Cerevel Therapeutics Reports First Quarter 2022 Financial Results and Business Updates

May 10, 2022

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

Data for the darigabat Phase 2 proof-of-concept trial in focal epilepsy now expected mid-year 2023, revised from 2H 2022

$550.9M in cash, cash equivalents and marketable securities as of March 31, 2022; additional $37.5M from tavapadon risk-sharing arrangement received in April 2022

Conference call today at 8:00 a.m. ET

CAMBRIDGE, Mass., May 10, 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 quarter ended March 31, 2022 and provided key pipeline and business updates.

“Cerevel remains in an enviable position of strength as we seek to transform what is possible in neuroscience,” said Tony Coles, M.D., chairperson and chief executive officer of Cerevel Therapeutics. “We bring together the highest standard of clinical trial execution with the pipeline, the people, and the capital necessary to deliver new solutions for people living with vexing neuroscience diseases.”

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: Emraclidine is an M4-selective positive allosteric modulator (PAM) in development for schizophrenia as a once-daily medication without the need for titration.

- 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. ***Cerevel is on track to initiate both trials in mid-year 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 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.
  - Cerevel recently presented Phase 1b emraclidine data at the 2022 Congress of the Schizophrenia International Research Society (SIRS), which took place on April 6-10, 2022.

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. Due to slower enrollment than anticipated and COVID-19 disruptions at the clinical trial sites, ***Cerevel has added trial sites in additional countries and now expects data in mid-year 2023.***
- Cerevel recently presented darigabat data at the American Academy of Neurology (AAN) Annual Meeting, which took place on April 2-7, 2022.
  - Cerevel outlined preclinical data for darigabat that demonstrated robust anticonvulsant activity in a model of drug-resistant focal seizures. Treatment with darigabat resulted in a dose-dependent reduction in spontaneous and recurrent hippocampal paroxysmal discharges (an objective biomarker of focal seizures), demonstrating comparable antiepileptic activity to diazepam at doses of 3 and 10 mg/kg.
  - In a separate poster presentation, Cerevel described the successful implementation of novel data capture measures used during the COVID-19 pandemic to ensure data integrity in the ongoing Phase 2 trial of darigabat in patients with focal epilepsy.

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) are ongoing, along with the corresponding open-label extension trial (TEMPO-4).
- ***Data readouts from the Phase 3 program are expected beginning in the first half of 2023.***
- At the AAN Annual Meeting, Cerevel presented data demonstrating consistent clinical pharmacology across a wide range of doses of tavapadon in several Phase 1 clinical trials, supporting its potential as a promising next-generation treatment for Parkinson's disease.
- Cerevel also presented a study characterizing medication utilization among Parkinson's disease patients prescribed levodopa or dopamine agonist treatments. The results show that levodopa treatment occurs more consistently than dopamine agonist treatment, as patients prescribed dopamine agonists had relatively high treatment modification and discontinuation rates and low medication adherence.

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

In March 2022, based on the results of a multiple-dose nonclinical EEG study, Cerevel ceased development of CVL-936, a D2/D3 receptor subtype antagonist for the treatment of substance use disorder.

Financial Results for the First Quarter 2022

- **Cash Position:** Cash, cash equivalents and marketable securities as of March 31, 2022, were $550.9 million. This cash position does not include the additional $37.5 million received in April 2022 from the tavapadon risk-sharing arrangement. ***The Company's cash, cash equivalents and marketable securities are expected to continue to support operations into 2024.***
- **R&D Expense:** Research and development expense for the first quarter ended March 31, 2022, was $55.0 million, compared to $36.6 million for the prior year period. Total research and development expense includes equity-based

compensation expense of $4.0 million and $1.8 million for the three months ended March 31, 2022 and 2021, respectively. The increase in R&D expense is primarily attributable to continued advancement of Cerevel's clinical programs for tavapadon, emraclidine, and darigabat; investment in preclinical and discovery efforts; and higher personnel and other infrastructure costs as Cerevel expands capabilities to advance its pipeline.

- **G&A Expense:** General and administrative expense for the first quarter ended March 31, 2022, was $17.5 million, compared to $14.0 million for the prior year period. Total general and administrative expense includes equity-based compensation expense of $4.6 million and $4.3 million for the three months ended March 31, 2022 and 2021, respectively. The increase in G&A expense is primarily due to higher personnel costs as Cerevel continued to grow the organization, the initiation of commercial planning activities, and higher fees and services supporting ongoing business activities.

Conference Call Information

Cerevel will host a conference call and webcast today, Tuesday, May 10, at 8:00 a.m. ET to discuss its first quarter 2022 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 4497847. 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 preclinical 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, the timing for the darigabat Phase 2 proof-of-concept trial in focal epilepsy 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; the ability to compete with other companies currently marketing or engaged in the development of treatments for relevant indications; the size and growth potential of the markets for product candidates and ability to serve those markets; the rate and degree of market acceptance of product candidates, if approved; 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-K filed with the SEC on March 1, 2022 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.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited, in thousands, except share amounts and per share amounts)

	For the Three Months Ended March 31,	
	2022	**2021**
Operating expenses:		
Research and development	$ 55,023	$ 36,561
General and administrative	17,507	14,010
Total operating expenses	72,530	50,571
Loss from operations	(72,530)	(50,571)
Interest income, net	295	15
Other income (expense), net	3,941	(425)
Loss before income taxes	(68,294)	(50,981)
Income tax benefit (provision), net	—	—
Net loss	$ (68,294)	$ (50,981)
Net loss per share, basic and diluted	$ (0.46)	$ (0.40)
Weighted-average shares used in calculating net loss per share, basic and diluted	147,984,926	127,225,535

TABLE 2

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

	As of	
	March 31, 2022	**December 31, 2021**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 91,764	$ 193,018
Marketable securities	451,180	372,670
Prepaid expenses and other current assets	10,606	12,329
Total current assets	553,550	578,017
Marketable securities	7,928	52,269
Property and equipment, net	29,736	28,449
Operating lease assets	22,927	23,251
Restricted cash	1,867	4,200
Other long-term assets	2,544	2,733
Total assets	$ 618,552	$ 688,919
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 8,183	$ 11,298
Accrued expenses and other current liabilities	24,572	28,803
Operating lease liabilities, current portion	2,563	2,437
Total current liabilities	35,318	42,538
Operating lease liabilities, net of current portion	33,409	34,110
Other long-term liabilities	28,326	33,542
Total stockholders' equity	521,499	578,729
Total liabilities and stockholders' equity	$ 618,552	$ 688,919

TABLE 3

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

	For the Three Months Ended March 31,	
	2022	**2021**
Net cash flows used in operating activities	$ (67,648)	$ (36,418)
Net cash flows used in investing activities	(38,542)	(4,660)
Net cash flows provided by financing activities	2,603	742
Net decrease in cash, cash equivalents and restricted cash	(103,587)	(40,336)
Cash, cash equivalents and restricted cash, beginning of the period	197,218	387,823
Cash, cash equivalents and restricted cash, end of the period	$ 93,631	$ 347,487

Note:
Cash, cash equivalents and restricted cash balances include restricted cash of $1.9 million and $4.2 million as of March 31, 2022 and March 31, 2021, respectively.