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) February 8, 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. corporate presentation, dated February 2021, is furnished as Exhibit 99.1 to this Form 8-K and is incorporated herein by reference.

Item 8.01. Other Events.

On February 8, 2021, Cassava Sciences, Inc. issued a press release, a copy of which is attached hereto as Exhibit 99.2 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibit No. Description

99.1	Cassava Sciences, Inc. corporate presentation, dated February 2021
99.2	Cassava Sciences, Inc. press release dated February 8, 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: February 8, 2021

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

Exhibit 99.1


CASSAVA
sciences
We Focus on Alzheimer's disease
February 2021

Forward-Looking Statements & Safe Harbor

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: our strategy and plans; the treatment of Alzheimer's disease; the status of current and future clinical studies with simufilam, including the interpretation of a 6-month interim analysis of open-label study results; changes to the open-label study, including future interim analysis; our intention to initiate a Cognition Maintenance Study and a Phase 3 clinical program with simufilam in 2021; results of our EOP2 meeting with FDA and the timing of further announcements; our ability to manufacture drug supply for a Phase 3 program and to enter into a long-term commercial drug supply agreement; the timing of validation studies with SavaDx; our ability to expand therapeutic indications for simufilam outside of Alzheimer's disease; expected cash use in future periods; plans to publish results of a Phase 2b study in a peer-reviewed journal; verbal commentaries made by our employees; and potential benefits, if any, of the our product candidates. These statements may be identified by words such as "may," "anticipate," "believe," "could," "expect," "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 presentation 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, potential health benefits, if any, of changes in levels of biomarkers, the severity and duration of health care precautions given the COVID-19 pandemic, any unanticipated impacts of the pandemic on our business operations, including those described in the section entitled "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2019 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 presentation 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 presentation. 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 or information. 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).

Cassava Sciences Highlights

- Our goal is to defeat Alzheimer's disease.
- Alzheimer's disease is one of the greatest unmet medical needs, with no disease-modifying medicines.
- Our scientific approach is unique, our clinical data is highly differentiated.
- Our science programs have been developed with scientific and financial support from the National Institutes of Health (NIH).

- We are developing **simufilam**, a proprietary drug candidate to treat Alzheimer's disease and SavaDx, a blood-based investigational diagnostic.
- **Simufilam is Phase 3 ready in 2021.**
- Key drivers of our clinical development program:
  - A decade of research in basic biology
  - Clear scientific rationale
  - Published pre-clinical results
  - Well-understood mechanism of action
  - Clean safety profile
  - Evidence of target engagement in patients
  - Unprecedented CSF biomarker data
  - Phase 2b clinical results
  - Early data on cognition and behavior
  - Successful End-of-Phase 2 meeting with FDA

Meet the Team

Remi Barbier - Chairman, President & CEO

EXELIXIS XOMA ARQULE

Lindsay H. Burns, PhD - SVP Neuroscience

Abgenix élan UNIVERSITY OF CAMBRIDGE

Nadav Friedmann, PhD/MD - CMO, Board member

Eight FDA drug approvals prior to Cassava Sciences.

Johnson & Johnson Abbot Daiichi-Sankyo

Michael Zamloot - SVP Technical Operations

Four FDA drug approvals prior to Cassava Sciences.

Boehringer Ingelheim Ciba-Geigy

Jim Kupiec, MD – Chief Clinical Development Officer ***Two FDA drug approvals prior to Cassava Sciences.***

Pfizer SANOFI Ciba-Geigy

Eric Schoen - Chief Financial Officer

VERMILLION PRICEWATERHOUSECOOPERS

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Independent Directors

Sanford Robertson

- Founding Partner - Francisco Partners
- Founder & Chairman - Robertson, Stephens & Company

Robert Gussin, PhD

- Formerly, Johnson & Johnson, Chief Scientific Officer and Corporate VP, Science and Technology

Patrick Scannon, MD/PhD

- Formerly, Founder & CSO/CMO - XOMA Corporation

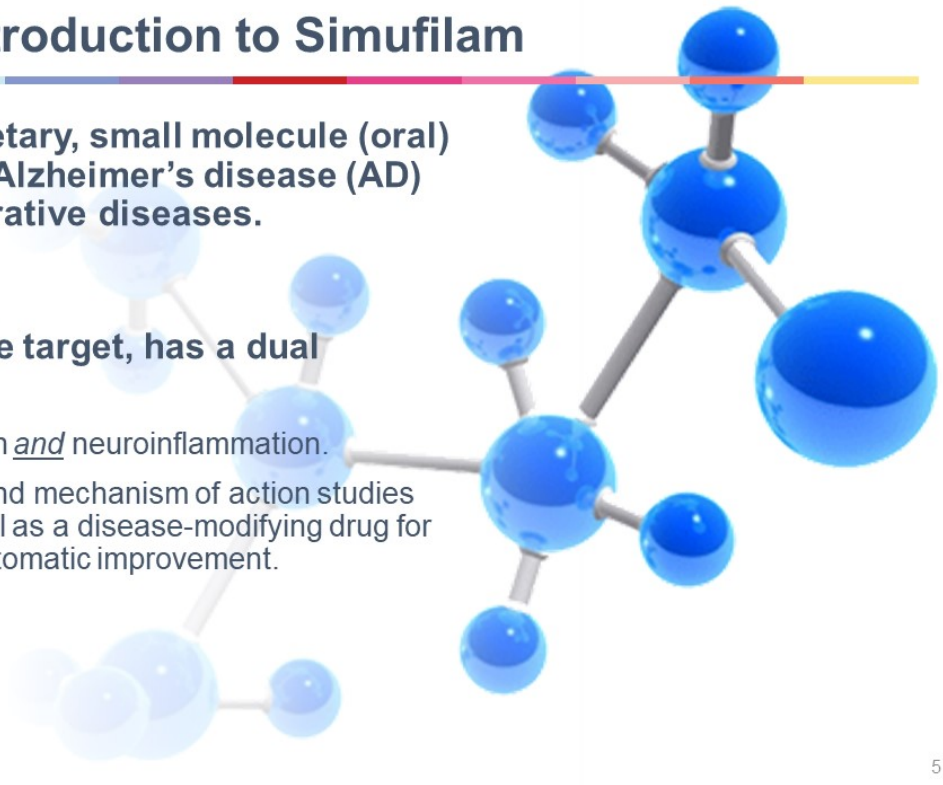
Michael O'Donnell

- Partner, Morrison & Foerster LLP

Introduction to Simufilam

- **Simufilam is our proprietary, small molecule (oral) drug candidate to treat Alzheimer's disease (AD) and other neurodegenerative diseases.**

- **Simufilam binds a single target, has a dual mechanism of action:**
  - Reduces neurodegeneration *and* neuroinflammation.
  - Published preclinical data and mechanism of action studies support simufilam's potential as a disease-modifying drug for AD that also provides symptomatic improvement.



