



Cassava Sciences Reports Third Quarter Financial Results for 2022 and Business Updates

November 7, 2022

– \$174.7 Million Cash and Cash Equivalents at September 30, 2022 –

– Over 650 Patients Now Enrolled in Phase 3 Program -

– New Clinical Data for Simufilam in Alzheimer’s Disease Expected –

AUSTIN, Texas, Nov. 07, 2022 (GLOBE NEWSWIRE) -- Cassava Sciences, Inc. (Nasdaq: SAVA), a clinical-stage biotechnology company focused on Alzheimer’s disease, today announced financial results for the third quarter ended September 30, 2022 and provided a clinical update on its Phase 3 clinical program of simufilam in Alzheimer’s disease. Simufilam is Cassava Sciences’ lead drug candidate for the proposed treatment of Alzheimer’s disease.

“The clinical development of oral simufilam for Alzheimer’s disease continues to make headway,” said Remi Barbier, President & CEO. “We now have over 650 patients enrolled in our on-going Phase 3 studies of simufilam in Alzheimer’s disease, up from 150 patients approximately six months ago. We also look forward to presenting new clinical data for simufilam from two other ongoing studies in Alzheimer’s disease.”

Net loss for third quarter 2022 was \$20.3 million, or \$0.51 per share, compared to a net loss of \$9.6 million, or \$0.24 per share, for the same period in 2021. Net cash used in operations was \$56.2 million during the first nine months of 2022. Net cash use for operations for full-year 2022 is expected to be approximately \$80 to \$90 million, consistent with previous guidance. Cash and cash equivalents were \$174.7 million as of September 30, 2022, with no debt.

Financial Results for Third Quarter 2022

- At September 30, 2022, cash and cash equivalents were \$174.7 million, with no debt.
- Net loss was \$20.3 million, or \$0.51 per share. This compares to a net loss of \$9.6 million, or \$0.24 per share, for the same period in 2021. Net loss increased compared to the prior period due primarily to a significant increase in our R&D activities for a Phase 3 program of simufilam in Alzheimer’s disease.
- Net cash used in operations was \$56.2 million during the first nine months of 2022.
- Net cash use in operations for full year 2022 is expected to be approximately \$80 to \$90 million, consistent with previous guidance.
- Research and development (R&D) expenses were \$18.5 million. This compared to \$8.0 million for the same period in 2021. R&D expenses increased compared to the prior period due primarily to increased activities and expenses related to clinical and pre-clinical studies and support functions.
- General and administrative (G&A) expenses were \$2.8 million. This compared to \$1.7 million for the same period in 2021. G&A expenses increased compared to the prior period due primarily to increased activities and expenses related to legal services as well as depreciation and amortization.

Overview of On-going Phase 3 Clinical Program

Cassava Sciences’ Phase 3 program consists of two randomized controlled trials of oral simufilam in patients with mild-to-moderate Alzheimer’s disease. The two studies are named RETHINK-ALZ and REFOCUS-ALZ. In 2021, both studies received Special Protocol Assessments (SPA) from the U.S. Food and Drug Administration.

Over 650 patients are now enrolled in our Phase 3 studies. Studies are being conducted in over 100 clinical trial sites across the U.S., Canada, Puerto Rico, South Korea and Australia.

Cassava Sciences’ RETHINK-ALZ Phase 3 study is designed to evaluate the safety and efficacy of oral simufilam 100 mg in enhancing cognition and slowing functional decline over 52 weeks. This randomized, double-blind, placebo-controlled study plans to enroll approximately 750 patients with mild-to-moderate Alzheimer’s disease. Patients are randomized (1:1) to simufilam 100 mg or matching placebo twice daily.

Cassava Sciences’ REFOCUS-ALZ Phase 3 study is designed to evaluate the safety and efficacy of oral simufilam 100 mg and 50 mg over 76 weeks. This randomized, double-blind, placebo-controlled study plans to enroll approximately 1,000 patients with mild-to-moderate Alzheimer’s disease. Patients are randomized (1:1:1) to simufilam 100 mg, 50 mg, or matching placebo twice daily.

Both of Cassava Sciences' Phase 3 studies have the same co-primary efficacy endpoints: ADAS-Cog12 (a cognitive scale) and ADCS-ADL (a functional scale). A secondary efficacy endpoint is iADRS, a clinical tool that combines cognitive and functional scores from ADAS-Cog & ADCS-ADL.

Open-label Study – closed enrollment

In March 2020, we initiated a long-term, open-label study to evaluate simufilam, our lead drug candidate, in patients with mild-to-moderate Alzheimer's disease. The study is intended to monitor the long-term safety and tolerability of simufilam 100 mg twice daily for 12 or more months. The open-label study has reached its final target enrollment of approximately 200 patients with Alzheimer's disease. We expect to announce open-label study results approximately yearend 2022, consistent with our prior guidance.

