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, 2022

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 November 7, 2022, 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 November 7, 2022
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: November 7, 2022

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

EXHIBIT 99.1

Cassava Sciences Reports Third Quarter Financial Results for 2022 and Business Updates

– $174.7 Million Cash and Cash Equivalents at September 30, 2022 –

– Over 650 Patients Now Enrolled in Phase 3 Program -

– New Clinical Data for Simufilam in Alzheimer's Disease Expected –

AUSTIN, Texas, Nov. 07, 2022 (GLOBE NEWSWIRE) -- Cassava Sciences, Inc. (Nasdaq: SAVA), a clinical-stage biotechnology company focused on Alzheimer's disease, today announced financial results for the third quarter ended September 30, 2022 and provided a clinical update on its Phase 3 clinical program of simufilam in Alzheimer's disease. Simufilam is Cassava Sciences' lead drug candidate for the proposed treatment of Alzheimer's disease.

"The clinical development of oral simufilam for Alzheimer's disease continues to make headway," said Remi Barbier, President & CEO. "We now have over 650 patients enrolled in our on-going Phase 3 studies of simufilam in Alzheimer's disease, up from 150 patients approximately six months ago. We also look forward to presenting new clinical data for simufilam from two other ongoing studies in Alzheimer's disease."

Net loss for third quarter 2022 was $20.3 million, or $0.51 per share, compared to a net loss of $9.6 million, or $0.24 per share, for the same period in 2021. Net cash used in operations was $56.2 million during the first nine months of 2022. Net cash use for operations for full-year 2022 is expected to be approximately $80 to $90 million, consistent with previous guidance. Cash and cash equivalents were $174.7 million as of September 30, 2022, with no debt.

Financial Results for Third Quarter 2022

- At September 30, 2022, cash and cash equivalents were $174.7 million, with no debt.
- Net loss was $20.3 million, or $0.51 per share. This compares to a net loss of $9.6 million, or $0.24 per share, for the same period in 2021. Net loss increased compared to the prior period due primarily to a significant increase in our R&D activities for a Phase 3 program of simufilam in Alzheimer's disease.
- Net cash used in operations was $56.2 million during the first nine months of 2022.
- Net cash use in operations for full year 2022 is expected to be approximately $80 to $90 million, consistent with previous guidance.
- Research and development (R&D) expenses were $18.5 million. This compared to $8.0 million for the same period in 2021. R&D expenses increased compared to the prior period due primarily to increased activities and expenses related to clinical and pre-clinical studies and support functions.
- General and administrative (G&A) expenses were $2.8 million. This compared to $1.7 million for the same period in 2021. G&A expenses increased compared to the prior period due primarily to increased activities and expenses related to legal services as well as depreciation and amortization.

Overview of On-going Phase 3 Clinical Program
Cassava Sciences' Phase 3 program consists of two randomized controlled trials of oral simufilam in patients with mild-to-moderate Alzheimer's disease. The two studies are named RETHINK-ALZ and REFOCUS-ALZ. In 2021, both studies received Special Protocol Assessments (SPA) from the U.S. Food and Drug Administration.

Over 650 patients are now enrolled in our Phase 3 studies. Studies are being conducted in over 100 clinical trial sites across the U.S., Canada, Puerto Rico, South Korea and Australia.

Cassava Sciences' RETHINK-ALZ Phase 3 study is designed to evaluate the safety and efficacy of oral simufilam 100 mg in enhancing cognition and slowing functional decline over 52 weeks. This randomized, double-blind, placebo-controlled study plans to enroll approximately 750 patients with mild-to-moderate Alzheimer's disease. Patients are randomized (1:1) to simufilam 100 mg or matching placebo twice daily.

Cassava Sciences' REFOCUS-ALZ Phase 3 study is designed to evaluate the safety and efficacy of oral simufilam 100 mg and 50 mg over 76 weeks. This randomized, double-blind, placebo-controlled study plans to enroll approximately 1,000 patients with mild-to-moderate Alzheimer's disease. Patients are randomized (1:1:1) to simufilam 100 mg, 50 mg, or matching placebo twice daily.

Both of Cassava Sciences' Phase 3 studies have the same co-primary efficacy endpoints: ADAS-Cog12 (a cognitive scale) and ADCS-ADL (a functional scale). A secondary efficacy endpoint is iADRS, a clinical tool that combines cognitive and functional scores from ADAS-Cog & ADCS-ADL.

