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, 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 2.02. Results of Operations and Financial Condition.

On February 28, 2024, 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, 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 28, 2024

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

Cassava Sciences Reports Full-year 2023 Financial Results and Corporate Updates

- **$121.1 Million In Cash and Cash Equivalents at December 31, 2023, With an Additional $21.8 Million Raised In 2024 From Exercise of Warrants.**
- **A Total of Over 555 Study Participants Have Completed Our Phase 3 Studies.**
- **Topline Data Readout for Our 52-Week Phase 3 Trial Expected Year-End 2024.**
- **Internal Investigation by Outside Counsel Has Found No Evidence to Substantiate Allegations of Research Misconduct by the Company.**

AUSTIN, Texas, Feb. 28, 2024 (GLOBE NEWSWIRE) -- Cassava Sciences, Inc. (Nasdaq: SAVA), a biotechnology company focused on Alzheimer's disease, today reported financial and operating results for the full year ended December 31, 2023 and presented corporate updates.

"I see Alzheimer's disease as one of the last great frontiers in medicine," said Remi Barbier, President & CEO. "It's clear to me these patients need new and more simplified treatment options. In 2024 and beyond, we'll continue to try to make a meaningful difference in the lives of people who suffer from Alzheimer's disease. I believe our Phase 3 program of simufilam in Alzheimer's will reach important milestones in 2024, particularly in patients with mild disease."

Simufilam is Cassava Sciences' investigational drug candidate for the proposed treatment of Alzheimer's disease dementia.

Net loss for full year 2023 was $97.2 million, or $2.32 per share, compared to a net loss of $76.2 million, or $1.90 per share, in 2022. Net cash used in operations full-year 2023 was $82.0 million, consistent with previous guidance. Cash use for operations for the first half of 2024 is expected to be $35 to $45 million, driven primarily by expenses for our clinical program in Alzheimer's disease. In 2024, the Company raised gross proceeds of approximately $21.8 million from the exercise of common stock warrants though February 26, 2024.

"We expect our research and development expenses to decrease modestly in 2024 as a result of decreased spending for our Phase 3 program, as patient screening and enrollment are now complete for the Phase 3 clinical studies," said Eric Schoen, Chief Financial Officer. "We also expect the decrease in Phase 3 program costs to be partially offset by increased enrollment in the open-label study as well as higher expenses in other parts of our operations."

Financial Results for Full-year 2023

- At December 31, 2023, cash and cash equivalents were $121.1 million, compared to $201 million at December 31, 2022, with no debt.
- In 2024 through February 26, 2024, we received gross proceeds of $21.8 million from the exercise of warrants, resulting in the issuance of 989,000 shares of common stock. (This amount is not included in the above cash and cash equivalents at December 31, 2023.)
- Net loss was $97.2 million, or $2.32 per share. This compares to a net loss of $76.2 million, or $1.90 per share, in 2022. Net loss increased due primarily to increases in patient enrollment and associated costs to conduct the Phase 3 clinical program, as well as other studies with simufilam.
- Net cash used in operations full-year 2023 was $82 million.
- Net cash use in operations for first half 2024 is expected to be $35 to $45 million, driven primarily by expenses for our program in Alzheimer's disease.
- Research and development (R&D) expenses were $89.4 million. This compared to $68 million for 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 $16.5 million. This compared to $12.0 million for 2022. G&A expenses increased due to increases in stock-based compensation as well as activities and expenses related to legal services.

Recent corporate highlights include the following:

- In January 2024, we completed a dividend distribution of common stock warrants to shareholders. The warrants allow the holder to purchase additional shares of our common stock. The warrants trade on Nasdaq (SAVAW), separate from our common stock (SAVA). Unless earlier redeemed, the warrants will expire and cease to be exercisable on November 15, 2024. The warrants are redeemable at our sole option at any time with a redemption date on or after April 15, 2024. Cassava Sciences will provide at least 20 calendar days' notice by press release of the date selected, if any, for a redemption.
- In February 2024, we reported that 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 for two years (n=40) declined 1 point on ADAS-Cog (± 1.65 SE) as a group. Continuous treatment consisted of one year on open-label drug, six months randomized to drug and six months back on open-label drug. Non-continuous treatment consisted of the same, except randomized to placebo in that six-month period.
- In December 2023, we reported the appointment of three new members to the Board of Directors. Clause Nicaise, MD, Pierre Gravier, MS and Robert Anderson, Jr. are all highly respected, astute leaders in their fields. Their collective

expertise in drug development, M&A, cybersecurity and dealing with large, complex governmental agencies will add a balance of experience and perspectives to the Board.

