Cassava Sciences Reports First Quarter 2021 Financial Results and Announces Guidance on Clinical Data Release

April 21, 2021

- 9 Month Interim Analysis of Open-label Study to be Presented at a Major Scientific Conference in July 2021 as an Oral Presentation -

- Initiation of Pivotal Phase 3 Program Remains On-track for 2nd Half 2021 -

- Initiation of Cognition Maintenance Study On-track for June 2021 -

- Cash and cash equivalents were $282.2 million at March 31, 2021 -

AUSTIN, Texas, April 21, 2021 (GLOBE NEWSWIRE) -- Cassava Sciences, Inc. (Nasdaq: SAVA), a clinical-stage biotechnology company focused on Alzheimer's disease, today announced financial results for the first quarter ended March 31, 2021 and guidance regarding the release of new clinical data with simufilam. Simufilam is the Company's lead drug candidate to treat Alzheimer's disease.

"Alzheimer's is a progressive disease, so a patient's cognition is expected to worsen over time," said Remi Barbier, President & CEO. "Patients' cognition scores actually improved following 6 months of open-label treatment with simufilam. Showing similar drug effects following 9 months of open-label treatment would be remarkable, yet consistent with simufilam's mechanism of action. Eventually, we'd like this drug candidate to benefit cognition for a year or longer."

In July 2021, Cassava Sciences plans to announce results of a pre-specified interim analysis that summarizes safety and cognition data on approximately the first 50 subjects to complete at least 9 months of open-label drug treatment. The Company will present these data July 26 - 29th at the *2021 Alzheimer's Association International Conference* (AAIC). AAIC's scientific committee has invited the Company's scientists to present the dataset as an oral presentation.

About the Open-label Study with Simufilam
In March 2020, Cassava Sciences initiated a long-term, open-label study to evaluate simufilam in patients with Alzheimer's disease. This study is funded by a research grant award from the National Institutes of Health (NIH). The open-label study is intended to monitor the long-term safety and tolerability of simufilam 100 mg twice-daily for 12 months or longer in patients with Alzheimer's disease. Another study objective is to measure changes in cognition on ADAS-Cog, a standard test of cognition in Alzheimer's disease. The study's clinical protocol has pre-specified cognition measurements at 6, 9 and 12 months.

The study's target enrollment is approximately 150 subjects with mild-to-moderate Alzheimer's disease (recently increased by 50 subjects). One-hundred subjects have enrolled in this study across multiple clinical sites in the U.S. and Canada.

On February 2, 2021, Cassava Sciences announced positive results of a first interim analysis that summarizes clinical data on the first 50 subjects to complete 6 months of open-label treatment. Patients' cognition scores improved from baseline following 6 months of simufilam treatment, with no safety issues. Six months of simufilam treatment improved cognition scores by 1.6 points on ADAS-Cog11, a 10% mean improvement from baseline to month 6.

In September 2021, Cassava Sciences plans to announce results of an interim analysis that summarizes safety and cognition data on approximately the first 50 subjects to complete at least 12 months of open-label drug treatment.

About the Cognition Maintenance Study (CMS)
In June 2021, Cassava Sciences plans to initiate a double-blind, randomized, placebo-controlled study in patients with Alzheimer's disease. Patients who have completed at least one year of open-label treatment with simufilam qualify to enroll in the *Cognition Maintenance Study* (CMS). Study subjects in the CMS will be randomized (1:1) to simufilam or placebo for six months. The CMS is designed to compare simufilam's effects on cognition in Alzheimer's patients who continue with drug treatment versus patients who discontinue drug treatment.

About the Phase 3 Clinical Program
Cassava Sciences plans to initiate a Phase 3 program of simufilam in Alzheimer's disease in the second half of 2021. The Phase 3 program consists of two large, double-blind, randomized, placebo-controlled studies in patients with mild-to-moderate Alzheimer's disease dementia.

Cassava Sciences' first Phase 3 study is designed to evaluate *disease-modifying* effects of simufilam in Alzheimer's disease. The goal is to demonstrate a slower rate of decline in cognition and health function in subjects treated with simufilam compared to placebo. Approximately 1,000 subjects to be enrolled, randomized (1:1:1) to simufilam 100 mg, 50 mg or placebo BID, and treated for 18 months. The co-primary efficacy endpoints are ADAS-Cog, a cognitive scale, and ADCS-ADL, a functional scale, both widely used clinical tools in trials of Alzheimer's disease.

Cassava Sciences' second Phase 3 study is designed to evaluate *symptomatic improvement* in Alzheimer's disease. The goal is to demonstrate improved cognition and health function in subjects treated with simufilam compared to placebo. Approximately 600 subjects to be enrolled, randomized (1:1) to simufilam 100 mg or placebo BID, and treated for 12 months. The co-primary efficacy endpoints are ADAS-Cog, a cognitive scale, and ADCS-ADL, a functional scale.

Slide Deck

Cassava Sciences' latest corporate presentation is available on its website under the Investors/Presentations page: https://www.CassavaSciences.com

Financial Results for First Quarter 2021
Net loss was $3.5 million, or $0.09 per share, compared to a net loss of $1.2 million, or $0.05 per share, for the same period in 2020. Net cash used in operations was $2.3 million during the first quarter of 2021.

Net cash use for operations for full-year 2021 is expected to be approximately $20 to $25 million. Cash and cash equivalents were $282.2 million as of March 31, 2021, with no debt.

