Rein Therapeutics Announces Preliminary Blinded Phase 2 RENEW Data Showing Encouraging Lung Function Trends in Patients with Idiopathic Pulmonary Fibrosis and Reports Third Quarter 2026 Financial Results

November 16, 2026

- *33% of evaluable patients demonstrated improvement over baseline in forced vital capacity (FVC) at Week 12*
- *From baseline, change in FVC ranged from an improvement of 338 ml to a decline of 349 ml at Week 12*
- *Low discontinuation rates, and favorable safety and tolerability observed across placebo and treatment groups, with no serious adverse events assessed as related to study treatment*
- *Study has achieved 75% enrollment, with 90 patients randomized to date; on track to report topline data in 2027*

Figure 1

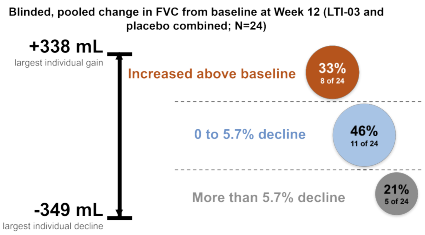


Figure 1

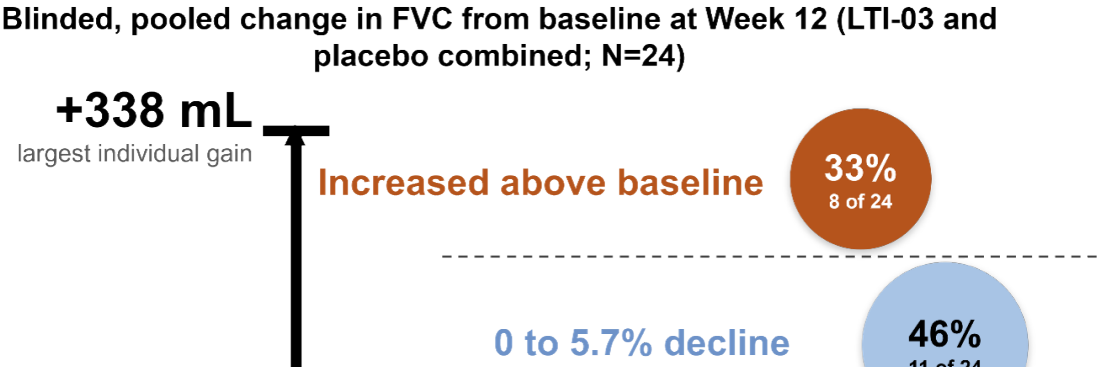
AUSTIN, Texas, Nov. 16, 2026 (GLOBE NEWSWIRE) -- Rein Therapeutics ("Rein") (NASDAQ: RNTX), a biopharmaceutical company advancing a novel pipeline of first-in-class medicines in orphan pulmonary and fibrosis indications, today announced preliminary blinded twelve-week observations from the ongoing RENEW Phase 2 trial evaluating its lead drug candidate, LTI-03, in patients with idiopathic pulmonary fibrosis (IPF). The Company also reported financial results for the third quarter ended September 30, 2026.

“During the third quarter, we continued to make rapid progress in our Phase 2 RENEW trial for LTI-03 supported by strong enrollment and investigator enthusiasm,” said Brian Windsor, Ph.D., President and Chief Executive Officer of Rein Therapeutics. “As we continue to enroll patients in the study, today’s blinded look at the data shows encouraging lung function trends and a favorable safety and tolerability profile across the study population, reinforcing our confidence in the potential of LTI-03 to deliver a differentiated clinical and safety profile for patients with significant unmet need. We remain committed to advancing the study toward completion and look forward to reporting unblinded topline data in 2027.”

Third Quarter 2026 and Recent Business Updates

Clinical Updates
The RENEW study is a randomized, placebo-controlled Phase 2 trial evaluating inhaled LTI-03 in patients with IPF. The trial remains blinded while enrollment continues. The preliminary analysis included 24 patients with evaluable baseline and Week 12 forced vital capacity (FVC) measurements.

