# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
# Washington, D.C. 20549

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# FORM 8-K

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## CURRENT REPORT

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

**Date of Report (Date of earliest event reported): August 3, 2023**

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**Cassava Sciences, Inc.**
(Exact name of registrant as specified in its charter)

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| **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)

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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 2.02. Results of Operations and Financial Condition.**

On August 3, 2023, the Registrant issued a press release, a copy of which is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

The information provided in this Current Report, including Exhibit 99.1 attached hereto, is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section. Such information shall not be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, regardless of any incorporation by reference language in such filing.

**Item 9.01. Financial Statements and Exhibits.**

| Exhibit Number | Description |
|---|---|
| 99.1 | Press Release dated August 3, 2023 |
| 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: August 3, 2023

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

**EXHIBIT 99.1**

# Cassava Sciences Reports Q2 2023 Financial Results and Operating Updates

- **Results of a randomized, controlled trial of oral simufilam in Alzheimer's disease announced July 2023.**
- **Over 1,587 patients now enrolled in Phase 3 studies of simufilam in Alzheimer's disease, an increase of over 340 patients in the last three months.**
- **Completion of patient enrollment for Phase 3 program still expected Q4 2023.**
- **$168.4 Million in Cash and Cash Equivalents at June 30, 2023.**

AUSTIN, Texas, Aug. 03, 2023 (GLOBE NEWSWIRE) -- Cassava Sciences, Inc. (Nasdaq: SAVA), a clinical-stage biotechnology company focused on Alzheimer's disease, today announced financial results for the second quarter ended June 30, 2023. Net loss was $26.4 million, or $0.63 per share, compared to a net loss of $19.3 million, or $0.48 per share, for the same period in 2022. Net cash used in operations was $33.2 million during the first half of 2023. Net cash use in second half 2023 is expected to be $40 to $50 million, driven primarily by expenses for our clinical program in Alzheimer's disease.

"In July 2023, we announced clinical results of a randomized controlled trial with oral simufilam in over 150 patients with Alzheimer's disease," said Remi Barbier, President & CEO. "In this study simufilam treatment for 6 months slowed cognitive decline by 38% versus placebo over six-month in patients with mild-to-moderate Alzheimer's disease. In addition, oral simufilam continues to be safe, well-tolerated. We believe these clinical results are noteworthy."

Cassava Sciences continues to evaluate its lead oral drug candidate, simufilam, in Alzheimer's disease. Over 1,587 patients with mild-to-moderate Alzheimer's disease are now enrolled in a Phase 3 program of simufilam, an increase of over 340 patients in the last three months. The target enrollment is approximately 1,750 patients. Cassava Sciences expects to complete patient enrollment for its Phase 3 program in Q4 2023.

**Financial Results for Second Quarter 2023**

- At June 30, 2023, cash and cash equivalents were $168.4 million, with no debt.
- Net loss was $26.4 million, or $0.63 per share. This compares to a net loss of $19.3 million, or $0.48 per share, for the same period in 2022. Net loss increased due primarily to increases in the rate of patient enrollment and associated costs to conduct the Phase 3 clinical program, as well as other studies with simufilam.
- Net cash used in operations was $33.2 million during the first six months of 2023.
- Net cash use in operations for second half 2023 is expected to be $40 to $50 million, driven primarily by expenses for our clinical program in Alzheimer's disease.
- Research and development (R&D) expenses were $25.0 million. This compared to $16.9 million for the same period in 2022. R&D expenses increased due primarily to increasing patient enrollment and costs to conduct the Phase 3 clinical program, as well as other studies with simufilam.
- General and administrative (G&A) expenses were $3.8 million. This compared to $3.0 million for the same period in 2022. G&A expenses increased due primarily to increases in stock-based compensation and activities and expenses related to legal services.

**On-going Phase 3 Studies with Simufilam**

Cassava Sciences is currently evaluating oral simufilam for Alzheimer's disease dementia in two Phase 3 clinical studies. These are large, randomized, double-blind, placebo-controlled trials. The Phase 3 program is recruiting a total of approximately 1,750 patients with mild-to-moderate Alzheimer's disease who also meet other study eligibility criteria. Both Phase 3 studies have received a Special Protocol Assessment (SPA) from the U.S. Food and Drug Administration. Our Phase 3 studies recruit Alzheimer's patients in clinical sites in the United States, Canada, Puerto Rico, South Korea and Australia.