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Clinical Development

- ✓ *2017: simufilam is safe, well-tolerated in human volunteers.*
- ✓ *2019: positive results on CSF biomarkers of disease in an open-label Phase 2a study of simufilam in AD patients.*
- ✓ *2020: positive results on CSF biomarkers of disease in a double-blind, randomized, placebo-controlled Phase 2b study of simufilam in AD patients.*
- ✓ *2021: positive results on cognition in a 6-month interim analysis of an on-going, open-label study in AD patients.*

We plan to initiate a Phase 3 study of simufilam in Alzheimer's disease in 2nd half 2021.

CASSAVA sciences

Science & Technology

Lindsay Burns, PhD – SVP Neuroscience

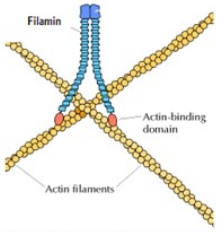
Nadav Friedmann, PhD/MD – Chief Medical Officer

Jim Kupiec, MD - Chief Clinical Development Officer

Simufilam Mechanism of Action

The Target of Simufilam is Altered Filamin A (FLNA)

Filamin A (FLNA) is a scaffolding protein highly expressed in the brain.



FLNA cross-links actin to provide structure and motility, but also interacts with >90 proteins, influencing many signaling pathways.

The Alzheimer's brain carries an *altered* form of FLNA. Altered FLNA is critical to amyloid beta toxicity.

Mechanism of Action

The altered form of FLNA is a proteopathy in the AD brain.

Altered FLNA <u>enables</u> $A\beta_{42}$ signaling via:

i. α7-nicotinic acetylcholine receptor (α7nAChR)
→ hyperphosphorylates tau

ii. Toll-like receptor 4 (TLR4)
→ releases inflammatory cytokines

Simufilam binds altered FLNA, restores its proper shape/function, <u>disables</u> $A\beta_{42}$ signaling via α7nAChR and TLR4.

Through a single target,
simufilam reduces neurodegeneration and neuroinflammation.

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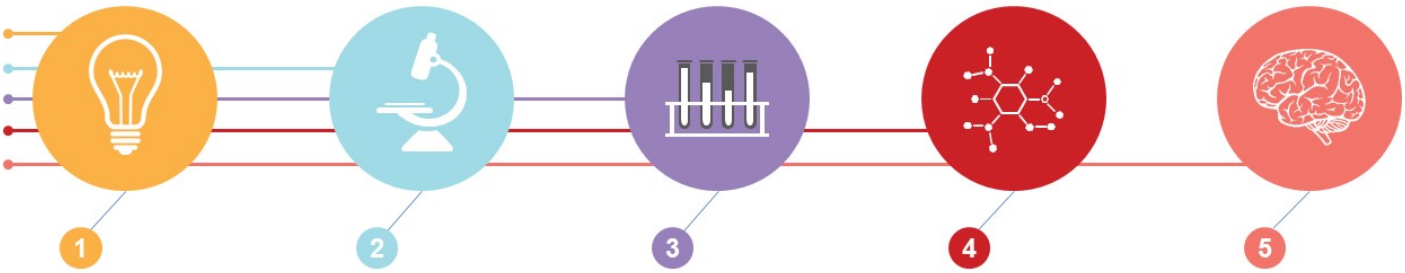
10+ Year In-house Discovery/Development Program



<2008
Basic research around neurobiology of Filamin A (FLNA).

2009
Discovery that altered FLNA associates with α7nAChR when Aβ signals.

2010
Screening/testing of compounds that bind altered FLNA and block α7nAChR/Aβ interaction.

2011
Simufilam (formerly, PTI-125) binds altered FLNA with high affinity, blocks α7nAChR/Aβ interactions. Preclinical testing of simufilam.

2017 - present
IND filing. Clinical testing of simufilam. Positive Phase 2 results reported in Alzheimer's patients.

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Summary of Preclinical Effects

Simufilam	Intracerebro-ventricular (ICV) $A\beta_{42}$ infusion mouse model	Triple transgenic AD mouse model	Post-mortem human AD brain tissue	Post-mortem human age-matched control brain tissue treated with $A\beta_{42}$ in vitro
Reduced FLNA linkage to α7nAChR/TLR4	√	√	√	√
Reduced $A\beta_{42}$ bound to α7nAChR	√	√	√	√
Reduced amyloid deposits and NFTs	√	√		
Reduced tau hyperphosphorylation	√	√		√
Improved function of α7nAChR, NMDAR and insulin receptors	√	√	√	√
Improved synaptic plasticity (activity-dependent Arc expression)		√		√
Reduced inflammatory cytokine levels	√	√		
Improved cognition/behavior		√		

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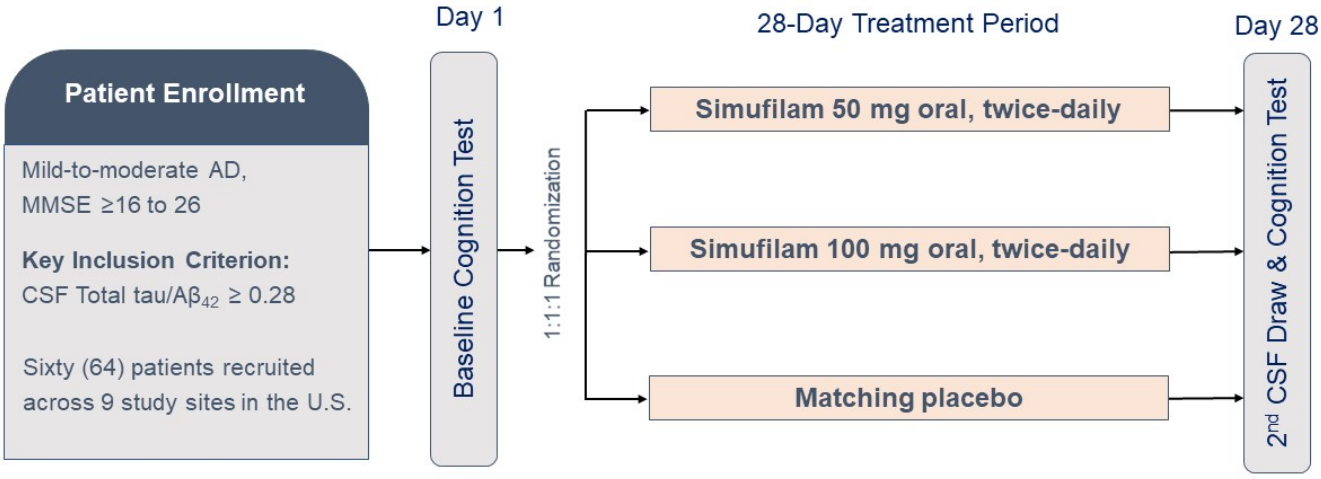
Clinical Hypothesis

Hypothesis	Phase 2b Study Objective
Simufilam is a disease-modifying drug for Alzheimer's disease that also provides symptomatic improvement.	Evaluate safety, biomarkers and cognition in a randomized, placebo-controlled study of simufilam.

