Cerevel Therapeutics Reports Third Quarter 2023 Financial Results and Business Updates

November 1, 2023

Raised $499 million of net proceeds from public offering of common stock, expected to support operations into 2026

2024 data readout timelines for emraclidine, darigabat, and tavapadon remain on track

Tavapadon investor webcast scheduled for December 11, 2023

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

CAMBRIDGE, Mass., Nov. 01, 2023 (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 third quarter ended September 30, 2023 and provided key pipeline and business updates.

“Cerevel is bringing forward one of the broadest neuroscience pipelines in the industry, with novel approaches to treating challenging diseases, and we remain focused on execution as we head into multiple data readouts in 2024,” said Ron Renaud, president and chief executive officer of Cerevel Therapeutics. “We are well-capitalized, with runway into 2026, and we have a strong team in place to advance our late-stage pipeline of potential new treatments for schizophrenia, epilepsy, and Parkinson’s disease.”

Tavapadon Investor Webcast on December 11, 2023
Cerevel will host an investor webcast on December 11, 2023 from 10:00 to 11:30 a.m. ET focused on the tavapadon program in Parkinson’s disease.

Pipeline Highlights
Leveraging its deep understanding of neurocircuitry and targeted receptor subtype selectivity, Cerevel is advancing its broad and diverse pipeline of novel neuroscience product 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.

- Cerevel is conducting two adequately-powered placebo-controlled Phase 2 trials in schizophrenia in which emraclidine is being studied as a once-daily medication without the need for titration, known as EMPOWER-1 and EMPOWER-2.
  - EMPOWER program data are expected in the second half of 2024.
  - The 52-week open-label safety extension trial, EMPOWER-3, is also continuing enrollment.
  - In order to support a potential registrational package for emraclidine in schizophrenia, Cerevel is also prioritizing the completion of the necessary non-clinical and clinical pharmacology studies in addition to its EMPOWER program.
- To support development in Alzheimer's disease psychosis as a second potential indication for emraclidine, Cerevel initiated a Phase 1 multiple ascending dose trial 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, and a corresponding open-label safety extension trial.
  - Data readout for the REALIZE trial is expected mid-year 2024.
- Cerevel has also initiated the ADAPT trial, a Phase 2 proof-of-concept trial in panic disorder.

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).
- Data is expected in the first half of 2024 for TEMPO-3 and in the second half of 2024 for TEMPO-1 and TEMPO-2.

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.
- The timeline for this trial remains under review.

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 and substance use disorder.
- **Selective M4 agonist** program for the treatment of psychiatric and neurological indications.
- **Selective PDE4 inhibitor** (PDE4D-sparing) program for the treatment of psychiatric, neuroinflammatory and other disorders.

Financial Results for the Third Quarter 2023

- **Cash Position:** Cash, cash equivalents and marketable securities as of September 30, 2023 totaled $758.2 million. In October 2023, we completed a follow-on public offering of our common stock raising approximately $498.7 million in aggregate net proceeds, including the full exercise of the underwriters' option to purchase additional shares. ***Cerevel's cash, cash equivalents, and marketable securities are expected to support all planned data readouts in 2024 and fund operations into 2026.***

- **R&D Expense:** Research and development expense for the third quarter and nine months ended September 30, 2023 was $85.3 million and $237.5 million, respectively, compared to $71.4 million and $198.9 million for the prior year periods. Total research and development expense includes equity-based compensation expense of $6.8 million and $20.3 million for the third quarter and nine months ended September 30, 2023, respectively. These amounts compare to equity-based compensation expense of $4.4 million and $13.2 million for the prior year periods. The increases in research and development expense were primarily due to the continued advancement of our emraclidine and tavapadon programs as well as an increase in personnel costs, including equity-based compensation, as we continue to expand capabilities to advance our pipeline.

