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 12, 2026

Filana Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-41905**	**91-1911336**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(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	FLNA	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 March 12, 2026, 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 March 12, 2026
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.

Filana Therapeutics, Inc.
a Delaware corporation

Date: March 12, 2026

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

EXHIBIT 99.1

Filana Therapeutics Reports Fourth Quarter and Full Year 2025 Financial Results

Working to advance TSC-related epilepsy program, with a focus on capital efficiency

AUSTIN, Texas, March 12, 2026 (GLOBE NEWSWIRE) -- Filana Therapeutics, Inc. (formerly Cassava Sciences, Inc.) (NASDAQ: FLNA, "Filana Therapeutics", the "Company"), a biotechnology company focused on developing novel medicines to modulate the filamin A protein for the treatment of central nervous system (CNS) disorders, such as Tuberous Sclerosis Complex (TSC)-related epilepsy, and other diseases associated with dysregulation or overexpression of filamin A, today reported financial results for the fourth quarter and year ended December 31, 2025, and provided a business update.

Net loss for 2025 was $91.0 million, or $1.88 per share, compared to a net loss of $24.3 million, or $0.53 per share (basic), in 2024. Net cash used in operations was $32.3 million in 2025, consistent with previous guidance.

The Company met cash guidance for year-end 2025, reporting $95.5 million, and estimates cash at June 30, 2026 in a range from $47 to $50 million. The Company estimates net cash use in operations for first half of 2026 in a range from $14 to $17 million, plus a payment of a $31.25 million estimated loss contingency related to the potential settlement of certain securities litigation recorded in 2025.

"At Filana Therapeutics, our name reflects our deep commitment to science and to patients affected by diseases tied to filamin A dysregulation, including TSC-related epilepsy. We are driven by the urgent need for new treatment options that can meaningfully improve patients' lives," said **Rick Barry, President and Chief Executive Officer** of Filana Therapeutics, Inc. "In partnership with our advisors, we are working diligently to address the FDA's requests and look forward to sharing a progress update in the coming months."

Corporate Updates:

- **Name change to Filana Therapeutics, Inc.:** Filana Therapeutics' new name and brand reflect the Company's strategic focus on developing novel medicines to modulate the filamin A protein for the treatment of CNS disorders, such as TSC-related epilepsy, and other diseases associated with dysregulation or overexpression of filamin A.
- **TSC Program Update**: The Company is actively addressing FDA's request for information detailed in the Clinical Hold Letter received in December 2025, including the submission of additional pre-clinical data and protocol design modifications. The Company intends to submit a response to FDA as soon as practicable.

Financial Results for the Fourth Quarter and Full Year 2025:

- **Cash and cash equivalents** were $95.5 million, with no debt, as of December 31, 2025. This compares to cash and cash equivalents of $128.6 million at December 31, 2024. The Company estimates cash at June 30, 2026, in a range from $47 to $50 million.
- **Total shares outstanding** as of March 9, 2026, were 48.3 million.
- **Net loss** for the year ended December 31, 2025, was $91.0 million, or $1.88 per share. This compares to a net loss of $24.3 million, or $0.53 per share (basic) for the same period in 2024. Net loss increased primarily due to a $108.1 million gain in 2024 from change in fair value of warrant liabilities that was not repeated in 2025.
- **Net cash used in operations** was $32.3 million in 2025, consistent with previous guidance. The Company estimates net cash use in operations for first half of 2026 in a range from $14 to $17 million, plus a payment of $31.25 million estimated loss contingency related to the potential settlement of certain securities litigation recorded in 2025.
- **Research and development (R&D) expenses** for the year ended December 31, 2025, decreased to $26.6 million from $69.6 million in 2024, representing a 62% reduction. This decrease was due primarily to the phase out of the Alzheimer's disease (AD) development program beginning the fourth quarter 2024 and completed in second quarter 2025. The Company's planned clinical program in TSC-related epilepsy is expected to cost significantly less than the discontinued AD program.
- **General and administrative (G&A) expenses** for the year ended December 31, 2025, decreased to $68.8 million from $71.8 million in 2024. The 4% decrease was due primarily to a $40.0 million SEC-related loss contingency recorded in 2024, which was partially offset by $9.9 million in insurance recoveries. This compared to a $31.3 million securities litigation loss contingency and $4 million of other litigation contingencies recorded in 2025, for which there were no insurance recoveries. The change also included a $2.6 million increase in stock-based compensation expense due to new awards granted in late 2024, as well as cost decreases as severance costs recorded in the prior year were not repeated in 2025.

