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 3, 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.)

7801 N. Capital of Texas Highway, Suite 260
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 3, 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 August 3, 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: August 3, 2022

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

Cassava Sciences Reports Second Quarter Financial Results for 2022, Mid-year Corporate Update and Interim Analysis of Open-label Study

- **Phase 3 Program - Over 400 Patients Are Now Enrolled in Our Phase 3 Clinical Studies.**
- **Open-label Study – Results of an Interim Analysis on the First 100 Patients Who Have Completed at Least 12 Months of Open-label Treatment with Simufilam Follow:**
  - **Drug Appears Safe and Well Tolerated.**
  - **Overall ADAS-Cog11 Scores Improved an Average of 1.5 Points (S.D. ± 6.6; P<0.05)**
  - **63% of the 100 Patients Showed an Improvement in ADAS-Cog11 Scores, and This Group of Patients Improved an Average of 5.6 Points (S.D. ± 3.8).**
  - **An Additional 21% of the 100 Patients Declined Less Than 5 Points on ADAS-Cog11, and This Group of Patients Declined an Average of 2.7 Points (S.D. ± 1.4).**
- **Cognition Maintenance Study - Completion of Patient Enrollment is Expected Q4 2022.**
- **Financial Results - Net Loss for Q2 2022 Was $19.3 Million, or $0.48 Per Share.**
- **Cash Position - $197.2 Million of Cash and Cash Equivalents at June 30, 2022.**

AUSTIN, Texas, Aug. 03, 2022 (GLOBE NEWSWIRE) -- Cassava Sciences, Inc. (Nasdaq: SAVA), a clinical-stage biotechnology company focused on Alzheimer's disease, today announced financial results for the second quarter ended June 30, 2022, a mid-year corporate update, and interim clinical results of an open-label study with simufilam. Simufilam is Cassava Sciences' lead drug candidate for the proposed treatment of Alzheimer's disease. SavaDx is Cassava Sciences' investigational diagnostic candidate to detect Alzheimer's disease from a simple blood draw.

"I'm pleased with our operating performance in the first half of 2022," said Remi Barbier, President & CEO. "I'm also humbled by the hard work of our team members and clinical partners. Persistence and a focus on performance are key when you're trying to beat Alzheimer's disease."

Update on Patient Enrollment for Phase 3 Program
A total of over 400 patients are now enrolled in our on-going Phase 3 program of simufilam in Alzheimer's disease. Enrollment is almost evenly split between the two Phase 3 studies.

Overview of Phase 3 Program with Simufilam in Alzheimer's Disease
Our Phase 3 program consists of two double-blind, randomized, placebo-controlled studies of simufilam in patients with mild-to-moderate Alzheimer's disease. Both Phase 3 studies have Special Protocol Assessments (SPA) from the U.S. Food and Drug Administration. Both studies have the same co-primary efficacy endpoints: ADAS-Cog12 (a cognitive scale) and ADCS-ADL (a functional scale). A secondary efficacy endpoint for both studies is iADRS, a clinical tool that combines cognitive and functional scores from ADAS-Cog & ADCS-ADL. Patients are now being screened in clinical trial sites in the U.S., Canada, Puerto Rico and Australia.

RETHINK-ALZ is the trade name of our 52-week Phase 3 study. This randomized, double-blind, placebo-controlled study is designed to evaluate the safety & efficacy of oral simufilam 100 mg or placebo, twice daily, over 52 weeks in approximately 750 patients with Alzheimer's disease.

REFOCUS-ALZ is the trade name of our 76-week Phase 3 study. This randomized, double-blind, placebo-controlled study is designed to evaluate the safety & efficacy of oral simufilam 100 mg, 50 mg or placebo, twice daily, over 76 weeks in approximately 1,000 patients with Alzheimer's.

Future Open-label Extension Study for the Phase 3 Program
In the second half of 2022, we expect to initiate an open-label extension study for our Phase 3 program. This new study is designed to provide no-cost access to simufilam to patients with Alzheimer's disease who have successfully completed a Phase 3 study of simufilam.

On-going Open-label Study with Simufilam in Alzheimer's Disease
In March 2020, we initiated a long-term, open-label study to evaluate simufilam 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 over 12 months or more. This study has reached its target enrollment of approximately 200 patients. We expect all patients for this study will complete drug treatment in Q4 2022. We expect to announce top-line clinical results for this study approximately year-end 2022.

On-going Open-label Study - Interim Analysis on 100 Subjects at 12 Months
An interim analysis was conducted on the first 100 evaluable patients who completed at least 12 months of open-label treatment with simufilam 100 mg twice daily. Top-line results of this interim analysis show that from baseline to month-12:

- Drug appears safe and well tolerated.

- Overall ADAS-Cog11 scores improved an average of 1.5 points (S.D. ± 6.6; P<0.05)
- 63% of the 100 patients showed an improvement in ADAS-Cog11 scores, and this group of patients improved an average of 5.6 points (S.D. ± 3.8).
- An additional 21% of the 100 patients declined less than 5 points on ADAS-Cog11, and this group of patients declined an average of 2.7 points (S.D. ± 1.4).

