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): May 7, 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 May 7, 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 May 7, 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: May 7, 2026

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

EXHIBIT 99.1

Filana Therapeutics Reports Q1 2026 Financial Results and Business Update

AUSTIN, Texas, May 07, 2026 (GLOBE NEWSWIRE) -- Filana Therapeutics, Inc. (NASDAQ: FLNA, "Filana Therapeutics", the "Company"), a biotechnology company currently focused on developing therapies for Tuberous Sclerosis Complex (TSC)-related epilepsy, today reported financial results for the first quarter ended March 31, 2026 and provided a business update on the development of simufilam, an oral small molecule intended to modulate filamin A protein.

"2026 has been a year of important progress and new beginnings for Filana Therapeutics. Our new name reflects who we are—a team dedicated to rigorous science and to bringing new treatment options to patients with TSC-related epilepsy and their families," said **Rick Barry, President and Chief Executive Officer** of Filana Therapeutics, Inc. "We believe the recent publication of preclinical data in *Epilepsia* and our presentation at the Eighteenth Eilat Conference on New Antiepileptic Drugs and Devices further support the biological rationale behind simufilam and our approach to the potential treatment of TSC-related epilepsy. We remain focused on generating the necessary data to resolve the FDA's Clinical Hold and advance the program. We are committed to keeping our stakeholders informed and look forward to sharing updates as they develop."

Recent Updates:

Corporate Developments

- **Name Change to Filana Therapeutics**: The new name and brand reflect a shared purpose to develop medicines that modulate filamin A – targeting CNS disorders like TSC-related epilepsy and other conditions associated with filamin A dysregulation or overexpression.

Regulatory

- **TSC Program Update**: The Company is actively working to address FDA's Clinical Hold, including the planned submission of additional pre-clinical data and protocol design modifications. The timeline for initiation of a clinical trial will depend on the Company's ability to provide the requested information to FDA and on satisfactory completion of FDA's review.

Scientific Presentations and Publications

- **Presentation of TSC-Related Epilepsy Program Overview at Eilat XVIII**: On May 5, 2026, Filana presented an overview of its TSC-related epilepsy program at the Eighteenth Eilat Conference on New Antiepileptic Drugs and Devices (Eilat XVIII) in Madrid, Spain. The presentation highlighted the biological rationale supporting continued evaluation of simufilam in TSC-related epilepsy.
- **Publication in *Epilepsia* of Preclinical Simufilam Data**: The preclinical data published in *Epilepsia* showed that simufilam attenuated seizure progression in a well-accepted mouse model of severe TSC-related epilepsy[1]. The results, together with published findings in an earlier animal model[2], underscore a positive correlation between seizure outcomes and plasma exposure to simufilam, supporting the continued evaluation of simufilam for the treatment of TSC-related epilepsy, which affects approximately 45,000 people in the U.S.[2,3]

Financial Results for First Quarter 2026

- **Cash and cash equivalents** at March 31, 2026 were $86.6 million, compared to $95.5 million as of December 31, 2025. The Company has no debt. The Company estimates cash at June 30, 2026 in a range from $47 to $50 million.
- **Research and development (R&D)** expenses were $4.5 million. This compared to $13.7 million for the same period in 2025. This 67% decrease was due primarily to the previously reported phase out of the Alzheimer's disease development program, completed in the second quarter of 2025. Expenses for the TSC-related epilepsy program are expected to be significantly lower compared to those for the Alzheimer's disease program.
- **General and administrative (G&A)** expenses were $6.6 million. This compared to $10.9 million for the same period in 2025. The 39% decrease was due primarily to legal loss contingencies of $3.0 million recorded in Q1 2025 not being repeated in 2026.
- **Net cash used in operations** was $8.9 million during the first quarter of 2026. Net cash used in operations for first-half 2026 is expected to be 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.
- **Net loss** was $10.3 million, or $0.21 per share. This compares to a net loss of $23.4 million, or $0.48 per share, for the same period in 2025.
- **Shares outstanding** were 48.3 million as of May 4, 2026.

About TSC and TSC-related Epilepsy

TSC is a rare genetic disorder resulting from a mutation in the *TSC1* or *TSC2* gene. These mutations affect the mechanistic target of rapamycin (mTOR) pathway and can cause tumors to grow in multiple organs[3,4]. Epilepsy is the most common health issue affecting the TSC community, with 80% to 90% of TSC patients experiencing seizures[5]. TSC-related epilepsy affects approximately 45,000 people in the U.S.[2,3] Most patients start having seizures within their first year of life[2]. Even with multiple approved treatments, more than 60% of TSC patients remain refractory to antiepileptic therapy[6].

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. *Stansley B, Islam MM, Aguiar DJ, Fuchs Z, Catron M, Morairty S, et al. The small molecule simufilam dose-dependently attenuates the worsening of seizures in a mouse model of tuberous sclerosis complex. Epilepsia. 2026;00:1–13. https://doi.org/10.1002/epi.70227https://www.tscalliance.org/researchers/preclinical-research/*
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. *https://www.tscalliance.org/understanding-tsc/genetics/*
5. *Crino P, Nathanson K, Petri Henske, E. The Tuberous Sclerosis Complex. N Engl J Med. (2006) 355 (13):1345-56. DOI: 10.1056/NEJMra055323*
6. *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, 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 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, 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.

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

	Three months ended March 31,	
	2026	2025
Operating expenses		
Research and development	$ 4,544	$ 13,666
General and administrative	6,624	10,920
Total operating expenses	11,168	24,586
Operating loss	(11,168)	(24,586)
Interest income	789	1,265
Other income (loss), net	48	(82)
Net loss	$ (10,331)	$ (23,403)
Net loss per share, basic and diluted	$ (0.21)	$ (0.48)
Weighted-average shares used in computing net loss per share, basic and diluted	48,308	48,262

CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited, in thousands)

	March 31, 2026	December 31, 2025
Assets		
Current assets		
Cash and cash equivalents	$ 86,573	$ 95,502
Prepaid expenses and other current assets	1,391	2,207
Total current assets	87,964	97,709
Property and equipment, net	20,403	20,646
Total assets	$ 108,367	$ 118,355
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable and other accrued expenses	$ 39,189	$ 41,647
Accrued development expense	605	364
Accrued compensation and benefits	246	1,625
Other curent liabilities	75	198
Total current liabilities	40,115	43,834
Other non- current liabilities	111	118
Total liabilities	40,226	43,952
Stockholders' equity		
Common Stock and additional paid-in-capital	574,556	570,487
Accumulated deficit	(506,415)	(496,084)

Total stockholders' equity	68,141	74,403
Total liabilities and stockholders' equity	$ 108,367	$ 118,355