Phase 2b - Study Design

Double-blind, Randomized, Placebo-controlled, Multi-center Study



Primary Endpoint: Biomarkers of disease

Secondary Endpoint: Cognition

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Phase 2b Results – Safety & Baseline

- **Simufilam was safe and well-tolerated**
- **No serious adverse events**
- **No drug-related patient discontinuation**
- **No drug-related adverse events**
  - Common, non-persistent side-effects observed in placebo & drug groups

- **Baseline characteristics were well-balanced between treatment groups, assigned through (1:1:1) randomization.**

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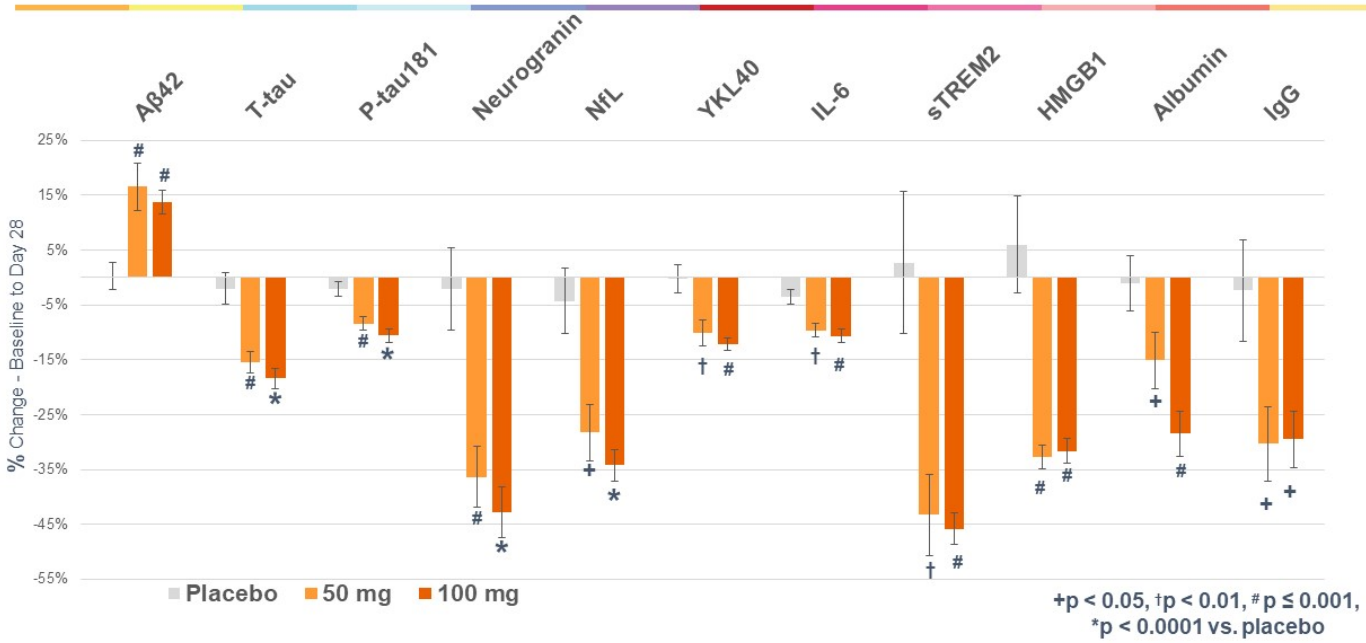
Phase 2b Summary of Results - CSF Biomarkers



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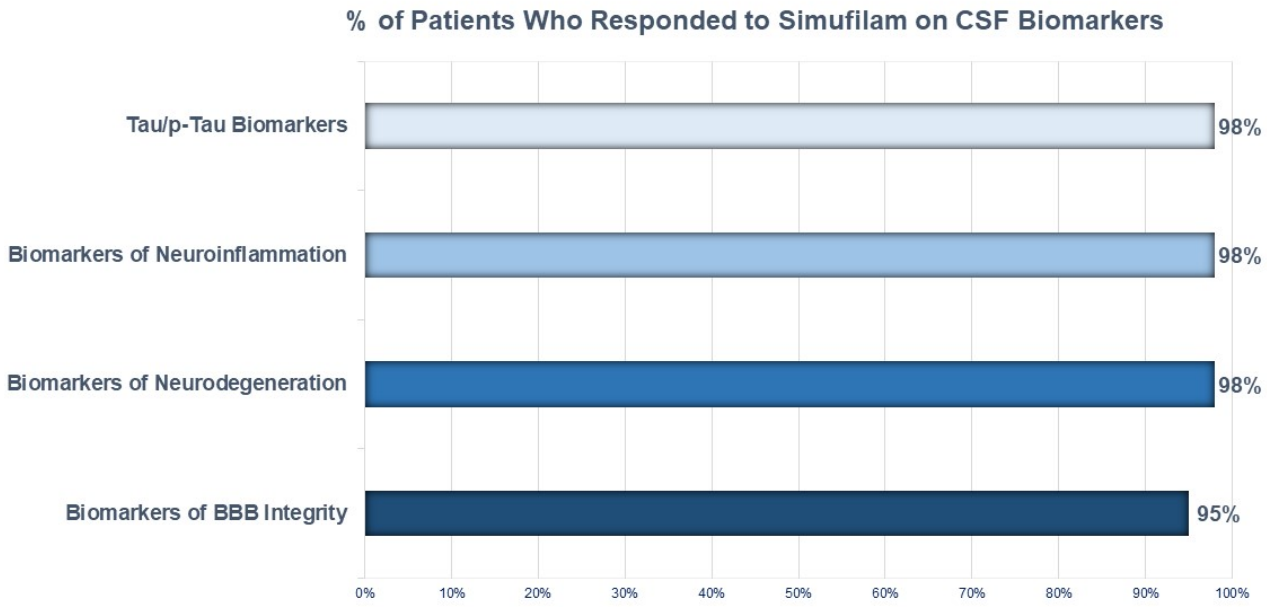
Phase 2b Results – Patient Responder Analysis