- In October 2023, we reported a potentially significant safety finding based on interim magnetic resonance imaging (MRI) brain data from Alzheimer's patients who are enrolled in our 76-week Phase 3 trial (REFOCUS-ALZ). These MRI data suggest simufilam is not associated with treatment-emergent amyloid-related imaging abnormalities, or ARIA. ARIA is a medical term used to describe a spectrum of brain MRI imaging abnormalities, such as edema and brain bleeds, and is a known risk factor for patients taking monoclonal antibody infusion drugs directed against beta amyloid.
- In September 2023, we reported a positive interim safety review of simufilam in on-going Phase 3 clinical trials in patients with Alzheimer's disease. A routine, scheduled meeting of a Data and Safety Monitoring Board (DSMB) recommended that both of Cassava Sciences' Phase 3 studies of simufilam continue as planned, without modification.
- In September 2023, we also reported new research that confirms the biological activity of simufilam. Researchers at the Cochin Institute (Paris, France) used a highly precise cell-based assay to show that simufilam interrupts amyloid binding to the α7 nicotinic acetylcholine receptor (α7nAChR). Their data show that simufilam potently disrupts a known pathological action of amyloid β using a robust and highly sensitive assay based on a technique called TR-FRET. Four academic institutions have now generated data in support of the biological activity of simufilam.
- In June 2023, we reported new research that examined the effects of simufilam on the mechanistic Target of Rapamycin (mTOR). Scientific literature shows overactive mTOR plays a key role in aging, Alzheimer's disease and other conditions. When functioning normally, mTOR monitors cellular needs and is activated by insulin. The new published research shows mTOR is overactive in lymphocytes isolated from blood collected from Alzheimer's patients versus healthy controls. After oral administration of simufilam 100 mg twice daily to Alzheimer's patients for 28 days, lymphocytes showed normalized mTOR activity and restored sensitivity to insulin. These data suggest a meaningful impact of simufilam on mTOR signaling. The suppression of overactive mTOR signaling and its improved responsiveness to insulin represents a mechanistic benefit of simufilam beyond the disruption of pathogenic signaling pathways of soluble amyloid. These improvements in mTOR signaling may also result from reversing an altered conformation of FLNA, allowing FLNA to dissociate from the insulin receptor when insulin binds and initiates signaling. Because mTOR contributes to age-related cellular changes, simufilam's suppression of mTOR overactivation, concurrent with improved insulin sensitivity, may slow certain aging processes and attenuate this pathological feature of Alzheimer's disease, potentially benefiting brain function and memory.
- In August 2021, certain individuals, later revealed to be short sellers of the Company's securities, publicly alleged that we had engaged in research misconduct. Today we report that an internal investigation conducted by outside counsel engaged by our Board of Directors has found no evidence to substantiate allegations that the Company or its employees engaged in or were aware of research misconduct.

Status of Phase 3 Clinical Program

Background - Our Phase 3 program consists of two global, double-blind, randomized, placebo-controlled studies of simufilam in patients with mild-to-moderate Alzheimer's disease dementia.

Phase 3 Trials – In Fall 2021, we announced the initiation of two pivotal Phase 3 studies of simufilam in Alzheimer's disease. Our first Phase 3 study, called RETHINK-ALZ, is designed to evaluate the safety and efficacy of simufilam 100 mg tablets twice-daily versus matching placebo over 52 weeks (NCT04994483). Our second Phase 3 study, called REFOCUS-ALZ, is designed to evaluate the safety and efficacy of oral simufilam 100 mg and 50 mg tablets twice-daily versus matching placebo over 76 weeks (NCT05026177). Clinical sites are in the United States, Canada, Puerto Rico, Australia, and South Korea. Premier Research International is the clinical research organization (CRO) supporting the conduct of our Phase 3 clinical program.

