

**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 14, 2025

Cassava Sciences, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or Other Jurisdiction of Incorporation)

001-41905

(Commission File Number)

91-1911336

(I.R.S. Employer Identification No.)

**6801 N Capital of Texas Highway, Building 1; Suite 300
Austin, Texas 78731**

(Address of Principal Executive Offices) (Zip Code)

(512) 501-2444

(Registrant's telephone number, including area code)

(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 August 14, 2025, 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 Number** **Description**

99.1	Press Release dated August 14, 2025
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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.
a Delaware corporation

Date: August 14, 2025

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

Cassava Reports Q2 2025 Financials Results and Provides Business Update

- Following positive preclinical data, simufilam development to advance with a clinical study expected to begin in H1 2026 for the potential treatment of TSC-related epilepsy
- Recent appointment of experienced neuroscience leaders to guide the clinical development strategy for simufilam
- Advanced settlement negotiations ongoing to resolve certain securities litigation; \$31.25 million estimated loss contingency recorded in Q2 for resolution
- \$112.4 million in cash and cash equivalents at June 30, 2025

AUSTIN, Texas, Aug. 14, 2025 (GLOBE NEWSWIRE) -- Cassava Sciences, Inc. (NASDAQ: SAVA, “Cassava”, the “Company”), a biotechnology company focused on developing novel, investigational treatments for central nervous system (CNS) disorders such as Tuberous Sclerosis Complex (TSC)-related epilepsy, today reported financial results for the second quarter ended June 30, 2025 and provided a business update.

Net loss was \$44.2 million compared to net income of \$6.2 million for the same period in 2024. Net cash used in operations was \$16.3 million during the first half of 2025, consistent with previous guidance. Net cash use in second half 2025 is expected to be \$47 to \$51 million, which includes a \$31.25 million estimated loss contingency related to the potential settlement of certain securities litigation recorded in the second quarter.

“2025 has been transformational for Cassava. We have initiated a new program focused on TSC-related epilepsy, a rare disease for which patients urgently need more treatment options. Two encouraging animal model studies—one conducted at Yale and another with the TSC Alliance—support the exploration of simufilam as a novel, first-in-class approach to this disease,” said **Rick Barry, President and Chief Executive Officer** of Cassava.

Corporate Highlights:

The Company is advancing simufilam as a potential treatment for TSC-related epilepsy, with positive preclinical progress and the appointment of experienced neuroscience leaders.

TSC-related epilepsy (Proof-of-concept study planned for H1 2026)

The program builds on groundbreaking work by Dr. Angélique Bordey, published in *Neuron*¹ and *Science Translational Medicine*² which showed treatment with simufilam alleviated neuronal abnormalities and reduced seizure frequency by 60% compared to vehicle in a mouse model of focal onset seizures.

- **Target indication:** Tuberous sclerosis complex (TSC)-related epilepsy. TSC affects approximately 50,000 people in the US.³
- **Recent Developments:** Simufilam demonstrated positive preclinical results in a well-accepted mouse model of TSC-related epilepsy. Simufilam attenuated the progression of seizure activity with a statistically significant correlation between simufilam dose and the number of seizures by the end of the study. Not all parameters measured reached statistical significance. The study, conducted in collaboration with the TSC Alliance and the TSC Preclinical Consortium, provides further support for the potential use of simufilam as a first-in-class treatment for TSC-related epilepsy. The Company intends to present data and analyses in an upcoming scientific conference and publication.
- **Collaboration:** Yale University license agreement (February 2025)
- **Current status:** Preparations are underway to initiate a proof-of-concept study in H1 2026 for TSC-related epilepsy, including conduct of final pre-IND studies and development of the regulatory strategy.

Appointment of Experienced Neuroscience Professionals: Dr. Joseph Hulihan appointed as Chief Medical Officer (CMO), bringing expertise in neurotherapeutics and epilepsy to Cassava. Dr. Hulihan will devote approximately half of his professional time to Cassava, advising on the clinical development of simufilam for the treatment of TSC-related epilepsy. This follows the appointment of **Angélique Bordey, PhD**, who joined Cassava as Senior Vice President (SVP), Neuroscience, while continuing her tenured academic position at Yale School of Medicine on a part time basis, as well as **Jack Moore, PhD**, who joined the Company as SVP, Clinical Development.

Financial Results for Second Quarter 2025

- **Cash and cash equivalents** were \$112.4 million, with no debt, as of June 30, 2025. This compares to cash and cash equivalents of \$128.6 million as of December 31, 2024.
- **Total shares outstanding** as of August 12, 2025 were 48.3 million.
- **Net loss** for the quarter ended June 30, 2025 was \$44.2 million or \$0.92 per basic and diluted share. This compares to a net income of \$6.2 million or \$0.13 per basic and diluted share, for the same period in 2024. Net loss in 2025 included a \$31.25 million estimated loss contingency recorded related to the potential settlement of certain securities litigation. Net loss in 2025 also included \$4.6 million is stock-based compensation expense, a non cash item, compared to \$2.6 million in the same period in 2024. Net income in 2024 resulted from the change in fair value of warrant liabilities, a non-cash item.

