Cerevel Therapeutics Reports First Quarter 2021 Financial Results and Business Updates

May 17, 2021

Announced strategic $125 million non-dilutive financing for tavapadon

Welcomed Abraham Ceesay as President

Appointed Scott Akamine as Chief Legal Officer

Phase 1b trial for CVL-231 in schizophrenia on track for data mid-year 2021

Phase 1 acute anxiety data for darigabat now expected in the fourth quarter of 2021

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

CAMBRIDGE, Mass., May 17, 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 March 31, 2021 and provided key pipeline and business highlights.

“Cerevel has made great progress in our quest to become the premier neuroscience company. We completed a $125 million non-dilutive financing to fund tavapadon, our most advanced asset, added key talent to our executive team, and advanced our extensive clinical and pre-clinical pipeline,” said Tony Coles, M.D., chairperson and chief executive officer of Cerevel Therapeutics. “As we continue execution of our ongoing clinical trials, we are also building the additional capabilities needed for our long-term success. We look forward to key data readouts from two of our near-term trials.”

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: Cerevel’s CVL-231 is an M4-selective positive allosteric modulator (PAM) currently in a Phase 1b trial in schizophrenia.

- Cerevel presented data from the Phase 1 single ascending dose trial of CVL-231 in healthy volunteers at the Schizophrenia International Research Society (SIRS) Conference on April 18.
- Cerevel’s ongoing Phase 1b trial for CVL-231 includes a placebo-controlled pharmacodynamic assessment of change in the Positive and Negative Syndrome Scale (PANSS) total score.
- ***Data from this trial are expected mid-year 2021.***

Darigabat (formerly CVL-865): Cerevel’s 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 the acute anxiety trial are expected in the fourth quarter of 2021.***
- Cerevel is also conducting the REALIZE trial, a Phase 2 proof-of-concept trial in focal epilepsy. This trial remains ongoing and 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: Cerevel’s tavapadon is a D1/D5 partial agonist currently in Phase 3 trials for the treatment of Parkinson’s disease.

- In April 2021, Cerevel announced a $125 million non-dilutive financing that will fully fund the tavapadon Phase 3 program through New Drug Application (NDA) submission.
- All three of Cerevel’s Phase 3 trials in early- and late-stage Parkinson’s disease (TEMPO-1, -2, and -3) are ongoing. Cerevel has also begun dosing rollover and de novo patients in the corresponding open-label extension trial, known as TEMPO-4.
- ***Data readouts from the Phase 3 program are expected beginning in the first half of 2023.***

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

- Cerevel submitted an Investigational New Drug (IND) application for CVL-871 in the first quarter of 2021.
- ***Cerevel plans to initiate screening in a Phase 2a exploratory trial in dementia-related apathy in the next few weeks and data are anticipated in the second half of 2022.***

CVL-936: Cerevel's CVL-936 is a D3-preferring dopamine D3/D2 antagonist in development for substance use disorder.

- 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 pre-clinical toxicology 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.

- Cerevel's CVL-354 is a Kappa Opioid Receptor Antagonist (KORA) being evaluated as a potential therapy for major depressive disorder (MDD) and substance use disorder.
- ***Cerevel plans to submit an IND for CVL-354 in the second quarter of 2021.***
- Cerevel's 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 by the end of 2021, with plans to develop in MDD and schizophrenia.***

Financial Results for the First Quarter 2021

- **Cash Position:** Cash and cash equivalents as of March 31, 2021 were $343.3 million, compared to $47.5 million as of March 31, 2020. This cash position does not include the recently announced $125 million non-dilutive tavapadon financing. ***This financing provides Cerevel with the flexibility to allocate capital to earlier stage assets and is expected to extend Cerevel's cash runway into 2024.***
- **R&D Expenses:** Research and development expenses for the first quarter ended March 31, 2021 were $36.6 million compared to $27.0 million for the prior year period. Total research and development expenses include equity-based compensation expense of $1.8 million and $0.9 million for the three months ended March 31, 2021 and 2020, respectively. 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 first quarter ended March 31, 2021 were $14.0 million compared to $10.7 million for the prior year period. Total general and administrative expenses include equity-based compensation expense of $4.3 million and $2.1 million for the three months ended March 31, 2021 and 2020, respectively. The increase was driven primarily by one-time non-cash expenses associated with stock option compensation and general and administrative infrastructure to support the growth of the company.

Conference Call Information

Cerevel will host a conference call and webcast today, May 17, at 8:00 a.m. EDT to discuss its first 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 4926779. 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, the amount and timing of payments we may receive pursuant to the tavapadon financing transaction, the sufficiency of our financial resources, including to fund the tavapadon Phase 3 development program through NDA submission and to allocate capital to earlier stage assets, 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: that we may not realize the expected benefits of the financing transaction; 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 Annual Report on Form 10-K filed with the SEC on March 24, 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:

Kate Contreras

W2O/Real Chemistry

kcontreras@realchemistry.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 March 31,	
	2021	2020
Operating expenses:		
Research and development	$ 36,561	$ 26,959
General and administrative	14,010	10,743
Total operating expenses	50,571	37,702
Loss from operations	(50,571)	(37,702)
Interest income, net	15	204
Other income (expense), net	(425)	(15,710)
Loss before income taxes	(50,981)	(53,208)
Income tax (provision) benefit, net	-	-
Net loss and comprehensive loss	$ (50,981)	$ (53,208)
Net loss per share, basic and diluted	$ (0.40)	$ (0.87)
Weighted-average shares used in calculating net loss per share, basic and diluted	127,225,535	60,944,732

TABLE 2

CEREVEL THERAPEUTICS HOLDINGS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited, in thousands)

	As of March 31, 2021	As of December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 343,287	$ 383,623
Prepaid expenses and other current assets	6,524	6,937
Total current assets	349,811	390,560
Property and equipment, net	27,597	24,165
Operating lease assets	24,187	24,459
Restricted cash	4,200	4,200
Other long-term assets	2,309	1,889
TOTAL ASSETS	$ 408,104	$ 445,273
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 7,755	$ 4,993
Accrued expenses and other current liabilities	24,257	22,519
Operating lease liabilities, current portion	2,139	2,036
Total current liabilities	34,151	29,548
Operating lease liabilities, net of current portion	32,952	30,969
Other long-term liabilities	965	236
Stockholders' equity	340,036	384,520
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 408,104	$ 445,273

TABLE 3

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

	For the Three Months Ended March 31, 2021	2020
Net cash flows used in operating activities	$ (36,418)	$ (29,454)
Net cash flows used in investing activities	(4,660)	(2,556)
Net cash flows provided by financing activities	742	-
Net decrease in cash, cash equivalents and restricted cash	(40,336)	(32,010)
Cash, cash equivalents and restricted cash, beginning of the period	387,823	83,682
Cash, cash equivalents and restricted cash, end of the period	$ 347,487	$ 51,672

Note:

Cash, cash equivalents and restricted cash balances include restricted cash of $4.2 million and $4.1 million as of March 31, 2021 and March 31, 2020, respectively.