UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported) July 29, 2021

Cassava Sciences, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**000-29959**	**91-1911336**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification Number)**

7801 N Capital of Texas Highway, Suite 260
Austin, Texas 78731
(Address of principal executive offices, including zip code)

(512) 501-2444
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2 below):

☐ Written communication pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communication pursuant to Rule 14d-2(b) under the Exchange Act (17CFR 240.14d-2(b))

☐ Pre-commencement communication pursuant to Rule 13e-4(c) under the Exchange Act (17CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value	SAVA	Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).
Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐ ☐

Item 7.01. Regulation FD Disclosure.

A copy of the Cassava Sciences, Inc. presentation at the *2021 Alzheimer's Association International Conference* (AAIC) is furnished as Exhibit 99.1 to this Form 8-K and is incorporated herein by reference.

Item 8.01. Other Events.

On July 29, 2021, Cassava Sciences, Inc. issued two press releases, copies of which are attached hereto as Exhibits 99.2 and 99.3 and are incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibit No. Description

99.1	Cassava Sciences, Inc. 2021 AAIC presentation
99.2	Cassava Sciences, Inc. 2021 AAIC Cognition Results press release, dated July 29, 2021
99.3	Cassava Sciences, Inc. 2021 AAIC Biomarker Results press release, dated July 29, 2021

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Cassava Sciences, Inc.
a Delaware corporation

Date: August 3, 2021

By: /s/ ERIC J. SCHOEN
Eric J. Schoen
Chief Financial Officer

Encouraging Interim Results at 9 Months from an Open-Label Study of Simufilam in Patients with Alzheimer's Disease

Lindsay H. Burns

Tamara Doehner, John Puente, Brian Beck, Yaneicy Gonzalez Rojas, Evelyn Lopez-Brignoni, Boris Nikolov, Hoau-Yan Wang, Zhe Pei, Antonio Hernandez, Carrie A. Crowley, Nadav Friedmann

CASSAVA sciences

alzheimer's association

AAIC 21

Forward-Looking Statements & Safe Harbor

Cautionary Note Regarding Forward-Looking Statements: This presentation contains forward-looking statements, including statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, relating to: the treatment or diagnosis of Alzheimer's disease; the status of current and future clinical studies with simufilam, including the interpretation of interim analyses of open-label study results at 6 or 9 months; plans to conduct additional interim analyses of an open-label study and the timing thereof; inherent limitations of the ADAS-Cog testing batteries; expectations regarding convergence of biomarker and cognition data; treatment benefits of simufilam; our intention to initiate a Phase 3 clinical program with simufilam; 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 involves a high degree of risk, and historically only a small number of research and development programs result in commercialization of a product. Clinical results from our 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.

This presentation may also contain statistical data and drug information based on independent industry publications or other publicly available information. We have not independently verified the accuracy or completeness of the data contained in these publicly available sources of data and information. Accordingly, we make no representations as to the accuracy or completeness of such data. You are cautioned not to give undue weight to such data.

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

Disclosures

- The open-label safety study with simufilam is funded by a clinical research grant award from the National Institutes of Health (NIH).
- Simufilam is a proprietary drug candidate of Cassava Sciences, Inc.
- Lindsay Burns, PhD; Nadav Friedmann, PhD, MD; Carrie Crowley; and Antonio Hernandez, PsyD, are employees of Cassava Sciences.
- Hoau-Yan Wang, PhD, Zhe Pei, PhD, and Kuo-Chieh Lee are affiliated with City University of New York School of Medicine. Professor HY Wang is a consultant to Cassava Sciences.
- Clinicaltrials.gov registration # NCT04388254, registered 14 May 2020.

