
**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): October 29, 2019

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 October 29, 2019, 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 October 29, 2019](#)

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: October 29, 2019

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

Cassava Sciences Announces Recent Clinical Highlights and Third Quarter 2019 Financial Results

- Phase 2a Study Showed Statistically Significant Decreases ($p < 0.001$) in Clinical Biomarkers of Alzheimer's Disease -

- Phase 2b Study in Patients with Alzheimer's Disease Initiated in Multiple Clinical Sites -

- Clinical Results in Alzheimer's Disease Selected as Late-Breaking News at CTAD 2019 -

AUSTIN, Texas, Oct. 29, 2019 (GLOBE NEWSWIRE) -- Cassava Sciences, Inc. (Nasdaq: SAVA), a clinical-stage biopharmaceutical company focused on Alzheimer's disease, today announced recent clinical highlights and reported financial results for the third quarter ended September 30, 2019.

Net loss for the third quarter 2019 was \$0.7 million, or \$0.04 per share, as compared to a net loss of \$1.3 million, or \$0.11 per share, for the same period in 2018. Net cash used was \$0.7 million during the third quarter of 2019. Cassava Sciences ended the third quarter 2019 with \$17.8 million of cash and equivalents, and no debt.

"Cassava Sciences had a productive quarter with our clinical research program in Alzheimer's," said Remi Barbier, President & CEO. "We are encouraged by the robust biomarker data from a Phase 2a study in Alzheimer's with lead drug candidate, PTI-125. PTI-125 is a twice-daily oral drug that targets both the neurodegeneration and the inflammatory components of Alzheimer's. We're seeing the research community shift from an amyloid-centric view, with all its noise and confusion, to one that targets neurodegeneration and neuroinflammation. PTI-125's mechanism of action supports this evolution in Alzheimer's drug development. That gets us excited."

Clinical Highlights

- In September, 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 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 neurodegeneration, decreased 22% ($p < 0.0001$); neurogranin, a marker for cognitive decline, decreased 32% ($p < 0.0001$); and neuroinflammatory marker YKL-40, an indicator of microglial activation, decreased 9% ($p < 0.0001$). We believe these and other data provide evidence of target engagement in patients with Alzheimer's disease.
- All evaluable patients showed a biomarker response to PTI-125. The drug was well tolerated, with no observable drug-related adverse events.
- As a result of positive clinical results from its Phase 2a study of PTI-125, Cassava Sciences recently initiated a Phase 2b study. This Phase 2b is designed to evaluate safety, tolerability and drug effects of PTI-125 in Alzheimer's disease. This blinded, randomized, placebo-controlled, oral dose study will enroll approximately 60 patients with mild-to-moderate Alzheimer's disease. Patients will be dosed with PTI-125 100 mg, 50 mg or matching placebo, twice daily for 28 continuous days. The primary endpoint is improvement in biomarkers of neurodegeneration and neuroinflammation from baseline to Day 28. The study is supported by a clinical research grant award from NIH.
- In October, Cassava Sciences announced that results of its Phase 2a study of PTI-125 were selected for a late-breaking oral presentation by the 12th *International Conference on Clinical Trials on Alzheimer's Disease (CTAD)*, which takes place December 4-7th, 2019.

Financial Highlights

- At September 30, 2019, cash and cash equivalents were \$17.8 million, compared to \$19.8 million at December 31, 2018, with no debt.
- Cash used was \$0.7 million during the third quarter of 2019, net of reimbursements received from NIH.
- Net cash use for full year 2019 is expected to be \$3.0 - \$5.0 million, consistent with previous financial guidance.
- Net loss for the third quarter 2019 was \$0.7 million, or \$0.04 per share, as compared to a net loss of \$1.3 million, or \$0.11 per share, for the same period in 2018.
- Research grant funding reimbursements of \$1.5 million from NIH were recorded as a reduction in research and development expenses (R&D). This compared to \$1.1 million of NIH grant receipts received for the same period in the prior year.
- R&D expenses, after deducting the grant reimbursement, were negative \$0.1 million. This compared to \$0.4 million for the same period in the prior year, representing a 112% decrease. The decrease was due primarily to an increase in NIH grant funding in 2019 compared to the prior year, combined with a decrease in non-cash stock-based compensation expense.
- General and administrative expenses were \$0.8 million, consistent with the same period in 2018.

