Cerevel Therapeutics Provides Update on Pipeline Progress along with Fourth Quarter and Full Year 2020 Financial Results

March 24, 2021

Data readout of Phase 1b trial of CVL-231 in patients with schizophrenia now expected mid-year 2021

IND submitted for CVL-871 in dementia-related apathy

Conference call and webcast scheduled for today at 8:00 AM EDT

CAMBRIDGE, Mass., March 24, 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 fourth quarter and full year ended December 31, 2020 and provided key business updates.

"Cerevel made tremendous progress as an organization in 2020, as we initiated enrollment in all of our current clinical trials and debuted as a public company," said Tony Coles, chairman and chief executive officer of Cerevel Therapeutics. "With multiple expected clinical data readouts and IND submissions, 2021 will be another pivotal year for Cerevel as we leverage our targeted approach to solve the most vexing problems in neuroscience."

Pipeline Highlights

Leveraging its deep understanding of neurocircuitry and receptor subtype selectivity, Cerevel continues to execute on its broad, diverse pipeline of novel neuroscience drug candidates. In the second half of 2020, the Company began dosing patients in all six ongoing clinical trials for its lead programs, which are on track for multiple data readouts over the next three years.

CVL-231: Cerevel is currently conducting a Phase 1b trial of CVL-231, its M4-selective positive allosteric modulator (PAM), in schizophrenia.

- In the fourth quarter of 2020, Cerevel began dosing patients in Part B of the Phase 1b trial, which includes a placebo-controlled pharmacodynamic assessment of change in the Positive and Negative Syndrome Scale (PANSS) total score. ***Data from this trial are now expected mid-year 2021.***

Darigabat (formerly CVL-865): Cerevel's α2/3/5-selective $GABA_A$ receptor PAM is 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. ***Data for this trial are expected in the second half of 2021.***
- Cerevel is also conducting the REALIZE trial, a Phase 2 proof-of-concept trial in focal epilepsy. Cerevel began dosing patients in this trial in the second half of 2020, and, as of March 2021, multiple patients have completed the 8-week maintenance portion of the trial and have chosen 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: In the second half of 2020, Cerevel began dosing patients in all three of its Phase 3 trials of tavapadon in early and late-stage Parkinson's disease known as TEMPO-1, TEMPO-2 and TEMPO-3. ***Initial 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. Cerevel submitted an IND for CVL-871 in the first quarter of 2021. In the second quarter of 2021, Cerevel plans to initiate a randomized, double-blind, placebo-controlled exploratory Phase 2a trial to evaluate safety, tolerability, and pharmacodynamics in patients with apathy and mild-to-moderate dementia. ***Data for this trial are anticipated 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). ***As of March 2021, Cerevel expects to receive cooperative grant funding from the National Institute on Drug Abuse (NIDA) to support the development of this compound in opioid use disorder.*** Cerevel initiated a Phase 1 single ascending dose (SAD) trial in healthy volunteers in January 2020. Cerevel concluded dosing of Cohort 1 of the Phase 1 SAD trial after receiving sufficient clinical data for the intended purposes of the trial. Cerevel intends to conduct a multiple dose canine electroencephalogram study prior to resuming Phase 1 SAD and multiple ascending dose (MAD) evaluations.

Preclinical Programs: In addition to its five clinical-stage programs, Cerevel has an active discovery enablement effort and a number of preclinical programs.

- Cerevel's CVL-354 is a Kappa Opioid Receptor Antagonist (KORA) being evaluated as a potential therapy for major depressive disorder (MDD) and SUD. ***Cerevel plans to submit an IND for CVL-354 in the second quarter of 2021.***
- PDE4 is a well-established target with therapeutic potential in multiple disease areas including MDD, schizophrenia and neuroinflammatory conditions. Cerevel is evaluating a range of selective PDE4 inhibitors that spare 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 a selective PDE4B inhibitor by the end of 2021, with plans to develop in MDD and schizophrenia.***