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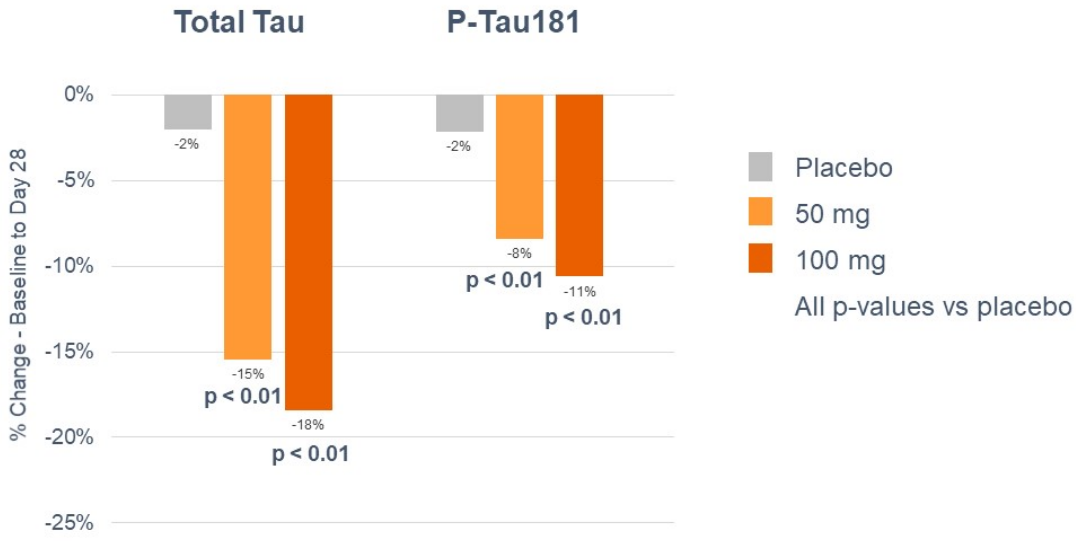
Phase 2b Results – CSF Total Tau and P-Tau181 Decreased



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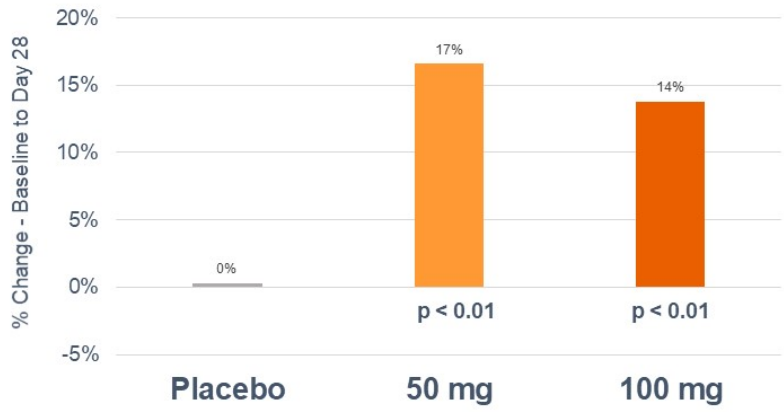
Phase 2b Results – CSF $A\beta_{42}$, Increased, As Expected

Change in Levels of CSF Amyloid-β_{42} Day 0 to Day 28



Note: CSF amyloid-β_{42} levels are low in early stages of dementia in patients with Alzheimer's disease.

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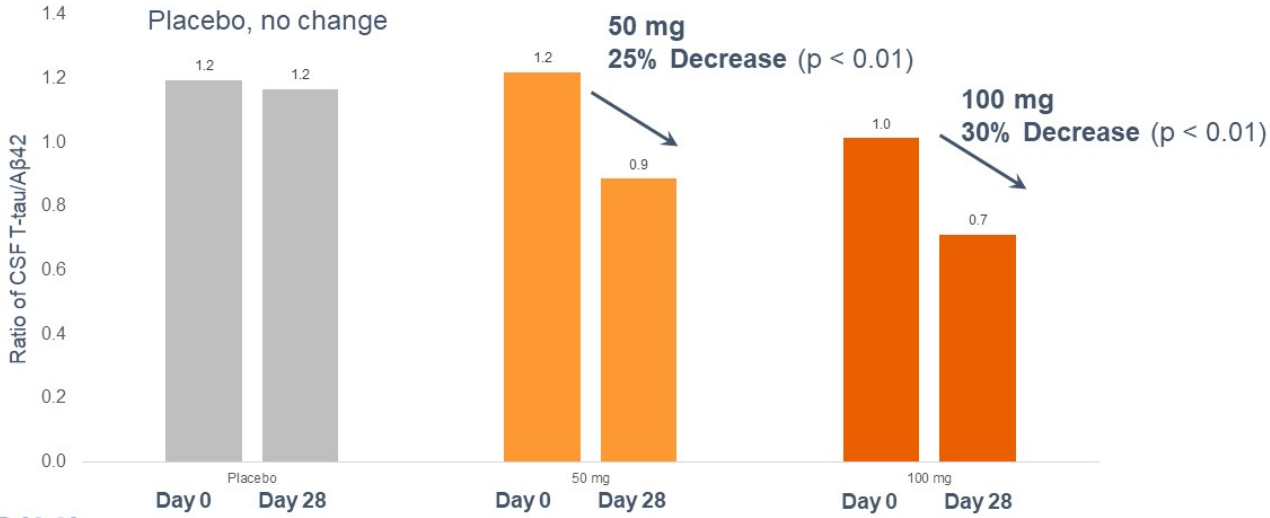
Phase 2b Results - Total tau/Aβ$_{42}$ Decreased Significantly