Cognition Maintenance Study (CMS) – on-going

In May 2021, we initiated a Cognition Maintenance Study (CMS). This is a randomized, double-blind, placebo-controlled study of oral simufilam in patients with mild-to-moderate Alzheimer's disease. Patients are randomized (1:1) to simufilam 100 mg or matching placebo twice daily for six months. To enroll in the CMS, patients must have previously completed 12 months or more of open-label treatment with simufilam. The CMS is designed to evaluate simufilam's effects on in Alzheimer's patients who *continue* with drug treatment versus patients who *discontinue* drug treatment. Over 100 patients are now enrolled in the CMS and over 65 patients have completed this study. We expect to announce CMS study results approximately Q3 2023, consistent with our prior guidance.

SavaDx – on-going

This earlier-stage program refers to the detection of Alzheimer's disease with a simple blood test. SavaDx was initially designed as an antibody-based detection system for altered filamin A (FLNA). We are currently evaluating a new approach—based on mass spectrometry—to detect FLNA in plasma without the use of antibodies. Mass spectrometry is an analytical tool that measures the mass-to-charge ratio (m/z) of a molecule present in a sample.

About Simufilam

Simufilam (sim-uh-FILL-am) is Cassava Sciences' proprietary, small molecule (oral) drug that restores the normal shape and function of altered filamin A (FLNA) protein in the brain. Cassava Sciences owns worldwide development and commercial rights to its research programs in Alzheimer's disease, and related technologies, without royalty obligations to any third party.

About Cassava Sciences, Inc.

Cassava Sciences, Inc. 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. The Company's product candidates have not been approved by any regulatory authority and their safety, efficacy or other desirable attributes have not been established.

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, relating to: our strategy and plans; expected cash use in future periods; the treatment of Alzheimer's disease; the status of current and future clinical studies with simufilam; the timing, enrollment, duration, geography and other details of a Phase 3 clinical program with simufilam; plans to release clinical results of our open-label study or CMS study, and the timing thereof; the development path for SavaDx and the use of mass spec as an alternative method of detection; and potential benefits, if any, of our product candidates. These statements may be identified by words such as "may," "anticipate," "believe," "could," "expect," "would," "forecast," "intend," "plan," "possible," "potential," and other words and terms of similar meaning.*

Drug development and commercialization involve a high degree of risk, and only a small number of research and development programs result in commercialization of a product. Our interim data and analysis should not be relied upon as predictive of full study results for any of our studies. Our clinical results from earlier-stage clinical trials may not be indicative of full results or 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.

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, to demonstrate the specificity, safety, efficacy or potential health benefits of our product candidates, the severity and duration of health care precautions given the COVID-19 pandemic, any unanticipated impacts of the pandemic on our business operations, and including those described in the section entitled "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2021, 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.

– Financial Tables Follow –

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

Three months ended September 30,		Nine months ended September 30,	
2022	2021	2022	2021

Operating expenses				
Research and development, net of grant reimbursement	\$	18,526	\$	8,041
General and administrative		2,819		1,712
Total operating expenses		<u>21,345</u>		<u>9,753</u>
Operating loss		(21,345)		(9,753)
Interest income		878		15
Other income, net		210		176
Net loss	\$	<u>(20,257)</u>	\$	<u>(9,562)</u>
			\$	50,380
			\$	14,471
				8,703
				<u>3,953</u>
				<u>59,083</u>
				<u>18,424</u>
				(18,424)
				35
				176
				<u>(18,213)</u>
Net loss per share, basic and diluted	\$	(0.51)	\$	(0.24)
			\$	(1.43)
			\$	(0.46)
Weighted-average shares used in computing net loss per share, basic and diluted		40,050		39,957
				40,009
				39,218

CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited, in thousands)

	September 30, 2022	December 31, 2021
Assets		
Current assets		
Cash and cash equivalents	\$	174,662
Prepaid expenses and other current assets		8,610
Total current assets		<u>183,272</u>
Property and equipment, net		23,130
Operating lease right-of-use assets		144
Intangible assets, net		740
Other assets		—
Total assets	\$	<u>207,286</u>
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	\$	3,534
Accrued development expense		4,096
Accrued compensation and benefits		160
Operating lease liabilities, current		102
Other accrued liabilities		416
Total current liabilities		<u>8,308</u>
Operating lease liabilities, non-current		62
Other non-current liabilities		197
Total liabilities		<u>8,567</u>
Stockholders' equity		
Common Stock and additional paid-in-capital		463,137
Accumulated deficit		<u>(264,418)</u>
Total stockholders' equity		<u>198,719</u>
Total liabilities and stockholders' equity	\$	<u>207,286</u>
		\$
		233,437
		11,045
		<u>244,482</u>
		20,616
		210
		1,075
		399
		<u>266,782</u>
		\$
		7,126
		2,803
		1,877
		97
		631
		<u>12,534</u>
		139
		194
		<u>12,867</u>
		461,221
		<u>(207,306)</u>
		<u>253,915</u>
		<u>266,782</u>



Source: Cassava Sciences, Inc.