Cerevel Therapeutics Reports Second Quarter 2022 Financial Results and Business Updates

August 1, 2022

Initiated two parallel, adequately-powered Phase 2 trials of emraclidine in schizophrenia with data expected 1H 2024

Phase 1 trial of emraclidine to be initiated by year-end to support future development in Alzheimer's disease psychosis

Panic disorder selected as second indication for darigabat, planning underway for Phase 2 proof-of-concept

Cash, cash equivalents and marketable securities of $531M as of June 30, 2022, expected to support operations into 2024

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

CAMBRIDGE, Mass., Aug. 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 quarter ended June 30, 2022 and provided key pipeline and business updates.

"At Cerevel, it is our aspiration to become the premier neuroscience company. We are well on our way to achieving this distinction with a broad and deep pipeline of potential new therapies and compelling early data in schizophrenia, which has led us to initiate a potentially pivotal Phase 2 program for emraclidine," said Tony Coles, M.D., chairperson and chief executive officer of Cerevel Therapeutics. "With five data readouts expected next year, a robust set of mid- to late-stage assets, world-class capabilities in drug development, and an ability to execute rapidly to advance our late-stage programs, Cerevel is well-positioned to transform what is possible in neuroscience."

Pipeline Highlights

Leveraging its deep understanding of neurocircuitry and targeted receptor subtype selectivity, Cerevel is executing on its broad, diverse pipeline of novel neuroscience drug candidates. Below are the latest updates for Cerevel's lead programs.

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

- In June 2022, Cerevel initiated its Phase 2 program in schizophrenia:
  - Cerevel is conducting two adequately-powered placebo-controlled Phase 2 trials, known as EMPOWER-1 and EMPOWER-2. ***Data for both trials are expected in the first half of 2024.***
  - The primary endpoint is the change from baseline in the Positive and Negative Syndrome Scale (PANSS) total score after six weeks of in-patient treatment.
  - Each trial will enroll 372 individuals living with schizophrenia and experiencing an acute exacerbation of psychotic symptoms who exhibit baseline PANSS total scores from 85 to 120, inclusive.
  - 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 trials will enable the full exploration of the therapeutic dose range of emraclidine.
  - In order to accelerate a potentially registrational package for emraclidine in schizophrenia, Cerevel is prioritizing nonclinical and clinical pharmacology studies. Cerevel expects to initiate a 52-week open-label safety extension trial, EMPOWER-3, in the third quarter of 2022. Data from the ongoing eight-week ambulatory blood pressure monitoring trial are expected by the end of 2022.
- ***To support future development in Alzheimer's disease psychosis, Cerevel also plans to initiate a Phase 1 multiple ascending dose trial by the end of the year*** to evaluate the safety, tolerability and pharmacokinetics of emraclidine in elderly healthy volunteers, 65-85 years old.

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

- Cerevel is conducting the REALIZE trial, a Phase 2 proof-of-concept trial in focal epilepsy. ***Cerevel expects data in mid-year 2023.***

- Based on the positive topline results reported in February 2022 for the Phase 1 trial of darigabat in acute anxiety, ***Cerevel has selected panic disorder as the second indication for development, in addition to epilepsy, and plans are underway for a Phase 2 proof-of-concept trial in panic disorder***, which is the second most common anxiety disorder and can be the most debilitating.
- Cerevel recently presented darigabat data at the American Society of Clinical Psychopharmacology Annual Meeting, which took place on May 31 – June 3, 2022.
    - Cerevel presented the positive topline results for its Phase 1 trial of darigabat in acute anxiety.
    - In a separate panel presentation, Cerevel discussed efforts to achieve diversity in clinical trials, an imperative that is a key component of a broader commitment to diversity, equity, and inclusion across all facets of the company.

Tavapadon: a **D1/D5 partial agonist** currently in Phase 3 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.***

CVL-871: 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 other related indications.
- **CVL-047**, a **selective PDE4 inhibitor** (PDE4D-sparing) for the treatment of MDD and schizophrenia.