Open-label Study – closed enrollment
In March 2020, we initiated a long-term, open-label study to evaluate simufilam, our lead drug candidate, in patients with mild-

to-moderate Alzheimer's disease. The study is intended to monitor the long-term safety and tolerability of simufilam 100 mg twice daily for 12 or more months. The open-label study has reached its final target enrollment of approximately 200 patients with Alzheimer's disease. We expect to announce open-label study results approximately yearend 2022, consistent with our prior guidance.

Cognition Maintenance Study (CMS) – on-going
In May 2021, we initiated a Cognition Maintenance Study (CMS). This is a randomized, double-blind, placebo-controlled study of oral simufilam in patients with mild-to-moderate Alzheimer's disease. Patients are randomized (1:1) to simufilam 100 mg or matching placebo twice daily for six months. To enroll in the CMS, patients must have previously completed 12 months or more of open-label treatment with simufilam. The CMS is designed to evaluate simufilam's effects on in Alzheimer's patients who *continue* with drug treatment versus patients who *discontinue* drug treatment. Over 100 patients are now enrolled in the CMS and over 65 patients have completed this study. We expect to announce CMS study results approximately Q3 2023, consistent with our prior guidance.

SavaDx – on-going
This earlier-stage program refers to the detection of Alzheimer's disease with a simple blood test. SavaDx was initially designed as an antibody-based detection system for altered filamin A (FLNA). We are currently evaluating a new approach—based on mass spectrometry—to detect FLNA in plasma without the use of antibodies. Mass spectrometry is an analytical tool that measures the mass-to-charge ratio (m/z) of a molecule present in a sample.

About Simufilam
Simufilam (sim-uh-FILL-am) is Cassava Sciences' proprietary, small molecule (oral) drug 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, Inc. 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. The Company's 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

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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, relating to: our strategy and plans; expected cash use in future periods; the treatment of Alzheimer's disease; the status of current and future clinical studies with simufilam; the timing, enrollment, duration, geography and other details of a Phase 3 clinical program with simufilam; plans to release clinical results of our open-label study or CMS study, and the timing thereof; the development path for SavaDx and the use of mass spec as an alternative method of detection; and potential benefits, if any, of our product candidates. These statements may be identified by words such as "may," "anticipate," "believe," "could," "expect," "would", "forecast," "intend," "plan," "possible," "potential," and other words and terms of similar meaning.*

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. Our interim data and analysis should not be relied upon as predictive of full study results for any of our studies. 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 –

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,	
	2022	2021	2022	2021
Operating expenses				
Research and development, net of grant reimbursement	$ 18,526	$ 8,041	$ 50,380	$ 14,471
General and administrative	2,819	1,712	8,703	3,953
Total operating expenses	21,345	9,753	59,083	18,424
Operating loss	(21,345)	(9,753)	(59,083)	(18,424)
Interest income	878	15	1,223	35
Other income, net	210	176	748	176
Net loss	$ (20,257)	$ (9,562)	$ (57,112)	$ (18,213)
Net loss per share, basic and diluted	$ (0.51)	$ (0.24)	$ (1.43)	$ (0.46)
Weighted-average shares used in computing net loss per share, basic and diluted	40,050	39,957	40,009	39,218

CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited, in thousands)

	September 30, 2022	December 31, 2021
Assets		
Current assets		
Cash and cash equivalents	$ 174,662	$ 233,437
Prepaid expenses and other current assets	8,610	11,045
Total current assets	183,272	244,482
Property and equipment, net	23,130	20,616
Operating lease right-of-use assets	144	210
Intangible assets, net	740	1,075
Other assets	—	399
Total assets	$ 207,286	$ 266,782
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 3,534	$ 7,126
Accrued development expense	4,096	2,803
Accrued compensation and benefits	160	1,877
Operating lease liabilities, current	102	97
Other accrued liabilities	416	631
Total current liabilities	8,308	12,534
Operating lease liabilities, non-current	62	139
Other non- current liabilities	197	194
Total liabilities	8,567	12,867
Stockholders' equity		
Common Stock and additional paid-in-capital	463,137	461,221
Accumulated deficit	(264,418)	(207,306)
Total stockholders' equity	198,719	253,915
Total liabilities and stockholders' equity	$ 207,286	$ 266,782