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): May 1, 2023

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 2.02. Results of Operations and Financial Condition.

On May 1, 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 May 1, 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: May 1, 2023

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

Cassava Sciences Reports Q1 2023 Financial Results and Operating Updates

- **Over 1,244 Alzheimer's patients now enrolled in Phase 3 studies of simufilam.**
- **Completion of patient enrollment for Phase 3 program still expected Q4 2023.**
- **$187.5 Million Cash and Cash Equivalents at March 31, 2023.**

AUSTIN, Texas, May 01, 2023 (GLOBE NEWSWIRE) -- Cassava Sciences, Inc. (Nasdaq: SAVA), a clinical-stage biotechnology company focused on Alzheimer's disease, today announced financial results for the first quarter ended March 31, 2023. Net loss was $24.3 million, or $0.58 per share, compared to a net loss of $17.5 million, or $0.44 per share, for the same period in 2022. Net cash used in operations was $13.3 million during the first quarter of 2023. New guidance for net cash use in first half 2023 is expected to be $30 to $40 million, which is revised downward from our previous guidance of $45 to $50 million, due primarily to the timing of certain clinical payment obligations.

Cassava Sciences is evaluating its lead drug candidate, simufilam, in people with Alzheimer's disease. Over 1,244 patients with mild-to-moderate Alzheimer's disease are now enrolled in our Phase 3 program of simufilam, up from over 1,000 enrolled patients as of February 28, 2023. The target enrollment is approximately 1,750 patients.

"In Q1 2023, we announced results of a one-year, open-label Phase 2 safety study of simufilam in over 200 patients with Alzheimer's disease," said Remi Barbier, President & CEO. "The dataset for this study shows long-term safety for simufilam. Notably, the data also show differences in changes in ADAS-Cog scores in mild and moderate subgroups. We believe this is an encouraging result, as it clearly shows an improvement in ADAS-Cog over 1 year in mild patients taking simufilam that is well outside the expected range of historical placebo decline from numerous other studies."

Mr. Barbier continued, "Looking forward, our top priority is to complete patient enrollment for our Phase 3 program. We also look forward to announcing science updates, including completion of patient dosing for our Cognition Maintenance Study. In this randomized, placebo-controlled study, over 100 patients with mild-to-moderate Alzheimer's who completed at least one year of open-label treatment with simufilam are subsequently randomized to placebo or simufilam for six months. This is known as a randomized, withdrawal study design. While complex, I think this study design may yield interesting clinical data in Q3. Separately, in Q2 we expect to announce new evidential data for the biological activity of simufilam on filamin A protein."

Financial Results for First Quarter 2023

- At March 31, 2023, cash and cash equivalents were $187.5 million, with no debt.
- Net loss was $24.3 million, or $0.58 per share. This compares to a net loss of $17.5 million, or $0.44 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 $13.3 million during the first quarter of 2023.
- Net cash use in operations for the first half 2023 is now expected to be $30 to $40 million, compared to previous guidance of $45 to $50 million due primarily to the timing of certain payment obligations for studies of simufilam.
- Research and development (R&D) expenses were $22.1 million. This compared to $14.9 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 $4.4 million. This compared to $2.9 million for the same period in 2022. G&A expenses increased due primarily to increased activities and expenses related to legal services.

About Cassava Sciences' Phase 3 Program
We are conducting a Phase 3 clinical evaluation of simufilam in people with Alzheimer's disease dementia. This program consists of two on-going, randomized, double-blind, placebo-controlled studies. Both Phase 3 studies have received a Special Protocol Assessment (SPA) from the U.S. Food and Drug Administration. 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. Our Phase 3 studies are actively recruiting Alzheimer's patients in over 100 clinical sites in the United States, Canada, Puerto Rico, South Korea and Australia. For detailed information about Cassava Sciences' Phase 3 program, please visit the website for ClinicalTrials.gov: https://ClinicalTrials.gov/ct2/show/NCT04994483?term=simufilam&draw=2&rank=3

About Simufilam
Simufilam is a novel drug candidate designed to treat and slow the progression of Alzheimer's disease. Simufilam binds tightly to an altered conformation of the filamin A protein (FLNA) that is present in the brain of the Alzheimer's patient and is critical to the toxicity of Aβ42. Simufilam is wholly owned by Cassava Sciences, without royalty or payment obligation 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 our website: https://www.CassavaSciences.com

For More Information Contact:

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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: our strategy and plans; the size and scope of our pivotal Phase 3 trial and its likelihood of success; the interpretation of clinical data generated in our open-label study; the timing of clinical results of the Cognition Maintenance Study; the treatment of Alzheimer's disease dementia; the status of current and future clinical studies with simufilam, including anticipated patient enrollment goals in 2023 for our Phase 3 studies; the safety or efficacy of simufilam in patients; the release of evidential data by a third-party related to the biological activity of simufilam; the use of mass spectrometry as an alternative method of detection for SavaDx or the timing of new data release for SavaDx; expected cash use in future periods; 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.

Simufilam and SavaDx are investigational product candidates. They are not approved by any regulatory authority and their safety, efficacy or other desirable attributes have not been established in patients. All clinical data from our open-label study are inherently exploratory in nature and, as with all open-label data, should be interpreted with caution. Data results from our open-label study does not constitute, and should not be interpreted as, clinical evidence of therapeutic safety or benefit for simufilam.

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 March 31,	
	2023	2022
Operating expenses		
Research and development, net of grant reimbursement	$ 22,120	$ 14,906
General and administrative	4,392	2,915
Total operating expenses	26,512	17,821
Operating loss	(26,512)	(17,821)
Interest income	2,051	31
Other income, net	190	263
Net loss	$ (24,271)	$ (17,527)
Net loss per share, basic and diluted	$ (0.58)	$ (0.44)
Weighted-average shares used in computing net loss per share, basic and	41,739	39,962

diluted

CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited, in thousands)

	March 31, 2023	December 31, 2022
Assets		
Current assets		
Cash and cash equivalents	$ 187,467	$ 201,015
Prepaid expenses and other current assets	7,532	10,211
Total current assets	194,999	211,226
Property and equipment, net	22,609	22,864
Operating lease right-of-use assets	—	122
Intangible assets, net	503	622
Total assets	$ 218,111	$ 234,834
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable and accrued expenses	$ 8,242	$ 4,017
Accrued development expense	5,276	2,280
Accrued compensation and benefits	212	170
Operating lease liabilities, current	—	104
Other accrued liabilities	179	492
Total current liabilities	13,909	7,063
Operating lease liabilities, non-current	—	35
Other non- current liabilities	197	197
Total liabilities	14,106	7,295
Stockholders' equity		
Common Stock and additional paid-in-capital	511,828	511,091
Accumulated deficit	(307,823)	(283,552)
Total stockholders' equity	204,005	227,539
Total liabilities and stockholders' equity	$ 218,111	$ 234,834