Cassava Sciences Reports Q1 2024 Financial Results and Clinical Updates on Phase 3 Trials of Simufilam

May 10, 2024

- **$126.3 Million In Total Gross Proceeds from Warrant Distribution.**
- **Over 1,900 Patients with Alzheimer's Disease Are Randomized in Phase 3 Trials of Simufilam.**
- **Over 735 Patients Have Completed a Phase 3 Trial of Simufilam.**

AUSTIN, Texas, May 10, 2024 (GLOBE NEWSWIRE) -- Cassava Sciences, Inc. (Nasdaq: SAVA), a biotechnology company focused on Alzheimer's disease, today reported financial results for first quarter ended March 31, 2024. Net income was $25.0 million compared to a net loss of $24.3 million for the same period in 2023. Net cash used in operations was $19.1 million during the first quarter of 2024. Cash use for operations for the first half of 2024 is still expected to be $35 to $45 million, driven primarily by expenses for our clinical program in Alzheimer's disease.

Current Updates on Phase 3 Clinical Program
Background - Our Phase 3 program consists of two global, double-blind, randomized, placebo-controlled studies of simufilam in patients with mild-to-moderate Alzheimer's disease dementia. The goal is to evaluate overall risk/benefit for simufilam 100 mg twice-daily versus placebo in a large population of people with Alzheimer's disease over 12 and 18 months.

The target study population is people with mild-to-moderate Alzheimer's (MMSE score of 16-27) who are biomarker-positive for Alzheimer's disease pathology, and who meet other inclusion/exclusion eligibility criteria of the study protocols.

Phase 3 Trials – Our first Phase 3 study, called RETHINK-ALZ, is designed to evaluate the safety and efficacy of simufilam 100 mg tablets twice-daily versus matching placebo over 52 weeks (NCT04994483). Our second Phase 3 study, called REFOCUS-ALZ, is designed to evaluate the safety and efficacy of oral simufilam 100 mg and 50 mg tablets twice-daily versus matching placebo over 76 weeks (NCT05026177). Clinical sites are in the United States, Canada, Puerto Rico, Australia, and South Korea. Premier Research International is the clinical research organization (CRO) supporting the conduct of our Phase 3 clinical program.

Patient Enrollment – Both Phase 3 studies are fully enrolled. Approximately 1,900 patients are randomized in these studies, with approximately 800 patients randomized in the 52-week study (RETHINK-ALZ) and approximately 1,100 patients randomized in the 76-week study (REFOCUS-ALZ). Approximately 90% of patients are recruited from clinical sites in the U.S. and Canada. The overall drop-out rate for both Phase 3 studies is in the range of 20% to 22%, which is generally consistent with expectations. (A longer study will generally have a higher dropout rate versus a similar shorter study).

Patient Completion – Over 435 patients have completed the 52-week RETHINK-ALZ study. Over 300 patients have completed the 76-week REFOCUS-ALZ study, for a total of over 735 completers.

Data Safety and Monitoring Board (DSMB) – The DSMB is composed of independent clinical research experts who periodically review interim patient safety data. Routine, scheduled DSMB meetings were held September 2023 and March 2024. Both DSMB meetings recommended that the Phase 3 studies continue as planned, without modification.

Co-primary Efficacy Outcomes – The pre-specified efficacy endpoints are ADAS-Cog12, a cognitive scale, and ADCS-ADL, a functional scale. iADRS is a combination of scores from ADAS-Cog and ADCS-ADL. Because the distribution of study participants is numerically skewed towards mild patients, we expect to rely predominantly on mild patients to evaluate drug safety and efficacy.

Phase 3 Efficacy Results – All efficacy data from our Phase 3 program remain blinded. No interim analyses on efficacy outcomes are planned. We anticipate top-line data readout for our 52-week study (RETHINK-ALZ) approximately year-end 2024. We anticipate top-line data readout for our 76-week study (REFOCUS-ALZ) approximately mid-year 2025.

Open-label Extension Study – This study is designed to provide no-cost access to oral simufilam for up to one year to Alzheimer's patients who have successfully completed a Phase 3 study of simufilam and who meet other entry criteria. Approximately 90% of patients who've completed treatment in a Phase 3 study have opted to enter the open-label extension study. To date, over 655 patients have entered the open-label extension study.

Financial Results for First Quarter 2024

- At March 31, 2024, cash and cash equivalents were $124.2 million, with no debt.
- The total gross proceeds received from the cash-exercise of Warrants were $126.3 million, including approximately $104.0 million received in April and May 2024.
- Net income was $25.0 million compared to a net loss of $24.3 million for the same period in 2023. Net income resulted

from the change in fair value of warrant liabilities, a non-cash item. This warrant gain was partially offset by increases in patient enrollment and associated costs to conduct the Phase 3 clinical program, as well as other studies with simufilam.

- Net cash used in operations was $19.1 million during the first quarter of 2024.
- Net cash use in operations for first half 2024 is expected to be $35 to $45 million, consistent with previous guidance and driven primarily by expenses for our program in Alzheimer's disease.
- Research and development (R&D) expenses were $16.2 million. This compared to $22.1 million for the same period in 2023. R&D expenses decreased due primarily to the completion of patient screening and enrollment for our Phase 3 clinical program in the fall of 2023.
- General and administrative (G&A) expenses were $3.7 million. This compared to $4.4 million for the same period in 2023. G&A expenses decreased due primarily to higher legal expenses being offset by approximately $3.0 million in insurance recoveries during the three months ended March 31, 2024. Insurance recoveries are recorded as a reduction to G&A expense. The decrease was partially offset by a $1.1 million increase in stock-based compensation expense due to new grant awards in 2023.
- In January 2024, we completed a dividend distribution of common stock warrants to shareholders ("Warrants"). The Warrants allowed the holder to purchase shares of our common stock for an effective price of $22.00 per share. The deadline to cash-exercise Warrants was May 6th, 5pm New York City time. There is no further opportunity to exercise Warrants. Warrants outstanding that were not validly exercised were being redeemed by the Company starting on or around May 7, 2024, for a nominal payment of $0.001 per Warrant.