Entry Criteria – Criteria that potential patients must meet to be included in a Phase 3 study include an MMSE score of 16 to 27; a Clinical Dementia Rating (CDR)-Global Scale score of 0.5, 1 or 2; elevated plasma p-tau181 or prior evidence of Alzheimer's neuropathology by PET or cerebrospinal fluid; and other inclusion/exclusion eligibility criteria.

Patient Enrollment – In November 2023, we announced the completion of patient enrollment in both Phase 3 studies. Approximately 1,900 patients are randomized in these studies, with approximately 800 patients randomized in the 52-week study (RETHINK-ALZ) and approximately 1,100 patients randomized in the 76-week study (REFOCUS-ALZ).

Preliminary Baseline Characteristics (all numbers are approximate) – Mean patient age for both studies is 74. Seventy percent (70%) of patients entered the studies with mild Alzheimer's disease (MMSE 20-27), with remaining patients entering the study with moderate disease (MMSE 16-19). Both studies have a mean MMSE score of 22. Both studies have a mean ADAS-Cog score of 25. Both studies have a mean ADCS-ADL score of 65.

Patient Completion – Over 340 patients have completed the 52-week RETHINK-ALZ study. Over 215 patients have completed the 76-week REFOCUS-ALZ study, for a total of over 555 completers.

Efficacy Outcomes – Efficacy endpoints are ADAS-Cog12, a cognitive scale, and ADCS-ADL, a functional scale and iADRS, which is a combination of scores from ADAS-Cog and ADCS-ADL. Because the distribution of study participants is numerically skewed towards mild patients, we expect to rely predominantly on mild patients to evaluate drug safety and efficacy.

Phase 3 Efficacy Results – All efficacy data from our Phase 3 program remain blinded. No interim analyses on efficacy outcomes are planned. We anticipate top-line data readout for our 52-week study (RETHINK-ALZ) approximately year-end 2024. We anticipate top-line data readout for our 76-week study (REFOCUS-ALZ) approximately mid-year 2025.

Statistical Analysis Plan – We have initiated a discussion with the U.S. Food and Drug Administration (FDA) to finalize a statistical analysis plan (SAP), which is a formal document defining the detailed analysis that our independent biostatisticians will undertake as to efficacy data collected in our Phase 3 trials. The SAP includes in-depth technical details and descriptions on the intended clinical trial analysis, the statistical methods and models that will be used, the population being analyzed, the data variables that will be analyzed, how missing data will be accounted for, descriptions of covariates to be included in the statistical model, and other statistical factors, all of which will be prospectively defined, documented and finalized prior to unblinding of any efficacy outcomes.

Open-label Extension Study – In October 2022, we announced the initiation of an open-label extension study for our Phase 3 program. This study is designed to provide no-cost access to oral simufilam for up to one year to Alzheimer's patients who have successfully completed a Phase 3 study of simufilam and who meet other entry criteria. Patient enrollment for this study began in November 2022. To date, over 500 patients entered the open-label extension study.

Update on SavaDx
SavaDx is an early-stage program focused on detecting the presence of Alzheimer's disease from a small sample of blood. Development activity related to SavaDx accounts for less than 1% of our research budget. Working with third parties, we continue to evaluate the use of mass spectrometry to detect FLNA or other proteins of interest. The data and information generated from these evaluations continues to be under review for potential intellectual property rights.

Findings of Internal Investigation
Beginning in August 2021, certain individuals, later revealed to be short sellers of the Company's securities, publicly alleged that the Company and certain of its employees and third-party collaborators had engaged in research misconduct in connection with the development of simufilam. These allegations related in part to research that was conducted at the City University of New York (CUNY) pursuant to research contracts with the Company. The Company takes allegations of research misconduct seriously. Accordingly, the Company's Board of Directors engaged the law firm Orrick Herrington & Sutcliffe LLP to investigate these allegations. The investigation had access to Company personnel, communications, documents, data, and information, and counsel was assisted by technical experts with relevant experience and knowledge. The investigation has found no evidence to substantiate allegations that the Company or its employees engaged in or were aware of research misconduct.

