Cerevel Therapeutics Reports Second Quarter 2021 Financial Results and Business Updates

August 11, 2021

Announced positive topline results for CVL-231 in Phase 1b trial in schizophrenia

Raised $328 million in net proceeds from follow-on offering of common stock and announced redemption of outstanding public warrants

Received Fast Track designation and initiated screening in Phase 2a trial of CVL-871 in dementia-related apathy

Virtual R&D Update Event scheduled for October 7, 2021

Conference call and webcast scheduled today at 8:00 a.m. ET

CAMBRIDGE, Mass., Aug. 11, 2021 (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 June 30, 2021 and provided key pipeline and business updates.

"This quarter we began to deliver on Cerevel's aspiration to become the premier neuroscience company with the release of positive data for CVL-231 in schizophrenia," said Tony Coles, M.D., chairperson and chief executive officer of Cerevel Therapeutics. "Including our tavapadon financing and redemption of our public warrants, we have now added more than $800 million in capital as a public company, and we are well-equipped to rapidly advance our broad and diverse pipeline of novel compounds. With multiple data readouts expected over the next three years, we believe that Cerevel has the pipeline, the capital, and the momentum needed to transform the possibilities for neuroscience therapies."

Pipeline Highlights

Leveraging its deep understanding of neurocircuitry and receptor subtype selectivity, Cerevel continues to execute on its broad pipeline of novel neuroscience drug candidates.

CVL-231: CVL-231 is an M4-selective positive allosteric modulator (PAM) in development as a once-daily medication for schizophrenia without the need for titration. Cerevel recently announced positive topline data for its Phase 1b trial of CVL-231 in people with schizophrenia.

- In the Phase 1b trial, CVL-231 demonstrated a clinically meaningful and statistically significant improvement of 19.5 and 17.9 points (placebo-adjusted 12.7 and 11.1 points) in the Positive and Negative Syndrome Scale (PANSS) Total score at 6 weeks for the 30 mg QD and 20 mg BID groups, respectively.
- CVL-231 was generally well-tolerated in the clinical trial, with incidence of treatment emergent adverse events for both dose cohorts similar to placebo, including heart rate and blood pressure increases.
- Rates of gastrointestinal side effects were infrequent and similar with placebo, with rates of nausea at 7% for the CVL-231 groups and 4% for placebo.
- Modest asymptomatic elevations in blood pressure and heart rate were observed with CVL-231 compared with placebo, which decreased over time. Placebo-adjusted heart rate changes two hours post-dose at Week 6 were 4.4 and 5.3 beats per minute for the CVL-231 30 mg QD and 20 mg BID groups, respectively. The average blood pressure changes at Week 6 for both CVL-231 cohorts showed no clinically meaningful differences versus placebo.
- Discontinuation rates were similar between placebo and treatment groups (22% for each arm, including placebo).
- CVL-231 was not associated with extrapyramidal side effects, akathisia or weight gain.
- While there were no clinically meaningful differences on the Brief Assessment of Cognition in Schizophrenia (BACS) Symbol Coding Test, changes in the Clinical Global Impression – Severity Scale (CGI-S) were consistent with other metrics, with the 30 mg QD dose showing a statistically significant improvement of 0.9 points versus placebo at Week 6 and the 20 mg BID group also achieving a clinically meaningful outcome.
- Cerevel expects to present additional data from this trial at upcoming scientific meetings.
- ***Additionally, the company plans to rapidly advance CVL-231 with a comprehensive Phase 2 development program for schizophrenia*** *and to evaluate the potential of this mechanism in other populations, including dementia-related psychosis.*

Darigabat (formerly CVL-865): Darigabat is an α2/3/5-selective $GABA_A$ receptor PAM currently under development for anxiety and epilepsy.