About TSC and TSC-related Epilepsy

TSC is a rare genetic disorder resulting from a mutation in the *TSC1* or *TSC2* gene. This affects the mechanistic target of rapamycin (mTOR) pathway and can cause tumors to grow in multiple organs[1]. Epilepsy is the most common health issue

affecting the TSC community, with 80% to 90% of TSC patients experiencing seizures[1]. TSC-related epilepsy affects approximately 45,000 people in the U.S.[2] Most patients start having seizures within their first year of life[3]. Even with multiple approved treatments, more than 60% of TSC patients remain refractory to antiepileptic therapy[4].

About Filana Therapeutics, Inc.

Filana Therapeutics, Inc. (NASDAQ: FLNA), is a biotechnology company focused on developing novel, investigational therapies to modulate the filamin A protein for the treatment of central nervous system disorders, such as tuberous sclerosis complex (TSC)-related epilepsy, and other diseases associated with dysregulation or overexpression of filamin A.

For more information, please visit: https://www.FilanaTx.com

References:

1. *Crino P, Nathanson K, Petri Henske, E. The Tuberous Sclerosis Complex. N Engl J Med. (2006) 355 (13):1345-56. DOI: 10.1056/NEJMra055323*
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. *Chu-Shore, C. J., Major, P., Camposano, S., Muzykewicz, D., & Thiele, E. A. (2010). The natural history of epilepsy in tuberous sclerosis complex. Epilepsia, 51(7), 1236–1241. https://doi.org/10.1111/j.1528-1167.2009.02474.x*

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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: our ability to successfully engage with, and satisfactorily respond to, requests for additional information from the U.S. Food and Drug Administration (FDA) concerning the full clinical hold on our investigational new drug application (IND) for simufilam in TSC-related epilepsy and the timing and outcomes of such interactions, the potential resolution of certain securities litigation and our loss contingency estimates and timing of payments related thereto, the timing and plans to conduct clinical studies with simufilam following approval of our IND, our plans to conduct additional preclinical studies of simufilam relating to seizures in TSC, 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 our ability to provide FDA with additional information, including additional pre-clinical data, and modifying the proposed clinical trial protocol design, to satisfy completion of FDA's review and release of full clinical hold, 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 Filana Therapeutics, 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 Quarterly Report on Form 10-Q for the period ended September 30, 2025, 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 –

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

	Three months ended December 31,		Year Ended December 31,	
	2025	2024	2025	2024
Operating expenses				
Research and development	$ 3,853	$ 20,530	$ 26,590	$ 69,637
General and administrative	9,699	8,957	68,800	71,809
Total operating expenses	13,552	29,487	95,390	141,446
Operating loss	(13,552)	(29,487)	(95,390)	(141,446)
Interest income	974	1,800	4,620	8,510
Other income (loss), net	39	90	(203)	411
Gain from change in fair value of warrant liabilities	—	—	—	108,183
Net loss	$ (12,539)	$ (27,597)	$ (90,973)	$ (24,342)
Net loss per share, basic	$ (0.26)	$ (0.57)	$ (1.88)	$ (0.53)
Net loss per share, diluted	(0.26)	(0.57)	(1.88)	(1.46)
Weighted-average shares used in computing net loss per share, basic	48,308	48,099	48,297	46,329
Weighted-average shares used in computing net loss per share, diluted	48,308	48,099	48,297	46,604

CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited, in thousands)

	Year Ended December 31,	
	2025	2024
Assets		
Current assets		
Cash and cash equivalents	$ 95,502	$ 128,574
Prepaid expenses and other current assets	2,207	7,958
Total current assets	97,709	136,532
Property and equipment, net	20,646	21,001
Total assets	$ 118,355	$ 157,533
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable and other accrued expenses	$ 41,647	$ 7,654
Accrued development expense	364	2,440
Accrued compensation and benefits	1,625	1,357
Other accrued liabilities	198	299
Total current liabilities	43,834	11,750
Other non- current liabilities	118	79
Total liabilities	43,952	11,829
Stockholders' equity		
Common Stock and additional paid-in-capital	570,487	550,815

Accumulated deficit	(496,084)	(405,111)
Total stockholders' equity	74,403	145,704
Total liabilities and stockholders' equity	$ 118,355	$ 157,533