge, Massachusetts**	**02141**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's Telephone Number, Including Area Code: 844 304-2048

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	CERE	The NASDAQ Stock Market LLC

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 December 19, 2022, Cerevel Therapeutics Holdings, Inc. issued a press release announcing results from the ambulatory blood pressure monitoring trial of emraclidine in people living with schizophrenia. A copy of the press release is being filed as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release issued by Cerevel Therapeutics Holdings, Inc. on December 19, 2022, filed 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.

CEREVEL THERAPEUTICS HOLDINGS, INC.

Date: December 19, 2022

By: /s/ Mark Bodenrader
Mark Bodenrader
Interim Chief Financial Officer

Cerevel Therapeutics Announces Positive Results in Emraclidine Ambulatory Blood Pressure Monitoring Trial

Data provide clear evidence that emraclidine does not induce an increase in blood pressure with chronic dosing in people living with schizophrenia

Emraclidine demonstrated a mean change from baseline in 24-hour ambulatory systolic blood pressure at week eight of -2.7 mmHg for 10 mg QD and -0.4 mmHg for 30 mg QD

Trial ruled out a 3 mmHg or greater increase in 24-hour mean systolic blood pressure for both doses of emraclidine based on the upper bound of the 95% confidence interval, per FDA guidance

Emraclidine was generally well-tolerated, with a side effect profile consistent with prior trials

Comprehensive Phase 2 program in schizophrenia on track to read out in 1H 2024

CAMBRIDGE, Mass. – December 19, 2022 – Cerevel Therapeutics (Nasdaq: CERE), a company dedicated to unraveling the mysteries of the brain to treat neuroscience diseases, announced today results from the Phase 1 randomized, double-blind trial studying the effect of emraclidine on 24-hour ambulatory blood pressure over an eight-week period in people living with schizophrenia. The objective of the trial was to accurately characterize any potential blood pressure effect for both doses of emraclidine studied (10 and 30 mg QD).

On the primary endpoint, emraclidine demonstrated a mean change from baseline at week eight in 24-hour ambulatory systolic blood pressure (SBP) of -2.7 mmHg for the 10 mg QD group and -0.4 mmHg for the 30 mg QD group. The upper bound of the two-sided 95% confidence interval for the change from baseline at week eight was -0.3 mmHg for the 10 mg QD group and 2.1 mmHg for the 30 mg QD group. As a result, the trial ruled out an increase in blood pressure for both doses (defined per FDA guidance as $\geq$3 mmHg change from baseline). The secondary endpoints of the trial demonstrated findings consistent with the primary endpoint, corroborating the overall trial results. Emraclidine was generally well-tolerated in this trial, with a side effect profile consistent with prior trials.

“These results provide another example of Cerevel’s disciplined approach to drug development and validate the potential of emraclidine to be a transformative treatment for people living with schizophrenia,” said Tony Coles, M.D., chairperson and chief executive officer of Cerevel Therapeutics. “As a trained cardiologist, I am pleased that these results clearly support our conclusion that emraclidine does not cause a change in blood pressure when dosed in schizophrenia patients. Our comprehensive Phase 2 clinical program is well underway, as we seek to bring this much-needed new treatment option to people living with schizophrenia as quickly as possible.”

This ambulatory blood pressure monitoring trial was designed in line with FDA guidance (Assessment of Pressor Effects of Drugs, Guidance for Industry) to provide an accurate characterization of any potential sustained pressor effects of emraclidine over 24 hours of ambulatory monitoring in adults between the ages of 30- and 60-years old living with schizophrenia. Trial participants were evaluated at two doses, 10 mg QD and 30 mg QD, and

the change from baseline to week eight, the primary endpoint, was assessed independently for each dose.

About Emraclidine
Emraclidine is a positive allosteric modulator designed to selectively target the M4 muscarinic receptor subtype. Emerging evidence suggests that activation of M4 muscarinic acetylcholine receptor subtypes can reduce striatal dopamine signaling and reduce psychotic symptoms, without blocking dopamine receptors. Current pharmacologic treatments for schizophrenia primarily target excessive striatal dopaminergic signaling by directly antagonizing postsynaptic dopamine D2 receptor subtypes.

In June 2022, Cerevel initiated its Phase 2 development program evaluating emraclidine in schizophrenia in two adequately-powered, placebo-controlled trials, known as EMPOWER-1 and EMPOWER-2. These trials are expected to read out in the first half of 2024. In September 2022, the company also initiated EMPOWER-3, a 52-week open-label safety extension trial, in order to accelerate a potentially registrational package for emraclidine in schizophrenia.

About Cerevel Therapeutics
Cerevel Therapeutics is dedicated to unraveling the mysteries of the brain to treat neuroscience diseases. The company is tackling diseases with a targeted approach to neuroscience that combines expertise in neurocircuitry with a focus on receptor selectivity. Cerevel Therapeutics has a diversified pipeline comprising five clinical-stage investigational therapies and several preclinical compounds with the potential to treat a range of neuroscience diseases, including Parkinson's, epilepsy, schizophrenia, and dementia-related apathy. Headquartered in Cambridge, Mass., Cerevel Therapeutics is advancing its current research and development programs while exploring new modalities through internal research efforts, external collaborations, or potential acquisitions. For more information, visit www.cerevel.com.

Special Note Regarding Forward-Looking Statements
This press release contains forward-looking statements that are based on management's beliefs and assumptions and on information currently available to management. In some cases, you can identify forward-looking statements by the following words: "may," "will," "could," "would," "should," "expect," "intend," "plan," "anticipate," "believe," "estimate," "predict," "project," "potential," "continue," "ongoing" or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. These statements involve risks, uncertainties and other factors that may cause actual results, levels of activity, performance, or achievements to be materially different from the information expressed or implied by these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this press release, we caution you that these statements are based on a combination of facts and factors currently known by us and our projections of the future, about which we cannot be certain. Forward-looking statements in this press release include, but are not limited to, statements about: the potential attributes and benefits of our product candidates, including with respect to blood pressure effect; the format, timing and objectives of our product development activities and clinical trials, including the emraclidine ambulatory blood pressure monitoring trial, Phase 2 program in schizophrenia and other statements regarding the design of clinical trials and preclinical studies and the timing of initiation, completion and data readouts for clinical trials; the timing and outcome of regulatory interactions, including whether programs meet the criteria to serve as registrational; the ability to compete with other companies currently marketing or engaged in the development of treatments

for relevant indications; the size and growth potential of the markets for product candidates and ability to serve those markets; and the rate and degree of market acceptance of product candidates, if approved. We cannot assure you that the forward-looking statements in this press release will prove to be accurate. Furthermore, if the forward-looking statements prove to be inaccurate, the inaccuracy may be material. Actual performance and results may differ materially from those projected or suggested in the forward-looking statements due to various risks and uncertainties, including, among others: clinical trial results may not be favorable; uncertainties inherent in the product development process (including with respect to the timing of results and whether such results will be predictive of future results); topline data remains subject to audit and verification procedures; the impact of COVID-19 and the post-COVID landscape on the timing, progress and results of clinical trials; our ability to recruit and enroll suitable patients in our clinical trials; whether and when, if at all, our product candidates will receive approval from the FDA or other regulatory authorities, and for which, if any, indications; competition from other biotechnology companies; uncertainties regarding intellectual property protection; and other risks identified in our SEC filings, including those under the heading "Risk Factors" in our Quarterly Report on Form 10-Q filed with the SEC on November 8, 2022 and our subsequent SEC filings. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. The forward-looking statements in this press release represent our views as of the date of this press release. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this press release.

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