Cerevel Therapeutics Reports Third Quarter 2022 Financial Results and Business Updates

November 8, 2022

Completed $599 million dual convertible debt and equity financing to advance a robust neuroscience therapeutics pipeline

Initiated EMPOWER-3, a 52-week open-label extension trial of emraclidine in people with schizophrenia

Received FDA Fast Track designation for emraclidine in Alzheimer's disease psychosis; Phase 1 trial in healthy, elderly volunteers to be initiated by year-end

Cash, cash equivalents and marketable securities of $1,030 million as of September 30, 2022, expected to support operations into 2025

Conference call today at 8:00 a.m. ET

CAMBRIDGE, Mass., Nov. 08, 2022 (GLOBE NEWSWIRE) -- Cerevel Therapeutics, (Nasdaq: CERE), a company dedicated to unraveling the mysteries of the brain to treat neuroscience diseases, today reported financial results for the quarter ended September 30, 2022 and provided key pipeline and business updates.

"Our goal at Cerevel is to become the premier neuroscience company, and our recent financing puts us in an enviable position with the capital required to advance our diverse pipeline of novel neuroscience drug candidates," said Tony Coles, M.D., chairperson and chief executive officer of Cerevel Therapeutics. "We have made rapid progress in advancing important programs for schizophrenia, Parkinson's disease, epilepsy, Alzheimer's disease psychosis, and other devastating neuroscience conditions as we seek to bring new treatment options to patients and their families."

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**, with future development planned in **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 primary endpoint is the change from baseline in the Positive and Negative Syndrome Scale (PANSS) total score after six weeks of in-patient treatment.
  - Each trial will enroll 372 individuals living with schizophrenia and experiencing an acute exacerbation of psychotic symptoms who exhibit baseline PANSS total scores from 85 to 120, inclusive.
- In order to accelerate a potentially registrational package for emraclidine in schizophrenia, Cerevel is prioritizing nonclinical and clinical pharmacology studies:
  - Cerevel recently initiated a 52-week open-label safety extension trial, EMPOWER-3.
  - Data from the ongoing eight-week ambulatory blood pressure monitoring trial are expected by the end of this year.
- To support development in **Alzheimer's disease psychosis** , Cerevel also plans to initiate a Phase 1 multiple ascending dose trial by the end of the year 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.
  - Fast Track is an FDA process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. The designation will allow for early and more frequent communication and meetings with the FDA regarding the development of emraclidine for the treatment of Alzheimer's disease psychosis. A drug candidate that receives Fast Track designation is also eligible for rolling review, and potentially priority review, of the marketing application.

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. Cerevel expects data in mid-year 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 as the second indication for development, in addition to epilepsy. Plans are underway for a Phase 2 proof-of-concept trial in panic disorder, which is the second most common anxiety disorder and can be the most debilitating.
- The Phase 2 proof-of-concept panic disorder trial will initiate in 2023.

Tavapadon: a **D1/D5 partial agonist** currently in Phase 3 for the treatment of **Parkinson's disease** .

- All three of Cerevel's Phase 3 trials in early- and late-stage Parkinson's disease (TEMPO-1, -2, and -3) are ongoing, along with the corresponding open-label extension trial (TEMPO-4).
    - Enrollment in the TEMPO trials has been impacted due to residual post-COVID landscape challenges and other factors.
    - As a result, the Company anticipates a delay in the TEMPO-3 readout beyond the first half of 2023. Following a detailed review of all environmental factors, the Company plans to provide updated timing on the TEMPO-3 readout in the first quarter of 2023.
    - Timelines for TEMPO-1 and TEMPO-2 are also currently under review.

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.
    - Cerevel is also re-evaluating the timeline of the Phase 2a exploratory trial and no longer expects the data to read out in the first half of 2023. The Company plans to provide an updated timeline in the first quarter of 2023.
- In the second quarter of 2021, Cerevel received Fast Track designation from the FDA for the development of CVL-871 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.