- **Net cash used in operations** was \$16.3 million during the first half of 2025, consistent with previous guidance.
- **Net cash used in operations for second half 2025** is expected to be \$47 to \$51 million, which includes a \$31.25 million estimated loss contingency related to the potential settlement of certain securities litigation recorded in the second quarter. The Company estimates cash at year-end 2025 in a range from \$61 to \$65 million.
- **Research and development (R&D) expenses** for the quarter ended June 30, 2025 were \$5.1 million. This compared to \$15.2 million for the same period in 2024. This 66% decrease was due primarily to the phase out of the Alzheimer's disease development program, which was completed in the second quarter of 2025. R&D expense for the quarter ended June 30, 2025 included \$1.2 million is stock-based compensation expense, a non cash item, compared to \$1.0 million in the same period in 2024.
- **General and administrative (G&A) expenses** for the quarter ended June 30, 2025 were \$40.3 million. This compared to \$46.2 million for the same period in 2024. The 13% decrease was due primarily to a \$40.0 million SEC-related loss contingency recorded in 2024, compared to a \$31.25 million securities litigation estimated loss contingency recorded in 2025. General and administrative expense in the second quarter of 2025 included approximately \$3.6 million of legal related costs as well as \$3.4 million in non-cash stock-based compensation expense. Non-cash stock-based compensation totaled \$1.6 million in the same period in 2024.

About TSC and TSC-related Epilepsy

TSC is a rare genetic disorder resulting from a mutation in the *TSC1* or *TSC2* gene in the mechanistic target of rapamycin (mTOR) pathway and involves multiple organs including the brain, heart, kidney, eye, skin, and lung^{2,4}. Clinical findings range from minor skin abnormalities to more severe manifestations such as focal brain malformations, epileptic seizures, and TSC-Associated Neuropsychiatric Disorders (TAND)⁵. Symptoms typically change over time, making disease management challenging. Lifelong care and advocacy are important, especially for children with TSC⁶.

TSC affects approximately 50,000 people in the US³. Epilepsy is the most common medical condition in people with TSC⁷, with median seizure onset occurring in the first few months of life⁸. Between 80% and 90% of TSC patients experience seizures¹. Two-thirds of TSC patients have refractory epilepsy and experience life-long seizures¹. Current therapies, including antiepileptic drugs and mTOR inhibitors, are not fully effective, and are associated with serious adverse events².

About Cassava Sciences, Inc.

Cassava Sciences, Inc. (NASDAQ: SAVA), is a biotechnology company focused on developing novel, investigational treatments, including simufilam, for central nervous system disorders, such as tuberous sclerosis complex (TSC)-related epilepsy, and potentially other indications. Simufilam is a proprietary, investigational oral small molecule believed to modulate activity of the filamin A protein, which regulates diverse aspects of neuronal development¹. The Company is based in Austin, Texas.

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

References:

1. Zhang L, Bartley CM, Gong X, Hsieh, LS.; LinTV, Feliciano DM, Bordey A. "MEK-ERK1/2-Dependent FLNA Overexpression Promotes Abnormal Dendritic Patterning in Tuberous Sclerosis Independent of mTOR. *Neuron* (2014) 84 (1), 78-91. DOI: 10.1016/j.neuron.2014.09.009
2. Zhang L, Huang T, Teaw S, Nguyen LH, Hsieh LS, Wong X, Burns LH, Bordey A. Filamin A inhibition reduces seizure activity in a mouse model of focal cortical malformations.. *Science Translational Medicine*. (2020) 12(531):eaay0289. DOI: 10.1126/scitranslmed.aay0289
3. <https://www.tscalliance.org/understanding-tsc/what-is-tsc/>,
4. Crino P, Nathanson K, Petri Henske, E. *The Tuberous Sclerosis Complex*. *N Engl J Med*. (2006) 355 (13):1345-56. doi: 10.1056/NEJMra055323
5. [https://www.massgeneral.org/neurology/tsc/patient-education/about-tsc#:~:text=Tuberous%20sclerosis%20complex%20\(TSC\)%20is,or%20all%20of%20these%20organs](https://www.massgeneral.org/neurology/tsc/patient-education/about-tsc#:~:text=Tuberous%20sclerosis%20complex%20(TSC)%20is,or%20all%20of%20these%20organs)
6. <https://www.myepilepsyteam.com/resources/tuberous-sclerosis-complex-tsc-your-guide>
7. <https://www.massgeneral.org/neurology/tsc/patient-education/how-tsc-affects-brain-seizures>
8. Conte E, Boccanegra B, Dinoi G, Pusch M, De Luca A, Liantonio A, Imbrici P. *Therapeutic Approaches to Tuberous Sclerosis Complex: From Available Therapies to Promising Drug Targets*. *Biomolecules*. (2024) 14(9):1190. DOI: 10.3390/biom14091190.

