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 7, 2024

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 No.)

6801 N Capital of Texas Highway, Building 1; Suite 300
Austin, Texas 78731
(Address of Principal Executive Offices) (Zip Code)

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

(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:

☐ Written communications 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 communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 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 8.01. Other Events.

On February 7, 2024, the Registrant issued a press release, a copy of which is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

Exhibit Number	Description
99.1	Press Release dated February 7, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

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

Cassava Sciences, Inc.

Date: February 7, 2024

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

No Decline in Cognition Scores in Patients with Mild Alzheimer's Disease Who Received Simufilam Continuously For 24 Months

- **ADAS-Cog Scores Were Stable in a Group of Patients with Mild Alzheimer's Who Received Drug Candidate Simufilam Continuously, Baseline to Month 24.**
- **Mild Alzheimer's Patients Who Received Simufilam Non-Continuously Declined a Group Average of 1 Point on ADAS-Cog, Baseline to Month 24.**
- **Oral Simufilam Safe, Well-Tolerated.**

AUSTIN, Texas, Feb. 07, 2024 (GLOBE NEWSWIRE) -- Cassava Sciences, Inc. (Nasdaq: SAVA), a biotechnology company, today reported top-line results of a two-year clinical safety study of simufilam, an investigational oral drug for the proposed treatment of Alzheimer's disease dementia. The study enrolled over 200 patients with mild to moderate Alzheimer's and consisted of two open-label treatment phases and a randomized, placebo-controlled withdrawal phase. Average changes in ADAS-Cog scores, baseline to month 24, indicate the following:

- Patients with mild Alzheimer's disease who received simufilam treatment continuously for two years (n=47) had no decline in ADAS-Cog scores (± 1.51 SE) as a group.
- Patients with mild Alzheimer's who received simufilam treatment non-continuously (n=40) declined 1 point on ADAS-Cog (± 1.65 SE) as a group. Non-continuous treatment consisted of one year on open-label drug, six months on placebo and six months back on open-label drug.
- In patients with mild Alzheimer's, the largest separation between the continuous and non-continuous treatment groups occurred at the end of the 6-month randomized, placebo-controlled withdrawal phase.
- Patients with moderate Alzheimer's who received simufilam treatment continuously for two years (n=32) declined 11.05 points on ADAS-Cog (± 1.91 SE) as a group.

"We're fighting Alzheimer's disease by testing simufilam, a new type of drug that has a completely different mechanism of action from monoclonal antibody drug treatments," said Remi Barbier, President & CEO. "Stable ADAS-Cog scores over 2 years is clearly a desirable clinical outcome in Alzheimer's. Our data in mild patients may emphasize the importance of treating patients early in the disease."

This was a 24-month safety study (NCT04388254). It included a pre-specified exploratory efficacy endpoint of mean change in ADAS-Cog11 scores. The study enrolled over 200 patients with mild-to-moderate Alzheimer's disease (MMSE 16-26) who were recruited from 16 U.S. clinical sites.

The safety study was conducted in three continuous phases:

- a 12-month, open-label treatment phase, followed by
- a 6-month randomized, placebo-controlled withdrawal phase[1], followed by
- 6 additional months of open-label treatment.

Study participants received simufilam oral tablets 100 mg twice-daily in the open-label treatment phases, and simufilam or matching placebo during the randomized withdrawal phase.

All study participants who completed 12 months of open-label simufilam treatment were eligible to participate in the 6-month randomized, placebo-controlled withdrawal phase. Likewise, all study participants who completed the randomized, placebo-controlled withdrawal phase were eligible for 6 additional months of open-label treatment.

Alzheimer's is a degenerative disease of the brain. Over time, a patient's cognition progressively worsens as the disease takes its toll. The science literature suggests that patients with mild Alzheimer's decline by a group average of approximately 3 points per year on the ADAS-Cog scale. With disease progression, patients move from mild to moderate to, eventually, severe Alzheimer's disease. Cognitive decline becomes more pronounced, and presumably more difficult to treat, in advanced stages of the disease.

Patients with mild Alzheimer's disease (n=87) entered the open-label study with MMSE 21-26, with ten exceptions.[2] Patients with moderate Alzheimer's entered the open-label study with MMSE 16-20, with one patient who entered with MMSE 15.

Mild patients who received simufilam for 24 continuous months (n=47) showed an average change of 0.07 points on ADAS-Cog11 (± 1.51 SE), baseline to month 24, as a group.

Mild Alzheimer's patients who received 12 months of open-label simufilam, followed by placebo in the 6-month randomized, placebo-controlled withdrawal phase, followed by an additional 6 months of open-label simufilam (n=40), declined by an average of 1.04 points on ADAS-Cog11 (± 1.65 SE), baseline to month 24, as a group.

Mean ADAS-Cog scores at baseline were approximately balanced in the group of mild Alzheimer's patients who received drug continuously versus non-continuously (15.2 and 14.6, respectively).

Safety Data

Oral simufilam 100 mg tablets twice daily appeared safe and well tolerated in this study. There were no drug-related serious adverse events. The most common treatment-emergent adverse events (TEAEs) were Covid-19 and urinary tract infection, with 33 occurrences of each.