- **Blinded outcomes consistent with expectations; FVC change at Week 12 indicates encouraging distribution:**
  - At Week 12, preliminary blinded lung function observations included:
    - 33% of patients (8 of 24) demonstrated an improvement in FVC from baseline.
    - 46% of patients (11 of 24) experienced an FVC decline of no more than 5.7%, a threshold below which some studies have indicated a greater than 2X likelihood of progression to lung transplant or death.
    - 21% of patients (5 of 24) experienced an FVC decline in FVC from baseline of more than 5.7%.
  - These observations represent pooled results across patients randomized to placebo or one of two LTI-03 dose levels. Treatment assignments remain blinded, and the findings do not establish a treatment effect or allow comparisons between LTI-03 and placebo.



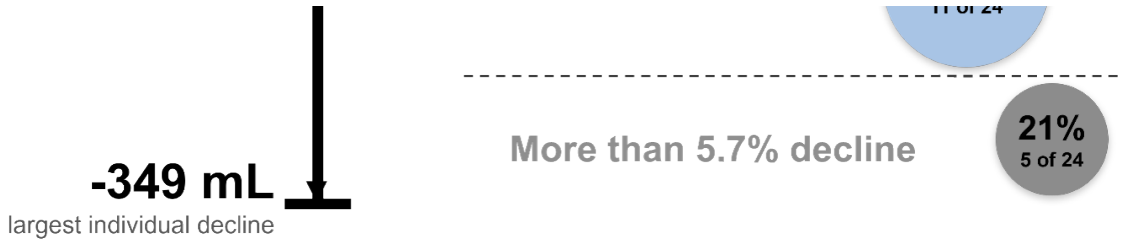


Figure 1: Blinded, pooled sponsor data (LTI-03 and placebo participants combined). N=24: participants with a Week 12 FVC result. Change in FVC from baseline to Week 12 calculated as a percentage of each participant's own baseline. Baseline was calculated as the mean of the qualifying Screening and Day 1 pre-dose values. Groupings are descriptive and were not pre-specified. These thresholds were used to describe the distribution of blinded, pooled data; they do not predict outcomes for RENEW participants and cannot show a treatment effect. The 5.7% threshold is drawn from an individual participant data meta-analysis of the placebo arms of 12 IPF trial cohorts, in which a relative decline in FVC of more than 5.7% over 3 months was the threshold that best distinguished higher mortality risk (adjusted hazard ratio 2.6; Khan et al., Am J Respir Crit Care Med 2022). At a stricter 5% line, 75% (18 of 24) improved or declined less than 5%. The bar runs from the largest individual gain to the largest individual decline in FVC at Week 12: the full range, not a confidence interval. Not drawn to scale. These are single-participant values and cannot show a treatment effect.

- **Favorable safety and tolerability profile:**
  - Preliminary blinded safety observations from the ongoing RENEW trial suggest a favorable safety and tolerability profile.
  - No serious adverse events related to study treatment have been reported as of the interim data cutoff.
  - Adverse events have been predominantly mild or moderate, with cough representing the most frequently reported adverse event and generally mild in severity.
  - Low rates of discontinuation, with 92% of enrolled participants remaining on or completing the study.
  - The trial remains blinded, and treatment-specific safety and tolerability will be further characterized as additional data become available.
- **On track to report topline data in 2027:** As of November, Rein has achieved 75% of the trial's planned enrollment, with 90 out of approximately 120 patients randomized to date across the United States, United Kingdom, Australia, Germany and Poland. Enrollment is tracking ahead of schedule and the Company remains on track to report topline data in 2027.

"Blinded interim data from our ongoing Phase 2 RENEW trial provides an early look at the safety, tolerability and lung function trends we are observing across the study population. The improvements in FVC from baseline observed in 33% of evaluable patients is particularly encouraging, as improvements in lung function are not expected in this patient population," said Cory Hogaboam, Ph.D., Chief Scientific Officer. "In addition to the lung function improvements we are seeing in the study, adverse events across all patients have been mild to moderate, with no serious adverse events attributable to the drug and low discontinuation rates, with 92% of participants remaining on or completing the study. While the study remains blinded, these observations collectively strengthen our belief that LTI-03 has the potential to transform the treatment landscape for IPF."

