Cerevel Therapeutics Reports Fourth Quarter and Full Year 2022 Financial Results and Business Updates

February 22, 2023

Emraclidine Phase 1 healthy elderly volunteer trial enrollment underway to support development in Alzheimer's disease psychosis

Emraclidine Phase 2 schizophrenia data readout remains on track for 1H 2024

Clinical trial timeline updates provided for additional lead programs

Cash, cash equivalents, and marketable securities of $950 million as of December 31, 2022, expected to support operations into 2025

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

CAMBRIDGE, Mass., Feb. 22, 2023 (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, 2022 and provided key pipeline and business updates.

"Cerevel is progressing in its quest to become the premier neuroscience company, and 2022 was another important year in that journey," said Tony Coles, M.D., chairman and chief executive officer of Cerevel Therapeutics. "From the positive results in our emraclidine blood pressure trial that were announced recently to the strengthening of our balance sheet with a nearly $600 million capital raise mid-year, Cerevel continues to achieve critical milestones that support our mission to change what is possible in neuroscience. With targeted investments in the pipeline supported by strong fiscal discipline, we expect to continue that momentum forward through 2023 and beyond."

Pipeline Highlights
Leveraging its deep understanding of neurocircuitry and targeted receptor subtype selectivity, Cerevel is advancing its broad and diverse pipeline of novel neuroscience product candidates.

Below are the latest updates for Cerevel's lead programs.

Emraclidine: an M4-selective positive allosteric modulator (PAM) in development for schizophrenia and Alzheimer's disease psychosis.

- In June 2022, Cerevel initiated its Phase 2 program in schizophrenia, in which emraclidine is being studied as a once-daily medication without the need for titration.
  - Cerevel is conducting two adequately-powered placebo-controlled Phase 2 trials, known as EMPOWER-1 and EMPOWER-2. Enrollment for these trials is on track and data for both trials are expected in the first half of 2024.
  - The 52-week open-label safety extension trial, EMPOWER-3, is also continuing enrollment.

- To support a potential registrational package for emraclidine in schizophrenia, Cerevel is prioritizing the completion of the necessary nonclinical and clinical pharmacology studies.

  - Cerevel recently announced positive data in a Phase 1 ambulatory blood pressure monitoring trial that has provided clear evidence that emraclidine does not induce an increase in blood pressure with chronic dosing in people living with schizophrenia, an important risk-mitigating step for continued development.

- To support development of a second potential indication for Alzheimer's disease psychosis, Cerevel initiated a Phase 1 multiple ascending dose trial in the fourth quarter of 2022 to evaluate the safety, tolerability and pharmacokinetics of emraclidine in healthy elderly volunteers, 65-85 years old.
  - The FDA granted Fast Track designation for emraclidine for the treatment of hallucinations and delusions associated with Alzheimer's disease psychosis.

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.
  - Enrollment in the REALIZE trial has been impacted due to the residual post-COVID environment and other factors that are resulting in slower-than-expected enrollment in many clinical trials. As a result, the Company anticipates a delay in the REALIZE readout beyond 2023. Following a detailed review of all environmental factors, the Company plans to provide updated timing on the REALIZE readout by mid-year.
- Cerevel also plans to initiate a Phase 2 proof-of-concept panic disorder trial in the second quarter of 2023.
  - Based on the positive topline results reported in February 2022 for the Phase 1 trial of darigabat in healthy volunteers in a panic symptoms model, Cerevel has selected panic disorder as the second indication for

development of darigabat.

Tavapadon: a D1/D5 partial agonist currently in Phase 3 for the treatment of Parkinson's disease.

- Tavapadon has the potential to be a first-in-class D1/D5 selective partial agonist for Parkinson's disease, as both monotherapy and adjunctive treatment.
- All three of Cerevel's Phase 3 trials as monotherapy (early-stage) and adjunctive (late-stage) in Parkinson's disease (TEMPO-1, -2, and -3) are ongoing, along with the corresponding open-label extension trial (TEMPO-4).
- Following a detailed review of all environmental factors, Cerevel now expects data from TEMPO-3 in mid-year 2024 and TEMPO-1 and TEMPO- 2 in the second half of 2024.

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

- Cerevel is conducting a Phase 2a exploratory trial in dementia-related apathy.
- Following a review of timelines and factors affecting enrollment, data is now expected for this trial in the second half of 2024.

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 and substance use disorder.
- **Selective M4 agonist** program for the treatment of psychiatric and neurological indications.
- **Selective PDE4 inhibitor** (PDE4D-sparing) program for the treatment of psychiatric, neuroinflammatory and other disorders.

Financial Results for the Fourth Quarter and Full Year 2022

- **Cash Position:** Cash, cash equivalents and marketable securities as of December 31, 2022, were $950.2 million, compared to $618.0 million as of December 31, 2021. Relative to 2021, the increase in Cerevel's cash position primarily reflects $573.0 million of net proceeds received from our August 2022 follow-on public offering of common stock and concurrent issuance of convertible notes, partially offset by cash used in operations.