Efficacy Data Presentation

The pre-specified cognition endpoints were analyzed on the Full Analysis Set (FAS) by Pentara Corporation, an independent consulting firm that specializes in complex statistical analysis of clinical trial results. Suzanne Hendrix, PhD, CEO of Pentara, has over 150 peer-reviewed publications of clinical trial results and statistical approaches for clinical trials, many focusing on statistical methodology for Alzheimer's disease.

We expect to report data from the two-year clinical safety study in a science forum.

Prior Results
Top-line results of the 6-month randomized withdrawal phase (i.e., the Cognition Maintenance Study) were announced July 5, 2023. Please see: https://www.cassavasciences.com/news-releases/news-release-details/oral-simufilam-slowed-cognitive-decline-randomized-withdrawal

Top-line results of the 12-month open-label phase were announced on January 24, 2023. Please see: https://www.cassavasciences.com/news-releases/news-release-details/cassava-sciences-announces-positive-top-line-clinical-results

Study Limitations
Data results from our two-year open-label safety study, or any phase thereof, do not constitute, and should not be interpreted as, regulatory evidence of safety or efficacy for simufilam in Alzheimer's disease dementia. Rigorous evidence for drug safety and efficacy is derived from one or more large, randomized, placebo-controlled studies. The open-label design and limited size of this study, and each sub-group of this study, may introduce clinical or statistical bias or may generate results that may not fully distinguish between drug effects and random variation. In addition, we do not know how long a washout period may be needed to remove lingering drug effects, if any, from prior treatment with open-label simufilam. Different methods of statistical analysis of clinical data from the same study may lead to objectively different numerical results. These and other statistical and clinical features of our open-label study add complexity or limitations to the scope of data interpretation.

'Top-line data' is a summary of the clinical data prior to the completion of a full and final audit or quality-control of the clinical database. We are communicating top-line data so that stakeholders may have timely access to a summary of the open-label study findings prior to us receiving the final dataset. Final data may change from top-line data.

On-going Phase 3 Studies of Simufilam in Alzheimer's Disease
Cassava Sciences is evaluating oral simufilam for Alzheimer's disease dementia in two global Phase 3 clinical studies, both of which are fully enrolled. A total of 1,929 patients with mild-to-moderate Alzheimer's disease dementia who met study eligibility criteria were randomized into the Phase 3 program from sites in the U.S., Puerto Rico, Canada, Australia and South Korea.

The first Phase 3 trial (NCT04994483) has a 52-week treatment period; 804 Alzheimer's patients were randomized into this study. Top-line results for the 52-week Phase 3 study are expected approximately year-end 2024.

The second Phase 3 trial (NCT05026177) has a 76-week treatment period; 1,125 Alzheimer's patients were randomized into this study. Top-line results for the 76-week Phase 3 study are expected approximately mid-year 2025.

About Simufilam
Simufilam is Cassava Sciences' proprietary, small molecule (oral) drug candidate 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 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 product candidates have not been approved by any regulatory authority, and their safety, efficacy or other desirable attributes have not been established in humans.

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

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Cautionary Note Regarding Forward-Looking Statements and Other Notices:
Simufilam is our investigational product candidate. It is not approved by any regulatory authority in any jurisdiction and its safety, efficacy or other desirable attributes, if any, have not been established in patients.

Drug development involves a high degree of risk, and only a small number of research and development programs result in regulatory approval and commercialization of a product. Clinical results from our prior studies may not be indicative of results of

future 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.

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 design, scope, conduct or intended purpose of our two-year, open-label study or Phase 3 program of simufilam in patients with Alzheimer's disease; the ability of simufilam to provide patients with drug effects; the apparent ability of simufilam to favor patients with mild Alzheimer's disease; the apparent safety or tolerance of simufilam in our open-label clinical trials; our current expectations regarding timing of clinical data for our Phase 3 studies; any expected clinical results of Phase 3 studies; the treatment of people with Alzheimer's disease dementia; the safety or efficacy of simufilam in people with Alzheimer's disease dementia; our expectation to present the clinical safety study at a science forum, comments made by our employees regarding simufilam, drug effect, and the treatment of Alzheimer's disease; and potential benefits, if any, of our product candidates. These statements may be identified by words such as "may," "anticipate," "believe," "could," "expect," "would", "forecast," "intend," "plan," "possible," "potential," and other words and terms of similar meaning.

Such statements are based largely on our current expectations and projections about future events. Such statements speak only as of the date of this news release and are subject to a number of risks, uncertainties and assumptions, including, but not limited to, those risks relating to the ability to conduct or complete clinical studies on expected timelines, to demonstrate the specificity, safety, efficacy or potential health benefits of our product candidates, and including those described in the section entitled "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2022, and subsequent reports filed with the SEC. The foregoing sets forth some, 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 news release 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 represent the views of Pentara Corporation, the National Institutes of Health or any other government agency.

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[1] The 6-month randomized withdrawal phase has previously been referred to as the 'Cognition Maintenance Study', or CMS.

[2] Ten patients entered with MMSE > 26 due to prior participation in a study of simufilam (n=2) or evidence of Alzheimer's disease pathology (n=8).