

**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 6, 2020

Cassava Sciences, Inc.

(Exact Name of Registrant as Specified in 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 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2). 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 6, 2020, 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 May 6, 2020](#)

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 6, 2020

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

Cassava Sciences Reports First Quarter 2020 Financial Results and Provides Business Update

- Anticipates Early Data Readout for Phase 2b Study of PTI-125 in Alzheimer's Disease -

- Approximately \$2.9 Million in NIH Research Grants Awarded in 2020 -

- Open-Label Study of PTI-125 Initiated in Alzheimer's Disease -

AUSTIN, Texas, May 06, 2020 (GLOBE NEWSWIRE) -- Cassava Sciences, Inc. (Nasdaq: SAVA), a clinical-stage biotechnology company focused on Alzheimer's disease, today announced recent business highlights and financial results for the first quarter ended March 31, 2020. Net loss was \$1.2 million, or \$0.05 per share, compared to a net loss of \$1.4 million, or \$0.08 per share, for the same period in 2019. Net cash used in operations was \$1.2 million during the first quarter of 2020. Net cash use in full-year 2020 is expected to be approximately \$5 million. Cash and cash equivalents were \$25.6 million as of March 31, 2020, with no debt.

"Cassava Sciences had a productive quarter with its research programs in Alzheimer's disease," said Remi Barbier, President & CEO. "As a result, we anticipate having top-line results for our Phase 2b study of PTI-125, our lead drug candidate for Alzheimer's, earlier than mid-2020."

Phase 2b Study – Early data readout on effects of PTI-125 on tau protein anticipated

In March 2020, Cassava Sciences announced the completion of a double-blind, randomized, placebo-controlled study of PTI-125 in 64 patients with mild-to-moderate Alzheimer's disease, 50-85 years of age, with $16 \leq \text{MMSE} \leq 26$. Study participants received PTI-125 100 mg, 50 mg or matching placebo, twice-daily, for 28 continuous days. The primary efficacy endpoint is the effect of PTI-125 vs placebo on CSF levels of tau protein, and other biomarker assessments.

Open-label Study – Initiated in March, approximately 20% enrolled

In March 2020, Cassava Sciences announced the initiation of an open-label, multi-center study of PTI-125 at 100 mg twice-daily for 12 months. Every study participant receives drug treatment in an open-label design. This on-going study has a target enrollment of approximately 100 patients with mild-to-moderate Alzheimer's disease. The study is approximately 20% enrolled.

Finance Update – \$2.9 million of new NIH research grant awards announced in 2020

Cassava Sciences' scientific programs continue to be supported by research grant awards from the National Institutes of Health (NIH), the nation's foremost medical research agency. In April 2020, the Company announced it had been awarded a new \$2,500,000 research grant from NIH. In March 2020, NIH awarded the Company supplemental research funding in the amount of \$374,000. The NIH's *National Institute on Aging* awarded the Company these research grant award following an in-depth, peer review of PTI-125. Peer review, one of the gold standards of science, is a process where independent, outside scientists evaluate the merits of new research.

Operations Update – No major disruptions to date

In these times of pandemic, Cassava Sciences' top priorities are to protect the health, well-being, and safety of its employees and partners, while still focusing on the key drivers of its business. The company believes it remains on-track to achieve its major strategic objectives for 2020. The Company has not experienced major disruptions across its drug manufacturing operations or supply of materials. Its broad spectrum of technical consultants, scientific advisors and service providers continue to provide timely services. The Company has adapted flexible business practices, such as remote work arrangements and temporary travel restrictions, to insure it continues to operate safely and cautiously while meeting its public health responsibilities.

Cassava Sciences recognizes the on-going pandemic has created an unstable and uncertain situation in the national economy. The Company continues to closely monitor the latest information to make timely, informed business decisions and public disclosures regarding the potential impact of pandemic on its operations. However, the scope of this pandemic is unprecedented and its long-term impact on the Company's operations and financial condition cannot be reasonably estimated at this time.

Financial Highlights for First Quarter 2020

- At March 31, 2020, cash and cash equivalents were \$25.6 million, compared to \$23.1 million at December 31, 2019, with no debt.
- Cash balance included \$3.6 million in proceeds from exercise of warrants in the first quarter of 2020. Approximately 1.6 million warrants remain outstanding, each with an exercise price of \$1.25 per share. All warrants expire February 2021.
- Net cash used in operations during the quarter ended March 31, 2020 was \$1.2 million, net of reimbursements received from NIH grant awards.
- Net cash use for full year 2020 is expected to be approximately \$5.0 million, consistent with previous financial guidance.
- Research grant funding reimbursements of \$1.3 million were received from NIH and recorded as a reduction in research and development (R&D) expenses. This compared to \$0.8 million of NIH grant receipts received for the same period in 2019.