A Key Diagnostic Criteria for AD Decreased Significantly in Both Drug Groups

Change in Ratio of CSF T-tau/Aβ$_{42}$ Day 0 to Day 28



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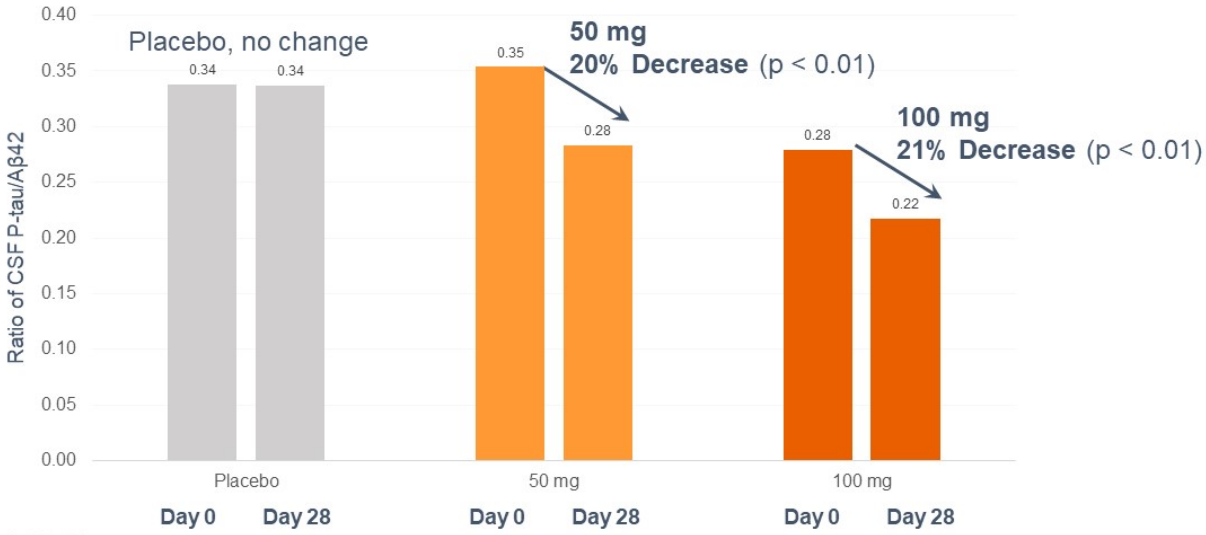
Phase 2b Results - P-tau/Aβ$_{42}$ Decreased Significantly

A Key Diagnostic Criteria for AD Decreased Significantly in Both Drug Groups

Change in Ratio of CSF P-tau/Aβ$_{42}$ Day 0 to Day 28



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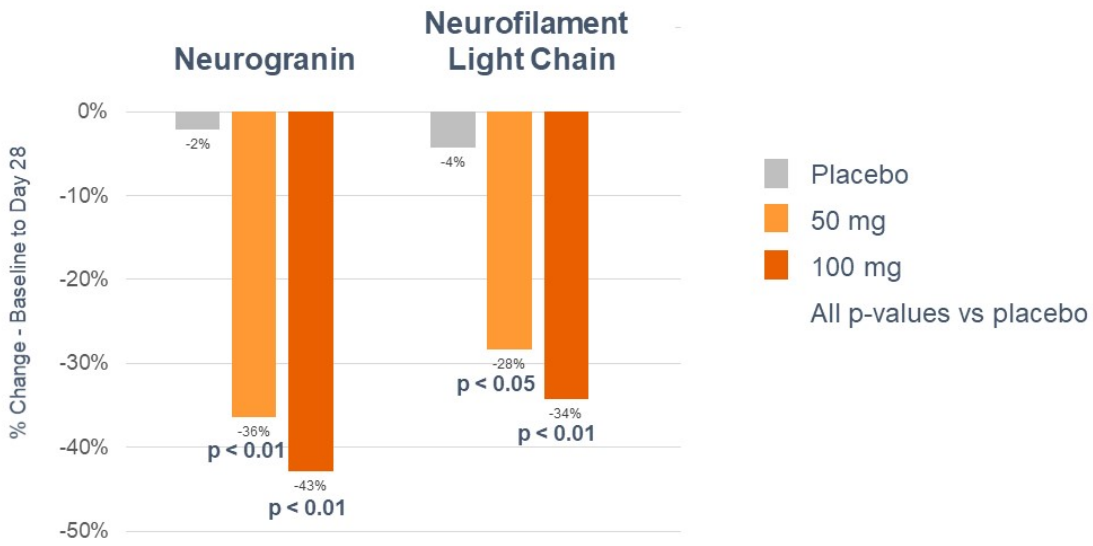
Phase 2b Results - Decrease in CSF Neurodegeneration



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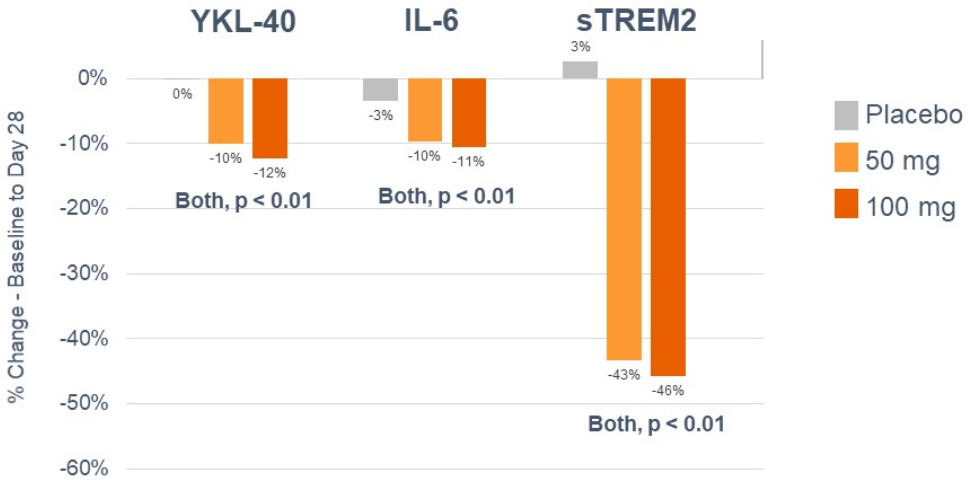
Phase 2b Results - Decrease in CSF Neuroinflammation

Biomarkers of Neuroinflammation Decreased Significantly in Both Drug Groups

Change in Levels of CSF YKL-40, IL-6 and soluble TREM2, Day 0 to Day 28



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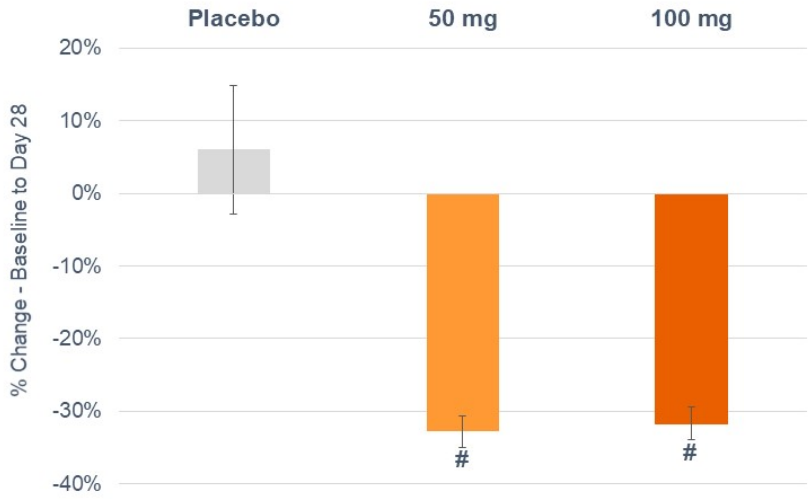
Phase 2b Results – CSF HMGB1 Decreased

Elevated Levels of HMGB1 Triggers Neuroinflammation, Neurite Degeneration and Cell Death.