About Simufilam
Simufilam is Cassava Sciences' proprietary oral drug candidate. This investigational drug binds to altered filamin A protein in the brain and restores its normal shape and function. By targeting altered filamin A, simufilam may help patients with Alzheimer's achieve better health outcomes. Cassava Sciences owns exclusive, worldwide rights to its investigational product candidates 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.

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

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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 statements regarding: the design, scope, conduct, continuation, completion, intended purpose, or future results of our on-going Phase 3 program of simufilam in patients with Alzheimer's disease; the timing of anticipated milestones; the suitability of clinical data from our Phase 3 program to support the filing of an NDA; interim MRI safety data for the Phase 3 program, including ARIA; the finalization of our SAP; 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 "anticipate," "believe," "could," "expect," "forecast," "intend," "may," "plan," "possible," "potential," "will," 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, the ability to demonstrate the specificity, safety, efficacy or potential health benefits of our product candidates, 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, comments made by our employees regarding simufilam, drug effect, and the treatment of Alzheimer's disease; potential benefits, if any, 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 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.

All our pharmaceutical assets under development are investigational product candidates. These have not been approved for use in any medical indication by any regulatory authority in any jurisdiction and their safety, efficacy or other desirable attributes, if any, have not been established in any patient population. Consequently, none of our product candidates are approved or available for sale anywhere in the world.

Our clinical results from earlier-stage clinical trials may not be indicative of future 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.

We are in the business of new drug discovery, development and commercialization. Our research and development activities are long, complex, costly and involve a high degree of risk. Holders of our common stock should carefully read our Annual Report on Form 10-K in its entirety, including the risk factors therein. Because risk is fundamental to the process of drug discovery, development and commercialization, you are cautioned to not invest in our publicly traded securities unless you are prepared to sustain a total loss of the money you have invested.

– Financial Tables Follow –

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

	Three months ended December 31,		Year Ended December 31,	
	2023	2022	2023	2022
Operating expenses				
Research and development, net of grant reimbursement	$ 18,731	$ 17,652	$ 89,423	$ 68,032
General and administrative	4,058	3,285	16,534	11,988
Total operating expenses	22,789	20,937	105,957	80,020
Operating loss	(22,789)	(20,937)	(105,957)	(80,020)
Interest income	1,579	1,554	7,833	2,777
Other income, net	291	249	907	997
Net loss	$ (20,919)	$ (19,134)	$ (97,217)	$ (76,246)
Net loss per share, basic and diluted	$ (0.50)	$ (0.47)	$ (2.32)	$ (1.90)
Weighted-average shares used in computing net loss per share, basic and diluted	42,188	40,775	41,932	40,202

CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited, in thousands)

	Year Ended December 31,	
	2023	2022
Assets		
Current assets		
Cash and cash equivalents	$ 121,136	$ 201,015
Prepaid expenses and other current assets	8,497	10,211
Total current assets	129,633	211,226
Property and equipment, net	21,854	22,864
Operating lease right-of-use assets	—	122
Intangible assets, net	176	622
Total assets	$ 151,663	$ 234,834
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable and other accrued expenses	$ 10,573	$ 4,017
Accrued development expense	3,037	2,280
Accrued compensation and benefits	200	170
Operating lease liabilities, current	—	104

Other accrued liabilities	385	492
Total current liabilities	14,195	7,063
Operating lease liabilities, non-current	—	35
Other non- current liabilities	—	197
Total liabilities	14,195	7,295
Stockholders' equity		
Common Stock and additional paid-in-capital	518,237	511,091
Accumulated deficit	(380,769)	(283,552)
Total stockholders' equity	137,468	227,539
Total liabilities and stockholders' equity	$ 151,663	$ 234,834