

**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 12, 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 August 12, 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 August 12, 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: August 12, 2020

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

Cassava Sciences Announces Second Quarter 2020 Financial Results and Mid-year Business Review

- Final Clinical Results of a Phase 2b Study in Alzheimer's Disease with Lead Drug Candidate, PTI-125, Expected to be Announced September 2020 -

- SavaDx Demonstrates Direct Evidence of Target Engagement & Treatment Effects -

- Open-label Study Of PTI-125 Reaches >50% Enrollment -

AUSTIN, Texas, Aug. 12, 2020 (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, 2020 and provided a mid-year business review.

Financial Update

For the second quarter ended June 30, 2020, net loss was \$1.1 million, or \$0.05 per share, compared to a net loss of \$1.1 million, or \$0.06 per share, for the same period in 2019. Net cash used in operations was \$2.0 million during the first six months of 2020. Net cash use in full-year 2020 is still expected to be approximately \$5.0 million. The Company's cash and cash equivalents were \$25.3 million as of June 30, 2020, with no debt.

Update on Market Awareness

In June 2020, Cassava Sciences' stock was added to the Russell 2000[®] and Russell 3000[®] Indexes. These indexes are intended to provide institutional investors and other market participants with exposure to the performance of certain segments of the U.S. stock market.

Update on Phase 2b Study With PTI-125

In Q2 2020, Cassava Sciences completed a randomized, placebo-controlled, double-blind study of its lead drug candidate, PTI-125, in patients with mild-to-moderate Alzheimer's disease (N=64). This study was substantially funded by a research grant award from the National Institutes of Health (NIH).

As previously reported, the drug was safe and well-tolerated. An outside lab (with whom the Company had no prior work experience) generated an initial bioanalysis in which the study missed its pre-specified primary outcome, defined as a drug effect on cerebrospinal fluid (CSF) levels of tau protein and other biomarker assessments. The data set from that initial bioanalysis showed unnaturally high variability and other problems, such as no correlation among changes in levels of biomarkers over 28 days, even in the placebo group, and different biomarkers of disease moving in opposite directions in the same patient. Overall, we believe data from the initial bioanalysis can be interpreted as anomalous and highly improbable.

We are now conducting a comprehensive analysis of clinical results of our Phase 2b study, including evaluating the effects of PTI-125 on cognition. Data collected from this analysis will constitute final clinical results of our Phase 2b study of PTI-125 in Alzheimer's disease. We anticipate announcing such results in September 2020.

"Our Phase 2b study was well-conducted, but we believe the analysis of results is a re-do," said Remi Barbier, President & CEO. "This effort is on-going. I believe the outcome of our Phase 2b study will be better understood after final clinical results are announced in September 2020."

Update on Open-label Study with PTI-125 – Initiated in March, Now Over 50% 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 has exceeded 50% enrollment.

Update on SavaDx

On July 15, 2020, scientists for Cassava Sciences were invited by a scientific conference to give a keynote presentation on SavaDx, an investigational diagnostic to detect Alzheimer's disease with a simple blood test. In addition to showing that SavaDx could distinguish and stratify patients with Alzheimer's disease, this presentation provided direct evidence for target engagement and for the treatment effects of PTI-125. Target engagement is a crucial step in drug research because it shows that our small molecule drug candidate binds to its intended site of action in cells and confirms that treatment effects are caused by the drug hitting its target. The science presentation is available on-line at: <https://www.cassavasciences.com/static-files/7aa9f438-9c73-4380-a804-86a509d5de26>

Financial Highlights for Second Quarter 2020

- At June 30, 2020, cash and cash equivalents were \$25.3 million, compared to \$23.1 million at December 31, 2019, with no debt.
- Cash balance included \$3.8 million in proceeds from exercise of warrants in the first six months of 2020. Approximately 1.4 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 six months ended June 30, 2020 was \$2.0 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 \$1.1 million were received from NIH and recorded as a reduction in research and development (R&D) expenses in the second quarter of 2020. This compared to \$1.4 million of NIH grant receipts received for the same period in 2019.
- R&D expenses were \$0.6 million compared to \$0.3 million for the same period in 2019. The decrease was due primarily to lower NIH reimbursement compared to the prior year.
- General and administrative (G&A) expenses were \$0.8 million, consistent with the same period in 2019.

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 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*.

About SavaDx

SavaDx is Cassava Sciences' investigational diagnostic to detect Alzheimer's disease. The goal of SavaDx is to make the detection of Alzheimer's as simple as getting a blood test, possibly years before the appearance of any overt clinical symptoms. This clinical-stage program is substantially funded by a research grant award from the National Institutes of Health (NIH).

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. 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.

^{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>

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

For More Information

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The content of this presentation is solely the responsibility of Cassava Sciences and does not necessarily represent the official views of the National Institutes of Health (NIH).

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, including biomarker and cognition data; the interpretation of results of our Phase 2 clinical studies; potential health benefits, if any, of changes in levels of biomarkers; variability in levels of biomarkers of disease; expected pace of patient enrollment in our open-label study of PTI-125; the timing of validation studies with SavaDx; verbal commentaries made by Cassava Sciences' employees; and potential benefits, if any, of the Company's product candidates for Alzheimer's disease are 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.

– Financial Tables Follow –

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

	Three months ended June 30,		Six months ended June 30,	
	2020	2019	2020	2019
Operating expenses				
Research and development, net of grant reimbursement	\$ 591	\$ 308	\$ 1,135	\$ 882
General and administrative	818	845	1,596	1,722
Gain on sale of property and equipment	(246)	—	(346)	—
Total operating expenses	<u>1,163</u>	<u>1,153</u>	<u>2,385</u>	<u>2,604</u>
Operating loss	(1,163)	(1,153)	(2,385)	(2,604)
Interest income	27	94	99	186
Net loss	<u>\$ (1,136)</u>	<u>\$ (1,059)</u>	<u>\$ (2,286)</u>	<u>\$ (2,418)</u>
Net loss per share, basic and diluted	<u>\$ (0.05)</u>	<u>\$ (0.06)</u>	<u>\$ (0.09)</u>	<u>\$ (0.14)</u>
Weighted-average shares used in computing net loss per share, basic and diluted	<u>24,779</u>	<u>17,162</u>	<u>24,630</u>	<u>17,162</u>

CONDENSED BALANCE SHEETS
(unaudited, in thousands)

	June 30, 2020	December 31, 2019
Assets		
Current assets		
Cash and cash equivalents	\$ 25,254	\$ 23,081
Other current assets	186	268
Total current assets	<u>25,440</u>	<u>23,349</u>
Property and equipment, net	13	47
Operating lease right-of-use assets	45	90
Total assets	<u>\$ 25,498</u>	<u>\$ 23,486</u>
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	\$ 416	\$ 453
Accrued development expense	755	777
Accrued compensation and benefits	84	58
Operating lease liabilities, current	45	90
Other accrued liabilities	14	9
Total current liabilities	<u>1,314</u>	<u>1,387</u>
Total liabilities	<u>1,314</u>	<u>1,387</u>
Stockholders' equity		
Common Stock and additional paid-in-capital	195,057	190,686
Accumulated deficit	<u>(170,873)</u>	<u>(168,587)</u>

Total stockholders' equity	<u>24,184</u>	<u>22,099</u>
Total liabilities and stockholders' equity	<u>\$ 25,498</u>	<u>\$ 23,486</u>