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): August 8, 2024

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

Delaware	**001-41905**	**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 August 8, 2024, the Registrant issued a press release announcing financial results for the quarter ended June 30, 2024, 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 3.01. Notice of Delisting or Failure to Satisfy a Continued Listing Rule or Standard; Transfer of Listing.

On August 5, 2024, Cassava Sciences, Inc. (the "Company") issued a press release regarding the passing of one of its long-time directors, Sanford Robertson on August 3, 2024. Mr. Robertson served as a member of the Audit Committee of the Company's Board of Directors at the time of his death.

Mr. Robertson's death reduced the number of directors currently serving on the Company's Audit Committee to two, rendering the Company noncompliant with Rule 5605(c)(2) of the listing rules of The NASDAQ Stock Market LLC ("Nasdaq"), which requires that the Audit Committee of a Nasdaq-listed company have at least three members, each meeting independence and certain other criteria.

In accordance with Nasdaq listing rules, the Company notified Nasdaq on August 7, 2024, of the resulting non-compliance with the listing rules caused by Mr. Robertson's passing. Pursuant to Nasdaq Listing Rule 5605(c)(4)(B), the Company is entitled to a cure period to regain compliance with Nasdaq Listing Rule 5605(c)(2), which cure period will expire upon the earlier of the Company's next annual meeting of stockholders or August 3, 2025.

The Company also informed Nasdaq that the Company's Board of Directors (the "Board") plans regain compliance with the listing rules at its earliest opportunity by appointing an additional independent director of the Company to fill the vacancy on the Company's Audit Committee.

Item 9.01. Financial Statements and Exhibits.

Exhibit No.	**Description**
99.1	Press Release dated August 8, 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: August 8, 2024

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

EXHIBIT 99.1

Cassava Sciences Reports Q2 2024 Financial Results and Operational Updates

- **$207.3 Million in Cash and Cash Equivalents at June 30, 2024.**
- **Company in Advanced Discussions to Resolve SEC Investigation. $40 Million Estimated Loss Contingency Recorded in Q2 for Resolution.**
- **Conference Webcast Scheduled for Today at 8:30AM ET.**

AUSTIN, Texas, Aug. 08, 2024 (GLOBE NEWSWIRE) -- Cassava Sciences, Inc. (Nasdaq: SAVA), a biotechnology company focused on a novel treatment for Alzheimer's disease, today reported financial results for the second quarter ended June 30, 2024. Net income was $6.2 million compared to a net loss of $26.4 million for the same period in 2023. Net cash used in operations was $37.4 million during the first half of 2024, consistent with previous guidance. Net cash use in second half 2024 is expected to be $80 to $90 million, which includes an estimated $40 million loss contingency related to advanced discussions to resolve the SEC's investigation of the Company recorded in the second quarter.

"We have made significant progress over the last few months," Rick Barry, Cassava's Executive Chairman said. "The Cassava Clinical Operations team in conjunction with Premier Research have done a brilliant job in executing our Phase 3 program. We expect our last patient/last visit for our ReTHINK trial in early Q4 and a top-line read out from the trial by year-end. We also expect our second Phase 3 trial, ReFOCUS, to read out in mid-year 2025. The success of our warrant program earlier in the second quarter – which provided over $123 million net in equity capital to Cassava – has provided the Company with a strong balance sheet with enough liquidity to get well past our Phase 3 readouts. We are very grateful for the confidence that investors, principal investigators, patients and their loved ones have shown in Cassava. Our team's urgent focus is to deliver a best-in-class therapy for Alzheimer's patients."

Current Updates on 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. The goal is to evaluate overall risk/benefit for oral simufilam twice-daily versus placebo in a large population of people with Alzheimer's disease over 12 and 18 months.

The target study population is people with mild-to-moderate Alzheimer's (MMSE score of 16-27) who are biomarker-positive for Alzheimer's disease pathology, and who meet other inclusion/exclusion eligibility criteria of the study protocols.

Phase 3 Trials – 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.

Patient Enrollment – Both Phase 3 studies are fully enrolled. 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). Approximately 90% of patients are recruited from clinical sites in the U.S. and Canada. The overall drop-out rate for both Phase 3 studies is in the range of 20% to 23%, which is generally consistent with expectations. A longer study will generally have a higher dropout rate versus a similar shorter study.

Patient Completion – Over 555 patients have completed the 52-week RETHINK-ALZ study. Over 420 patients have completed the 76-week REFOCUS-ALZ study, for a total of over 975 completers.

Data and Safety Monitoring Board (DSMB) – The DSMB is composed of independent clinical research experts who periodically review interim patient safety data. Routine, scheduled DSMB meetings were held September 2023 and March 2024. Both DSMB meetings recommended that the Phase 3 studies continue as planned, without modification.

Co-primary Efficacy Outcomes – The pre-specified efficacy endpoints for the Phase 3 studies are ADAS-Cog12, a cognitive scale, and ADCS-ADL, a functional scale.

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) by the end of 2024. We anticipate top-line data readout for our 76-week study (REFOCUS-ALZ) approximately mid-year 2025.

