Cerevel Therapeutics Reports Second Quarter 2023 Financial Results and Business Updates

August 2, 2023

Three new executives added to leadership team: Ron Renaud, Susan Altschuller, Paul Burgess

Emraclidine EMPOWER data now expected second half 2024

Darigabat ADAPT trial in panic disorder initiated

Cash, cash equivalents, and marketable securities of $825.1 million as of June 30, 2023, expected to support a data-rich 2024 and fund operations into 2025

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

CAMBRIDGE, Mass., Aug. 02, 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 second quarter ended June 30, 2023 and provided key pipeline and business updates.

“The science and innovation at Cerevel are extraordinary, matched only by the passion and dedication of the team I’ve had the honor to get to know over the last two months,” said Ron Renaud, president and chief executive officer of Cerevel Therapeutics. “We remain focused on execution as we prepare for a pivotal year in 2024 with data from multiple late-stage clinical trials in schizophrenia, epilepsy, and 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.
  - Due to recent slower-than-expected enrollment in the U.S. and delays in the startup of certain ex-U.S. clinical sites, data for both trials are now 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 Phase 2 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 also recently 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.

- Due to continued challenges that clinical sites have experienced in identifying the appropriate patient population for this novel indication, the timeline for this trial is 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 Second Quarter 2023

- **Cash Position:** Cash, cash equivalents and marketable securities as of June 30, 2023, were $825.1 million. ***Cerevel's cash, cash equivalents, and marketable securities are expected to support all planned data readouts in 2024 and fund operations into 2025.***

- **R&D Expense:** Research and development expense for the second quarter and six months ended June 30, 2023, was $74.1 million and $152.3 million, respectively, compared to $72.5 million and $127.6 million for the prior year periods. Total research and development expense includes equity-based compensation expense of $7.2 million and $13.6 million for the second quarter and six months ended June 30, 2023, respectively. These amounts compare to equity-based compensation expense of $4.8 million and $8.8 million for the prior year periods. The increases in R&D expense reflect the advancement of our tavapadon and darigabat programs, including the initiation of our Phase 2 proof-of-concept trial for darigabat in panic disorder, as well as increases in personnel costs, including equity-based compensation. Additionally, expenses associated with emraclidine for the comparative periods reflect an increase in expense incurred in the current year for the advancement of our two ongoing Phase 2 trials and the open-label extension trial in schizophrenia, and the initiation of our Phase 1 trial to support future development in Alzheimer's disease psychosis in December 2022, offset by a decrease in expense incurred in relation to our ambulatory blood pressure monitoring trial that was completed in December 2022.

- **G&A Expense:** General and administrative expense for the second quarter and six months ended June 30, 2023, was $22.8 million and $44.1 million, respectively, compared to $20.5 million and $38.0 million for the prior year periods. Total general and administrative expense include equity-based compensation expense of $7.3 million and $13.5 million for the second quarter and six months ended June 30, 2023, respectively. These amounts compare to equity-based compensation expense of $5.3 million and $9.9 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, August 2, at 8:00 a.m. ET to discuss its second 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; and the

sufficiency of our cash position. 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 May 3, 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 June 30,		For the Six Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
Operating expenses:				
Research and development	$ 74,081	$ 72,539	$ 152,262	$ 127,562
General and administrative	22,762	20,467	44,132	37,974
Total operating expenses	96,843	93,006	196,394	165,536
Loss from operations	(96,843)	(93,006)	(196,394)	(165,536)
Interest income, net	9,820	667	18,896	962
Interest expense	(2,640)	—	(5,276)	—
Other income (expense), net	(9,765)	1,868	(20,855)	5,809
Loss before income taxes	(99,428)	(90,471)	(203,629)	(158,765)
Income tax benefit (provision), net	(107)	—	(192)	—
Net loss	$ (99,535)	$ (90,471)	$ (203,821)	$ (158,765)
Net loss per share, basic and diluted	$ (0.63)	$ (0.61)	$ (1.30)	$ (1.07)
Weighted-average shares used in calculating net loss per share, basic and diluted	157,050,677	148,295,716	156,850,632	148,141,180

TABLE 2

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

	As of

	June 30, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 175,763	$ 136,521
Marketable securities	560,663	755,509
Prepaid expenses and other current assets	15,247	13,621
Total current assets	751,673	905,651
Marketable securities	88,637	58,126
Property and equipment, net	27,246	27,467
Operating lease assets	21,016	21,820
Restricted cash	1,960	1,867
Other long-term assets	3,821	2,891
Total assets	$ 894,353	$ 1,017,822
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities	$ 65,560	$ 72,564
Operating lease liabilities, net of current portion	29,537	31,190
2027 convertible senior notes, net	336,446	335,482
Financing liabilities	112,310	57,348
Total stockholders' equity	350,500	521,238
Total liabilities and stockholders' equity	$ 894,353	$ 1,017,822

TABLE 3

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

	For the Six Months Ended June 30,	
	2023	2022
Net cash flows used in operating activities	$ (172,250)	$ (125,304)
Net cash flows provided by investing activities	172,536	25,752
Net cash flows provided by financing activities	39,049	42,419
Net increase (decrease) in cash, cash equivalents and restricted cash	39,335	(57,133)
Cash, cash equivalents and restricted cash, beginning of the period	138,388	197,218
Cash, cash equivalents and restricted cash, end of the period	$ 177,723	$ 140,085

Note:

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