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 28, 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 February 28, 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 February 28, 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: February 28, 2023

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

Cassava Sciences Reports Full-year 2022 Financial Results and Operating Updates

- **In Q2 2023, We Expect to Complete Patient Dosing for our Cognition Maintenance Study in Alzheimer's disease.**
- **In Q3 2023, We Expect to Announce Results of our Cognition Maintenance Study.**
- **In Q4 2023, We Expect to Complete Patient Enrollment for our Phase 3 Studies of Simufilam in Alzheimer's disease.**
- **Mid-year 2023, We Expect an Independent Third Party to Present Evidential Data for The Biological Activity of Simufilam Outside of Neurodegeneration.**
- **Cash And Cash Equivalents Were $201 Million at December 31, 2022.**

AUSTIN, Texas, Feb. 28, 2023 (GLOBE NEWSWIRE) -- Cassava Sciences, Inc. (Nasdaq: SAVA), a clinical-stage biotechnology company focused on Alzheimer's disease, today announced financial results for the year ended December 31, 2022, and provided operating updates. Simufilam is Cassava Sciences' oral drug candidate for the proposed treatment of Alzheimer's disease dementia.

"Setting aside headwinds, 2022 was highlighted by positive developments with patient enrollment in our Phase 3 clinical studies of simufilam in Alzheimer's disease", said Remi Barbier, President & CEO. "Over 1,000 patients with Alzheimer's are now enrolled in these two studies. By year-end 2023, we expect to reach our enrollment target of approximately 1,750 patients for the Phase 3 studies. Recently, we announced top-line results for an open-label study. In this study, over 200 mild-to-moderate Alzheimer's patients were treated with simufilam for a year. Simufilam was well-tolerated, 47% of patients improved on ADAS-Cog scores over 12 months and an additional 23% of patients declined less than 5 points on ADAS-Cog. I believe these are noteworthy trial results, even as I am keenly aware that the gold standard in Alzheimer's research requires results from randomized, controlled studies."

Alzheimer's disease is a major public health issue. It imposes an immense burden on patients, their families and caregivers. Anti-amyloid antibody drugs that have received FDA approval are a step in the right direction. But by themselves, anti-amyloid drugs may not be enough for patients. Anti-amyloid drugs can slow cognitive decline modestly, but they can also cause brain bleeds in elderly patients, they require monthly trips to the local infusion center and periodical monitoring with MRI, they're expensive and they lack Medicare coverage because they bypassed the full FDA approval process. Patients have waited many years for anti-amyloid drugs to be FDA-approved. Now that the wait is over, Cassava Sciences sees an even greater need to develop the next generation of innovative treatments, even if some of these potential treatments challenge scientific orthodoxy.

"It's the spirit of innovation and our intense desire to help patients and their families that fuels our drive to develop simufilam as an oral drug candidate for people with Alzheimer's disease," said Remi Barbier.

Cassava Sciences' Scientific Goals for 2023

- In Q2 2023, we expect to complete patient dosing for our on-going Cognition Maintenance Study, in which over 100 patients with mild-to-moderate Alzheimer's disease are randomized (1:1) to simufilam or placebo for six months.
- In Q3 2023, we expect to announce top-line results of the Cognition Maintenance Study.
- In Q4 2023, we expect to complete patient enrollment for both of our Phase 3 studies.
- Mid-year 2023, we expect an independent, third party to present evidential data for the biological activity of simufilam outside the field of neurodegeneration.
- Mid-year 2023, we expect an independent, third party to generate new data for SavaDx using mass spectrometry.

Financial Highlights

- At December 31, 2022, cash and cash equivalents were $201 million, compared to $233.4 million at December 31, 2021, with no debt. Year-end cash balance included net proceeds of $47.3 million from the sale of 1.7 million shares of common stock completed in November 2022.
- Net cash used in operations full-year 2022 was $77.5 million, net of reimbursements received from National Institutes of Health (NIH) grant awards.
- Net cash use for operations for the first half of 2023 is expected to be approximately $45 to $50 million, driven primarily by expenses for our clinical program in Alzheimer's disease.
- Research and development (R&D) expenses for the year ended December 31, 2022 were $68.0 million compared to $24.8 million for the same period in 2021. This increase was due primarily to costs to conduct the ongoing Phase 3 clinical program in simufilam, costs of an ongoing cognition maintenance study and open-label study in simufilam, and costs related to manufacture of clinical trial supplies, as well as increased pre-clinical study and personnel expenses compared to

the prior year. These expenses are net of grant funding received from NIH, which is recorded as a reduction in R&D expenses.

- Research grant funding reimbursements of $0.9 million were received from NIH and recorded as a reduction in R&D expenses. This compared to $3.9 million of NIH grant receipts received for 2021.
- General and administrative (G&A) expenses for the year ended December 31, 2022 were $12.0 million compared to $8.1 million for 2021. This increase was primarily due to higher legal fees, personnel costs, insurance costs and depreciation and amortization as compared to 2021.

Ongoing Phase 3 Studies with Simufilam
Cassava Sciences is currently evaluating simufilam tablets for Alzheimer's disease dementia in two Phase 3 clinical studies. These are 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. The 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.

About Simufilam
Simufilam (sim-uh-FILL-am) is the chemical name for 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:
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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, regulatory 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, 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, 2021, 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 –

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited, in thousands, except per share amounts)

	Three months ended December 31,		Year Ended December 31,	
	2022	2021	2022	2021
Operating expenses				
Research and development, net of grant reimbursement	$ 17,652	$ 10,342	$ 68,032	$ 24,813
General and administrative	3,285	4,102	11,988	8,055
Total operating expenses	20,937	14,444	80,020	32,868
Operating loss	(20,937)	(14,444)	(80,020)	(32,868)
Interest income	1,554	14	2,777	49
Other income, net	249	258	997	434
Net loss	$ (19,134)	$ (14,172)	$ (76,246)	$ (32,385)
Net loss per share, basic and diluted	$ (0.47)	$ (0.35)	$ (1.90)	$ (0.82)
Weighted-average shares used in computing net loss per share, basic and diluted	40,775	39,960	40,202	39,405

CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited, in thousands)

	Year Ended December 31,	
	2022	2021
Assets		
Current assets		
Cash and cash equivalents	$ 201,015	$ 233,437
Prepaid expenses and other current assets	10,211	11,045
Total current assets	211,226	244,482
Property and equipment, net	22,864	20,616
Operating lease right-of-use assets	122	210
Intangible assets, net	622	1,075
Other assets	—	399
Total assets	$ 234,834	$ 266,782
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 4,017	$ 7,126
Accrued development expense	2,280	2,803
Accrued compensation and benefits	170	1,877
Operating lease liabilities, current	104	97
Other accrued liabilities	492	631
Total current liabilities	7,063	12,534
Operating lease liabilities, non-current	35	139
Other non- current liabilities	197	194
Total liabilities	7,295	12,867
Stockholders' equity		
Common Stock and additional paid-in-capital	511,091	461,221
Accumulated deficit	(283,552)	(207,306)
Total stockholders' equity	227,539	253,915
Total liabilities and stockholders' equity	$ 234,834	$ 266,782