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): February 28, 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 February 28, 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 February 28, 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: February 28, 2022

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

EXHIBIT 99.1

Cassava Sciences Reports Full-year 2021 Financial Results and Operating Updates

AUSTIN, Texas, Feb. 28, 2022 (GLOBE NEWSWIRE) -- Cassava Sciences, Inc. (Nasdaq: SAVA), a clinical-stage biotechnology company focused on Alzheimer's disease, today announced financial results for the year ended December 31, 2021 and provided clinical and business updates.

"In second half 2021, we initiated two separate Phase 3 clinical studies with our lead drug candidate, simufilam, in patients with Alzheimer's disease," said Remi Barbier, President & CEO. "This was a large, complex endeavor. We deeply appreciate every member of the team inside and outside the Company who contributed to this effort. Our challenge for 2022 and beyond is to enroll over 1,700 patients into our Phase 3 clinical program. With this evolution, we intend to prove once again that we are a small company capable of doing big things."

Cassava Sciences' Phase 3 studies are now recruiting patients with mild to moderate Alzheimer's disease. Drug has been shipped to nearly 100 clinical trial sites across North America, with additional sites planned in the U.S. and overseas. Over 200 patients have been screened to date.

"We are encouraged by our clinical investigators' high level of enthusiasm," said Jim Kupiec, MD, Chief Clinical Development Officer. "Looking ahead, we see continued collaboration with the clinical community to ensure qualifying patients with Alzheimer's disease are successfully enrolled into our Phase 3 studies."

"Our balance sheet has $233.4 million of cash, against expected cash use of $25 to $35 million in first half 2022, depending on patient enrollment rates and the timing of certain legal expenses," said Eric Schoen, Chief Financial Officer. "Higher cash use may indicate faster enrollment rates."

Net loss for full year 2021 was $32.4 million, or $0.82 per share, compared to a net loss of $6.3 million, or $0.24 per share, in 2020. Net cash used in operations full-year 2021 was $30.2 million, consistent with previous guidance. An additional $22.2 million was used primarily for an all-cash purchase of office property in Austin, Texas, which is expected to serve as Cassava Sciences' corporate headquarters in 2022 and beyond.

Financial Highlights

- At December 31, 2021, cash and cash equivalents were $233.4 million, compared to $93.5 million at December 31, 2020, with no debt.

- Net cash used in operations full-year 2021 was $30.2 million, net of reimbursements received from the National Institutes of Health (NIH) grant awards. An additional $22.2 million was used primarily for the purchase of office property in Austin, Texas, which is expected serve as the Company's corporate headquarters in 2022 and beyond.

- Net cash use for operations for the first half of 2022 is expected to be approximately $25 to $35 million, driven primarily by expenses for our ongoing Phase 3 program in Alzheimer's disease.

- Research and development (R&D) expenses for the year ended December 31, 2021 were $24.8 million compared to $3.1 million for the same period in 2020. This increase was due primarily to costs related to manufacture of clinical trial supplies for and the initiation of a Phase 3 clinical program with simufilam, costs of an on-going open-label study and cognition maintenance extension study with simufilam, as well as increased personnel expenses compared to the prior year. These expenses are net of grant funding received from NIH, which is recorded as a reduction in R&D expenses.

- Research grant funding reimbursements of $3.9 million were received from NIH and recorded as a reduction in R&D expenses. This compared to $4.2 million of NIH grant receipts received for 2020.

- General and administrative (G&A) expenses for the year ended December 31, 2021 were $8.1 million compared to $3.7 million for 2020. This increase was primarily due to higher legal fees, personnel costs, insurance costs and depreciation and amortization as compared to 2020.

Overview of Phase 3 Clinical Program - RETHINK-ALZ and REFOCUS-ALZ
The 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 FDA. Both Phase 3 studies were initiated in Fall 2021.

The 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. Secondary objectives include the assessment of simufilam's effect on neuropsychiatric symptoms and caregiver burden. This randomized, double-blind, placebo-controlled study plans to enroll approximately 750 patients with mild-to-moderate Alzheimer's disease in the U.S. and Canada and, eventually, overseas.

Details of the RETHINK-ALZ Phase 3 study include:

- Subjects to be 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; both are standard clinical tools in trials of Alzheimer's disease.
- A secondary efficacy endpoint is iADRS, a widely used clinical tool in trials of Alzheimer's disease that combines cognitive and functional scores from ADAS-Cog & ADCS-ADL.
- Other secondary endpoints include plasma biomarkers of disease and NPI, a clinical tool to assess dementia-related behavior.

The 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 in the U.S. and Canada and, eventually, overseas.

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

- Subjects to be 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; both are standard clinical tools in trials of Alzheimer's disease.
- A secondary efficacy endpoint is iADRS, a widely used clinical tool in trials of Alzheimer's disease that combines cognitive and functional scores from ADAS-Cog & ADCS-ADL.
- Other secondary endpoints include CSF, plasma and imaging biomarkers of disease and NPI, a clinical tool to assess dementia-related behavior.

Open-label Study

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. Another study objective is to measure changes in cognition and biomarkers.