# p < 0.001 vs. placebo

Note: HMGB1 = High-Mobility Group Box 1

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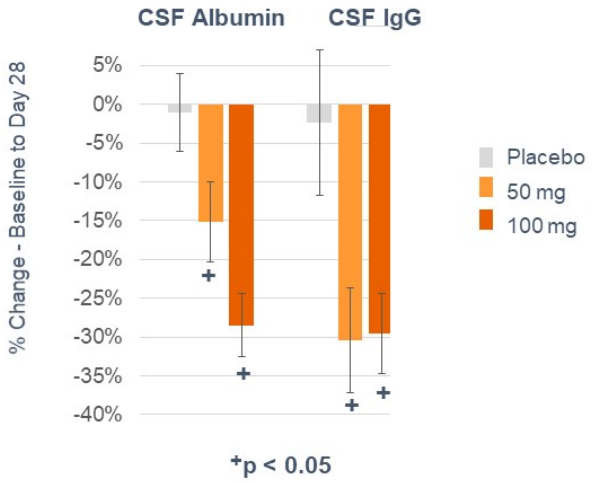
Phase 2b Results – Improved Blood-brain Barrier Integrity



$^{+}p < 0.05$

Albumin Ratio by Treatment Group

	Day 0	Day 28	Change
Placebo	24	24	No change
50 mg simufilam	25	20	- 5 (-20%)
100 mg simufilam	25	18	- 7 (28%)

*Note: Albumin Ratio ((CSF/plasma)*100) is a clinical test for BBB permeability because albumin protein is not synthesized in CSF. Hence, albumin in CSF necessarily comes from plasma through the BBB.*

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Cognition

- **CANTAB** (Cambridge, England) **is a validated, computer-based battery of memory tests that are sensitive to subtle changes in cognition.**
  - Tests are independent of language skills, speed, gender or education.
- **Patients were assessed on 'Episodic Memory' and 'Spatial Working Memory'.**
  - Patients advance through progressively more difficult levels.
  - Outcome measure = total errors, with errors imputed for more difficult levels not reached.
  - Lower score is better.
- **Patients were assessed on Day 1 (pre-dose) and Day 28.**

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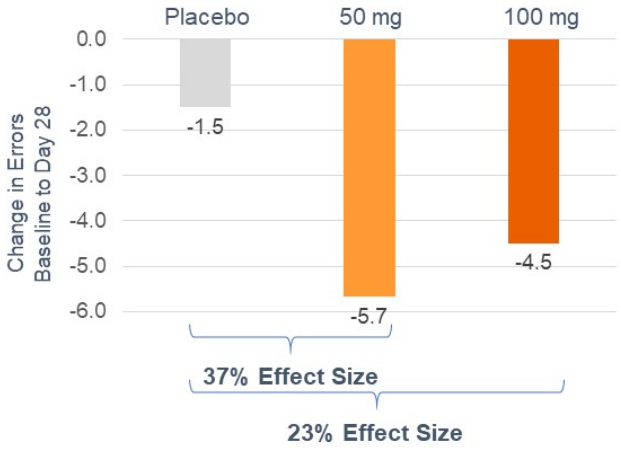
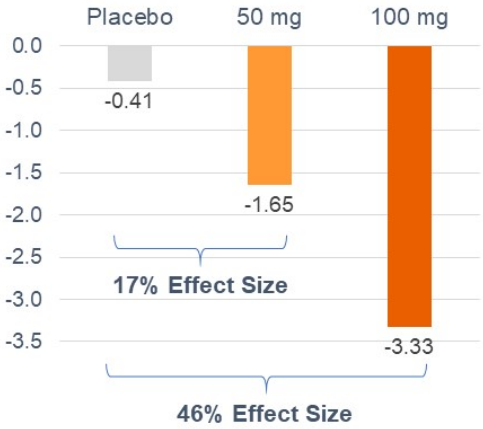
Phase 2b Results – Memory Measurements Improved

Episodic Memory Improved



Spatial Working Memory Improved



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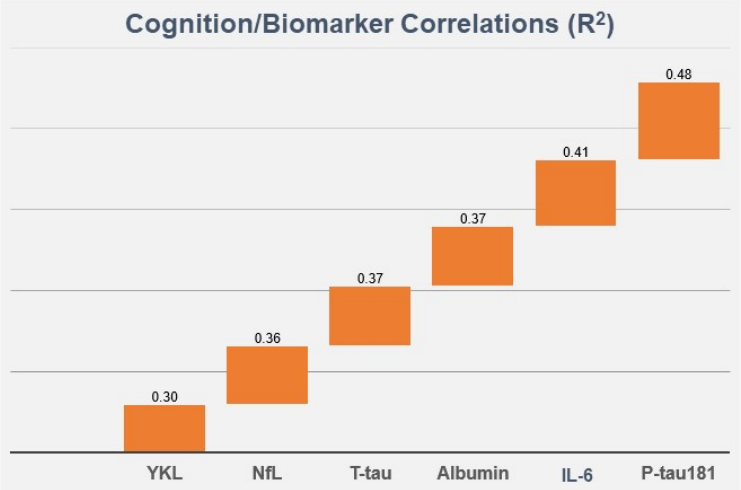
Phase 2b Results - Cognition/Biomarker Correlation

Cognitive Improvement Correlated Most (R^2 = 0.5) With Decreases in CSF P-tau181



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Phase 2b Study Conclusions

- Simufilam showed promising treatment effects in a placebo-controlled study in patients with mild-to-moderate Alzheimer's disease.
- Simufilam improved a panel of validated biomarkers of disease pathology, neuroinflammation and BBB integrity.
- Simufilam appeared to enhance cognition.
- Phase 2b data replicate prior clinical results and are consistent with published preclinical data and mechanism of action studies.

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Open-label Study

- **We are conducting an on-going one-year, open-label safety study of simufilam, with scientific and financial support from the National Institutes of Health (NIH).**

- **Patients are evaluated for safety, cognition and behavior.**
  - Cognition is evaluated on ADAS-Cog11.
  - AD-behavior is evaluated on NPI (Neuropsychiatric Inventory).

- **Total target enrollment is increased, up to 150 patients with mild-to-moderate AD.**
  ≈ 80 patients enrolled as of February 2021.

Interim Analyses planned at 6 and 12 months.

