

**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 26, 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 March 26, 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 March 26, 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: March 26, 2020

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

Cassava Sciences Announces Full-year 2019 Financial Results and Anticipated Key Milestones for 2020

-Top-Line Results of a Phase 2b in Alzheimer's On Track for Mid-Year 2020 -
 - Cash Balance Exceeds \$26 Million at January 31, 2020 -
 - \$5 Million Net Cash Use Expected in 2020 -

AUSTIN, Texas, March 26, 2020 (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, 2019 and provided corporate milestones for 2020.

Net loss in full-year 2019 was \$4.6 million, or \$0.27 per share, compared to a net loss in 2018 of \$6.6 million, or \$0.61 per share. Net cash used in operations in full-year 2019 was \$2.5 million. Cash and cash equivalents were \$23.1 million as of December 31, 2019. Subsequently, Cassava Sciences received \$3.6 million from the exercise of 2.9 million common stock warrants, increasing its net cash balance to more than \$26 million at January 31, 2020. Net cash use in full-year 2020 is expected to be approximately \$5 million.

"As we enter 2020, our financial considerations once again reflect a thoughtful balance between maintaining fiscal discipline and advancing our product candidates aimed at Alzheimer's disease," said Eric Schoen, Chief Financial Officer.

"Our foundational strategy is to focus on the internal development of a first-in-class program aimed at Alzheimer's disease and other neurodegenerative conditions," said Remi Barbier, President & CEO. "This emphasis on breakthrough innovations in neuroscience drives our actions and gives us the confidence to achieve our anticipated milestones for 2020 and beyond."

Anticipated Corporate Milestones for 2020

Cassava Sciences' scientific approach for the treatment of Alzheimer's disease is to improve both neurodegeneration and neuroinflammation with its lead investigational drug, PTI-125. The Company believes the ability to improve multiple vital functions in the brain represents a new, different and crucial approach to address Alzheimer's disease. The Company is also developing SavaDx (formerly known as PTI-125Dx), an investigational diagnostic aimed at detecting Alzheimer's disease with a simple blood test. The Company's anticipated key milestone achievements for 2020 include:

- Completion of patient enrollment for a Phase 2b study of PTI-125 in Alzheimer's disease.
Status: completed and announced Q1 2020.
- Biomarker analysis, statistical analysis and data analytics for the Phase 2b study.
Status: on-going.
- Top-line results for the Phase 2b study.
Status: announcement expected approximately mid-2020.
- Initiation of an open-label extension study of PTI-125 in Alzheimer's disease.
Status: completed and announced Q1 2020.
- Publication of prior clinical results with PTI-125 in a peer-reviewed journal.
Status: completed and announced Q1 2020.
- Development of proprietary antibodies and other detection systems for SavaDx.
Status: announcement expected 2nd half 2020.
- Initiation of a validation/disease specificity study of SavaDx.
Status: announcement expected 2nd half 2020.
- Technical update of SavaDx at a major scientific conference.
Status: announcement expected approximately mid-2020.

Business Highlights 2019 to Date

Phase 2a Study of PTI-125

- In September 2019, Cassava Sciences reported positive clinical results in Alzheimer's disease with its lead drug candidate, PTI-125. In a first-in-patient, Phase 2a study funded by the National Institutes of Health (NIH), treatment with PTI-125 for 28 days significantly reduced biomarkers of disease pathology, neuroinflammation and neurodegeneration, consistent with years of basic research and pre-clinical data. Key biomarker results of the Phase 2a study include: total tau (T-tau) decreased 20% (p<0.001); phosphorylated tau (P-tau) decreased 34% (p<0.0001); neurofilament light chain (NfL), a marker for degeneration of axons, decreased 22% (p<0.0001); neurogranin, a marker for degeneration of dendrites, decreased 32% (p<0.0001); and neuroinflammatory marker YKL-40, an indicator of microglial activation, decreased 9%

($p < 0.0001$). All evaluable patients showed a biomarker response to PTI-125. PTI-125 was safe and well-tolerated.

- In December 2019, results of the Phase 2a study were presented as a late-breaking oral presentation at the *CTAD Alzheimer's Congress*, a major international conference for researchers in the field of Alzheimer's disease.
- In February 2020, Phase 2a study results were published in *The Journal of Prevention of Alzheimer's Disease*, a peer-reviewed clinical journal.

Phase 2b Study of PTI-125

- In September 2019, Cassava Sciences announced the initiation of a Phase 2b confirmatory clinical study in Alzheimer's patients, with funding provided by NIH. This blinded, randomized, placebo-controlled, multi-center, multi-dose research study is designed to evaluate the safety and tolerability of PTI-125, and its effects on biomarkers of disease. Study participants received PTI-125 100 mg, 50 mg or matching placebo, twice-daily, for 28 continuous days. The study was conducted in 9 U.S. clinical sites. The primary endpoint is improvements in levels of biomarkers of disease from baseline to Day 28.
- In January 2020, Cassava Sciences announced the completion of patient enrollment for this Phase 2b study (N=64 patients with mild-to-moderate Alzheimer's disease).
- In February 2020, study participants received their final dose of treatment. In March 2020, study participants successfully underwent final, routine follow-ups. No issues were noted. Cerebrospinal fluid and plasma samples from study participants are being shipped to independent, third party labs for biomarker analysis. Biomarker analysis will be conducted under blinded conditions to avoid bias, meaning no one will know whether a test sample came from a subject who was on drug or placebo until the study is unblinded. Biomarker analysis, statistical analysis, data analytics and interpretation of results are expected to be conducted through approximately May 2020.
- Cassava Sciences expects to announce top-line results for its Phase 2b study approximately mid-year 2020.

