Filana Therapeutics Reports Q3 2026 Financial Results and Provides Business Update

Nov 05, 2026

– Patient screening in Phase 2a study of simufilam in TSC-related epilepsy expected to begin by Q1 2027, following recent lift of FDA clinical hold

– Recent publication in Cells[1] provides new insights into simufilam's potential mechanism of action

AUSTIN, Texas, Nov. 05, 2026 (GLOBE NEWSWIRE) -- Filana Therapeutics, Inc. (NASDAQ: FLNA, "Filana Therapeutics", the "Company") today reported financial results for the third quarter ended September 30, 2026.

"Simufilam has the potential to make a meaningful difference for patients with TSC-related epilepsy. We began working toward activating clinical study sites as soon as FDA lifted the clinical hold in September. Patient screening is expected to begin by the first quarter of 2027," said **Rick Barry, President and Chief Executive Officer** of Filana Therapeutics. "We are encouraged by the excitement among leading clinical investigators and the TSC community for this upcoming study."

Clinical Development Update

- **FDA clinical hold lifted:** In September 2026, the FDA lifted the clinical hold on Filana's investigational new drug (IND) application for simufilam in Tuberous Sclerosis Complex (TSC)-related epilepsy. Following this decision, the Company is advancing preparations for its planned Phase 2a study.
- **Phase 2a study preparations:** The study is expected to enroll approximately 40 patients ages 12 to 55 at approximately 13 clinical sites in the United States. The randomized, double-blind study will evaluate two doses of simufilam, each administered in addition to standard of care therapy. The study consists of a four-week baseline assessment, a 16-week treatment period, and an optional 48-week extension. Patient screening is expected to begin by the first quarter of 2027.

Scientific Publications

- **New preclinical research published in Cells[1]:** The October publication by researchers at Yale School of Medicine provides additional insight into simufilam's potential mechanism of action. The study evaluated simufilam in TSC2-deficient human cells and identified effects on cellular stress-related signaling and mitochondrial function. These findings add to previously reported preclinical research supporting the investigation of simufilam in TSC-related epilepsy[2,3].

Financial Results for Third Quarter 2026

- **Cash and cash equivalents** at September 30, 2026 were $47.0 million. The Company has no debt.
- **Research and development (R&D) expenses** for the third quarter of 2026 were $3.9 million. This compared to $4.0 million for the same period in 2025. This 2% decrease was due primarily to decreases in preclinical and stock-based compensation expenses, partially offset by increased expenses preparing for the TSC-related epilepsy clinical program.
- **General and administrative (G&A) expenses** for the third quarter of 2026 were $7.4 million. This compared to $7.9 million for the same period in 2025. The 6% decrease was due primarily to lower stock-based compensation expenses compared to the prior year period.
- **Net cash used in operations** was $18.8 million during the first nine months of 2026.
- **Litigation Settlement Escrow Payment**: On July 23, 2026, the Company transferred $31.25 million into escrow in connection with the potential settlement of certain securities litigation recorded in 2025. This payment is recorded as restricted cash on the consolidated balance sheets subject to a court approved disposition.
- **Net cash used in operations for second-half 2026** is expected to be in a range from $11 to $15 million. The Company estimates cash and cash equivalents at year-end 2026 in a range from $38 to $42 million.
- **Net loss for the third quarter of 2026** was $10.7 million, or $0.22 per share. This compares to a net loss of $10.8 million, or $0.22 per share, for the same period in 2025.
- **Shares outstanding** were 50.3 million as of November 5, 2026.

About TSC and TSC-related Epilepsy

Tuberous Sclerosis Complex (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[4,5]. Epilepsy is the most common health issue affecting the TSC community, with 80% to 90% of TSC patients experiencing seizures[6]. TSC-related epilepsy affects approximately 45,000 people in the U.S.[2,4] 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[7].

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:

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For More Information Contact:

Investors
Mike Moyer
mmoyer@lifesciadvisors.com

Company
Eric Schoen, Chief Financial Officer
(512) 501-2450
ESchoen@FilanaTx.com
IR@FilanaTx.com

Cautionary Note Regarding Forward-Looking Statements:

This news release contains forward-looking statements that may include but are not limited to statements regarding: the timing and plans to initiate and conduct clinical studies with simufilam in TSC-related epilepsy; the design, structure, duration, objectives, endpoints, patient population, conduct, enrollment, completion, and potential results of our planned Phase 2a clinical trial; our ability to work with clinical investigators and the TSC community to advance the trial efficiently; the potential for simufilam as a treatment for TSC-related epilepsy and other potential indications; the potential resolution of certain securities litigation and our loss contingency estimates related thereto; 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 initiate, enroll, conduct, and complete the planned Phase 2a study of simufilam in TSC-related epilepsy; our ability to engage clinical trial sites and participants; our ability to work effectively with clinical research organizations, vendors, investigators, patient advocacy organizations, and the TSC community; potential changes to the clinical trial protocol, trial design, endpoints, timing, patient population, or development plans; our ability to generate clinical data that support further development of simufilam; 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 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 September 30,		Nine months ended September 30,	
	2026	2025	2026	2025
Operating expenses				
Research and development	$ 3,868	$ 3,955	$ 11,715	$ 22,737
General and administrative	7,406	7,905	20,120	59,101
Total operating expenses	11,274	11,860	31,835	81,838
Operating loss	(11,274)	(11,860)	(31,835)	(81,838)
Interest income	520	1,167	2,056	3,646
Other income (loss), net	28	(114)	119	(242)
Net loss	$ (10,726)	$ (10,807)	$ (29,660)	$ (78,434)
Net loss per share, basic and diluted	$ (0.22)	$ (0.22)	$ (0.61)	$ (1.62)
Weighted-average shares used in computing net loss per share, basic and diluted	48,461	48,308	48,359	48,293

CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited, in thousands)

	September 30, 2026	December 31, 2025
Assets		
Current assets		
Cash and cash equivalents	$ 46,990	$ 95,502
Restricted cash	31,250	—
Prepaid expenses and other current assets	1,817	2,207
Total current assets	80,057	97,709
Property and equipment, net	20,001	20,646
Total assets	$ 100,058	$ 118,355
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable and other accrued expenses	$ 40,772	$ 41,647
Accrued development expense	369	364
Accrued compensation and benefits	648	1,625
Other current liabilities	157	198
Total current liabilities	41,946	43,834
Other non- current liabilities	136	118
Total liabilities	42,082	43,952
Stockholders' equity		

Common Stock and additional paid-in-capital	583,720	570,487
Accumulated deficit	(525,744)	(496,084)
Total stockholders' equity	57,976	74,403
Total liabilities and stockholders' equity	$ 100,058	$ 118,355

Source: Filana Therapeutics, Inc.