

**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): March 23, 2021

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 Number)

7801 N Capital of Texas Highway, Suite 260, Austin, TX 78731
(Address of Principal Executive Offices) (Zip Code)

512-501-2444
(Registrant's telephone number, including area code)

Not Applicable
(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 March 23, 2021, 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 99.1. Press release dated March 23, 2021](#)

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: March 23, 2021

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

Cassava Sciences Announces Full-year 2020 Financial Results and Business Highlights

AUSTIN, Texas, March 23, 2021 (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, 2020 and provided business updates. Unaudited cash and cash equivalents were approximately \$280 million as of February 2021.

"In Q1 2021 we announced that our lead drug candidate, simufilam, improved cognition scores in 50 patients with Alzheimer's disease who completed at least 6 months of open-label treatment," said Remi Barbier, President & CEO. "In mid-2021, we look forward to announcing cognition scores in patients who'll have completed at least 12 months of open-label treatment with simufilam. To our knowledge, no drug has stabilized, much less improved, cognition scores over 12 months in patients with Alzheimer's disease. For this reason, I feel there is a sense of anticipation around the upcoming release of 12-month clinical data from our open-label study, as well as our plans to conduct a pivotal Phase 3 program with simufilam in the second half of 2021. With solid science, the right people in place, cash in the bank and a clinical roadmap that makes sense, I think Cassava Sciences is positioned to becoming a premier organization to serve patients with Alzheimer's disease."

"We have approximately \$280 million in cash on our balance sheet, against expected cash use of approximately \$20 to \$25 million in 2021," said Eric Schoen, Chief Financial Officer. "We believe our cash levels support a pivotal Phase 3 clinical program of simufilam in Alzheimer's disease."

Cassava Sciences remains on-track to initiate two pivotal Phase 3 studies in second half of 2021. In mid-year 2021, the Company also plans to initiate a randomized, placebo-controlled cognition maintenance study in patients with mild-to-moderate Alzheimer's disease. Expected milestones for 2021 appear below.

Summary of Expected Milestones for 2021

Milestone	Anticipated Timing
• End-of-phase 2 (EOP2) meeting with FDA to gain general agreement around a Phase 3 clinical development program in Alzheimer's disease dementia.	Completed Q1 2021
• Announce cognition scores from a pre-planned interim analysis (6-month data) of an ongoing, open-label study of simufilam in Alzheimer's disease.	Completed Q1 2021
• Announce results of EOP2 meeting with FDA.	Completed Q1 2021
• Announce long-term, large-scale drug supply agreement for simufilam with contract manufacturer (Evonik).	Completed Q1 2021
Announce cognition scores of a pre-planned interim analysis (12-month data) of an ongoing, open-label study of simufilam in Alzheimer's disease.	Mid-2021
Initiation of a Cognition Maintenance Study (CMS) with simufilam – randomized, placebo-controlled design in Alzheimer's patients.	Mid-2021
Manufacture large-scale Phase 3 clinical trial supplies.	Ongoing, rolling basis
Initiation of a first Phase 3 study of simufilam -- 18-month, approx. 1,000+ patients with Alzheimer's disease.	Q3 2021
Initiation of a second Phase 3 study of simufilam -- 12-month, approx. 600+ patients with Alzheimer's disease.	Q4 2021
Complete patient enrollment of an on-going, open-label study of simufilam in Alzheimer's patients.	Ongoing, rolling basis
Publication of Phase 2b results in peer-reviewed journal.	2021
Initiate validation study with SavaDx – blood-based diagnostic to detect Alzheimer's disease.	2021

Net cash use in 2021 is expected to be driven by higher headcount and personnel expenses, manufacturing costs around large-scale drug supply, professional services expenses related to clinical programs, and operating costs such as insurance, office space and IT related expenses.

Full Year 2020 Financial Results: Net loss in full-year 2020 was \$6.3 million, or \$0.24 per share, compared to a net loss in 2019 of \$4.6 million, or \$0.27 per share. Net cash used in operations in full-year 2020 was \$5.4 million. Cash and cash equivalents were \$93.5 million as of December 31, 2020. Unaudited cash and cash equivalents were approximately \$280 million as of February 2021, including net proceeds of approximately \$189.7 million from the sale of 4.1 million shares of common stock completed February 12, 2021.

Financial Highlights

- At December 31, 2020, cash and cash equivalents were \$93.5 million, compared to \$23.1 million at December 31, 2019, with no debt. 2020 year-end cash balance includes net proceeds of \$70.3 million from the sale of 9.4 million shares of

common stock in a follow-on public offering completed November 2020 and proceeds of \$4.9 million from the exercise of 4.0 million common stock warrants during 2020. In 2021, all remaining warrants outstanding were exercised, resulting in additional proceeds of \$0.7 million.