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Open-Label Study of Simufilam

- Simufilam is an oral drug that targets altered filamin A protein in the brain. Restoring the normal shape of filamin A blocks toxic signaling of soluble $A\beta_{42}$.
- We are conducting a multi-center, one-year, open-label study in subjects (N>150) with mild-to-moderate Alzheimer's disease, MMSE ≥ 16 and ≤ 26.
- Outcome measures:
  - Safety
  - Cognition: Alzheimer's Disease Assessment Scale Cognitive subscale (ADAS-Cog11)
  - Behavior: Neuropsychiatric Inventory (NPI)
  - CSF biomarkers: Baseline, 6 months and 12 months

CASSAVA sciences

Interim Analysis

- We conducted a pre-planned interim analysis on the first 50 subjects who completed 9 months of open-label treatment with simufilam 100 mg b.i.d.
- CSF biomarkers were measured in a subset of subjects (N=25) after 6 months of open-label treatment with simufilam.

Baseline Overview

Simufilam 9-Month Interim Analysis, First 50 Subjects

Attribute	Mean (±SD)
Age (SD)	69 (±6.4)
# Females	23 (46%)
MMSE (SD)	22.6 (±2.9)
ADAS-Cog11 (SD)	16.6 (±7.7)
NPI (SD)	4.7 (±8.2)
# Trial Sites	7

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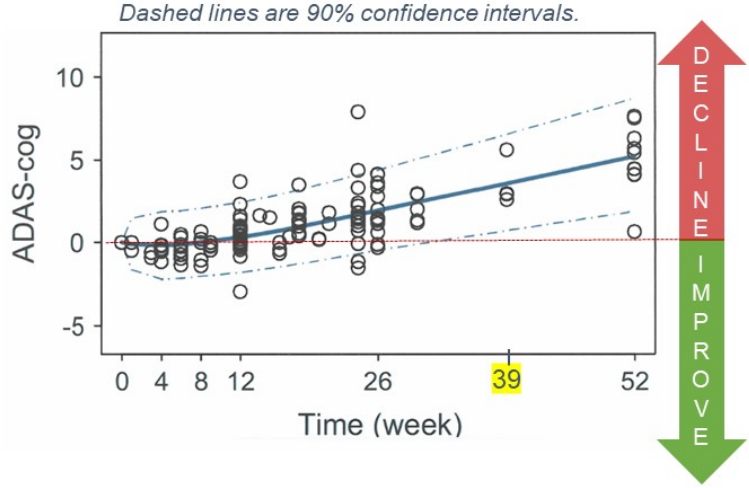
Expected Rate of Cognitive Decline in AD

Meta-analysis Of Placebo Group Decline[1]

Dashed lines are 90% confidence intervals.



- **Cognitive decline was reported in a meta-analysis of 20,000 patients with mild-to-moderate AD[1]:**
  5.5-point decline/year on ADAS-Cog11 in placebo groups.
- **Cognitive decline was reported in two P3 studies of Biogen's aducanumab in patients with early AD[2]:**
  5.2-point decline over 18 months on ADAS-Cog in placebo groups.

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Sources:

[1] *Disease Progression Meta-analysis Model in Alzheimer's disease* (Ito, et al., Pfizer Global Research), Alzheimer's & Dementia 6 (2010) 39-53

[2] *EMERGE and ENGAGE Topline Results (2020), https://investors.biogen.com/static-files/f91e95d9-2fce-46ce-9115-0628cfe96e83*

Cognition Results

ADAS-Cog11 scores improved 3 points at 9 months in the first 50 subjects.