- Cerevel is conducting a Phase 1 proof-of-principle trial in acute anxiety using a well-established CO_2 inhalation challenge model in healthy volunteers.
- This trial is being conducted at the Centre for Human Drug Research (CHDR), a single specialized site in the Netherlands. In July 2021, Dutch government authorities re-imposed restrictions due to the ongoing COVID-19 pandemic, now driven primarily by Delta variant cases in young unvaccinated adults following relaxation measures that ended in June 2021. Cerevel will continue to closely monitor the rapidly evolving regulatory landscape in the Netherlands and its impact on the clinical trial timeline.
- *While this trial remains ongoing and actively recruiting,* ***as a result of recent COVID-19 guidance by the Dutch authorities, data for the acute anxiety trial are now expected in the first half of 2022.***
- Cerevel is also conducting the REALIZE trial, a Phase 2 proof-of-concept trial in focal epilepsy. This trial remains ongoing; multiple patients have completed the 8-week maintenance portion of the trial and have opted to participate in the accompanying open-label extension trial (REALIZE OLE).
- ***Data from the REALIZE trial are expected in the second half of 2022.***

Tavapadon: Tavapadon is a D1/D5 partial agonist currently in Phase 3 trials 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) as well as the corresponding open-label extension trial (TEMPO-4) are ongoing.
- In April 2021, Cerevel completed a $125 million non-dilutive financing that will fully fund the tavapadon Phase 3 program through New Drug Application (NDA) submission.
- ***Data readouts from the Phase 3 program are expected beginning in the first half of 2023.***

CVL-871: CVL-871 is a D1/D5 partial agonist in development for treatment of dementia-related apathy.

- In the second quarter, Cerevel received Fast Track Designation from the FDA for the development of CVL-871 in dementia-related apathy.
- Cerevel has initiated screening in a Phase 2a exploratory trial in dementia-related apathy.
- ***Data for the dementia-related apathy trial are expected in the second half of 2022.***

CVL-936: CVL-936 is a D3-preferring dopamine D3/D2 antagonist in development for substance use disorder (SUD).

- In April 2021, Cerevel received a notice of award for cooperative grant funding from the National Institute on Drug Abuse (NIDA) to support the development of this compound in opioid use disorder.
- *Cerevel intends to initiate a multiple dose non-clinical safety pharmacology study before additional Phase 1 single and multiple ascending dose evaluations.*

Pre-clinical Programs: In addition to its five clinical-stage programs, Cerevel has an active drug discovery effort and a number of pre-clinical programs.

- CVL-354 is a Kappa Opioid Receptor Antagonist (KORA) being evaluated as a potential therapy for major depressive disorder (MDD) and SUD.
- *Cerevel submitted an Investigational New Drug (IND) application for CVL-354 in the second quarter of 2021 and expects to initiate a Phase 1 single and multiple ascending dose clinical trial in the third quarter of 2021.*
- CVL-047 is a selective PDE4 inhibitor that spares the PDE4D subtype, which is believed to contribute to the gastrointestinal side effects that have historically hindered development of PDE4 inhibitors in neuroscience indications.
- *Cerevel anticipates submitting an IND for CVL-047 in the fourth quarter of 2021, with plans for development in MDD and schizophrenia.*

Virtual R&D Update Event on October 7, 2021

Cerevel will host a virtual R&D Update on October 7, 2021 focused on the CVL-871 program in dementia-related apathy, with updates on CVL-231 in

schizophrenia and other programs. Additional details on the event will be released at a later date.

Financial Results for the Second Quarter 2021

- **Cash Position:** Cash and cash equivalents as of June 30, 2021 were $327.1 million. This cash position does not include net proceeds of approximately $328 million from Cerevel's follow-on offering in July 2021. Cerevel also announced the redemption of its outstanding public warrants in July and would receive up to approximately $57 million in additional proceeds, assuming full exercise of the public warrants. *The cash balance as of June 30th combined with these proceeds are expected to fund Cerevel's operations into 2024.*

- **R&D Expenses:** Research and development expenses for the six months and second quarter ended June 30, 2021 were $73.9 million and $37.3 million, respectively, compared to $49.1 million and $22.2 million for the prior year periods. Total research and development expenses include equity-based compensation expense of $3.9 million and $2.1 million for the six months and quarter ended June 30, 2021, respectively. These amounts compare to equity-based compensation expense of $1.8 million and $0.9 million for the prior year periods. The increase in R&D expenses is primarily attributable to continued execution of Cerevel's late-stage and early-stage trials and increased infrastructure costs to support continued growth and advancement of the pipeline.