Financial Results for the Third Quarter 2022

- **Cash Position:** Cash, cash equivalents and marketable securities as of September 30, 2022, were $1,030 million, inclusive of $238.3 million of net proceeds received from our August 2022 follow-on public offering of common stock and $334.8 million of net proceeds received from the concurrent issuance of convertible notes. ***The company's cash, cash equivalents and marketable securities are expected to continue to support operations into 2025.***
- **R&D Expense:** Research and development expense for the third quarter and nine months ended September 30, 2022, was $71.4 million and $198.9 million, respectively, compared to $40.2 million and $114.0 million for the prior year periods. Total research and development expense includes equity-based compensation expense of $4.4 million and $13.2 million for the third quarter and nine months ended September 30, 2022, respectively. These amounts compare to equity-based compensation expense of $2.5 million and $6.4 million for the prior year periods. The increase in R&D expense is primarily attributable to continued advancement of Cerevel's clinical programs for tavapadon, emraclidine, and darigabat; investment in preclinical and discovery efforts; and higher personnel and other infrastructure costs as Cerevel expands capabilities to advance its pipeline.
- **G&A Expense:** General and administrative expense for the third quarter and nine months ended September 30, 2022, was $23.7 million and $61.7 million, compared to $14.4 million and $41.6 million for the prior year periods. Total general and administrative expense includes equity-based compensation expense of $5.3 million and $15.2 million for the third quarter and nine months ended September 30, 2022. These amounts compare to equity-based compensation expense of $3.6 million and $11.0 million for the prior year periods. The increase in G&A expense is primarily due to higher personnel costs as Cerevel continued to grow the organization, the initiation of market development and pre-commercial planning activities,

and higher fees and services supporting ongoing business activities.

Conference Call Information

Cerevel will host a conference call and webcast today, November 8, 2022 at 8:00 a.m. ET to discuss its third quarter 2022 financial results and pipeline updates. To access the call, please register at this link. Once registered, you will receive the dial-in information and a unique PIN number.

A live webcast of the call, along with supporting slides, will be available on the investors section of Cerevel's website at investors.cerevel.com. Following the live webcast, an archived version of the call will be available on the 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, including the emraclidine Phase 2 program in schizophrenia, nonclinical and clinical pharmacology studies, ambulatory blood pressure monitoring trial and Phase 1 elderly healthy volunteer trial, the darigabat Phase 2 trial in focal epilepsy, the darigabat Phase 2 trial in panic disorder, the tavapadon Phase 3 trials (including plans to provide updated timing on the TEMPO-3 readout and review timelines for TEMPO-1 and TEMPO-2), the CVL-871 Phase 2a trial (including plans to provide an updated timeline) 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 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, cash equivalents and marketable securities. 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 August 1, 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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TABLE 1

CEREVEL THERAPEUTICS HOLDINGS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(unaudited, in thousands, except share amounts and per share amounts)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2022	**2021**	**2022**	**2021**
Operating expenses:				
Research and development	$ 71,385	$ 40,159	$ 198,947	$ 114,014
General and administrative	23,680	14,368	61,654	41,594
Total operating expenses	95,065	54,527	260,601	155,608
Loss from operations	(95,065)	(54,527)	(260,601)	(155,608)
Interest income (expense), net	2,706	13	3,668	38
Other income (expense), net	(7,579)	(7,545)	(1,770)	(10,709)
Loss before income taxes	(99,938)	(62,059)	(258,703)	(166,279)
Income tax benefit (provision), net	—	—	—	—
Net loss	$ (99,938)	$ (62,059)	$ (258,703)	$ (166,279)
Net loss per share, basic and diluted	$ (0.66)	$ (0.43)	$ (1.73)	$ (1.25)
Weighted-average shares used in calculating net loss per share, basic and diluted	152,304,645	144,022,109	149,544,252	132,971,450

TABLE 2

CEREVEL THERAPEUTICS HOLDINGS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited, in thousands)

	As of	
	September 30, 2022	**December 31, 2021**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 248,600	$ 193,018
Marketable securities	741,318	372,670
Prepaid expenses and other current assets	8,740	12,329
Total current assets	998,658	578,017
Marketable securities	39,863	52,269
Property and equipment, net	28,323	28,449
Operating lease assets	22,204	23,251
Restricted cash	1,867	4,200
Other long-term assets	2,797	2,733
Total assets	$ 1,093,712	$ 688,919
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities	$ 60,020	$ 42,538
Operating lease liabilities, net of current portion	31,948	34,110
2027 convertible senior notes, net	335,006	—
Financing liabilities and other long-term liabilities	63,376	33,542
Total stockholders' equity	603,362	578,729
Total liabilities and stockholders' equity	$ 1,093,712	$ 688,919

TABLE 3

CEREVEL THERAPEUTICS HOLDINGS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited, in thousands)

	For the Nine Months Ended September 30,	
	2022	**2021**
Net cash flows used in operating activities	$ (205,709)	$ (125,802)
Net cash flows used in investing activities	(362,102)	(9,431)
Net cash flows provided by financing activities	621,060	421,286
Net increase in cash, cash equivalents and restricted cash	53,249	286,053
Cash, cash equivalents and restricted cash, beginning of the period	197,218	387,823
Cash, cash equivalents and restricted cash, end of the period	$ 250,467	$ 673,876

Note:

Cash, cash equivalents and restricted cash balances include restricted cash of $1.9 million and $4.2 million as of September 30, 2022 and September 30, 2021, respectively.