P < 0.001 by paired *t* test: Baseline vs. 9 Months

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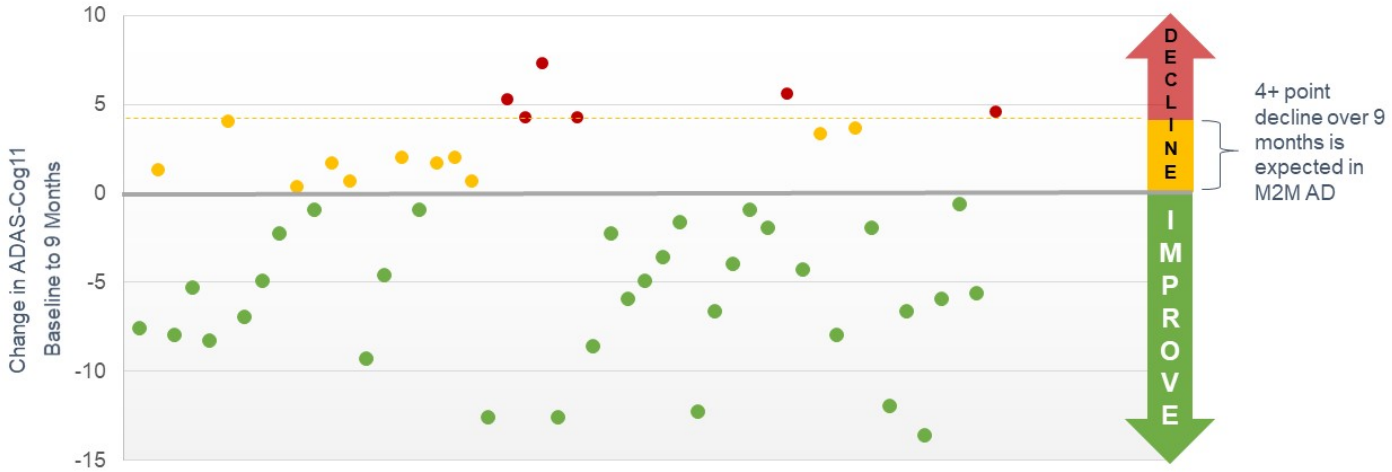
Individual Patient Changes in ADAS-Cog (N=50)

66% of Patients Improved at 9 Months (N=33)
22% of Patients Declined Less Than Expected (N=11)



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CSF Biomarkers

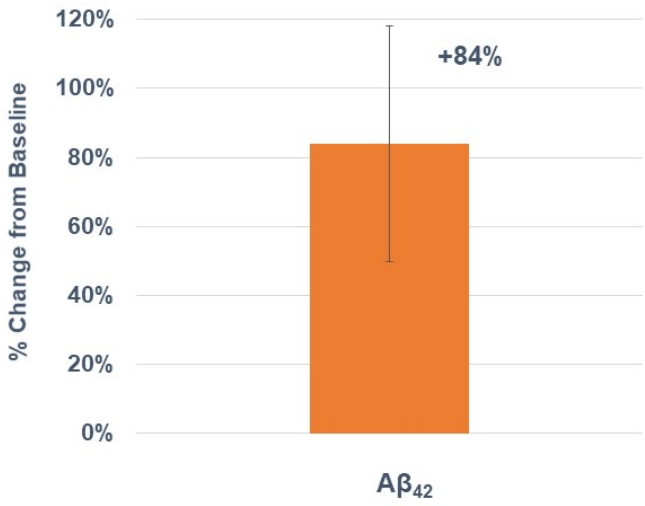
- **Biomarkers of disease were measured in a subset of subjects (N=25) who completed 6 months of simufilam treatment.**
  - Alzheimer's pathology: Amyloid β_{42}, Total Tau and P-tau181
  - Neurodegeneration: Neurogranin and Neurofilament Light Chain (NfL)
  - Neuroinflammation: YKL-40, soluble TREM2 and HMGB1
- **CSF was collected by lumbar puncture at baseline and again at 6 months.**
- **CSF samples were analyzed blind by an outside lab in a 96-well immunoassay (ELISA) format for each biomarker.**