Third Quarter 2026 Financial Results

- **Cash position:** Cash, cash equivalents and marketable securities were $36.5 million as of September 30, 2026. The Company's cash, cash equivalents and marketable securities as of September 30, 2026 are expected to fund its operations into the first quarter of 2028 through the completion of the Phase 2 RENEW clinical trial of LTI-03.

- **R&D expenses:** Research and development expenses were $4.4 million for the quarter ended September 30, 2026, compared to $1.7 million for the comparable prior year period. The increase of $2.7 million was primarily due to the increased spending on the RENEW phase 2 clinical trial versus the prior year when the FDA imposed a clinical hold on LTI-03, which was lifted in October 2025.

- **G&A expenses:** General and administrative expenses were $2.6 million for the quarter ended September 30, 2026, compared to $3.8 million for the comparable prior year period. The decrease was primarily due to decreased professional fees.

- **Net loss:** Net loss was $5.5 million for the quarter ended September 30, 2026, compared to $5.6 million for the comparable prior year period.

About LTI-03
LTI-03 is a first-in-class, investigational, inhaled peptide therapy derived from caveolin-1 biology, a key regulator of cellular signaling pathways involved in fibrosis, epithelial injury and tissue repair. LTI-03 is designed to inhibit profibrotic signaling while protecting alveolar epithelial cells that are important for maintaining and repairing lung tissue. The drug's dual mechanism is intended to address both progressive lung scarring and epithelial dysfunction, two important features of IPF. LTI-03 received Orphan Drug and Fast Track designations from the U.S. Food and Drug Administration for IPF.

About the Phase 2 RENEW Trial

RENEW is an ongoing randomized, double-blind, placebo-controlled Phase 2 clinical trial designed to evaluate the safety, tolerability and efficacy of inhaled LTI-03 in patients with IPF. The study is expected to enroll approximately 120 patients across clinical sites in the United States, United Kingdom, Australia, Poland, Germany, Bulgaria, and Romania. Participants are randomized to receive one of two LTI-03 dose levels or placebo over a 24-week treatment period. The primary endpoint is safety and tolerability as measured by the incidence of treatment-emergent adverse events. The secondary endpoints are efficacy assessments, including change from baseline in FVC, quantitative high-resolution computed tomography imaging and exploratory biomarkers associated with epithelial injury and fibrosis. The Company expects the trial to remain blinded throughout enrollment and patient follow-up, and to report topline results in 2027. For additional details, please refer to www.clinicaltrials.gov (identifier: NCT06968845).

About Rein Therapeutics

Rein Therapeutics is a clinical-stage biopharmaceutical company advancing a novel pipeline of first-in-class therapies to address significant unmet medical needs in orphan pulmonary and fibrosis indications. Rein's lead product candidate, LTI-03, is a novel, synthetic peptide with a dual mechanism targeting alveolar epithelial cell survival as well as inhibition of profibrotic signaling. LTI-03 has received Orphan Drug Designation in the U.S. Rein's second product candidate, LTI-01, is a proenzyme that has completed Phase 1b and Phase 2a clinical trials for the treatment of loculated pleural effusions. LTI-01 has received Orphan Drug Designation in the U.S. and E.U. and Fast Track Designation in the U.S.