**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 novel science is based on stabilizing—but not removing—a critical protein in the brain. Our product candidates have not been approved by any regulatory authority, and their safety, efficacy or other desirable attributes have not been established.

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

**For More Information Contact:**

Eric Schoen, Chief Financial Officer
(512) 501-2450 or ESchoen@CassavaSciences.com

***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, that may include but are not limited to: the design, scope, conduct or intended purpose of our randomized withdrawal study, whose top-line results we announced in July 2023, 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 safety or tolerance of simufilam in clinical studies; our current expectations regarding timing of and the target patient enrollment numbers 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; expected cash use in future periods; 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," "forecast," "intend," "plan," "possible," "potential," and other words and terms of similar meaning.*

*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 have not been established in patients.*

*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. Clinical results and analyses of our open-label study should not be relied upon as predictive of Phase 3 studies or any other study. 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, any unanticipated impacts of inflation 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, 2022, and future reports to be filed with the SEC. The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from expectations in any forward-looking statement. In light of these risks, uncertainties and assumptions, the forward-looking statements and events discussed in this news release are inherently uncertain and may not occur, and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Accordingly, you should not rely upon forward-looking statements as predictions of future events. Except as required by law, we disclaim any intention or responsibility for updating or revising any forward-looking statements contained in this news release. For further information regarding these and other risks related to our business, investors should consult our filings with the SEC, which are available on the SEC's website at www.sec.gov.*

– Financial Tables Follow –

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

| | Three months ended June 30, | | Six months ended June 30, | |
|---|---|---|---|---|
| | 2023 | 2022 | 2023 | 2022 |
| Operating expenses | | | | |
| Research and development, net of grant reimbursement | $ 24,969 | $ 16,948 | $ 47,089 | $ 31,854 |
| General and administrative | 3,808 | 2,969 | 8,200 | 5,884 |
| Total operating expenses | 28,777 | 19,917 | 55,289 | 37,738 |
| Operating loss | (28,777) | (19,917) | (55,289) | (37,738) |
| Interest income | 2,198 | 314 | 4,249 | 345 |
| Other income, net | 203 | 275 | 393 | 538 |
| Net loss | $ (26,376) | $ (19,328) | $ (50,647) | $ (36,855) |
| Net loss per share, basic and diluted | $ (0.63) | $ (0.48) | $ (1.21) | $ (0.92) |
| Weighted-average shares used in computing net loss per share, basic and diluted | 41,793 | 40,015 | 41,766 | 39,989 |

CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited, in thousands)

| | June 30, 2023 | December 31, 2022 |
|---|---|---|
| **Assets** | | |

| | | |
|---|---|---|
| Current assets | | |
| Cash and cash equivalents | $ 168,438 | $ 201,015 |
| Prepaid expenses and other current assets | 6,095 | 10,211 |
| Total current assets | 174,533 | 211,226 |
| Property and equipment, net | 22,328 | 22,864 |
| Operating lease right-of-use assets | — | 122 |
| Intangible assets, net | 387 | 622 |
| Total assets | $ 197,248 | $ 234,834 |
| **Liabilities and stockholders' equity** | | |
| Current liabilities | | |
| Accounts payable | $ 10,338 | $ 4,017 |
| Accrued development expense | 7,044 | 2,280 |
| Accrued compensation and benefits | 220 | 170 |
| Operating lease liabilities, current | — | 104 |
| Other accrued liabilities | 293 | 492 |
| Total current liabilities | 17,895 | 7,063 |
| Operating lease liabilities, non-current | — | 35 |
| Other non- current liabilities | — | 197 |
| Total liabilities | 17,895 | 7,295 |
| Stockholders' equity | | |
| Common Stock and additional paid-in-capital | 513,552 | 511,091 |
| Accumulated deficit | (334,199) | (283,552) |
| Total stockholders' equity | 179,353 | 227,539 |
| Total liabilities and stockholders' equity | $ 197,248 | $ 234,834 |