CSF Biomarkers and Baseline Levels

CSF Biomarker	Significance in AD and MCI	Mean concentration in CSF (pg/mL) ± SD
$A\beta_{42}$	AD pathology, low in CSF	122.8 ± 62.4
Total tau	Marker of neurodegeneration	163.5 ± 33.7
P-tau181	Marker of disrupted tau function	35.7 ± 2.1
Neurogranin	Synaptic loss/degeneration	2,147.6 ± 575.7
Neurofilament Light Chain (NfL)	Axonal loss/degeneration	291.6 ± 55.1
YKL-40	Marker of neuroinflammation	250.4 ± 35.8
sTREM2	Microglial-induced neuroinflammation	1,165.8 ± 421.2
HMGB1	Pathogenic “danger” molecule	722.6 ± 98.6

CSF Amyloid-β_{42}

CSF $A\beta_{42}$ increased significantly after 6 months of simufilam treatment.



P < 0.00001 by paired *t* test

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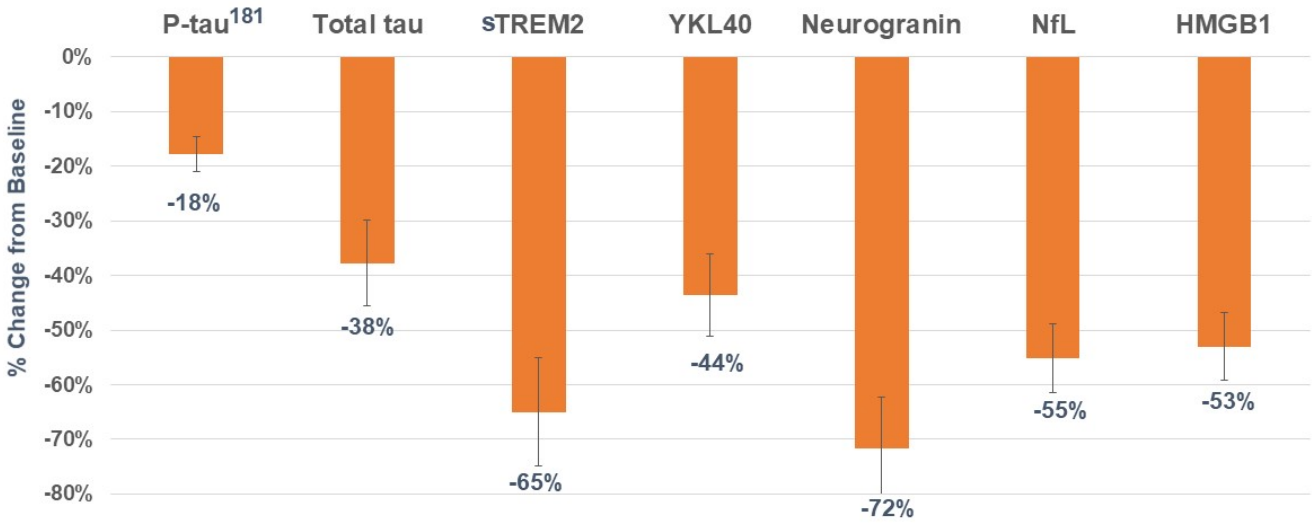
Significant Decreases in CSF Biomarkers at Month 6