Financial Results for the Fourth Quarter and Full Year 2020

- **Cash Position:** Cash and cash equivalents as of December 31, 2020 were $383.6 million, compared to $79.6 million as of December 31, 2019. Cerevel's cash position has been bolstered by the October 2020 completion of the go-public business combination with ARYA II and simultaneous PIPE transaction, which yielded net proceeds of approximately $440 million.
- **R&D Expenses:** Research and development expenses for the fourth quarter and full year ended December 31, 2020 were $30.1 million and $103.3 million, respectively. This compares to $22.0 million and $50.3 million, respectively, for the fourth quarter and full year ended December 31, 2019. Compared to the same periods in the prior year, the increase in R&D expenses is primarily attributable to advancement of Cerevel's lead clinical programs (tavapadon, darigabat and CVL-231), including initiation of dosing in all ongoing trials; investment in early discovery efforts such as the selective PDE4 inhibitor program and CVL-354; and increased headcount costs to support continued growth and advancement of the pipeline.
- **G&A Expenses:** General and administrative expenses for the fourth quarter and full year ended December 31, 2020 were $11.8 million and $45.8 million, respectively, compared to $14.4 million and $33.2 million, respectively, for the prior year comparative periods. The quarter-over-quarter reduction was driven primarily by one-time adjustments to equity-based compensation expenses resulting from completion of the go-public transaction. The increase for fiscal year 2020 relative to fiscal year 2019 was driven primarily by increased headcount costs to support organizational growth; increased investment in technology and IT infrastructure; and higher facility costs associated with the lease for Cerevel's new headquarters in Cambridge, MA. G&A expenses for 2020 also included approximately $5.5 million of one-time expenses related to completion of the go-public transaction and certain other financing activities.

Financial Outlook

- The Company anticipates R&D expenses for 2021 to increase relative to 2020, driven primarily by ramp-up of enrollment for the lead clinical programs, especially tavapadon and darigabat; continued investment in early discovery efforts; and increased hiring to support the expanding pipeline.
- Cerevel expects stabilization of G&A expenses by the end of the year as growth in the organizational infrastructure slows to a steady-state rate.
- ***Cerevel's cash balance is expected to continue to support the Company's operations into 2023.***

Conference Call Information
Cerevel will host a conference call and webcast today, March 24, at 8:00 a.m. EDT to discuss its fourth quarter and full year 2020 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 4288421. 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 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, cooperative grant funding from NIDA, R&D and G&A expense for 2021 and the sufficiency of our financial resources. 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: that 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 prospectus filed with the SEC on December 4, 2020 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.

TABLE 1

CEREVEL THERAPEUTICS HOLDINGS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited, in thousands, except per share amounts)

	For the Three Months Ended December 31,		For the Twelve Months Ended December 31,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	$ 30,135	$ 21,968	$ 103,303	$ 50,294
General and administrative	11,761	14,429	45,813	33,169
Total operating expenses	41,896	36,397	149,116	83,463
Loss from operations	(41,896)	(36,397)	(149,116)	(83,463)
Interest income, net	14	192	224	1,552
Other income (expense), net	8,702	(20,010)	(3,274)	(46,433)
Loss before income taxes	(33,180)	(56,215)	(152,166)	(128,344)
Income tax benefit (provision), net	3	(45)	24	(45)
Net loss and comprehensive loss	$ (33,177)	$ (56,260)	$ (152,142)	$ (128,389)
Reconciliation of net loss attributable to common stockholders:				
Net loss	$ (33,177)	$ (56,260)	$ (152,142)	$ (128,389)
Benefit related to the redemption of Series A-1 redeemable convertible preferred stock at less than the carrying value	3,871	—	3,871	—
Net loss attributable to common stockholders	$ (29,306)	$ (56,260)	$ (148,271)	$ (128,389)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.27)	$ (1.24)	$ (2.01)	$ (2.90)
Weighted-average shares used in calculating net loss per share, basic and diluted	109,136	45,482	73,643	44,209

TABLE 2

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

	As of December 31,	
	2020	2019

ASSETS		
Current assets:		
Cash and cash equivalents	$ 383,623	$ 79,551
Prepaid expenses and other current assets	6,937	7,526
Total current assets	390,560	87,077
Property and equipment, net	24,165	1,476
Operating lease assets	24,459	26,015
Restricted cash	4,200	4,131
Other long-term assets	1,889	2,107
TOTAL ASSETS	$ 445,273	$ 120,806
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 4,993	$ 2,109
Accrued expenses and other current liabilities	22,519	10,175
Operating lease liabilities, current portion	2,036	2,592
Total current liabilities	29,548	14,876
Operating lease liabilities, net of current portion	30,969	25,819
Other long-term liabilities	236	2,288
Stockholders' equity	384,520	77,823
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 445,273	$ 120,806

TABLE 3

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

	For the Years Ended December 31,	
	2020	2019
Net cash flows used in operating activities	$ (117,802)	$ (70,720)
Net cash flows used in investing activities	(18,892)	(1,099)
Net cash flows provided by financing activities	440,835	60,058
Net increase (decrease) in cash, cash equivalents and restricted cash	304,141	(11,761)
Cash, cash equivalents and restricted cash, beginning of the period	83,682	95,443
Cash, cash equivalents and restricted cash, end of the period	$ 387,823	$ 83,682

Note:
Cash, cash equivalents and restricted cash balances include restricted cash of $4.2 million and $4.1 million as of December 31, 2020 and December 31, 2019, respectively.

Media Contact:

Kate Contreras
W2O
kcontreras@w2ogroup.com

Investor Contact:

Matthew Calistri
Cerevel Therapeutics
matthew.calistri@cerevel.com