Cerevel Therapeutics Reports Third Quarter 2021 Financial Results and Pipeline Updates

November 10, 2021

Phase 1 data for darigabat in acute anxiety now expected by the end of Q1 2022

Submissions of additional PK/PD data for CVL-231 in schizophrenia accepted for presentation at the Annual Meeting of the American College of Neuropsychopharmacology

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

CAMBRIDGE, Mass., Nov. 10, 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 September 30, 2021 and provided key pipeline and business updates.

"We continue to execute on our vision of becoming the premier neuroscience company as we advance our pipeline and secure the capital required for our next stage of growth as a company," said Tony Coles, M.D., chairperson and chief executive officer of Cerevel Therapeutics. "We are advancing our clinical programs with speed and determination and preparing our company for the future in order to bring medicines to patients with neuroscience diseases including schizophrenia, anxiety, epilepsy, Parkinson's, and dementia-related apathy as quickly as possible."

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. In June 2021, Cerevel announced positive topline data for its Phase 1b trial of CVL-231 in people with schizophrenia.

- During its virtual R&D event on October 7, Cerevel discussed new pharmacokinetic (PK) and PET receptor occupancy data that will inform the design of the upcoming Phase 2 program.
- Cerevel will present additional PK and pharmacodynamic (PD) data at the Annual Meeting of the American College of Neuropsychopharmacology (ACNP) in December 2021.
- The comprehensive Phase 2 program for CVL-231 will consist of one or more adequately-powered placebo-controlled Phase 2b trials to evaluate the full dose range for CVL-231 in schizophrenia.
- At least one of the multiple dose arms will include the 30 mg once-daily dose regimen without titration. This dose regimen showed a statistically significant 12.7 point placebo-adjusted improvement on the Positive and Negative Symptom Scale (PANSS) Total Score in the Phase 1b trial.
- The anticipated Phase 2 trial design will follow established precedent and include six weeks of in-patient treatment with a patient profile similar to Part B of the Phase 1b trial and a primary endpoint of the change from baseline on the PANSS Total Score.
- Additionally, the company plans to evaluate the potential of this mechanism in other populations, including dementia-related psychosis.
- ***Cerevel expects to disclose the full details of its Phase 2 program in schizophrenia by mid-to-late Q1 2022.***

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.
- ***Data for this trial are now expected by the end of the first quarter 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.
- ***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 U.S. Food and Drug Administration (FDA) for the development of CVL-871 in dementia-related apathy.
- Cerevel is conducting a Phase 2a exploratory trial in dementia-related apathy.
- ***Data from this 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).

- Cerevel intends to initiate a multiple dose non-clinical safety pharmacology study before additional Phase 1 single and multiple ascending dose evaluations.

Other Programs: Cerevel has an active drug discovery effort and a number of earlier-stage programs, including CVL-354 and CVL-047.

- CVL-354 is a Kappa Opioid Receptor Antagonist (KORA) being evaluated as a potential therapy for major depressive disorder and SUD.
- 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.

Financial Results for the Third Quarter 2021

- **Cash Position:** Cash and cash equivalents as of September 30, 2021 were $669.7 million, which included $55.5 million from the exercise and redemption of Cerevel's outstanding public warrants. *This cash balance is expected to fund Cerevel's operations into 2024.*
- **R&D Expenses:** Research and development expenses for the nine months and third quarter ended September 30, 2021 were $114.0 million and $40.2 million, respectively, compared to $73.2 million and $24.0 million for the prior year periods. Total research and development expenses include equity-based compensation expense of $6.4 million and $2.5 million for the nine months and third quarter ended September 30, 2021, respectively. These amounts compare to equity-based compensation expense of $2.9 million and $1.1 million for the prior year periods. The increase in R&D expenses was primarily attributable to continued execution of Cerevel's late-stage and early-stage trials, increased investment in preclinical and discovery efforts, and infrastructure costs to support continued growth of the company.
- **G&A Expenses:** General and administrative expenses for the nine months and third quarter ended September 30, 2021 were $41.6 million and $14.4 million, respectively, compared to $34.1 million and $10.3 million for the prior year periods. Total general and administrative expenses include equity-based compensation expense of $11.0 million and $3.6 million for the nine months and third quarter ended September 30, 2021, respectively. These amounts compare to equity-based compensation expense of $7.0 million and $2.4 million for the prior year periods. 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, November 10, at 8:00 a.m. ET to discuss its third 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 9784674. 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 six 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, the presentation of additional CVL-231 PK/PD data at ACNP, the timing and status of our Phase 1 trial of darigabat in acute anxiety 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 IND submissions and other regulatory interactions, the sufficiency of our financial resources 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 August 11, 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 September 30,		For the Nine Months Ended September 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	$ 40,159	$ 24,026	$ 114,014	$ 73,168
General and administrative	14,368	10,336	41,594	34,052
Total operating expenses	54,527	34,362	155,608	107,220
Loss from operations	(54,527)	(34,362)	(155,608)	(107,220)
Interest income, net	13	1	38	210
Other income (expense), net	(7,545)	(4,684)	(10,709)	(11,976)
Loss before income taxes	(62,059)	(39,045)	(166,279)	(118,986)
Income tax benefit (provision), net	—	5	—	21
Net loss	$ (62,059)	$ (39,040)	$ (166,279)	$ (118,965)
Net loss per share, basic and diluted	$ (0.43)	$ (0.62)	$ (1.25)	$ (1.93)
Weighted-average shares used in calculating net loss per share, basic and diluted	144,022,109	63,270,340	132,971,450	61,726,114

TABLE 2

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

	As of	
	September 30, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 669,676	$ 383,623
Prepaid expenses and other current assets	5,353	6,937
Total current assets	675,029	390,560
Property and equipment, net	28,404	24,165
Operating lease assets	23,576	24,459
Restricted cash	4,200	4,200
Other long-term assets	2,271	1,889
Total assets	$ 733,480	$ 445,273
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 5,445	$ 4,993
Accrued expenses and other current liabilities	23,020	22,519
Operating lease liabilities, current portion	2,335	2,036
Total current liabilities	30,800	29,548
Operating lease liabilities, net of current portion	34,752	30,969
Other long-term liabilities	38,848	236
Total stockholders' equity	629,080	384,520
Total liabilities and stockholders' equity	$ 733,480	$ 445,273

TABLE 3

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

-	For the Nine Months Ended September 30,	
-	2021	2020
Net cash flows used in operating activities	$ (125,802)	$ (76,099)
Net cash flows used in investing activities	(9,431)	(11,341)
Net cash flows provided by financing activities	421,286	20,766
Net increase (decrease) in cash, cash equivalents and restricted cash	286,053	(66,674)
Cash, cash equivalents and restricted cash, beginning of the period	387,823	83,682
Cash, cash equivalents and restricted cash, end of the period	$ 673,876	$ 17,008

Note:
Cash, cash equivalents and restricted cash balances include restricted cash of $4.2 million as of September 30, 2021 and September 30, 2020.