P < 0.00001 for all by paired *t* test

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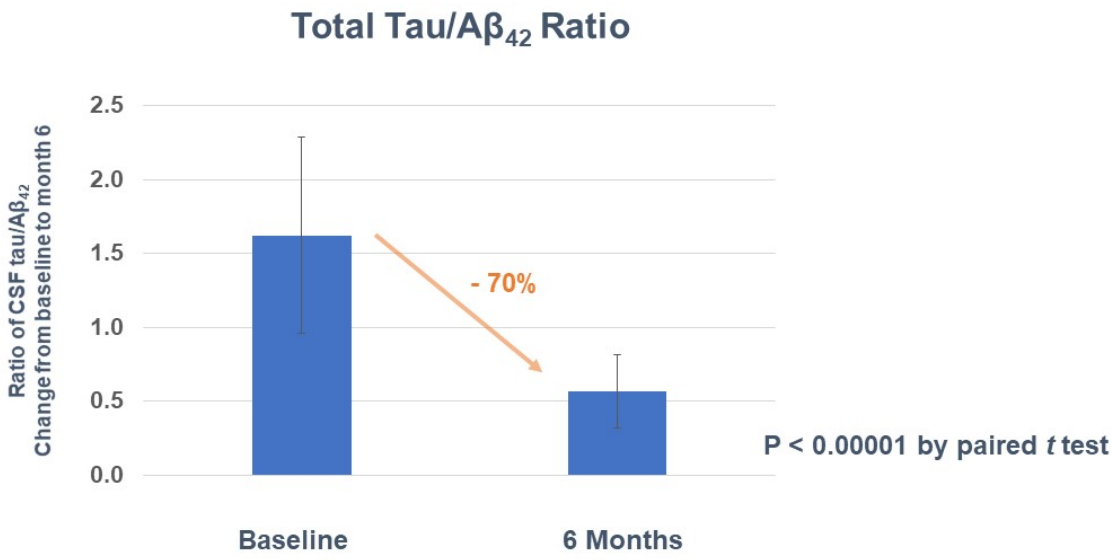
Diagnostic Criterion for AD Decreased Significantly



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Improved Behavior Disorders

- Alzheimer's is often accompanied by behaviors disorders, such as anxiety, agitation or delusions, that may become more frequent as disease progresses.
- At baseline, 34% of patients had no neuropsychiatric symptoms on the Neuropsychiatric Inventory (NPI) scale.
- At Month 9, >50% of patients had no neuropsychiatric symptoms on NPI.

Study Timeline	NPI Scale
Baseline	No neuropsychiatric symptoms in 34% of patients
6 months	No neuropsychiatric symptoms in 38% of patients
9 months	No neuropsychiatric symptoms in >50% of patients

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No Safety Issues

- Simufilam was safe and well-tolerated through 9 months of open-label treatment.
- No drug-related serious adverse events.
- Non-persistent side-effects commonly found in an elderly population are observed.
- <10% dropout rate.

Summary of 9-Month Open-Label Simufilam

- Cognition scores improved significantly ($p<0.001$) in patients with mild-to-moderate Alzheimer's disease after 9 months of open-label simufilam.
- Biomarker levels improved significantly (all $p<0.00001$) in patients with mild-to-moderate Alzheimer's disease after 6 months of open-label simufilam.
- Interim analysis data are consistent with prior clinical results, published preclinical data and mechanism of action.

Alzheimer's is a progressive disease that worsens over time. Improvements in cognition, biomarkers and behavior at 9 months suggest highly encouraging treatment effects.

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Next Steps with Simufilam

- A 12-month interim analysis of the open-label study is expected Q4 2021.
- A randomized, controlled trial with simufilam is currently recruiting 100+ subjects with mild-to-moderate Alzheimer's disease.
- A Phase 3 program with simufilam is scheduled for initiation Fall 2021.
  - Two randomized, controlled trials (12 months & 18 months).
  - Total target enrollment ~ 1,750 subjects with mild-to-moderate AD.

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THANK YOU!

- We thank patients who participated in this open-label study.
- We thank the Alzheimer's Association for this opportunity to present our clinical data with simufilam.
- We are grateful for the participation of clinical investigators and researchers Tamara Doehner, John Puente, Brian Beck, Yaneicy Gonzalez Rojas, Evelyn Lopez-Brignoni, Boris Nikolov, Hoau-Yan Wang and Zhe Pei and new investigators who support this study.
- We thank NIH for grant AG065152 in support of this study.