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First Interim Analysis, Open-label Study

- **First interim analysis is in first 50 patients who've completed 6 months of treatment.**
- **Simufilam improves cognition and behavior in Alzheimer's Disease.**
  - Cognition scores improved by 1.6 points on ADAS-Cog11, a 10% mean improvement from baseline to month 6.
  - Dementia-related behavior, such as anxiety, delusions and agitation, improved by 1.3 points on NPI, a 29% mean improvement from baseline to month 6.

Alzheimer's is a progressive disease. Over time, a patient's cognition will always worsen.

"Experience based on longitudinal studies of ambulatory patients with mild to moderate Alzheimer's disease suggest that scores on ADAS-cog decline by 6 - 12 points per year", according to FDA's Prescription Information sheet for ARICEPT® (donepezil), a drug approved for the treatment of dementia of the Alzheimer's type.

Second interim analysis (12 months) is expected mid-2021.

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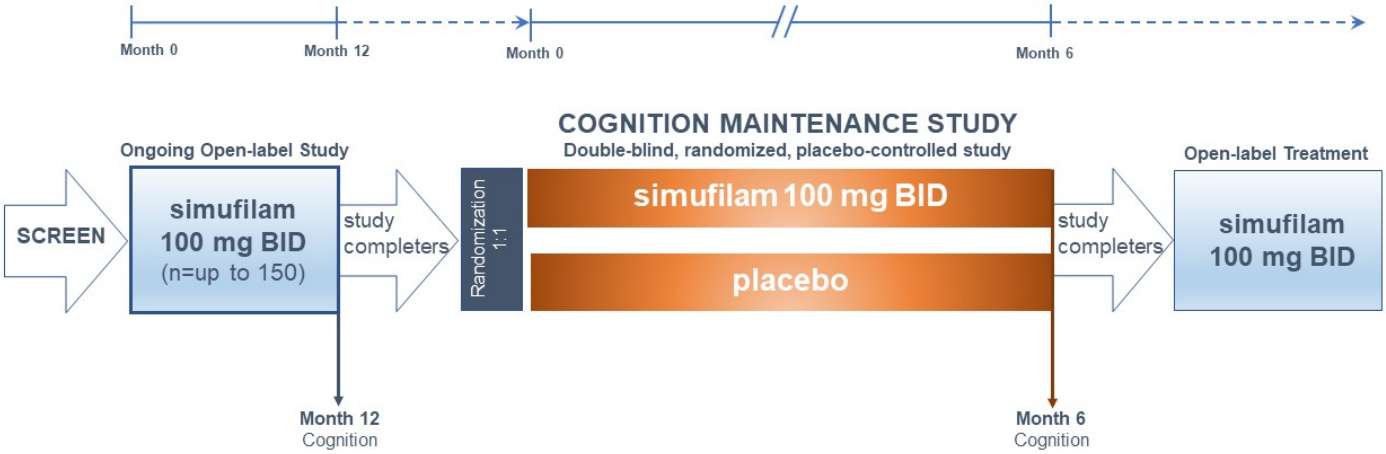
Cognition Maintenance Study (CMS)

CMS is designed to compare cognition in AD patients who've completed the open-label study and then continue vs. discontinue simufilam.



CMS initiation is expected mid-2021.

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Regulatory Status

- End-of-phase 2 (EOP2) meeting was held with FDA January 14, 2021.
- EOP2 meeting objectives were to gain general agreement around a Phase 3 clinical program and to identify outstanding data requirements, if any, to support the statutory requirements for a 505(b)(1) NDA submission and marketing approval of simufilam for the treatment of mild-to-moderate Alzheimer's disease.

Announcement regarding results of EOP2 meeting expected in February 2021, pending official FDA meeting minutes.

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Phase 3 Development Goals

- **The Phase 3 program consists of two Phase 3 studies to evaluate simufilam in patients with mild-to-moderate Alzheimer's disease dementia.**

- **First Phase 3 study is designed to show disease-modifying effects in AD.**
  - Goal is to show slower decline in AD patients treated with simufilam compared to placebo.
  - 18-month randomized, controlled study.

- **Second Phase 3 study is designed to show symptomatic relief of AD.**
  - Goal is to show symptomatic improvement in AD patients taking simufilam vs placebo.
  - 6-month randomized, controlled study.

We are on-track to initiate the Phase 3 program in the 2nd half 2021.

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SavaDx: Our Investigational Diagnostic for Alzheimer's

- The underlying science for simufilam supports the development of a diagnostic technology to detect Alzheimer's disease with a simple blood test, called SavaDx.
- Goal is to detect Alzheimer's disease before the appearance of memory loss.
- SavaDx development plan benefits from long-term scientific & financial support from NIH.

CASSAVA sciences

Financials

Eric Schoen - Chief Financial Officer

Unaudited Financials

Nasdaq ticker: SAVA		
Shares Outstanding		**35.8 million**
	Insider Ownership ≈	*2.1 million shares*
	Est. Public Float ≈	*33.7 million shares*
Unaudited Financials		
Cash Balance @ December 31, 2020:		**≈ $93.5 million**
Debt:		***none***
Est. Cash Use Full-year 2021:		**≈ $20 to $25 million**

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Intellectual Property

- **Simufilam is a novel molecule. Cassava Sciences owns composition of matter claims on simufilam and other novel, filamin-binding molecules.**
- **Cassava Sciences' patent protection for simufilam includes six issued patents and currently runs through 2033.**
  - Cassava Sciences owns exclusive, worldwide rights to simufilam and related technologies, without milestone or royalty obligations to any third party.
- **There is no patent protection for SavaDx, which is protected by trade secrets, know-how and other proprietary rights technology.**

Expected 2021 Milestones

Our goal is to initiate a Phase 3 study of simufilam in Alzheimer's disease 2nd half 2021.

- ✓ **End-of-phase 2 (EOP2) meeting with FDA to gain general agreement around a Phase 3 clinical development program in Alzheimer's disease dementia – *completed Jan 2021***
- ✓ **Results of interim analysis (6-month) of open-label study - *completed Feb 2021***

- **Results of EOP2 meeting with FDA.**
- **Results of interim analysis (12-month) of ongoing open-label study in Alzheimer's.**
- **Long-term supply agreement with contract manufacturer for simufilam.**
- **Manufacture large-scale Phase 3 clinical trial supplies (drug substance + oral tablets).**
- **Initiate Cognition Maintenance Study (CMS) mid-2021.**
- **Complete patient enrollment of on-going, open-label study of simufilam.**
- **Publication of Phase 2b results in peer-reviewed technical journal.**
- **Initiate validation study with SavaDx.**


Thank you!
CASSAVA
sciences

Appendix: Key Publications

Journal of Prevention of Alzheimer's Disease
2020; DOI: 10.14283
PTI-125 Reduces Biomarkers of Alzheimer's Disease In Patients:
http://link.springer.com/article/10.14283/jpad.2020.6

Neuroimmunology and Neuroinflammation
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Cassava Sciences Announces Significant Program Progress and Expected Key Milestones in 2021 for Its Clinical Program in Alzheimer's Disease

AUSTIN, TX – February 8, 2021 – Cassava Sciences, Inc. (Nasdaq: SAVA), a clinical-stage biotechnology company developing product candidates for Alzheimer's disease, today announced significant program progress and expected milestones for 2021.

