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): November 7, 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 November 7, 2024, the Registrant issued a press release announcing financial results for the quarter ended September 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 9.01. Financial Statements and Exhibits.

Exhibit Number	Description
99.1	Press Release dated November 7, 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.
a Delaware corporation

Date: November 7, 2024

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

EXHIBIT 99.1

Cassava Sciences Reports Q3 2024 Financial and Operating Results

- *Top-line Data for RETHINK-ALZ 52-week Phase 3 trial Expected Before the End of 2024*
- *$149.0 Million in Cash and Cash Equivalents at September 30, 2024. Expected To Support Operations Into 2026*
- *Conference Webcast Scheduled for Today at 8:30AM ET*

AUSTIN, Texas, Nov. 07, 2024 (GLOBE NEWSWIRE) -- Cassava Sciences, Inc. (Nasdaq: SAVA), a clinical-stage biotechnology company focused on developing a novel treatment for Alzheimer's disease, today reported financial results for the third quarter ended September 30, 2024.

"We look forward to the release of top-line results from RETHINK-ALZ, our first Phase 3 trial for simulfilam, by the end of 2024," said Rick Barry, President and Chief Executive Officer. "This will represent the culmination of three-plus years of concerted effort by our clinical team, principal investigators, patients and their caregivers."

Current Updates on Phase 3 Clinical Program

Background - Our Phase 3 program consists of two global, double-blind, randomized, placebo-controlled studies of simufilam, an investigational agent in development for the potential treatment of patients with mild-to-moderate Alzheimer's disease ("Alzheimer's" or "AD"). The program's goal is to evaluate the overall safety and efficacy of oral simufilam, administered 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 (mini-mental state examination, (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, RETHINK-ALZ (NCT04994483), is designed to evaluate the safety and efficacy of simufilam 100 mg tablets administered twice-daily versus matching placebo over 52 weeks. Our second Phase 3 study, REFOCUS-ALZ (NCT05026177), is designed to evaluate the safety and efficacy of two doses of oral simufilam tablets, 100 mg and 50 mg, administered twice-daily, versus matching placebo, over 76 weeks. Clinical sites are in the United States, Canada, Puerto Rico, Australia, and South Korea.

Patient Enrollment – Both Phase 3 studies are fully enrolled. Approximately 1,900 patients are randomized in these studies, with approximately 800 patients randomized into RETHINK-ALZ and approximately 1,100 patients randomized into REFOCUS-ALZ. Approximately 90% of patients are recruited from clinical sites in the U.S. and Canada. The overall drop-out rate was 21% for RETHINK-ALZ and has been 25% for REFOCUS-ALZ; these numbers are generally consistent with expectations.

Patient Completion – The Last Patient/Last Visit (LPLV) occurred several weeks ago for the RETHINK-ALZ study, with approximately 635 patients completed. To date, over 550 patients have completed the REFOCUS-ALZ study, for a total of over 1,185 completers.

Data and Safety Monitoring Board (DSMB) – The DSMB is composed of independent clinical research experts who periodically review interim patient safety data. Following a third routine, scheduled meeting in September 2024, the DSMB recommended that both of our Phase 3 studies continue as planned, without modification. This was consistent with recommendations of the DSMB following meetings in September 2023 and March 2024.

Co-primary Efficacy Outcomes – The pre-specified efficacy endpoints for the Phase 3 studies are Alzheimer's Disease Assessment Scale-Cognitive subscale 12 (ADAS-Cog12), a cognitive scale, and Alzheimer's Disease Cooperative Study – Activities of Daily Living subscale, (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 expect to report top-line data for RETHINK-ALZ before the end of 2024. We anticipate a top-line data readout for 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 88% of patients who have completed treatment in one of the two Phase 3 studies, RETHINK-ALZ or REFOCUS-ALZ, have opted to enter the open-label extension (OLE) study. To date, over 1,040 patients have entered the OLE study. The OLE 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 OLE trial for patients who have completed either of the two Phase 3 trials, in order to gather additional long-term data on the potential impact of simufilam treatment.

Financial Results for Third Quarter 2024

- At September 30, 2024, cash and cash equivalents were $149.0 million. The Company has no debt.
- Net loss was $27.9 million or $0.58 per share. This compares to a net loss of $25.7 million, or $0.61 per share, for the same period in 2023.