CASSAVA sciences

Cassava Sciences Announces Positive Cognition Data With Simufilam in Alzheimer's Disease

- **Simufilam Significantly Improves Cognition in Patients with Alzheimer's in Interim Analysis of Open-label Study at 9 Months**
- **Cognition Improved 3.0 Points on ADAS-Cog at 9 Months (p<0.001)**
- **Cognitive Improvements Track with Biomarker Improvements**
- **No Behavior Disorders in Over 50% of Patients**
- **No Safety Issues**
- **Improvements in Cognition, Biomarkers and Behavior Suggest Highly Encouraging Treatment Effects**
- **Oral Presentation at AAIC Today**

AUSTIN, TX – July 29, 2021 – Cassava Sciences, Inc. (Nasdaq: SAVA) announced positive clinical data today from an interim analysis of an open-label study with simufilam, the Company's investigational drug for the treatment of Alzheimer's disease.

In a clinical study funded by the National Institutes of Health (NIH), simufilam significantly improved cognition in Alzheimer's patients, with no safety issues. Simufilam improved cognition scores 3.0 points on ADAS-Cog11, an 18% mean improvement, baseline to month 9 (p<0.001). This interim analysis summarizes clinical data from the first 50 patients with mild-to-moderate Alzheimer's disease who completed 9 months of open-label simufilam treatment.

Cassava Sciences believes today's data is the first report of significant cognitive improvements at 9 months that also track with robust improvements in biomarkers in patients with Alzheimer's.

"We are very pleased with the overall consistency of data," said Remi Barbier, President & CEO. "Simufilam improved cognition, biomarkers and behavior, a triple-win for study participants. These clinical data combined with a clean safety profile and easy oral administration suggest highly encouraging and durable treatment effects for people living with Alzheimer's disease."

Alzheimer's is a progressive disease. Cognition will always decline over time. In patients with mild-to-moderate Alzheimer's disease, cognition scores decline over 4 points on ADAS-Cog over 9 months with over 90% certainty, as reported by the science literature[1].

[1] *Disease Progression Meta-analysis Model in Alzheimer's disease* (Ito, et al., Pfizer Global Research), Alzheimer's & Dementia 6 (2010) 39-53

Simufilam *improved* ADAS-Cog scores in 66% of patients at 9 months. An additional 22% of patients declined less than reported in the science literature at 9 months. Cognition outcomes suggest simufilam's treatment effects were broad-based.

Alzheimer's is often accompanied by behaviors disorders, such as anxiety, agitation or delusions. These may become more frequent as disease progresses. Simufilam *reduced* dementia-related behavior at 9 months on the Neuropsychiatric Inventory (NPI), a clinical tool widely used to measure changes in dementia-related behavior.

- At baseline, 34% of study subjects had no neuropsychiatric symptoms.
- At month 6, 38% of study subjects had no neuropsychiatric symptoms.
- At month 9, over 50% of study subjects had no neuropsychiatric symptoms.

The safety profile of simufilam in the interim analysis is consistent with prior human studies. There were no drug-related serious adverse events. Adverse events were mild and transient.

"Today's data with simufilam suggests disease modification," added Nadav Friedmann, PhD, MD, Chief Medical Officer. "It appears the drug's unique mechanism of action has potential to provide transformative treatment benefits following 9 months of dosing."

In February 2021, Cassava Sciences reported that simufilam improved cognition scores by 1.6 points on ADAS-Cog11, a 10% improvement, following six months of open-label treatment.

This press release is contemporaneous with another press release titled, "*Cassava Sciences Announce Positive Biomarker Data with Simufilam in Alzheimer's Disease*", which reports simufilam significantly improved all measured biomarkers of disease, neurodegeneration and neuroinflammation ($p<0.00001$) following 6 months of open-label treatment.

About Today's Oral Presentation at AAIC
Lindsay Burns, Senior VP, Neuroscience at Cassava Sciences, is scheduled to give a live podium presentation today at the Alzheimer's Association International Conference (AAIC) in Denver, CO and virtually. Dr. Burns' presentation is titled, "*Encouraging Interim Results at 9 Months from an Open-label Study of Simufilam in Alzheimer's Disease*" (AAIC abstract #54395).