- R&D expenses were \$0.5 million. This compared to \$0.6 million for the same period in 2019, representing a 5% decrease. While Phase 2 clinical program expenses were higher in Q1 2020, overall expense was reduced by greater NIH reimbursement.
- General and administrative (G&A) expenses were \$0.8 million. This compared to \$0.9 million for the same period in 2019, representing a 11% decrease. The decrease was due primarily to lower stock-based compensation expense compared to 2019.

About PTI-125

Cassava Sciences' lead therapeutic product candidate is for the treatment of Alzheimer's disease. PTI-125 is a proprietary, small molecule (oral) drug 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 is published in peer-reviewed scientific journals, including *Journal of Neuroscience*, *Neurobiology of Aging*, *Journal of Biological Chemistry* and *Journal of Prevention of Alzheimer's Disease*. The Company is also developing an investigational diagnostic, called SavaDx, to detect Alzheimer's disease with a simple blood test.

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. In the U.S. alone, approximately 5.8 million people are currently living with Alzheimer's disease, and approximately 487,000 people age 65 or older developed Alzheimer's in 2019.¹ The number of people living with Alzheimer's disease is expected to grow dramatically in the years ahead, resulting in a growing social and economic burden.²

About Cassava Sciences, Inc.

The mission of Cassava Sciences, Inc. is to detect and treat neurodegenerative diseases, such as Alzheimer's disease. 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. 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.

For more information, please visit: <https://www.CassavaSciences.com>

^{1, 2} Source: Alzheimer's Association. *2019 Alzheimer's Disease Facts and Figures*. Available online at: <https://www.alz.org/media/documents/alzheimers-facts-and-figures-2019-r.pdf>

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Cautionary Note Regarding Forward-Looking Statements: *This press release contains "forward-looking statements" for purposes of the Private Securities Litigation Reform Act of 1995 (the Act). Cassava Sciences claims the protection of the Safe Harbor for forward-looking statements contained in the Act. All statements other than statements of historical fact contained in this press release including, but not limited to, expected cash use in future periods; statements regarding the status of clinical studies with PTI-125; the timing of announcing clinical results of our Phase 2b study; the interpretation of results of clinical studies, potential health benefits, if any, of changes in levels of biomarkers; verbal commentaries made by Cassava Sciences' employees; and potential benefits, if any, of the Company's product candidates for Alzheimer's disease are all forward-looking statements. Such statements are based largely on the Company's current expectations and projections about future events. Such statements speak only as of the date of this press 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 Cassava Sciences' Annual Report on Form 10-K for the year ended December 31, 2019 and future reports to be filed with the SEC. In light of these risks, uncertainties and assumptions, the forward-looking statements and events discussed in this press 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, the Company disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this press 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.*

CASSAVA SCIENCES, INC.
 CONDENSED STATEMENTS OF OPERATIONS
 (unaudited, in thousands, except per share amounts)

	Three months ended March 31,	
	2020	2019
Operating expenses		
Research and development, net of grant reimbursement	\$ 544	\$ 574
General and administrative	778	877
Gain on sale of property and equipment	(100)	—
Total operating expenses	<u>1,222</u>	<u>1,451</u>
Operating loss	(1,222)	(1,451)
Interest income	72	92
Net loss	<u>\$ (1,150)</u>	<u>\$ (1,359)</u>
Net loss per share, basic and diluted	<u>\$ (0.05)</u>	<u>\$ (0.08)</u>
Weighted-average shares used in computing net loss per share, basic and diluted	<u>24,481</u>	<u>17,162</u>

CONDENSED BALANCE SHEETS
 (unaudited, in thousands)

	March 31, 2020	December 31, 2019
Assets		
Current assets		
Cash and cash equivalents	\$ 25,600	\$ 23,081
Other current assets	277	268
Total current assets	<u>25,877</u>	<u>23,349</u>
Property and equipment, net	33	47
Operating lease right-of-use assets	67	90
Total assets	<u>\$ 25,977</u>	<u>\$ 23,486</u>
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	\$ 608	\$ 453
Accrued development expense	387	777
Accrued compensation and benefits	72	58
Operating lease liabilities, current	67	90
Other accrued liabilities	11	9
Total current liabilities	<u>1,145</u>	<u>1,387</u>
Total liabilities	<u>1,145</u>	<u>1,387</u>
Stockholders' equity		
Common Stock and additional paid-in-capital	194,569	190,686
Accumulated deficit	(169,737)	(168,587)
Total stockholders' equity	<u>24,832</u>	<u>22,099</u>
Total liabilities and stockholders' equity	<u>\$ 25,977</u>	<u>\$ 23,486</u>