- Net cash used in operations was $55.7 million during the first nine months of 2024.
- Net cash used in operations for second half 2024 is expected to be $40 to $50 million, consistent with previous guidance. In addition, the Company intends to pay a previously announced $40 million SEC investigation settlement, which has been placed in escrow and excluded from cash and cash equivalents. The Company estimates cash and cash equivalents at year-end 2024 in a range from $117 to $127 million.
- Research and development (R&D) expenses were $17.7 million. This compared to $23.6 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. Patients are continually completing the Phase 3 program and a portion of completers are enrolling in the lower cost open-label extension study. These decreases were partially offset by an increase in stock-based compensation expense due to new grant awards in the third quarter of 2024.
- General and administrative (G&A) expenses were $12.9 million. This compared to $4.3 million for the same period in 2023. G&A expenses increased significantly due primarily to higher legal related expenses, increased compensation costs, including severance, as well as an increase in stock-based compensation expense due to new grant awards in late 2023 and 2024.

Webcast Details
Date: Thursday, November 7th Time: 8:30 a.m. Eastern Time
Audio Webcast: https://www.CassavaSciences.com/company-presentations
Or https://edge.media-server.com/mmc/p/tzb9j3sy

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.

Simufilam is an investigational oral, small molecule drug candidate currently being evaluated in two Phase 3 clinical trials for the potential treatment of Alzheimer's disease. Simufilam targets a specific site on filamin A, a scaffolding protein that is critical to certain receptor interactions in the brain. Cassava Sciences believes that simufilam interrupts amyloid-β42 binding to receptors in the brain and may affect the Alzheimer's disease process. Cassava Sciences owns exclusive, worldwide rights to its investigational product candidates and related technologies, without royalty obligations to any third party.

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

For More Information Contact:

Investors
Sandya von der Weid
svonderweid@lifesciadvisors.com

Media
Sitrick And Company
Mike_Sitrick@Sitrick.com

Company
Eric Schoen, Chief Financial Officer
(512) 501-2450
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 statements regarding: 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 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; 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 Quarterly Report on

Form 10-Q for the period ended June 30, 2024, 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. 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 of 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 is 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 Quarterly Reports on Form 10-Q 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 September 30,		Nine months ended September 30,	
	2024	2023	2024	2023
Operating expenses				
Research and development	$ 17,676	$ 23,603	$ 49,107	$ 70,692
General and administrative	12,947	4,276	62,852	12,476
Total operating expenses	30,623	27,879	111,959	83,168
Operating loss	(30,623)	(27,879)	(111,959)	(83,168)
Interest income	2,618	2,005	6,710	6,254
Other income, net	62	223	321	616
Gain from change in fair value of warrant liabilities	—	—	108,183	—
Net income (loss)	$ (27,943)	$ (25,651)	$ 3,255	$ (76,298)
Net income (loss) per share, basic	$ (0.58)	$ (0.61)	$ 0.07	$ (1.82)
Net income (loss) per share, diluted	(0.58)	(0.61)	(0.88)	(1.82)
Weighted-average shares used in computing net income (loss) per share, basic	47,976	42,002	45,734	41,845
Weighted-average shares used in computing net income (loss) per share, diluted	47,976	42,002	46,101	41,845

CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited, in thousands)

	September 30, 2024	December 31, 2023
Assets		
Current assets		
Cash and cash equivalents	$ 148,978	$ 121,136
Restricted cash	40,000	—
Prepaid expenses and other current assets	13,571	8,497

Total current assets	202,549	129,633
Property and equipment, net	21,135	21,854
Intangible assets, net	69	176
Total assets	$ 223,753	$ 151,663
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable and accrued expenses	$ 52,244	$ 10,573
Accrued development expense	2,543	3,037
Accrued compensation and benefits	1,950	200
Other accrued liabilities	297	385
Total current liabilities	57,034	14,195
Other non- current liabilities	80	—
Total liabilities	57,114	14,195
Stockholders' equity		
Common Stock and additional paid-in-capital	544,153	518,237
Accumulated deficit	(377,514)	(380,769)
Total stockholders' equity	166,639	137,468
Total liabilities and stockholders' equity	$ 223,753	$ 151,663