Today's AAIC presentation can be accessed on the 'Investors' page of the Company's website: https://www.CassavaSciences.com

About the Open-label Study
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 protocol has pre-specified interim analyses on safety and cognition for the first 50 subjects who complete 6, 9 and 12 months of drug treatment. The study protocol also specifies two biomarker measurements: i) from baseline to Month 6 in 25 study subjects, and ii) baseline to Month 12 in another 25 study subjects. The open-label study has completed its target enrollment of 150 subjects. By physician and patient request, clinical sites may continue to enroll additional subjects up through the upcoming initiation of the Company's Phase 3 pivotal program of simufilam.

Next Steps
Cassava Sciences is advancing simufilam into a Phase 3 clinical program in Alzheimer's disease. The Phase 3 program with simufilam plans to enroll over 1,500 patients with mild-to-moderate Alzheimer's disease. Study initiation is scheduled for Fall 2021.

About Simufilam
Simufilam (sim-uh-FILL-am) 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*. Simufilam is substantially supported by peer-reviewed research grant awards from the National Institutes of Health (NIH).

Simufilam and SavaDx were both developed in-house. 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. As of 2020, there were approximately 50 million people worldwide living with dementia, a figure expected to increase to 150 million by 2050.[2] 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
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or (512) 501-2450

Cassava Sciences' open-label study of simufilam in Alzheimer's disease is funded by clinical research grant #AG065152 from the National Institutes of Health (NIH/NIA).

The content of this press release is solely the responsibility of Cassava Sciences and does not necessarily represent the official views of the NIH/NIA.

[2] *Alzheimer's Disease International, Dementia Statistics*, available on-line.

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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*.*

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Cassava Sciences Announces Positive Biomarker Data with Simufilam in Alzheimer's Disease

- **Simufilam Significantly Improved Biomarkers in Alzheimer's Patients Treated for 6 Months**
- **Robust Improvements Seen in All Measured Biomarkers of Disease, Neurodegeneration and Neuroinflammation (p< 0.00001)**
- **Biomarker Improvements Track with Cognitive Improvements**
- **Oral Presentation at AAIC Today**

AUSTIN, TX – July 29, 2021 – Cassava Sciences, Inc. (Nasdaq: SAVA) today announced positive biomarker data from an open-label study of simufilam, the Company's investigational drug for the treatment of Alzheimer's disease.

In a clinical study funded by the National Institutes of Health (NIH), simufilam significantly improved all measured biomarkers in patients with Alzheimer's disease following 6 months of open-label treatment. Biomarkers are objective biological data. There are no placebo effects.

Cerebrospinal fluid (CSF) biomarkers of disease pathology, t-tau and p-tau181, decreased 38% and 18%, respectively (both p<0.00001). CSF biomarkers of neurodegeneration, neurogranin and Nfl, decreased 72% and 55%, respectively (both p<0.00001). CSF biomarkers of neuroinflammation, sTREM2 and YKL-40, decreased 65% and 44% (both p<0.00001). CSF biomarker data were collected from 25 patients with mild-to-moderate Alzheimer's disease who completed 6 months of simufilam treatment in an on-going open-label study.
"Six months of simufilam treatment robustly improved brain biomarkers," said Remi Barbier, President & CEO. "In this same study simufilam also improved cognition. These data suggest simufilam has potential to provide durable treatment effects for people living with Alzheimer's."

About Cerebrospinal Fluid (CSF) Biomarkers
A key objective of this analysis was to measure changes in levels of biomarkers in patients before and after 6 months of treatment with open label simufilam. Biomarker data were analyzed from CSF collected from 25 patients with mild-to-moderate Alzheimer's disease who are enrolled in an on-going open-label study and who agreed to undergo a lumbar puncture at baseline and again after 6 months of treatment. All bioanalyses were conducted blind by an outside lab. Simufilam robustly improved all measured CSF biomarkers (all p-values are baseline vs. 6-month levels by paired *t*-test):

Core markers of Alzheimer's pathology are total tau (T-tau), phosphorylated tau (P-tau181), and amyloid beta42 ($A\beta_{42}$). In Alzheimer's, tau levels are elevated and $A\beta_{42}$ is low.