- **G&A Expenses:** General and administrative expenses for the six months and second quarter ended June 30, 2021 were $27.2 million and $13.2 million, respectively. These amounts compare to $23.7 million and $13.0 million for the six months and second quarter for the prior year periods. Total general and administrative expenses include equity-based compensation expense of $7.4 million and $3.1 million for the six months and quarter ended June 30, 2021, respectively. These amounts compare to equity-based compensation expense of $4.6 million and $2.5 million for the same periods in 2020. The increase in G&A expenses was driven primarily by public company and personnel costs.

Conference Call Information

Cerevel will host a conference call and webcast today, August 11, at 8:00 a.m. ET to discuss its second quarter 2021 financial results and pipeline updates. To access the call, please dial 833-665-0655 (domestic) or 702-495-1044 (international) and refer to conference ID 8947263. 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 for approximately 90 days.

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 pre-clinical compounds with the potential to treat a range of neuroscience diseases, including Parkinson's, epilepsy, schizophrenia, and substance use disorder. 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 and timing of our product development activities and clinical trials, including the advancement of CVL-231 into a comprehensive Phase 2 program in schizophrenia, plans to evaluate the potential of this mechanism in other populations, including dementia-related psychosis, the timing and status of our Phase 1 trial of darigabat in acute anxiety and other statements regarding the design of clinical trials and pre-clinical studies and the timing of initiation, completion and data readouts for clinical trials, the timing and outcome of IND submissions and other regulatory interactions, receipt of proceeds from our warrant redemption, the sufficiency of our financial resources, including to fund the tavapadon Phase 3 development program through NDA submission, and 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 on the timing, progress and results of ongoing or planned clinical trials; other impacts of COVID-19, including operational disruptions or delays or to our ability to raise additional capital; 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 17, 2021 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.
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,	
	2021	**2020**	**2021**	**2020**
Operating expenses:				
Research and development	$ 37,294	$ 22,183	$ 73,855	$ 49,142
General and administrative	13,216	12,973	27,226	23,716
Total operating expenses	50,510	35,156	101,081	72,858
Loss from operations	(50,510)	(35,156)	(101,081)	(72,858)
Interest income, net	10	5	25	209
Other income (expense), net	(2,739)	8,418	(3,164)	(7,292)
Loss before income taxes	(53,239)	(26,733)	(104,220)	(79,941)
Income tax benefit (provision), net	—	16	—	16
Net loss and comprehensive loss	$ (53,239)	$ (26,717)	$ (104,220)	$ (79,925)
Net loss per share, basic and diluted	$ (0.42)	$ (0.44)	$ (0.82)	$ (1.31)
Weighted-average shares used in calculating net loss per share, basic and diluted	127,482,127	60,946,300	127,354,540	60,945,516

TABLE 2

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

	As of	
	June 30, 2021	**December 31, 2020**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 327,060	$ 383,623
Prepaid expenses and other current assets	4,722	6,937
Total current assets	331,782	390,560
Property and equipment, net	28,032	24,165
Operating lease assets	23,888	24,459
Restricted cash	4,200	4,200
Other long-term assets	3,102	1,889
Total assets	$ 391,004	$ 445,273
LIABILITIES AND STOCKHOLDERS' EQUITY		

Current liabilities:		
Accounts payable	$ 4,986	$ 4,993
Accrued expenses and other current liabilities	22,035	22,519
Operating lease liabilities, current portion	2,236	2,036
Total current liabilities	29,257	29,548
Operating lease liabilities, net of current portion	32,907	30,969
Other long-term liabilities	34,953	236
Total stockholders' equity	293,887	384,520
Total liabilities and stockholders' equity	$ 391,004	$ 445,273

TABLE 3

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

	For the Six Months Ended June 30,	
(In thousands)	**2021**	**2020**
Net cash flows used in operating activities	$ (82,026)	$ (56,017)
Net cash flows used in investing activities	(8,243)	(4,042)
Net cash flows provided by (used in) financing activities	33,706	(1,524)
Net decrease in cash, cash equivalents and restricted cash	(56,563)	(61,583)
Cash, cash equivalents and restricted cash, beginning of the period	387,823	83,682
Cash, cash equivalents and restricted cash, end of the period	$ 331,260	$ 22,099

Note:

Cash, cash equivalents and restricted cash balances include restricted cash of $4.2 million and $4.1 million as of June 30, 2021 and June 30, 2020, respectively.