- **G&A Expense:** General and administrative expense for the third quarter and nine months ended September 30, 2023 was $26.1 million and $70.2 million, respectively, compared to $23.7 million and $61.7 million for the prior year periods. Total general and administrative expense include equity-based compensation expense of $10.3 million and $23.9 million for the third quarter and nine months ended September 30, 2023, respectively. These amounts compare to equity-based compensation expense of $5.3 million and $15.2 million for the prior year periods. Compared to the same periods in the prior year, the increases in general and administrative expense were primarily driven by higher personnel costs, including equity-based compensation, partially offset by a reduction in spend associated with professional fees.

Conference Call Information

Cerevel will host a conference call and webcast today, November 1, at 8:00 a.m. ET to discuss its third quarter 2023 financial results and key pipeline and business 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 by combining its deep expertise in neurocircuitry with a focus on targeted receptor subtype selectivity and a differentiated approach to pharmacology. Cerevel Therapeutics has a diversified pipeline comprised of five clinical-stage investigational therapies and several preclinical compounds with the potential to treat a range of neuroscience diseases, including schizophrenia, Alzheimer's disease psychosis, epilepsy, panic disorder, and Parkinson's disease. 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 activities 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; the sufficiency of our cash runway; and our tavapadon investor webcast. 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, the post-COVID environment and other factors on the timing,

progress and results of clinical trials; our ability to recruit and enroll suitable patients in our clinical trials, including the effectiveness of mitigation measures; 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 2, 2023 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,	
	2023	**2022**	**2023**	**2022**
Operating expenses:				
Research and development	$ 85,252	$ 71,385	$ 237,514	$ 198,947
General and administrative	26,055	23,680	70,187	61,654
Total operating expenses	111,307	95,065	307,701	260,601
Loss from operations	(111,307)	(95,065)	(307,701)	(260,601)
Interest income, net	9,891	3,992	28,787	4,954
Interest expense	(2,644)	(1,286)	(7,920)	(1,286)
Other income (expense), net	7,822	(7,579)	(13,033)	(1,770)
Loss before income taxes	(96,238)	(99,938)	(299,867)	(258,703)
Income tax benefit (provision), net	(123)	—	(315)	—
Net loss	$ (96,361)	$ (99,938)	$ (300,182)	$ (258,703)
Net loss per share, basic and diluted	$ (0.61)	$ (0.66)	$ (1.91)	$ (1.73)
Weighted-average shares used in calculating net loss per share, basic and diluted	157,498,891	152,304,645	157,069,093	149,544,252

TABLE 2

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

	As of	
	September 30, 2023	**December 31, 2022**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 155,721	$ 136,521
Marketable securities	521,161	755,509

Prepaid expenses and other current assets	10,904	13,621
Total current assets	687,786	905,651
Marketable securities	81,340	58,126
Property and equipment, net	26,613	27,467
Operating lease assets	20,580	21,820
Restricted cash	1,960	1,867
Other long-term assets	3,683	2,891
Total assets	$ 821,962	$ 1,017,822
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities	$ 78,838	$ 72,564
Operating lease liabilities, net of current portion	28,673	31,190
2027 convertible senior notes, net	336,933	335,482
Financing liabilities	104,556	57,348
Total stockholders' equity	272,962	521,238
Total liabilities and stockholders' equity	$ 821,962	$ 1,017,822

TABLE 3

CEREVEL THERAPEUTICS HOLDINGS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(unaudited, in thousands)

	For the Nine Months Ended September 30,	
	2023	**2022**
Net cash flows used in operating activities	$ (244,881)	$ (205,709)
Net cash flows provided by (used in) investing activities	223,930	(362,102)
Net cash flows provided by financing activities	40,244	621,060
Net increase in cash, cash equivalents and restricted cash	19,293	53,249
Cash, cash equivalents and restricted cash, beginning of the period	138,388	197,218
Cash, cash equivalents and restricted cash, end of the period	$ 157,681	$ 250,467

Note:

Cash, cash equivalents and restricted cash balances include restricted cash of $2.0 million and $1.9 million as of September 30, 2023 and September 30, 2022, respectively.