- T-tau decreased 38% ($p<0.00001$)
- P-tau181 decreased 18% ($p<0.00001$)
- CSF $A\beta_{42}$ increased 84% ($p<0.00001$)

Elevated CSF levels of two proteins, neurogranin (Ng) and neurofilament Light Chain (NfL) indicate neurodegeneration.

- Ng decreased 72% ($p<0.00001$)
- NfL decreased 55% ($p<0.00001$)

Elevated levels of marker YKL-40 indicate neuroinflammation.

- YKL-40 decreased 44% ($p<0.00001$)

sTREM2 is a biomarker of microglia-induced neuroinflammation that has commanded substantial recent attention from researchers for its role in Alzheimer's and frontotemporal dementia.

- sTREM2 decreased 65% ($p<0.00001$)

HMGB1 protein, is a damage-related protein sometimes called a 'danger molecule' because it triggers additional neuroinflammation and loss of neurons.

- HMGB1 decreased 53% ($p<0.00001$)

In February 2021, Cassava Sciences reported that simufilam improved cognition scores by 1.6 points on ADAS-Cog11, a 10% mean improvement from baseline, following six months of open-label treatment.

This press release is contemporaneous with another press release titled, "*Cassava Sciences Announces Positive Cognition Data with Simufilam in Alzheimer's Disease*", which reports simufilam improved cognition scores by 3.0 points on ADAS-Cog at 9 months ($p<0.001$).

About Today's Oral Presentation at AAIC
Lindsay Burns, Senior VP, Neuroscience at Cassava Sciences, is scheduled to give a live podium presentation today at the Alzheimer's Association International Conference (AAIC) in Denver, CO and virtually. Dr. Burns' presentation is titled, "*Encouraging Interim Results at 9 Months from an Open-label Study of Simufilam in Alzheimer's Disease*" (AAIC abstract #54395).

Today's AAIC presentation can be accessed on the 'Investors' page of the Company's website: https://www.CassavaSciences.com

About the Open-label Study
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 protocol has pre-specified interim analyses on safety and cognition for the first 50 subjects who complete 6, 9 and 12 months of drug treatment. The study protocol also specifies two biomarker measurements: i) from baseline to Month 6 in 25 study subjects, and ii) baseline to Month 12 in another 25 study subjects. The open-label study has completed its target enrollment of 150 subjects. By physician and patient request, clinical sites may continue to enroll additional subjects up through the upcoming initiation of the Company's Phase 3 pivotal program of simufilam.

Next Steps
Cassava Sciences believes clinical results support advancing simufilam into a Phase 3 clinical program in Alzheimer's disease. Phase 3 program initiation is scheduled for Fall 2021.

About Simufilam
Simufilam (sim-uh-FILL-am) 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*. Simufilam is substantially supported by peer-reviewed research grant awards from the National Institutes of Health (NIH).

Simufilam and SavaDx were both developed in-house. 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. 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.

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[1] Alzheimer's Disease International, Dementia Statistics, *available on-line.*

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The content of this press release is solely the responsibility of Cassava Sciences and does not necessarily represent the official views of the NIH/NIA.

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: the treatment or diagnosis of Alzheimer's disease; the status of current and future clinical studies with simufilam, including the interpretation of interim analyses of open-label study results; plans to conduct additional interim analyses of an open-label study and the timing thereof; inherent limitations of the ADAS-Cog testing batteries; expectations regarding convergence of biomarker and cognition data, and treatment benefits of simufilam; 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 involves a high degree of risk, and historically only a small number of research and development programs result in commercialization of a product. Clinical results from our 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.

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