About Simufilam
Simufilam is Cassava Sciences' proprietary oral drug candidate. This investigational drug binds to altered filamin A protein in the brain and restores its normal shape and function. By targeting altered filamin A, simufilam may help patients with Alzheimer's achieve better health outcomes. Cassava Sciences owns exclusive, worldwide rights to its investigational product candidates and related technologies, without royalty obligations to any third party.

About Cassava Sciences, Inc.
Cassava Sciences is a clinical-stage biotechnology company based in Austin, Texas. Our mission is to detect and treat neurodegenerative diseases, such as Alzheimer's disease. Our novel science is based on stabilizing—but not removing—a critical protein in the brain.

For more information, please visit: https://www.CassavaSciences.com

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Cautionary Note Regarding Forward-Looking Statements:
This news release contains forward-looking statements, including statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, that may include but are not limited to statements regarding: the design, scope, conduct, continuation, completion, intended purpose, or future results of our on-going Phase 3 program of simufilam in patients with Alzheimer's disease; the timing of anticipated milestones; interim safety data for the Phase 3 program sourced from prior DSMB meetings or other sources; the treatment of people with Alzheimer's disease dementia; the safety or efficacy of simufilam in people with Alzheimer's disease dementia; expected cash use in future periods; comments made by our employees regarding simufilam, drug effects, and the treatment of Alzheimer's disease; and potential benefits, if any, of our product candidates. These statements may be identified by words such as "anticipate," "believe," "could," "expect," "forecast," "intend," "may," "plan," "possible," "potential," "will," and other words and terms of similar meaning.

Such statements are based largely on our current expectations and projections about future events. Such statements speak only as of the date of this news release and are subject to a number of risks, uncertainties and assumptions, including, but not limited to, those risks relating to the ability to conduct or complete clinical studies on expected timelines, the ability to demonstrate the specificity, safety, efficacy or potential health benefits of our product candidates, the apparent ability of simufilam to favor patients with mild Alzheimer's disease; the apparent safety or tolerance of simufilam in our open-label clinical trials; our current expectations regarding timing of clinical data for our Phase 3 studies; any expected clinical results of Phase 3 studies; the treatment of people with Alzheimer's disease dementia; and comments made by our employees regarding simufilam, drug effects, and the treatment of Alzheimer's disease; potential benefits, if any, of our product candidates and including those described in the section entitled "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2023, and future reports to be filed with the SEC. The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from expectations in any forward-looking statement. In light of these risks, uncertainties and assumptions, the forward-looking statements and events discussed in this news release are inherently uncertain and may not occur, and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Accordingly, you should not rely upon forward-looking statements as predictions of future events. Except as required by law, we disclaim any intention or responsibility for updating or revising any forward-looking statements contained in this news release. For further information regarding these and other risks related to our business, investors should consult our filings with the SEC, which are available on the SEC's website at www.sec.gov.

All our pharmaceutical assets under development are investigational product candidates. These have not been approved for use in any medical indication by any regulatory authority in any jurisdiction and their safety, efficacy or other desirable attributes, if any, have not been established in any patient population. Consequently, none of our product candidates are approved or available for sale anywhere in the world.

Our clinical results from earlier-stage clinical trials may not be indicative of future results from later-stage or larger scale clinical trials and do not ensure regulatory approval. You should not place undue reliance on these statements or any scientific data we present or publish.

We are in the business of new drug discovery and development. Our research and development activities are long, complex, costly and involve a high degree of risk. Holders of our common stock should carefully read our Annual Report on Form 10-K in its entirety, including the risk factors therein. Because risk is fundamental to the process of drug discovery and development, you are cautioned to not invest in our publicly traded securities unless you are prepared to sustain a total loss of the money you have invested.

– Financial Tables Follow –

CASSAVA SCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited, in thousands, except per share amounts)

	Three months ended March 31,	
	2024	2023
Operating expenses		
Research and development	$ 16,233	$ 22,120
General and administrative	3,701	4,392
Total operating expenses	19,934	26,512
Operating loss	(19,934)	(26,512)
Interest income	1,776	2,051
Other income, net	160	190
Gain from change in fair value of warrant liabilities	43,041	—
Net income (loss)	$ 25,043	$ (24,271)
Net income (loss) per share, basic	$ 0.58	$ (0.58)
Net loss per share, diluted	(0.43)	(0.58)
Weighted-average shares used in computing net income (loss) per share, basic	43,001	41,739
Weighted-average shares used in computing net loss per share, diluted	44,102	41,739

CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited, in thousands)

	March 31, 2024	December 31, 2023
Assets		
Current assets		
Cash and cash equivalents	$ 124,169	$ 121,136
Prepaid expenses and other current assets	9,830	8,497
Total current assets	133,999	129,633
Property and equipment, net	21,604	21,854
Intangible assets, net	115	176
Total assets	$ 155,718	$ 151,663
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable and accrued expenses	$ 9,603	$ 10,573
Accrued development expense	1,797	3,037
Accrued compensation and benefits	228	200
Warrant liabilities	65,368	—
Other accrued liabilities	125	385
Total current liabilities	77,121	14,195
Stockholders' equity		
Common Stock and additional paid-in-capital	434,323	518,237
Accumulated deficit	(355,726)	(380,769)
Total stockholders' equity	78,597	137,468
Total liabilities and stockholders' equity	$ 155,718	$ 151,663

Source: Cassava Sciences, Inc.