

**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): May 5, 2022

CASSAVA SCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or Other Jurisdiction of Incorporation)

000-29959

(Commission File Number)

91-1911336

(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 May 5, 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 May 5, 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: May 5, 2022

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

Cassava Sciences Reports First Quarter Financial Results for 2022 and Updates on Phase 3 Clinical Program

- \$209.7 Million Cash and Cash Equivalents at March 31, 2022 –

- Over 120 Patients Now Enrolled in Phase 3 Program -

AUSTIN, Texas, May 05, 2022 (GLOBE NEWSWIRE) -- Cassava Sciences, Inc. (Nasdaq: SAVA), a clinical-stage biotechnology company focused on Alzheimer's disease, today announced financial results for the first quarter ended March 31, 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.

Net loss was \$17.5 million, or \$0.44 per share, compared to a net loss of \$3.5 million, or \$0.09 per share, for the same period in 2021. Net cash used in operations was \$23.5 million during the first quarter of 2022, including over \$10 million of contractual pre-payments. Pre-payments are amounts paid for in advance of future research and development (R&D) services.

"We're seeing an uptick in the rate of patient enrollment," said Remi Barbier, President & CEO. "In part, the pandemic challenged some clinical sites, from staffing shortages to operational gaps. We hope these challenges are in the rearview mirror as we continue to move forward with our Phase 3 studies of simufilam in Alzheimer's disease, while keeping an eye on the balance sheet."

Financial Results for First Quarter 2022

- At March 31, 2022, cash and cash equivalents were \$209.7 million, with no debt.
- Net loss was \$17.5 million, or \$0.44 per share. This compares to a net loss of \$3.5 million, or \$0.09 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 and G&A expenses.
- Net cash used in operations was \$23.5 million during the first quarter of 2022.
- Net cash use in operations for the first half 2022 is now expected to be approximately \$35 to \$40 million, including significant (over \$10 million) contractual pre-payments made to R&D vendors for future services, such as our contract research organization for the Phase 3 clinical program of simufilam in Alzheimer's disease.
- Research and development (R&D) expenses were \$14.9 million. This compared to \$2.5 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 studies, clinical trial supplies and support functions and personnel expenses.
- General and administrative (G&A) expenses were \$2.9 million. This compared to \$1.0 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 and depreciation and amortization.

Overview of On-going Phase 3 Clinical Program

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.

A total of over 120 subjects have now been enrolled in our Phase 3 studies. Studies are being conducted in over 115 clinical trial sites across the U.S., Canada and Puerto Rico.

Overview of Each On-going Phase 3 Study - RETHINK-ALZ and REFOCUS-ALZ

Our Phase 3 study called "RETHINK-ALZ" 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.

Details of the RETHINK-ALZ Phase 3 study include:

- Subjects are randomized (1:1) to simufilam 100 mg or placebo twice daily.
- The co-primary efficacy endpoints are 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.

Our Phase 3 study called "REFOCUS-ALZ" 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.

Details of the REFOCUS-ALZ Phase 3 study, include:

- Subjects are randomized (1:1:1) to simufilam 100 mg, 50 mg, or placebo twice daily.
- The co-primary efficacy endpoints are 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 subjects with Alzheimer’s disease. We expect to announce full study results second half 2022.

Cognition Maintenance Study (CMS) – on-going

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. 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 cognition and health outcomes in Alzheimer’s patients who *continue* with drug treatment versus patients who *discontinue* drug treatment. The target enrollment for the CMS is approximately 100 subjects. Over 75 subjects have been enrolled in the CMS and 35 have completed the study.

SavaDx – on-going

SavaDx, is an early-stage program focused on detecting the presence of Alzheimer’s disease from a small sample of blood. For business, technical and personnel reasons, we continue to prioritize the development of simufilam, our lead drug candidate, over SavaDx.

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 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, including expected cash use for operations in the first half of 2022; 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 full results of our open-label clinical study and the timing thereof; the development path for SavaDx and the use of alternative methods 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 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 March 31,	
	2022	2021
Operating expenses		
Research and development, net of grant reimbursement	\$ 14,906	\$ 2,529
General and administrative	2,915	1,004
Total operating expenses	<u>17,821</u>	<u>3,533</u>
Operating loss	(17,821)	(3,533)
Interest income	31	7
Other income, net	263	—
Net loss	<u>\$ (17,527)</u>	<u>\$ (3,526)</u>
Net loss per share, basic and diluted	<u>\$ (0.44)</u>	<u>\$ (0.09)</u>
Weighted-average shares used in computing net loss per share, basic and diluted	<u>39,962</u>	<u>37,721</u>

CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited, in thousands)

	March 31, 2022	December 31, 2021
Assets		
Current assets		
Cash and cash equivalents	\$ 209,693	\$ 233,437
Prepaid expenses and other current assets	12,507	11,045
Total current assets	<u>222,200</u>	<u>244,482</u>
Property and equipment, net	20,863	20,616
Operating lease right-of-use assets	188	210
Intangible assets, net	940	1,075
Other assets	—	399
Total assets	<u>\$ 244,191</u>	<u>\$ 266,782</u>
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	\$ 3,332	\$ 7,126
Accrued development expense	2,925	2,803
Accrued compensation and benefits	172	1,877
Operating lease liabilities, current	99	97
Other accrued liabilities	261	631
Total current liabilities	<u>6,789</u>	<u>12,534</u>
Operating lease liabilities, non-current	114	139
Other non-current liabilities	194	194
Total liabilities	<u>7,097</u>	<u>12,867</u>
Stockholders' equity		
Common Stock and additional paid-in-capital	461,927	461,221
Accumulated deficit	(224,833)	(207,306)
Total stockholders' equity	<u>237,094</u>	<u>253,915</u>
Total liabilities and stockholders' equity	<u>\$ 244,191</u>	<u>\$ 266,782</u>