Cerevel Therapeutics Provides Update on Pipeline Progress along with Fourth Quarter and Full Year 2021 Financial Results

March 1, 2022

Announced positive results from Phase 1 healthy volunteer trial of darigabat in acute anxiety

On track to initiate two parallel adequately-powered Phase 2 trials of emraclidine in schizophrenia by mid-year 2022

Multiple late-stage clinical readouts expected in the next 18 months

Conference call today at 8:00 AM EST

CAMBRIDGE, Mass., March 01, 2022 (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, 2021 and provided key business updates.

"Cerevel continues to demonstrate that our targeted approach to neuroscience – which is grounded in a deep understanding of neurocircuitry, receptor subtype selectivity and differentiated pharmacology – can deliver hope for patients struggling with neuroscience diseases," said Tony Coles, M.D., chairman and chief executive officer of Cerevel Therapeutics. "By bringing together the people, the pipeline, and the capital we need – and taking a deliberate and thoughtful method to clinical trial design and execution – Cerevel is changing what is possible 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. Below are the latest updates for Cerevel's lead programs.

Emraclidine (formerly CVL-231): Emraclidine 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 emraclidine in people with schizophrenia. The results of the trial supported the advancement of emraclidine into a comprehensive Phase 2 program in schizophrenia. Cerevel also plans to explore additional indications including dementia-related psychosis.
- In January 2022, Cerevel announced the full details of its planned Phase 2 program in schizophrenia:
  - Cerevel will conduct two adequately-powered placebo-controlled Phase 2 trials that will enable the full exploration of the therapeutic dose range of emraclidine. ***Trials will be initiated by the middle of 2022, with data for both trials expected in the first half of 2024.***
  - Each trial will enroll 372 schizophrenia patients with an acute exacerbation of psychotic symptoms and who exhibit baseline Positive and Negative Syndrome Scale (PANSS) total scores from 85 to 120.
  - In each trial, patients will be randomized 1:1:1 into one of two emraclidine dose arms or placebo.
    - The first trial will test emraclidine 10 mg QD, emraclidine 30 mg QD, and placebo.
    - The second trial will test emraclidine 15 mg QD, emraclidine 30 mg QD, and placebo.
  - The primary endpoint will be change in the Positive and Negative Syndrome Scale (PANSS) total score after six weeks of in-patient treatment.
  - In parallel, Cerevel will be prioritizing nonclinical and clinical safety pharmacology studies.
  - Cerevel also plans to initiate a 52-week open-label safety extension trial to begin development of the patient safety database that will be required for registration.

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

- In February 2022, Cerevel announced positive topline results for its Phase 1 trial of darigabat in acute anxiety.
  - In healthy volunteers after eight days of treatment, both the 7.5 mg and 25 mg twice-daily doses of darigabat demonstrated a clinically meaningful and statistically significant improvement of 3.9 points ($p = 0.036$) and 4.5 points ($p = 0.008$), respectively, in the Panic Symptoms List (PSL-IV) total score compared with placebo.
  - The positive control alprazolam 1 mg twice-daily dose demonstrated a 1.6 point ($p = 0.286$) placebo-adjusted

improvement on the PSL-IV total score, in line with expectations for this trial design.

- Darigabat was generally well-tolerated in this trial, with no serious adverse events (AEs) and no treatment-related discontinuations in the darigabat cohorts.
- Ninety-seven percent of AEs reported in the two darigabat treatment cohorts were considered mild.

- Based on the results of the Phase 1 trial, Cerevel plans to advance development of darigabat in anxiety-related disorders.
- Cerevel is also conducting the REALIZE trial, a Phase 2 proof-of-concept trial in focal epilepsy. ***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 of 2021, Cerevel received Fast Track Designation from the FDA for the development of CVL-871 in dementia-related apathy.
- Cerevel is conducting a Phase 2a exploratory trial in dementia-related apathy.
- ***Data for this trial are anticipated in the first half of 2023.***

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 (MDD) and substance use disorder
- Selective M4 agonist program for the treatment of psychosis and related indications
- CVL-047, a selective PDE4 inhibitor (PDE4D-sparing) for the treatment of MDD and schizophrenia