- Net cash used in operations during the year ended December 31, 2020 was \$5.4 million, net of reimbursements received from NIH grant awards.
- Net cash use for full year 2021 is expected to be approximately \$20 - \$25 million, depending on the rate of clinical site initiation and enrollment rates in upcoming clinical studies of simufilam.
- Research and development expenses for the year ended December 31, 2020 were \$3.1 million compared to \$1.6 million for the same period in 2019, or a 95% increase. The increase was due primarily to costs related to the manufacture of Phase 3 clinical trial supplies in the fourth quarter of 2020 as well as lower NIH reimbursement compared to the prior year.
- Cassava Sciences received reimbursements of \$4.2 million in 2020 from research grant awards from NIH that are recorded as a reduction of research and development expense, compared to \$4.7 million in 2019.
- General and administrative expenses for the year ended December 31, 2020 were \$3.7 million compared to \$3.4 million for the same period in 2019, or a 10% increase. The increase was due primarily to higher insurance expenses compared to the prior year.

About Simufilam

Simufilam is a proprietary, small molecule (oral) drug candidate that restores the normal shape and function of altered filamin A (FLNA), a scaffolding 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 is also developing an investigational diagnostic, called SavaDx, to detect Alzheimer's disease with a simple blood test.

Simufilam and SavaDx were both developed in-house. Both product candidates are substantially funded by peer-review research grant awards from the National Institutes of Health (NIH). 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 Alzheimer's Disease

Alzheimer's disease is a progressive brain disorder that destroys memory and thinking skills. Currently, there are no drug therapies to halt Alzheimer's disease, much less reverse its course. As of 2020, there were approximately 50 million people worldwide living with dementia, a figure expected to increase to 150 million by 2050.¹ The annual global cost of dementia is now above \$1 trillion, according to *Alzheimer's Disease International*, a charitable organization.

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. 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; planned milestones for 2021; expected cash use in future periods; the treatment of Alzheimer's disease; the status of current and future clinical studies with simufilam, including the interpretation of an interim analysis of an open-label study; plans to conduct a second interim analysis of an open-label study and the timing thereof; planned enrollment and other changes to said open-label program; our intention to initiate a Phase 3 clinical program with simufilam and the timing, enrollment, duration and other details thereof; verbal commentaries made by our employees; and potential benefits, if any, of our product candidates. These statements may be identified by words such as "may," "anticipate," "believe," "could," "expect," "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, 2019 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 STATEMENTS OF OPERATIONS
(unaudited, in thousands, except per share amounts)

	Three months ended December 31,		Year ended December 31,	
	2020	2019	2020	2019
Operating expenses				
Research and development, net of grant reimbursement	\$ 1,519	\$ 738	\$ 3,053	\$ 1,568
General and administrative	1,105	838	3,739	3,391
Gain on sale of property and equipment	—	—	(346)	—
Total operating expenses	<u>2,624</u>	<u>1,576</u>	<u>6,446</u>	<u>4,959</u>
Operating loss	(2,624)	(1,576)	(6,446)	(4,959)
Interest income	6	60	112	328
Net loss	<u>\$ (2,618)</u>	<u>\$ (1,516)</u>	<u>\$ (6,334)</u>	<u>\$ (4,631)</u>
Net loss per share, basic and diluted	<u>\$ (0.09)</u>	<u>\$ (0.08)</u>	<u>\$ (0.24)</u>	<u>\$ (0.27)</u>
Weighted-average shares used in computing net loss per share, basic and diluted	<u>30,157</u>	<u>18,153</u>	<u>26,105</u>	<u>17,412</u>

CONDENSED BALANCE SHEETS
(unaudited, in thousands)

	December 31,	
	2020	2019
Assets		
Current assets		
Cash and cash equivalents	\$ 93,506	\$ 23,081
Other current assets	488	268
Total current assets	<u>93,994</u>	<u>23,349</u>
Property and equipment, net	11	47
Operating lease right-of-use assets	295	90
Total assets	<u>\$ 94,300</u>	<u>\$ 23,486</u>
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	\$ 911	\$ 453
Accrued development expense	719	777
Accrued compensation and benefits	83	58
Operating lease liabilities, current	58	90
Other accrued liabilities	94	9
Total current liabilities	<u>1,865</u>	<u>1,387</u>
Operating lease liabilities, non-current	235	—
Total liabilities	<u>2,100</u>	<u>1,387</u>
Stockholders' equity		
Common stock and additional paid-in-capital	267,121	190,686
Accumulated deficit	(174,921)	(168,587)
Total stockholders' equity	<u>92,200</u>	<u>22,099</u>

Total liabilities and stockholders' equity

\$ 94,300 \$ 23,486

¹ Alzheimer's Disease International, *Dementia Statistics*, available on-line and accessed March 22, 2021:
<https://www.alzint.org/about/dementia-facts-figures/dementia-statistics/>