Open-label Extension Study – This study is designed to provide no-cost access to oral simufilam to Alzheimer's patients who have successfully completed a Phase 3 study of simufilam and who meet other entry criteria. Approximately 89% of patients who've completed treatment in a Phase 3 study have opted to enter the open-label extension study. To date, over 870 patients have entered the open-label extension study. The open-label study is intended to continue for up to 36 months or until a new drug application for simufilam has been reviewed by FDA. Cassava also plans to add cognition and plasma biomarker monitoring to its open-label extension trial for patients who have completed the Phase 3 trials in order to gather additional long-term data on the potential impact of simufilam treatment.

Financial Results for Second Quarter 2024

- At June 30, 2024, cash and cash equivalents were $207.3 million, with no debt.
- Cash balance includes total gross proceeds received from the cash-exercise of common stock warrants in 2024 totaling $126.3 million, inclusive of approximately $104.0 million received in second quarter 2024. Holders exercised warrants for approximately 5.74 million common shares at a price of $22 per share in 2024. There are no remaining common stock warrants currently outstanding.
- Net income was $6.2 million compared to a net loss of $26.4 million for the same period in 2023. Net income resulted from the change in fair value of warrant liabilities, a non-cash item. This warrant gain was partially offset by an estimated $40.0 million loss contingency recorded in respect of a potential resolution of the SEC's investigation and costs to conduct the Phase 3 clinical program, as well as other studies with simufilam.
- Net cash used in operations was $37.4 million during the first six months of 2024, consistent with previous guidance.
- Net cash use in operations for second half 2024 is expected to be $80 to $90 million, which includes an estimated $40 million loss contingency related to advanced discussions to resolve the SEC's investigation. The Company estimates cash at year-end 2024 in a range from $117 to $127 million.
- Research and development (R&D) expenses were $15.2 million. This compared to $25.0 million for the same period in 2023. R&D expenses decreased due primarily to the completion of patient screening and enrollment for our Phase 3 clinical program in the fall of 2023.
- General and administrative (G&A) expenses were $46.2 million. This compared to $3.8 million for the same period in 2023. G&A expenses increased due primarily to the estimated loss contingency in respect of a potential SEC resolution as well as a $1.2 million increase in stock-based compensation expense due to new grant awards in late 2023 and 2024, increased compensation costs and higher legal related expenses.

Webcast Details
Date: Thursday, August 8th Time: 8:30 a.m. Eastern Time
Audio Webcast: https://www.CassavaSciences.com/company-presentations
Or https://edge.media-server.com/mmc/p/zjvmjjcr

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 potential for advanced discussions with SEC to result in a resolution of the SEC investigation and our loss contingency estimates related thereto; our ability to extend our existing open-label extension trials, as contemplated or at all; 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 assessment of interim safety data for the Phase 3 program at prior DSMB meetings; the treatment of people with Alzheimer's disease dementia; the safety or efficacy of simufilam in people with Alzheimer's disease dementia; expected cash balances and cash use in future periods; comments made by our employees regarding simufilam, drug effects, 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; and comments made by our employees regarding simufilam, drug effects, 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, 2023, and subsequent reports 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. 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 and development. 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 and subsequent filings with the SEC in their entirety, including the risk factors therein. Because risk is fundamental to the process of drug discovery and development, 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 –

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,	
	2024	2023	2024	2023
Operating expenses				
Research and development	$ 15,198	$ 24,969	$ 31,431	$ 47,089
General and administrative	46,204	3,808	49,905	8,200
Total operating expenses	61,402	28,777	81,336	55,289
Operating loss	(61,402)	(28,777)	(81,336)	(55,289)
Interest income	2,316	2,198	4,092	4,249
Other income, net	99	203	259	393
Gain from change in fair value of warrant liabilities	65,142	—	108,183	—
Net income (loss)	$ 6,155	$ (26,376)	$ 31,198	$ (50,647)
Net income (loss) per share, basic	$ 0.13	$ (0.63)	$ 0.70	$ (1.21)
Net income (loss) per share, diluted	0.13	(0.63)	(1.72)	(1.21)
Weighted-average shares used in computing net income (loss) per share, basic	46,202	41,793	44,601	41,766
Weighted-average shares used in computing net income (loss) per share, diluted	46,202	41,793	45,152	41,766

CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited, in thousands)

	June 30, 2024	December 31, 2023
Assets		

Current assets		
Cash and cash equivalents	$ 207,291	$ 121,136
Prepaid expenses and other current assets	14,831	8,497
Total current assets	222,122	129,633
Property and equipment, net	21,364	21,854
Intangible assets, net	82	176
Total assets	$ 243,568	$ 151,663
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable and accrued expenses	$ 52,552	$ 10,573
Accrued development expense	1,596	3,037
Accrued compensation and benefits	218	200
Other accrued liabilities	228	385
Total current liabilities	54,594	14,195
Stockholders' equity		
Common Stock and additional paid-in-capital	538,545	518,237
Accumulated deficit	(349,571)	(380,769)
Total stockholders' equity	188,974	137,468
Total liabilities and stockholders' equity	$ 243,568	$ 151,663