For More Information Contact:

Investors

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Company

Eric Schoen, Chief Financial Officer

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Cautionary Note Regarding Forward-Looking Statements:

This news release contains forward-looking statements that may include but are not limited to statements regarding: the potential resolution of the certain securities litigation and our loss contingency estimates related thereto, our plans to conduct preclinical studies of simufilam relating to seizures in TSC, the timing and plans to conduct clinical studies with simufilam in H1 2026, the potential for simufilam as a treatment for TSC-related epilepsy and other potential indications, plans to present preclinical results in an upcoming scientific conference or publication, the timing of anticipated milestones, expected cash balances and cash use in future periods. These statements may be identified by words such as “anticipate”, “before”, “believe”, “could”, “expect”, “forecast”, “intend”, “may”, “pending”, “plan”, “possible”, “potential”, “prepares for”, “will”, and other words and terms of similar meaning.

Such statements are based 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 advance preclinical studies related to TSC-related epilepsy, and other potential indications, the ability to successfully carry out the Company’s obligations under the Yale License Agreement, the ability to initiate an initial proof-of-concept study of simufilam in TSC-related epilepsy, and other risks inherent in drug discovery and development or specific to Cassava Sciences, Inc., as described in the section entitled “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2024, and subsequent 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. 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.

All of our pharmaceutical assets under development are investigational product candidates. These have not been approved for use in any medical indication by any regulatory authority in any jurisdiction and their safety, efficacy or other desirable attributes, if any, have not been established in any patient population. Consequently, none of our product candidates is approved or available for sale anywhere in the world.

Our clinical results from earlier-stage clinical trials or preclinical studies may not be indicative of future 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.

We are in the business of new drug discovery and development. Our research and development activities are long, complex, costly and involve a high degree of risk. Holders of our common stock should carefully read our Annual Report on Form 10-K and subsequent Quarterly Reports on Form 10-Q in their entirety, including the risk factors therein. Because risk is fundamental to the process of drug discovery and development, you are cautioned to not invest in our publicly traded securities unless you are prepared to sustain a total loss of the money you have invested.

– Financial Tables Follow –

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

	Three months ended June 30,		Six months ended June 30,	
	2025	2024	2025	2024
Operating expenses				
Research and development	\$ 5,116	\$ 15,198	\$ 18,782	\$ 31,431
General and administrative	40,276	46,204	51,196	49,905
Total operating expenses	<u>45,392</u>	<u>61,402</u>	<u>69,978</u>	<u>81,336</u>
Operating loss	(45,392)	(61,402)	(69,978)	(81,336)
Interest income	1,214	2,316	2,479	4,092
Other income (loss), net	(46)	99	(128)	259
Gain from change in fair value of warrant liabilities	—	65,142	—	108,183
Net income (loss)	<u>\$ (44,224)</u>	<u>\$ 6,155</u>	<u>\$ (67,627)</u>	<u>\$ 31,198</u>
Net income (loss) per share, basic	\$ (0.92)	\$ 0.13	\$ (1.40)	\$ 0.70
Net income (loss) per share, diluted	<u>(0.92)</u>	<u>0.13</u>	<u>(1.40)</u>	<u>(0.28)</u>
Weighted-average shares used in computing net income (loss) per	48,308	46,202	48,285	44,601

share, basic				
Weighted-average shares used in computing net income (loss) per share, diluted	48,308	46,202	48,285	45,152

CONDENSED CONSOLIDATED BALANCE SHEETS

(unaudited, in thousands)

	June 30, 2025	December 31, 2024
Assets		
Current assets		
Cash and cash equivalents	\$ 112,381	\$ 128,574
Prepaid expenses and other current assets	2,440	7,958
Total current assets	<u>114,821</u>	<u>136,532</u>
Property and equipment, net	20,563	21,001
Total assets	<u>\$ 135,384</u>	<u>\$ 157,533</u>
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable and other accrued expenses	\$ 42,822	\$ 7,654
Accrued development expense	3,788	2,440
Accrued compensation and benefits	563	1,357
Other current liabilities	159	299
Total current liabilities	<u>47,332</u>	<u>11,750</u>
Other non-current liabilities	79	79
Total liabilities	<u>47,411</u>	<u>11,829</u>
Stockholders' equity		
Common Stock and additional paid-in-capital	560,711	550,815
Accumulated deficit	<u>(472,738)</u>	<u>(405,111)</u>
Total stockholders' equity	<u>87,973</u>	<u>145,704</u>
Total liabilities and stockholders' equity	<u>\$ 135,384</u>	<u>\$ 157,533</u>