Cautionary Note Regarding Forward-Looking Statements

This press release may contain forward-looking statements of Rein Therapeutics, Inc. ("Rein", the "Company", "we", "our" or "us") within the meaning of the Private Securities Litigation Reform Act of 1995, including statements concerning the development of LTI-03, the design, conduct and expected results of the Phase 2 RENEW trial, the potential clinical benefits of LTI-03, future development milestones and the Company's financial resources. We use words such as "anticipate," "believe," "estimate," "expect," "hope," "intend," "may," "plan," "predict," "project," "target," "potential," "would," "can," "could," "should," "continue," and other words and terms of similar meaning to help identify forward-looking statements, although not all forward-looking statements contain these identifying words. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: (i) the risk that the Company may not be able to successfully continue its Phase 2 clinical trials of LTI-03; (ii) the risk that the Company may not report topline data derived from its Phase 2 trial in 2027 or, if it does, the risk that the data may not support or validate our expectations concerning the potential benefits of LTI-03; (iii) success in early phases of pre-clinical and clinical trials do not ensure later clinical trials will be successful; (iv) the risk that preliminary blinded interim observations may not predict subsequent or final study results; (v) the fact that the lung function observations described in this release are pooled across randomized treatment groups and cannot establish efficacy, dose response or superiority to placebo; (vi) the fact that the 5.7% FVC decline threshold is descriptive and is not a validated Week-12 measure of treatment response; (vii) the fact that preliminary adverse-event causality assessments may change as additional data become available; and (viii) the risk that the Company's present cash and cash equivalents may not be sufficient to fund the Company's operations into the first quarter of 2028 and (v) those other risks disclosed in the "Risk Factors" section of the Company's Annual Report on Form 10-K for the year ended December 31, 2025 filed with the SEC on March 26, 2026, and in subsequent filings that the Company makes with the SEC. These forward-looking statements should not be relied upon as representing the Company's views as of any date after the date of this press release, and the Company expressly disclaims any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

Rein Therapeutics Investor Relations & Media Contact:
Investor Relations
IR@ReinTx.com

REIN THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(UNAUDITED)
(In thousands, except share and per share data)

	September 30, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 943	$ 3,215
Short-term investments	34,550	—
Prepaid expenses and other current assets	1,292	1,111
Total current assets	36,785	4,326
Goodwill	6,330	6,330
Intangible assets	13,500	13,500
Long-term investments	994	—
Other non-current assets	1,821	2
Total assets	$ 59,430	$ 24,158

Liabilities, Convertible Preferred Stock and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,199	$ 3,976
Accrued expenses and other current liabilities	2,399	2,204
Total current liabilities	5,598	6,180
Deferred tax liability	1,060	1,060
Total liabilities	6,658	7,240
Commitments and contingencies (Note 13)		
Convertible preferred stock, $0.001 par value, 5,000,000 shares authorized at September 30, 2026 and at December 31, 2025; 24,610 shares issued and 12,232 shares outstanding at September 30, 2026 and at December 31, 2025	45,005	45,005
Stockholders' equity:		
Common stock, $0.001 par value; 200,000,000 shares and 100,000,000 authorized at September 30, 2026 and at December 31, 2025, respectively; 86,267,032 shares and 27,550,222 shares issued and outstanding at September 30, 2026 and at December 31, 2025, respectively	172	113
Additional paid-in capital	426,731	373,133
Accumulated other comprehensive loss	(115)	(62)
Accumulated deficit	(419,021)	(401,271)
Total liabilities, convertible preferred stock and stockholders' equity	$ 59,430	$ 24,158

REIN THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(UNAUDITED)
(In thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	**2025**	**2026**	**2025**
Revenue	$ —	$ —	$ —	$ —
Operating expenses:				
Research and development	4,375	1,681	11,086	9,028
General and administrative	2,624	3,811	7,219	8,944
Total operating expenses	6,999	5,492	18,305	17,972
Loss from operations	(6,999)	(5,492)	(18,305)	(17,972)
Other (expense) income, net	1,462	(89)	555	68
Net loss	$ (5,537)	$ (5,581)	$ (17,750)	$ (17,904)
Net loss per share—basic and diluted	$ (0.06)	$ (0.21)	$ (0.29)	$ (0.74)
Weighted average common shares outstanding —basic and diluted	88,325,917	26,361,386	62,134,091	24,171,173
Comprehensive loss:				
Net loss	$ (5,537)	$ (5,581)	$ (17,750)	$ (17,904)
Other comprehensive loss:				
Unrealized (loss) gain on investments, net of tax of $0	(45)	—	(57)	(33)
Foreign currency translation adjustments	(1)	—	4	7
Total other comprehensive loss	(46)	—	(53)	(26)
Total comprehensive loss	$ (5,583)	$ (5,581)	$ (17,803)	$ (17,930)

A photo accompanying this announcement is available at https://www.globenewswire.com/NewsRoom/AttachmentNg/22b5e69b-3a1b-4989-b1a9-5cc386743bf1