- **R&D Expenses:** Research and development expense for the fourth quarter and full year ended December 31, 2022 were $81.3 million and $280.3 million, respectively. This compares to $47.8 million and $161.9 million, respectively, for the fourth quarter and full year ended December 31, 2021. R&D expense for the fourth quarter and year ended December 31, 2022, include $5.0 million and $18.2 million of stock-based compensation expense, compared to $2.8 million and $9.2 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 emraclidine, tavapadon and darigabat; increased investment in 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, 2022, were $25.9 million and $87.6 million, respectively. This compares to $16.6 million and $58.2 million, respectively, for the fourth quarter and full year ended December 31, 2021. G&A expenses for the fourth quarter and year ended December 31, 2022, include $5.4 million and $20.6 million of stock-based compensation expense, compared to $3.7 million and $14.7 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 personnel costs and other costs to support organizational growth and the advancement of our programs.

Financial Outlook

- Cerevel anticipates R&D expenses for 2023 to increase relative to 2022, driven by increased costs associated with the advancement of the ongoing comprehensive Phase 2 program for emraclidine in schizophrenia; the recently initiated Phase 1 trial of emraclidine in healthy elderly volunteers to support development in Alzheimer's disease psychosis; the expected initiation of the Phase 2 trial of darigabat in panic disorder; and incremental personnel costs to support the growth and advancement of the pipeline.

- Cerevel expects G&A expenses to remain relatively consistent for 2023, as compared to the fourth quarter of 2022.

- ***Cerevel's cash, cash equivalents, and marketable securities are expected to continue to support operations into 2025.***

President Abraham Ceesay to Depart March 9

Cerevel also announced today that President Abraham Ceesay will leave the organization as of March 9, 2023 to become the chief executive officer at

a private biotechnology company.

Conference Call Information

Cerevel will host a conference call and webcast today, February 22, at 8:00 a.m. ET to discuss its fourth quarter and full year 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 by combining its deep expertise in neurocircuitry with a focus on targeted receptor subtype selectivity and a differentiated approach to pharmacology. 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 schizophrenia, Alzheimer's disease psychosis, epilepsy, panic disorder, and Parkinson's disease. 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, timing and objectives of our product development activities and clinical trials, including plans to provide updated timing on the REALIZE readout at a future date; the timing and outcome of regulatory interactions, including whether activities meet the criteria to serve as registrational; 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; our financial outlook, including with respect to our funding plans; and the sufficiency of 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: 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, the post-COVID environment and other factors on the timing, progress and results of clinical trials; our ability to recruit and enroll suitable patients in our clinical trials; 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 8, 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.
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,	
	2022	**2021**	**2022**	**2021**
Operating expenses:				
Research and development	$ 81,312	$ 47,841	$ 280,259	$ 161,855

General and administrative	25,935	16,649	87,589	58,243
Total operating expenses	107,247	64,490	367,848	220,098
Loss from operations	(107,247)	(64,490)	(367,848)	(220,098)
Interest income (expense), net	5,951	119	9,619	157
Other income (expense), net	8,648	5,316	6,878	(5,393)
Loss before income taxes	(92,648)	(59,055)	(351,351)	(225,334)
Income tax benefit (provision), net	(160)	0	(160)	0
Net loss	$ (92,808)	$ (59,055)	$ (351,511)	$ (225,334)
Reconciliation of net loss attributable to common stockholders:				
Net loss	$ (92,808)	$ (59,055)	$ (351,511)	$ (225,334)
Net loss per share, basic and diluted	$ (0.59)	$ (0.40)	$ (2.32)	$ (1.65)
Weighted-average shares used in calculating net loss per share, basic and diluted	156,373,651	147,302,283	151,265,635	136,576,536

TABLE 2

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

	As of December 31,	
	2022	**2021**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 136,521	$ 193,018
Marketable securities	755,509	372,670
Prepaid expenses and other current assets	13,621	12,329
Total current assets	905,651	578,017
Marketable securities	58,126	52,269
Property and equipment, net	27,467	28,449
Operating lease assets	21,820	23,251
Restricted cash	1,867	4,200
Other long-term assets	2,891	2,733
Total assets	$ 1,017,822	$ 688,919
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities	$ 72,564	$ 42,538
Operating lease liabilities, net of current portion	31,190	34,110
2027 convertible senior notes, net	335,482	—
Financing liabilities and other long-term liabilities	57,348	33,542
Total stockholders' equity	521,238	578,729
Total liabilities and stockholders' equity	$ 1,017,822	$ 688,919

TABLE 3

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

	For the year ended December 31,	
	2022	**2021**
Net cash flows used in operating activities	$ (293,187)	$ (178,546)

Net cash flows used in investing activities	(388,834)	(435,661)
Net cash flows provided by financing activities	623,191	423,602
Net increase (decrease) in cash, cash equivalents, and restricted cash	(58,830)	(190,605)
Cash, cash equivalents and restricted cash, beginning of the period	197,218	387,823
Cash, cash equivalents and restricted cash, end of the period	$ 138,388	$ 197,218

Note:

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