Open-Label Study of PTI-125

- In March 2020, Cassava Sciences announced the initiation of an open-label, multi-center, extension study that will monitor the long-term safety and tolerability of PTI-125 at 100 mg twice-daily for 12 months. The target enrollment is approximately 100 patients with mild-to-moderate Alzheimer's disease, including patients from prior studies of PTI-125. Study sites may initially slow the pace of patient enrollment to minimize any risks of exposing elderly patients to infectious disease during office visits.

SavaDx – detecting Alzheimer's disease with a simple blood test

- Cassava Sciences is continuing the development of proprietary antibodies and other detection systems for use with SavaDx. Assuming technical success with on-going efforts, the Company expects to initiate a validation/disease specificity study with SavaDx in the second half of 2020.
- Cassava Sciences expects to present a technical update for SavaDx at a major scientific conference in 2020, assuming no health or transportation restrictions.

Financial Highlights

- At December 31, 2019, cash and cash equivalents were \$23.1 million, compared to \$19.8 million at December 31, 2018, with no debt. The 2019 year-end cash balance included proceeds of \$5.9 million from the exercise of 4.6 million common stock warrants.
- In 2020, the Company received an additional \$3.6 million in proceeds from exercise of warrants, bringing its cash balance in excess of \$26.0 million at January 31, 2020.
- The Company has approximately 24.7 million common shares outstanding as of March 26, 2020. Approximately 1.6 million warrants remain outstanding at March 26, 2020. Each warrant has an exercise price of \$1.25 per share. All warrants expire February 2021.
- Net cash used in operations during the year ended December 31, 2019 was \$2.5 million, net of reimbursements received from NIH grant awards. Net cash use for full year 2020 is expected to be approximately \$5.0 million, depending on the timing of clinical studies and other events.
- Research and development expenses for the year ended December 31, 2019 were \$1.6 million compared to \$3.0 million for the same period in 2018, or a 47% decrease. While Phase 2 clinical program costs were higher in 2019, overall expense was reduced by greater NIH reimbursement as well as lower non-cash stock related compensation compared to the prior year.

- We received reimbursements of \$4.7 million in 2019 from research grant awards from NIH that we recorded as a reduction of research and development expense compared to \$3.0 million in 2018.
- Research and development expenses included non-cash stock related compensation costs of \$0.5 million for the year ended December 31, 2019 and \$1.0 million for the same period in 2018.
- General and administrative expenses for the year ended December 31, 2019 were \$3.4 million compared to \$3.7 million for the same period in 2018, or an 8% decrease. This was due primarily to a decrease in non-cash stock-based compensation expense. General and administrative expenses included non-cash stock-based compensation costs of \$0.8 million in the year ended December 31, 2019 compared to \$1.4 million for the same period in 2018.

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. PTI-125 seeks to simultaneously improve *both* 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 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 Contact:

Eric Schoen, Chief Financial Officer
Cassava Sciences, Inc.
eschoen@CassavaSciences.com
(512) 501-2450

For Media Inquiries Contact:

Kirsten Thomas, SVP
The Ruth Group
kthomas@TheRuthGroup.com
(508) 280-6592

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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 timing of validation studies with SavaDx; 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; potential benefits, if any, of the Company's product candidates for Alzheimer's disease; and the timing of a scientific update for SavaDx, 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 international outbreak of an infectious disease, 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, 2018 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.*

^{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>

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

	Three months ended December 31,		Twelve months ended December 31,	
	2019	2018	2019	2018
Operating expenses				
Research and development, net of grant reimbursement	\$ 738	\$ 2	\$ 1,568	\$ 2,969
General and administrative	838	748	3,391	3,693
Total operating expenses	<u>1,576</u>	<u>750</u>	<u>4,959</u>	<u>6,662</u>
Operating loss	(1,576)	(750)	(4,959)	(6,662)
Interest income	60	\$ 73	328	105
Net loss	<u>\$ (1,516)</u>	<u>\$ (677)</u>	<u>\$ (4,631)</u>	<u>\$ (6,557)</u>
Net loss per share, basic and diluted	<u>\$ (0.08)</u>	<u>\$ (0.04)</u>	<u>\$ (0.27)</u>	<u>\$ (0.61)</u>
Weighted-average shares used in computing net loss per share, basic and diluted	<u>18,153</u>	<u>17,162</u>	<u>17,412</u>	<u>10,682</u>

CONDENSED BALANCE SHEETS
(unaudited, in thousands)

	December 31,	
	2019	2018
Assets		
Current assets		
Cash and cash equivalents	\$ 23,081	\$ 19,807
Other current assets	268	233
Total current assets	<u>23,349</u>	<u>20,040</u>
Property and equipment, net	47	87
Operating lease right-of-use assets	90	—
Other assets	—	12
Total assets	<u>\$ 23,486</u>	<u>\$ 20,139</u>
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	\$ 453	\$ 294
Accrued development expense	777	156
Accrued compensation and benefits	58	61
Operating lease liabilities, current	90	—
Other accrued liabilities	9	—
Total current liabilities	<u>1,387</u>	<u>511</u>
Total liabilities	<u>1,387</u>	<u>511</u>
Stockholders' equity		
Common stock and additional paid-in-capital	190,686	183,584
Accumulated deficit	<u>(168,587)</u>	<u>(163,956)</u>
Total stockholders' equity	<u>22,099</u>	<u>19,628</u>
Total liabilities and stockholders' equity	<u>\$ 23,486</u>	<u>\$ 20,139</u>