In September 2021, the open-label study reached its final target enrollment of approximately 200 subjects with Alzheimer's disease. We expect to announce full study results second half 2022.

The study protocol has pre-specified interim analyses, including cognition measurements at 6, 9 and 12 months. ADAS-Cog scores improved 1.6 points, 3.0 points and 3.2 points from baseline in the first 50 study participants who completed, respectively, 6, 9 and 12 months of open-label treatment with simufilam. It is understood that cognition data from an open-label study has limitations compared to efficacy data from a fully completed, large, randomized controlled trial.

In 2022, we may conduct one or more *ad hoc* interim analyses on measurements of cognition on the open-label study.

Another objective of this study is to measure changes in levels of biomarkers in patients treated with open label simufilam. In July 2021, we announced positive biomarker data at 6 months. Biomarker data were analyzed from cerebrospinal fluid (CSF) collected from 25 study participants who agreed to undergo a lumbar puncture at baseline and again after 6 months of treatment. In this cohort of 25 study participants, simufilam robustly improved CSF biomarkers of disease pathology (t-tau and p-tau181 decreased 38% and 18%, respectively); CSF biomarkers of neurodegeneration (neurogranin and NfL, decreased 72% and 55%, respectively); and CSF biomarkers of neuroinflammation (sTREM2 and YKL-40, decreased 65% and 44%, respectively).

In 2022, we expect to measure changes in levels of biomarkers in patients treated with open label simufilam for 12 months.

Cognition Maintenance Study (CMS)
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 60 subjects have been enrolled in the CMS and 30 have completed the study.

SavaDx
Our investigational diagnostic product candidate, called 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. The regulatory pathway for SavaDx may eventually include formal analytical validation studies and clinical studies that support evidence of sensitivity, specificity and other variables in various healthy and diseased patient populations. We have not conducted such studies and do not expect to conduct such studies in 2022.

SavaDx is currently designed as an antibody-based detection system for altered filamin A (FLNA). In 2022, we plan to evaluate a new approach to detect FLNA without the use of antibodies.

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. Altered FLNA in the brain disrupts the normal function of neurons, leading to Alzheimer's pathology, neurodegeneration and neuroinflammation. The underlying science for simufilam is published in peer-

reviewed journals, including *Journal of Neuroscience*, *Neurobiology of Aging*, *Journal of Biological Chemistry*, *Neuroimmunology and Neuroinflammation* and *Journal of Prevention of Alzheimer's Disease.*
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' mission is to discover and develop innovations for chronic, neurodegenerative conditions. Over the past 10 years, Cassava Sciences has combined state-of-the-art technology with new insights in neurobiology to develop novel solutions for Alzheimer's disease. We are currently testing simufilam, our lead drug candidate for the proposed treatment of Alzheimer's disease, in Phase 3 clinical studies under Special Protocol Assessments from the FDA. Simufilam is also being tested in an open-label study and a randomized, double-blind, placebo-controlled Cognition Maintenance Study in patients with Alzheimer's disease. For more information, please visit: https://www.CassavaSciences.com

For More Information Contact:
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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 conduct ad hoc interim analyses on open-label clinical data 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, 2020, as supplemented by the section entitled "Risk Factors" in our Quarterly Report on SEC Form 10-Q for the quarter ended September 30, 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 December 31,		Year ended December 31,	
	2021	2020	2021	2020
Operating expenses				
Research and development, net of grant reimbursement	$ 10,342	$ 1,519	$ 24,813	$ 3,053
General and administrative	4,102	1,105	8,055	3,739
Gain on sale of property and equipment	—	—	—	(346)
Total operating expenses	14,444	2,624	32,868	6,446
Operating loss	(14,444)	(2,624)	(32,868)	(6,446)
Interest income	14	6	49	112
Other income, net	258	—	434	—
Net loss	$ (14,172)	$ (2,618)	$ (32,385)	$ (6,334)

Net loss per share, basic and diluted	$ (0.35)	$ (0.09)	$ (0.82)	$ (0.24)
Weighted-average shares used in computing net loss per share, basic and diluted	39,960	30,157	39,405	26,105

CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited, in thousands)

	December 31, 2021	December 31, 2020
Assets		
Current assets		
Cash and cash equivalents	$ 233,437	$ 93,506
Prepaid expenses and other current assets	11,045	488
Total current assets	244,482	93,994
Operating lease right-of-use assets	210	295
Property and equipment, net	20,616	11
Intangible assets, net	1,075	—
Other assets	399	—
Total assets	$ 266,782	$ 94,300
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 7,126	$ 911
Accrued development expense	2,803	719
Accrued compensation and benefits	1,877	83
Operating lease liabilities, current	97	58
Other accrued liabilities	631	94
Total current liabilities	12,534	1,865
Operating lease liabilities, non-current	139	235
Other non-current liabilities	194	—
Total liabilities	12,867	2,100
Stockholders' equity		
Common Stock and additional paid-in-capital	461,221	267,121
Accumulated deficit	(207,306)	(174,921)
Total stockholders' equity	253,915	92,200
Total liabilities and stockholders' equity	$ 266,782	$ 94,300