The 11-item *Alzheimer's Disease Assessment Scale–Cognitive subscale* (ADAS-Cog) was originally developed by the research community to measure cognitive impairment in patients with Alzheimer's disease. ADAS-Cog is often used in clinical studies of patients with Alzheimer's because it can help determine incremental improvements or declines in cognition over time.

Standard deviation ("S.D.") is a measure of how dispersed the data is in relation to the average. A low standard deviation generally shows the data are closely clustered around the average. A high standard deviation generally shows that the data is widely spread.

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, evidence of therapeutic benefit for simufilam.

Cognition Maintenance Study (CMS) with Simufilam in Alzheimer's Disease
In May 2021, we initiated a Cognition Maintenance Study (CMS). This is a double-blind, randomized, placebo-controlled study of simufilam in patients with mild-to-moderate Alzheimer's disease. Study participants are randomized (1:1) to simufilam or placebo for six months. The CMS is designed to evaluate simufilam's effects on cognition and health outcomes in Alzheimer's patients who *continue* with drug treatment versus patients who *discontinue* drug treatment. To enroll in the CMS, patients must have previously completed 12 months or more of open-label treatment with simufilam.

The target enrollment for the CMS is 100 or more patients. Over 50 patients have now completed this study. Our goal is to complete patient enrollment for the CMS in Q4 2022. We expect to announce clinical results of the CMS approximately third-quarter 2023.

SavaDx
Our investigational product candidate, called SavaDx, is an early-stage program focused on detecting the presence of Alzheimer's disease from a simple blood draw. SavaDx is currently designed as an antibody-based detection system for altered filamin A (FLNA) protein. Working with third parties, we continue to evaluate an innovative method to detect FLNA without the use of antibodies. For business, technical and personnel reasons, we continue to prioritize the development of simufilam, our novel drug candidate, over SavaDx.

Financial Update
Net loss for the second quarter 2022 was $19.3 million, or $0.48 per share, compared to a net loss of $5.1 million, or $0.13 per share, for the same period in 2021. Net cash used in operations was $34.6 million during the first six months of 2022. Net cash use for operations for full-year 2022 is expected to be approximately $80 to $90 million. Cash and cash equivalents were $197.2 million as of June 30, 2022, with no debt.

Financial Results for Second Quarter 2022

- At June 30, 2022, cash and cash equivalents were $197.2 million, with no debt.
- Net loss was $19.3 million, or $0.48 per share. This compares to a net loss of $5.1 million, or $0.13 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 $34.6 million during the first six months of 2022.
- Net cash use in operations for full year 2022 is expected to be approximately $80 to $90 million.
- Research and development (R&D) expenses were $16.9 million. This compared to $3.9 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 and personnel expenses.
- General and administrative (G&A) expenses were $3.0 million. This compared to $1.2 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.

About Simufilam
Simufilam (sim-uh-FILL-am) is a 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. For more information, please visit: https://www.CassavaSciences.com

For More Information Please Contact:
Eric Schoen, Chief Financial Officer, (512) 501-2450, or 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, 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 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 this study, 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 –

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,	
	2022	2021	2022	2021
Operating expenses				
Research and development, net of grant reimbursement	$ 16,948	$ 3,901	$ 31,854	$ 6,430
General and administrative	2,969	1,237	5,884	2,241
Total operating expenses	19,917	5,138	37,738	8,671
Operating loss	(19,917)	(5,138)	(37,738)	(8,671)
Interest income	314	13	345	20
Other income, net	275	—	538	—
Net loss	$ (19,328)	$ (5,125)	$ (36,855)	$ (8,651)
Net loss per share, basic and diluted	$ (0.48)	$ (0.13)	$ (0.92)	$ (0.22)
Weighted-average shares used in computing net loss per share, basic and diluted	40,015	39,953	39,989	38,843

CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited, in thousands)

	June 30, 2022	December 31, 2021
Assets		
Current assets		
Cash and cash equivalents	$ 197,232	$ 233,437
Prepaid expenses and other current assets	6,969	11,045
Total current assets	204,201	244,482
Property and equipment, net	22,155	20,616
Operating lease right-of-use assets	166	210
Intangible assets, net	859	1,075
Other assets	—	399
Total assets	$ 227,381	$ 266,782
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 4,758	$ 7,126
Accrued development expense	3,318	2,803
Accrued compensation and benefits	176	1,877
Operating lease liabilities, current	100	97
Other accrued liabilities	370	631
Total current liabilities	8,722	12,534
Operating lease liabilities, non-current	88	139
Other non- current liabilities	201	194
Total liabilities	9,011	12,867
Stockholders' equity		
Common Stock and additional paid-in-capital	462,531	461,221
Accumulated deficit	(244,161)	(207,306)
Total stockholders' equity	218,370	253,915
Total liabilities and stockholders' equity	$ 227,381	$ 266,782