Financial Results for the Second Quarter 2022

- **Cash Position:** Cash, cash equivalents and marketable securities as of June 30, 2022, were $531.2 million, inclusive of $37.5M from the tavapadon risk-sharing arrangement received in April 2022. ***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 second quarter and six months ended June 30, 2022, was $72.5 million and $127.6 million, respectively, compared to $37.3 million and $73.9 million for the prior year periods. Total research and development expense includes equity-based compensation expense of $4.8 million and $8.8 million for the second quarter and six months ended June 30, 2022, respectively. These amounts compare to equity-based compensation expense of $2.1 million and $3.9 million for the prior year periods. 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 second quarter and six months ended June 30, 2022, was $20.5 million and $38.0 million, compared to $13.2 million and $27.2 million for the prior year periods. Total general and administrative expense includes equity-based compensation expense of $5.3 million and $9.9 million for the second quarter and six months ended June 30, 2022. These amounts compare to equity-based compensation expense of $3.1 million and $7.4 million for the prior year periods. 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, August 1, 2022 at 8:00 a.m. ET to discuss its second quarter 2022 financial results and pipeline updates. To access the call, please register at this link. Once registered, you will receive the dial-in information and a unique PIN number.

A live webcast of the call, along with supporting slides, will be available on the investors section of Cerevel's website at investors.cerevel.com. Following the live webcast, an archived version of the call will be available on the website.

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, nonclinical and clinical pharmacology studies, ambulatory blood pressure monitoring trial, Phase 1 elderly healthy volunteer trial and plans for future development in other indications, including Alzheimer's disease psychosis, the timing for the darigabat Phase 2 proof-of-concept trial in focal epilepsy, the timing and details of the darigabat Phase 2 proof-of-concept trial in panic disorder, 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, including whether trials meet the criteria to serve as pivotal; 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-Q filed with the SEC on May 10, 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 June 30,		For the Six Months Ended June 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 72,539	$ 37,294	$ 127,562	$ 73,855
General and administrative	20,467	13,216	37,974	27,226
Total operating expenses	93,006	50,510	165,536	101,081
Loss from operations	(93,006)	(50,510)	(165,536)	(101,081)
Interest income, net	667	10	962	25
Other income (expense), net	1,868	(2,739)	5,809	(3,164)

Loss before income taxes	(90,471)	(53,239)	(158,765)	(104,220)
Income tax benefit (provision), net	—	—	—	—
Net loss	$ (90,471)	$ (53,239)	$ (158,765)	$ (104,220)
Net loss per share, basic and diluted	$ (0.61)	$ (0.42)	$ (1.07)	$ (0.82)
Weighted-average shares used in calculating net loss per share, basic and diluted	148,295,716	127,482,127	148,141,180	127,354,540

TABLE 2

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

	As of	
	June 30, 2022	**December 31, 2021**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 138,218	$ 193,018
Marketable securities	392,990	372,670
Prepaid expenses and other current assets	8,933	12,329
Total current assets	540,141	578,017
Marketable securities	—	52,269
Property and equipment, net	29,314	28,449
Operating lease assets	22,573	23,251
Restricted cash	1,867	4,200
Other long-term assets	2,762	2,733
Total assets	$ 596,657	$ 688,919
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 11,008	$ 11,298
Accrued expenses and other current liabilities	43,063	28,803
Operating lease liabilities, current portion	2,672	2,437
Total current liabilities	56,743	42,538
Operating lease liabilities, net of current portion	32,688	34,110
Other long-term liabilities	54,412	33,542
Total stockholders' equity	452,814	578,729
Total liabilities and stockholders' equity	$ 596,657	$ 688,919

TABLE 3

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

	For the Six Months Ended June 30,	
	2022	**2021**
Net cash flows used in operating activities	$ (125,304)	$ (82,026)
Net cash flows provided by (used in) investing activities	25,752	(8,243)
Net cash flows provided by financing activities	42,419	33,706
Net decrease in cash, cash equivalents and restricted cash	(57,133)	(56,563)
Cash, cash equivalents and restricted cash, beginning of the period	197,218	387,823

Cash, cash equivalents and restricted cash, end of the period	$ 140,085	$ 331,260

Note:

Cash, cash equivalents and restricted cash balances include restricted cash of $1.9 million and $4.2 million as of June 30, 2022 and June 30, 2021, respectively.