About PTI-125 and Cassava Sciences' Scientific Approach

The target of PTI-125 is an altered form of filamin A (FLNA), a scaffolding protein. Published studies have shown that altered FLNA in the brain disrupts the normal function of neurons, leading to Alzheimer's pathology, neurodegeneration and neuroinflammation. Cassava Sciences' lead drug candidate, PTI-125, is a small molecule that restores the normal shape and function of FLNA in the brain. This action improves the function of certain receptors in the brain and exerts powerful anti-neuroinflammatory effects.

Cassava Sciences is also developing an investigational diagnostic to detect Alzheimer's disease with a simple blood test. This program, called PTI-125Dx, also receives significant scientific and financial support from NIH.

The underlying science for Cassava Sciences' programs in neurodegeneration is published in several prestigious peer-reviewed technical journals, including *Journal of Neuroscience*, *Neurobiology of Aging*, and *Journal of Biological Chemistry*. As previously announced, NIH has awarded Cassava Sciences two research grants following an in-depth, confidential review of its science and technology. These two grant awards represent up to \$6.7 million of non-dilutive financing.

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 will develop Alzheimer's in 2019.¹ The number of people living with Alzheimer's disease is expected to grow dramatically in the years ahead, which may also result in a growing social and economic burden.²

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>

About Cassava Sciences, Inc.

The mission of Cassava Sciences is to detect and treat neurodegenerative diseases, such as Alzheimer's disease. Over the past ten 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 technology, without royalty obligations to any third-party.

For More Information Contact: For Media Inquiries Contact:

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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. Examples of such statements include, but are not limited to, expected cash use in future periods; statements regarding the status of Phase 2 clinical studies; the interpretation of clinical results, including potential health benefits, if any, of changes in levels of biomarkers; comments and commentaries made by its Chief Executive Officer; and other potential benefits, if any, of the Company's product candidates for Alzheimer's disease. The Company cautions that forward-looking statements are inherently uncertain. Such statements are based on current expectations, but actual results may differ materially due to various factors. Such statements involve risks and uncertainties, including, but not limited to, those risks and uncertainties relating to the ability to demonstrate the specificity, safety, efficacy or potential health benefits of our product candidates 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. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. 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. The content of this press release is solely the responsibility of the Company and does not necessarily represent the official views of the National Institutes of Health. 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 September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
Operating expenses				
Research and development, net of grant reimbursement	\$ (52)	\$ 436	\$ 830	\$ 2,967
General and administrative	831	848	2,553	2,945
Total operating expenses	<u>779</u>	<u>1,284</u>	<u>3,383</u>	<u>5,912</u>
Operating loss	(779)	(1,284)	(3,383)	(5,912)
Interest income	82	\$ 17	268	32
Net loss	<u>\$ (697)</u>	<u>\$ (1,267)</u>	<u>\$ (3,115)</u>	<u>\$ (5,880)</u>
Net loss per share, basic and diluted	<u>\$ (0.04)</u>	<u>\$ (0.11)</u>	<u>\$ (0.18)</u>	<u>\$ (0.69)</u>
Weighted-average shares used in computing net loss per share, basic and diluted	<u>17,162</u>	<u>11,959</u>	<u>17,162</u>	<u>8,498</u>

CONDENSED BALANCE SHEETS

(unaudited, in thousands)

	September 30, 2019	December 31, 2018
Assets		
Current assets		
Cash and cash equivalents	\$ 17,804	\$ 19,807
Other current assets	385	233
Total current assets	18,189	20,040
Property and equipment, net	61	87
Operating lease right-of-use assets	113	—
Other assets	12	12
Total assets	<u>\$ 18,375</u>	<u>\$ 20,139</u>
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	\$ 340	\$ 294
Accrued development expense	415	156
Accrued compensation and benefits	55	61
Operating lease liabilities, current	90	—
Other accrued liabilities	7	—
Total current liabilities	907	511
Operating lease liabilities, non-current	23	—
Total liabilities	930	511
Stockholders' equity		
Common Stock and additional paid-in-capital	184,516	183,584
Accumulated deficit	(167,071)	(163,956)
Total stockholders' equity	17,445	19,628
Total liabilities and stockholders' equity	<u>\$ 18,375</u>	<u>\$ 20,139</u>