Financial Results for the Fourth Quarter and Full Year 2021

- **Cash Position:** Cash, cash equivalents and marketable securities as of December 31, 2021, were $618.0 million, compared to $383.6 million as of December 31, 2020. Relative to 2020, the increase in Cerevel's cash position reflects the receipt of the first payment of approximately $31 million from the tavapadon financing agreements in April 2021, the completion of a $350 million follow-on offering in July 2021 following the announcement of positive Phase 1b data for emraclidine in schizophrenia, and approximately $55 million received from the redemption and exercise of Cerevel's public warrants.
- **R&D Expenses:** Research and development expense for the fourth quarter and full year ended December 31, 2021 were $47.8 million and $161.9 million, respectively. This compares to $30.1 million and $103.3 million, respectively, for the fourth quarter and full year ended December 31, 2020. R&D expense for the fourth quarter and year ended December 31, 2021, include $2.8 million and $9.2 million of stock-based compensation expense, compared to $0.4 million and $3.2 million for the prior year periods, respectively. Compared to the same periods in the prior year, the increases in R&D expense were primarily attributable to the continued advancement of Cerevel's clinical programs for tavapadon, darigabat and CVL-871; investment in our early discovery efforts; and increased personnel and other infrastructure costs to support continued growth and advancement of the pipeline.
- **G&A Expenses:** General and administrative expense for the fourth quarter and full year ended December 31, 2021, were $16.6 million and $58.2 million, respectively. This compares to $11.8 million and $45.8 million, respectively, for the fourth quarter and full year ended December 31, 2020. G&A expenses for the fourth quarter and year ended December 31, 2021, include $3.7 million and $14.7 million of stock-based compensation expense, compared to $0.3 million and $7.3 million, respectively, for the prior year periods. Compared to the same periods in the prior year, the increases in G&A expense were primarily driven by increased public company costs and increased personnel and other costs to support organizational growth. G&A expenses for 2021 included a net one-time expense of $2.5 million associated with the departure of certain executives, of which $1.8 million was related to stock-based compensation. G&A expense for 2020 included approximately $6.3 million of non-recurring expenses related to completion of our go-public transaction and other financing-related costs.

Financial Outlook

- The Company anticipates R&D expenses for 2022 to increase relative to 2021, driven by initiation of the comprehensive Phase 2 program for emraclidine; increased costs associated with advancement of the Phase 3 program for tavapadon; continued investment in darigabat, CVL-871 and early discovery efforts; and higher personnel costs to support the growth and advancement of its pipeline.
- Cerevel expects G&A expenses for 2022 to increase relative to 2021 to support the expansion and advancement of its pipeline and initiate pre-commercialization activities.
- ***The Company's cash, cash equivalents and marketable securities are expected to continue to support operations into 2024.***

Conference Call Information
Cerevel will host a conference call and webcast today, March 1, at 8:00 a.m. EST to discuss its fourth quarter and full year 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 6298779. 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 dementia-related apathy. 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 timing, details and objectives of the emraclidine Phase 2 program and related nonclinical and clinical safety pharmacology studies, evaluation of this mechanism in other populations, including dementia-related psychosis, the timing of other key upcoming milestones 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 regulatory interactions, expectations for R&D and G&A expenses in 2022 and the sufficiency of our cash, cash equivalents and marketable securities. 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 November 10, 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.

Media Contact:
Anna Robinson
Cerevel Therapeutics
anna.robinson@cerevel.com

Investor Contact:
Matthew Calistri
Cerevel Therapeutics
matthew.calistri@cerevel.com

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 December 31,		For the Twelve Months Ended December 31,	
	2021	**2020**	**2021**	**2020**
Operating expenses:				
Research and development	$ 47,841	$ 30,135	$ 161,855	$ 103,303
General and administrative	16,649	11,761	58,243	45,813
Total operating expenses	64,490	41,896	220,098	149,116
Loss from operations	(64,490)	(41,896)	(220,098)	(149,116)
Interest income, net	119	14	157	224
Other income (expense), net	5,316	8,702	(5,393)	(3,274)
Loss before income taxes	(59,055)	(33,180)	(225,334)	(152,166)
Income tax benefit (provision), net	—	3	—	24
Net loss	$ (59,055)	$ (33,177)	$ (225,334)	$ (152,142)
Reconciliation of net loss attributable to common stockholders:				
Net loss	$ (59,055)	$ (33,177)	$ (225,334)	$ (152,142)
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	$ (59,055)	$ (29,306)	$ (225,334)	$ (148,271)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.40)	$ (0.27)	$ (1.65)	$ (2.01)
Weighted-average shares used in calculating net loss per share, basic and diluted	147,302,283	109,135,851	136,576,536	73,643,315

TABLE 2

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

	As of December 31,	
	2021	**2020**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 193,018	$ 383,623
Marketable securities	372,670	—
Prepaid expenses and other current assets	12,329	6,937
Total current assets	578,017	390,560
Marketable securities	52,269	—
Property and equipment, net	28,449	24,165
Operating lease assets	23,251	24,459
Restricted cash	4,200	4,200
Other long-term assets	2,733	1,889
Total assets	$ 688,919	$ 445,273
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 11,298	$ 4,993
Accrued expenses and other current liabilities	28,803	22,519
Operating lease liabilities, current portion	2,437	2,036
Total current liabilities	42,538	29,548
Operating lease liabilities, net of current portion	34,110	30,969
Other long-term liabilities	33,542	236
Total stockholders' equity	578,729	384,520

Total liabilities and stockholders' equity	$ 688,919	$ 445,273

TABLE 3

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

	For the year ended December 31,	
	2021	**2020**
Net cash flows used in operating activities	$ (178,546)	$ (117,802)
Net cash flows used in investing activities	(435,661)	(18,892)
Net cash flows provided by financing activities	423,602	440,835
Net increase (decrease) in cash, cash equivalents, and restricted cash	(190,605)	304,141
Cash, cash equivalents and restricted cash, beginning of the period	387,823	83,682
Cash, cash equivalents and restricted cash, end of the period	$ 197,218	$ 387,823

Note:
Cash, cash equivalents and restricted cash balances include restricted cash of $4.2 million as of December 31, 2021 and December 31, 2020.