"We started 2021 with tremendous momentum, led by results of a 6-month interim analysis from an open-label study of simufilam, our drug candidate for Alzheimer's disease," said Remi Barbier, President & CEO. "I believe the rest of the year may be equally exciting."

Cassava Sciences' strategic focus for 2021 is to advance simufilam in a Phase 3 clinical program in Alzheimer's disease, to expand drug manufacturing capabilities in support of the clinical program, and to continue to lead the Company to deliver the full potential of its product portfolio.

Cassava Sciences' 2021 Scientific and Clinical Outlook
Cassava Sciences' product portfolio includes a small molecule drug for the treatment of Alzheimer's disease, called simufilam, and an investigational blood-based diagnostic to detect and monitor the progression of Alzheimer's disease, called SavaDx.

Expected progress and key milestones in 2021 across Cassava Sciences' product portfolio are summarized below.

- Based on recent positive clinical results and inbound demand from clinical sites, patients, and their caregivers, Cassava Sciences plans to expand the size of the ongoing open-label study of simufilam. The target enrollment will be increased by up to 50 additional patients with mild-to-moderate Alzheimer's disease, for a total target enrollment of up to 150 patients.

- Cassava Sciences has enrolled approximately 80 patients in the open-label study to date. To accommodate increased enrollment, the Company plans to open new clinical sites across the U.S. and Canada.

- Cassava Sciences expects to announce results of a second interim analysis of the ongoing open-label study when approximately 50 patients complete 12 months of drug treatment. This second interim analysis is expected to include clinical data around long-term safety, cognition and Alzheimer's-related behavior.

- Cassava Sciences plans to initiate a 6-month, double-blind, randomized, placebo-controlled study in patients with Alzheimer's disease who complete at least one year of open-label treatment with simufilam. This is a *Cognition Maintenance Study* (CMS), in which patients who complete one year of open-label treatment will subsequently be randomized (1:1) to simufilam or placebo for six months. The CMS is designed to compare simufilam's effects on cognition and behavior in patients who continue with drug treatment versus those who discontinue drug treatment. For ethical and other reasons, patients who successfully complete the six-month CMS will have the option to receive open-label simufilam.

- Cassava Sciences' clinical and regulatory strategy for simufilam is progressing as planned. In January 2021, the Company concluded a successful End-of-phase 2 (EOP2) meeting with the U.S Food and Drug Administration (FDA). The purpose of the EOP2 was to gain general agreement around a Phase 3 program to treat Alzheimer's disease dementia.

- As a result of the EOP2 meeting, Cassava Sciences believes its clinical program for simufilam is green-lighted to commence a large, Phase 3 clinical program in patients with Alzheimer's disease, pending official FDA meeting minutes of the EOP2 meeting.

- Cassava Sciences plans to initiate a Phase 3 program of simufilam in Alzheimer's disease in the second half of 2021.

- Cassava Sciences' Phase 3 program for simufilam consists of two large, double-blind, randomized, placebo-controlled studies of simufilam in patients with mild-to-moderate Alzheimer's disease dementia. The Company expects to announce details of its Phase 3 program in Q1 2021, pending official FDA meeting minutes of the EOP2 meeting.

- Cassava Sciences' first Phase 3 study will evaluate disease-modifying effects in Alzheimer's disease patients over 18 months. The goal of this study is to show a slower rate of decline in cognition and daily function in patients treated with simufilam, compared to patients treated with placebo.

- Cassava Sciences' second Phase 3 study will evaluate symptomatic improvement in Alzheimer's disease patients over 6 months. The goal of this study is to show improvement in cognition and daily function in patients treated with simufilam, compared to patients treated with placebo.

- Cassava Sciences believes its manufacturing strategy is on-track to ensure sufficient drug supply for a Phase 3 program, including both drug substance (i.e., active ingredient) and drug product (i.e., oral tablets).

- Cassava Sciences expects to conclude a long-term, commercial drug supply agreement for simufilam with a contract manufacturing organization. The goal is to ensure the integrity of the drug supply chain on a worldwide basis, in compliance with FDA standards.

- Cassava Sciences expects to initiate a validation study with SavaDx, its investigational diagnostic for the detection of Alzheimer's disease.

- Cassava Sciences is in discussions with scientific and clinical advisors about potentially expanding therapeutic indications for simufilam outside of Alzheimer's disease, but still within neurodegenerative conditions.

Other Expected Milestones and Announcements for 2021

- Cassava Sciences expects to announce publication of Phase 2b results in a peer-reviewed technical journal.

- Net cash use for full-year 2021 is expected to be in the range of $20 to $25 million, depending on enrollment rates in its clinical programs and other factors. On December 31, 2020, unaudited cash and cash equivalents were approximately $93 million.

Slide Deck
A copy of Cassava Sciences' latest corporate presentation is available on its website https://www.CassavaSciences.com, under the Investors/Presentations page.

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. In the U.S. alone, approximately 5.8 million people are currently living with Alzheimer's disease, and approximately 487,000 people age 65 or older developed Alzheimer's in 2019.[1] The number of people living with Alzheimer's disease is expected to grow dramatically in the years ahead, resulting in a growing social and economic burden.[2]

[1,2] *Source: Alzheimer's Association.* Disease Facts and Figures. *https://www.alz.org/media/documents/alzheimers-facts-and-figures-2019-r.pdf*

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 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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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.

Cassava Sciences Safe Harbor

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; the treatment of Alzheimer's disease; the status of current and future clinical studies with simufilam, including the interpretation of an interim analysis of open-label study results; planned enrollment and other changes to the open-label program; our intention to initiate a Phase 3 clinical program with simufilam in 2nd half 2021; results of our EOP2 meeting with FDA and the timing of further announcements; our ability to manufacture drug supply for a Phase 3 program and to enter into a long-term commercial drug supply agreement; the timing of validation studies with SavaDx; our ability to expand therapeutic indications for simufilam outside of Alzheimer's disease; expected cash use in future periods; plans to publish results of a Phase 2b study in a peer-reviewed journal; verbal commentaries made by our employees; and potential benefits, if any, of the our product candidates. These statements may be identified by words such as "may," "anticipate," "believe," "could," "expect," "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, 2019 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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