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): January 09, 2023

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 January 9, 2023, Cerevel Therapeutics Holdings, Inc. issued a press release announcing that it will present at the 41st Annual J.P. Morgan Healthcare Conference and providing a pipeline update. 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 January 9, 2023, 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: January 9, 2023

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

Cerevel Therapeutics to Present at 41st Annual J.P. Morgan Healthcare Conference and Provide Pipeline Update

Initiated Phase 1 healthy volunteer trial to support development of emraclidine in Alzheimer's disease psychosis in Q4 2022; second potential indication as a once-daily treatment

Phase 2 proof-of-concept darigabat panic disorder trial to be initiated in Q2 2023

Multiple data readouts and cash runway into 2025 to support advancement of diverse pipeline of novel neuroscience drug candidates

Cerevel presentation to take place on January 10 at 8:15 a.m. PT/11:15 a.m. ET

CAMBRIDGE, Mass. – January 9, 2023 – Cerevel Therapeutics (Nasdaq: CERE), a company dedicated to unraveling the mysteries of the brain to treat neuroscience diseases, will present tomorrow, Tuesday, January 10 at 8:15 a.m. PT/11:15 a.m. ET at the 41st Annual J.P. Morgan Healthcare Conference. During the presentation, Cerevel chairperson and chief executive officer, Dr. Tony Coles, will review the Company's lead programs and upcoming milestones. A question-and-answer session will follow the presentation.

"Cerevel continues to execute successfully in bringing forward our robust pipeline of neuroscience programs which aim to address devastating diseases such as schizophrenia, Alzheimer's disease psychosis, epilepsy, panic disorder, and Parkinson's disease," said Tony Coles, M.D., chairperson and chief executive officer of Cerevel. "We have clear momentum in our clinical programs, and we look forward to bringing innovative new treatment options to patients who desperately need new solutions. We are encouraged by the opportunities across our pipeline, and we look forward to providing updates on our progress throughout the year."

Pipeline Highlights
Leveraging its deep understanding of neurocircuitry and targeted receptor subtype selectivity, Cerevel is executing on its broad, diverse pipeline of novel neuroscience drug candidates.

Below are the latest updates for Cerevel's lead programs.

Emraclidine: an **M4-selective** positive allosteric modulator (PAM) in development for **schizophrenia** and **Alzheimer's disease psychosis**.

- In June 2022, Cerevel initiated its Phase 2 program in schizophrenia, in which emraclidine is being studied as a **once-daily medication without the need for titration**.
    - Cerevel is conducting two adequately-powered placebo-controlled Phase 2 trials, known as EMPOWER-1 and EMPOWER-2. Data for both trials are expected in the first half of 2024.
    - The 52-week open-label safety extension trial, EMPOWER-3, also remains ongoing.

- To support a potential registrational package for emraclidine in schizophrenia, Cerevel is prioritizing the completion of nonclinical and clinical pharmacology studies.

- Cerevel recently announced positive data in a Phase 1 ambulatory blood pressure monitoring trial providing clear evidence that emraclidine does not induce an increase in blood pressure with chronic dosing in people living with schizophrenia.

- To support development in a second potential indication for **Alzheimer's disease psychosis**, Cerevel initiated a Phase 1 multiple ascending dose trial in the fourth quarter of 2022 to evaluate the safety, tolerability and pharmacokinetics of emraclidine in elderly healthy volunteers, 65-85 years old.
  - The FDA granted Fast Track designation for emraclidine for the treatment of hallucinations and delusions associated with Alzheimer's disease psychosis.

Darigabat: an **α2/3/5-selective** $GABA_A$ receptor PAM currently under development for **epilepsy** and **panic disorder**.
- Cerevel is conducting the REALIZE trial, a Phase 2 proof-of-concept trial in focal epilepsy. Data is expected in mid-year 2023.
  - In a proof-of-principle photoepilepsy trial, darigabat demonstrated anticonvulsant activity comparable to lorazepam.
- Cerevel also plans to initiate a Phase 2 proof-of-concept panic disorder trial in the second quarter of 2023.
  - Based on the positive topline results reported in February 2022 for the Phase 1 trial of darigabat in acute anxiety, Cerevel has selected panic disorder, which is the second most common anxiety disorder and can be the most debilitating, as the second indication for development for darigabat.

Tavapadon: a **D1/D5 partial agonist** currently in Phase 3 for the treatment of **Parkinson's disease.**
- Tavapadon has the potential to be a first-in-class D1/D5 selective partial agonist for Parkinson's disease, as both monotherapy and adjunctive treatment.
- All three of Cerevel's Phase 3 trials as monotherapy (early-stage) and adjunctive (late-stage) in Parkinson's disease (TEMPO-1, -2, and -3) are ongoing, along with the corresponding open-label extension trial (TEMPO-4).

CVL-871: a **D1/D5 partial agonist** in development for treatment of **dementia-related apathy.**
- Cerevel is conducting a Phase 2a exploratory trial in dementia-related apathy.

In addition to these lead programs, Cerevel is advancing its early clinical pipeline and discovery programs which include:
- **CVL-354**, a **selective kappa opioid receptor antagonist (KORA)**, for the treatment of major depressive disorder (MDD) and substance use disorder.
- **Selective M4 agonist** program for the treatment of psychosis and other indications.
- **Selective PDE4 inhibitor** (PDE4D-sparing) program for the treatment of MDD and schizophrenia.

Webcast Information
The live webcast and accompanying slides can be accessed on the Investor Relations section of the Cerevel Therapeutics website here. A replay will be available in the same section of the company's website.

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; the format, timing and objectives of our product development activities and clinical trials; the timing and outcome of regulatory interactions, including whether trials 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; the rate and degree of market acceptance of product candidates, if approved; and the sufficiency of our cash runway. 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); 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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Media Contact:
Anna Robinson
Cerevel Therapeutics
anna.robinson@cerevel.com

Investor Contact:
Matthew Calistri
Cerevel Therapeutics
matthew.calistri@cerevel.com