Financial Highlights for First Quarter 2021

- At March 31, 2021, cash and cash equivalents were $282.2 million, compared to $93.5 million at December 31, 2020, with no debt. Cash balance included net proceeds of approximately $189.8 million from the sale of 4.1 million shares of common stock completed February 2021. Cash balance also included $0.7 million from exercise of common stock warrants in the quarter. There were no remaining common stock warrants outstanding as of March 31, 2021.

- Net cash used in operations during the quarter ended March 31, 2021 was $2.3 million, net of reimbursements received from NIH grant awards.

- Research grant funding reimbursements of $0.6 million were received from NIH and recorded as a reduction in research and development (R&D) expenses. This compared to $1.3 million of NIH grant receipts received for the same period in 2020.

- Net cash use for operations for full year 2021 is expected to be approximately $20 to $25 million, consistent with previous financial guidance. Net cash use in 2021 is expected to be driven by higher headcount and personnel expenses, manufacturing costs around large-scale drug supply, professional services expenses related to clinical programs, and operating costs such as insurance, office space and IT related expenses.

- R&D expenses were $2.5 million. This compared to $0.5 million for the same period in 2020, representing a 365% increase. This increase was due primarily to costs related to manufacture of clinical trial supplies in anticipation of launching a Phase 3 clinical program in simufilam, increased personnel expenses, as well as a decrease in grant funding received from NIH compared to the prior year.

- General and administrative (G&A) expenses were $1.0 million. This compared to $0.8 million for the same period in 2020, representing a 29% increase. This increase was due primarily to higher insurance costs and professional fees compared to the prior year.

About Simufilam
Simufilam is a proprietary, small molecule (oral) drug that restores the normal shape and function of altered filamin A (FLNA), a scaffolding protein, in the brain. Altered FLNA in the brain disrupts the normal function of neurons, leading to Alzheimer's pathology, neurodegeneration and neuroinflammation. The underlying science for simufilam is published in peer-reviewed journals, including *Journal of Neuroscience*, *Neurobiology of Aging*, *Journal of Biological Chemistry, Neuroimmunology and Neuroinflammation* and *Journal of Prevention of Alzheimer's Disease.* Cassava Sciences is also developing an investigational diagnostic, called SavaDx, to detect Alzheimer's disease with a simple blood test.

Simufilam and SavaDx were both developed in-house. Both product candidates are substantially funded by peer-review research grant awards from the National Institutes of Health (NIH). 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 Alzheimer's Disease
Alzheimer's disease is a progressive brain disorder that destroys memory and thinking skills. Currently, there are no drug therapies to halt Alzheimer's disease, much less reverse its course. As of 2020, there were approximately 50 million people worldwide living with dementia, a figure expected to increase to 150 million by 2050.[1] The annual global cost of dementia is now above $1 trillion**,** according to *Alzheimer's Disease International*, a charitable organization.

About Cassava Sciences, Inc.
Cassava Sciences' mission is to discover and develop innovations for chronic, neurodegenerative conditions. Over the past 10 years, Cassava Sciences has combined state-of-the-art technology with new insights in neurobiology to develop novel solutions for Alzheimer's disease. For more information, please visit: https://www.CassavaSciences.com.

For More Information Contact:
Eric Schoen, Chief Financial Officer
eschoen@CassavaSciences.com
(512) 501-2450

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, including the interpretation of an interim analysis of an open-label study; plans to conduct additional interim analyses of an open-label study and the timing thereof; planned enrollment*

targets to said open-label program; our intention to initiate a Phase 3 clinical program with simufilam and the timing, enrollment, duration and other details thereof; verbal commentaries made by our employees; 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 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, 2020 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.

The content of this press release is solely our responsibility and does not necessarily represent the official views of the National Institutes of Health (NIH).

– Financial Tables Follow –

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

	Three months ended March 31,	
	2021	2020
Operating expenses		
Research and development, net of grant reimbursement	$ 2,529	$ 544
General and administrative	1,004	778
Gain on sale of property and equipment	—	(100)
Total operating expenses	3,533	1,222
Operating loss	(3,533)	(1,222)
Interest income	7	72
Net loss	$ (3,526)	$ (1,150)
Net loss per share, basic and diluted	$ (0.09)	$ (0.05)
Weighted-average shares used in computing net loss per share, basic and diluted	37,721	24,481

CONDENSED BALANCE SHEETS
(unaudited, in thousands)

	March 31, 2021	December 31, 2020
Assets		
Current assets		
Cash and cash equivalents	$ 282,192	$ 93,506
Other current assets	1,574	488
Total current assets	283,766	93,994
Property and equipment, net	10	11
Operating lease right-of-use assets	274	295
Total assets	$ 284,050	$ 94,300
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 864	$ 911
Accrued development expense	1,553	719
Accrued compensation and benefits	99	83
Operating lease liabilities, current	84	58
Other accrued liabilities	50	94

Total current liabilities	2,650	1,865
Operating lease liabilities, non-current	213	235
Total liabilities	2,863	2,100
Stockholders' equity		
Common Stock and additional paid-in-capital	459,634	267,121
Accumulated deficit	(178,447)	(174,921)
Total stockholders' equity	281,187	92,200
Total liabilities and stockholders' equity	$ 284,050	$ 94,300

[1] *Alzheimer's Disease International, Dementia Statistics, available on-line and accessed April 20, 2021: https://www.alzint.org/about/dementia-facts-figures/dementia-statistics/*

Source: Cassava Sciences, Inc.