



Tvardi Therapeutics Announces Fourth Quarter and Full-Year 2025 Results and Provides Business Update

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Results from healthy volunteer study of next-generation STAT3 inhibitor, TTI-109, on track for Q2 2026

Topline data from Phase 2 trial of TTI-101 in hepatocellular carcinoma (HCC) are anticipated in H2 2026

Cash runway expected to be sufficient to fund operations into Q4 2026 after clinical readouts

HOUSTON, March 31, 2026 (GLOBE NEWSWIRE) -- Tvardi Therapeutics, Inc. ("Tvardi") (NASDAQ: TVRD), a clinical-stage biopharmaceutical company focused on the development of novel, oral, small molecule therapies targeting STAT3 to treat inflammatory and proliferative diseases, today announced its financial and operating results for the fourth quarter and full-year ended December 31, 2025, and provided a business update.

Recent Highlights:

- Additional analysis from the REVERT IPF Phase 2 trial demonstrated that TTI-101 was associated with a 9.4% baseline-weighted reduction in fibrosis score compared to 2.4% for placebo, as well as a 4.5-fold greater decline in IL-6, a central STAT3-driven inflammatory cytokine. These findings are consistent with preclinical data demonstrating reductions in established fibrosis and inflammatory signaling across multiple validated disease models.
- The healthy volunteer study of its next-generation STAT3 inhibitor, TTI-109, is ongoing, with topline data anticipated in the second quarter of 2026.
- The ongoing Phase 1b/2 REVERT LIVER CANCER trial will report topline results in the second half of 2026 to allow the data additional time to mature. This timing adjustment is intended to enhance the depth of insights gleaned from the program, including longitudinal and translational assessments, characterization of durability and dose optimization (including the addition of up to 15 participants in the monotherapy arm to explore once-a-day dosing), to better inform subsequent development and regulatory strategy.

Imran Alibhai, Ph.D., Chief Executive Officer of Tvardi, stated, "We entered 2026 with line-of-site to two significant clinical milestones: 1) healthy volunteer data from our next-generation STAT3 inhibitor, TTI-109, in the second quarter of this year, and 2) topline data from our ongoing Phase 2 trial of TTI-101 in HCC, which we anticipate in the second half."

"Further analysis of data from our Phase 2 IPF trial of TTI-101 that we announced in October revealed compelling trends. These data give us optimism for TTI-109, which has been developed to enhance TTI-101's ability to target STAT3 as a more efficient delivery vehicle with the potential to improve tolerability."

"At the same time, we eagerly await data from our ongoing Phase 2 REVERT LIVER CANCER trial, with a data readout expected in the second half of this year to allow for further data maturation. Interim results from this study have already shown clinically meaningful activity of TTI-101 both as monotherapy and in combination with established anti-cancer agents across treatment lines, and we believe the broader dataset will better position us to define the optimal development path and regulatory strategy for this important program."

"I believe we are well positioned to continue to advance these promising molecules, potentially offering new hope to patients requiring new, more effective treatment options while creating enduring value for our company," Dr. Alibhai concluded.

Upcoming Milestones:

- Preliminary topline data from a healthy volunteer study of the company's next-generation STAT3 inhibitor, TTI-109, anticipated in the second quarter of 2026
- Preliminary topline data from the company's ongoing REVERT LIVER CANCER Phase 1b/2 clinical trial of TTI-101, anticipated in the second half of 2026

Fourth Quarter and Full-Year 2025 Financial Results

Research and development expenses for the three months ended December 31, 2025, were \$5.5 million as compared to \$8.6

million for the comparable period in 2024. For the full year 2025, research and development expenses were \$18.0 million, as compared to \$23.7 million for the full year 2024. The decrease was primarily driven by declining clinical costs associated with TTI-101 offset by an increase in TTI-109 developmental costs.

General and administrative expenses were \$2.1 million for the three months ended December 31, 2025, as compared to \$2.2 million for the three months ended December 31, 2024. For the full year 2025, general and administrative expenses were \$8.7 million, as compared to \$4.5 million for the full year 2024. The increase was primarily driven by increases in professional fees, attributable to increased legal, accounting and audit fees incurred as a result of the merger with Cara Therapeutics and subsequent filings as a public company.

Net loss for the three months ended December 31, 2025, was \$7.3 million, as compared to a net loss of \$12.7 million for the comparable period in 2024. For the full year 2025, net loss was \$18.2 million, as compared to a net loss of \$29.4 million for the full year 2024.

Basic and diluted net loss per share attributable to common shareholders for the three months ended December 31, 2025, were a net loss of \$(0.78) on a basic and diluted basis, compared to a net loss of \$(4.94) on a basic and diluted basis for the comparable period in 2024. For the full year 2025, basic and diluted net loss attributable to common stockholders were \$(2.46) and \$(3.26), respectively, as compared to basic and diluted loss attributable to common stockholders of \$(11.42) for the full year 2024.

Cash, cash equivalents and short-term investments as of December 31, 2025, were \$30.8 million, as compared to \$31.6 million as of December 31, 2024. Tvardi anticipates that its current cash runway is sufficient to fund operations, as currently planned, through clinical readouts and into the fourth quarter of 2026.

About Tvardi Therapeutics

Tvardi is a clinical-stage biopharmaceutical company focused on the development of novel, oral small molecule therapies targeting STAT3 to treat inflammatory and proliferative diseases with significant unmet need. STAT3 is a central mediator across critical signaling pathways that drive uncontrolled, proliferation, survival and immune dysregulation. STAT3 is also positioned at the intersection of many signaling pathways integral to the survival and immune evasion of cancer cells. The company is conducting clinical trials with TTI-101 in hepatocellular carcinoma ([NCT05440708](#)) and TTI-109 in healthy volunteers. To learn more, please visit tvarditherapeutics.com or follow us on [LinkedIn](#) and [X \(Twitter\)](#).

Cautionary Statement Regarding Forward-looking Statements

Statements contained in this press release regarding matters that are not historical facts are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. Examples of these forward-looking statements include statements concerning the anticipated benefits of Tvardi’s product candidates; its ongoing clinical trials and anticipated timing of reporting data from such trials; potential indications for its product candidates; its anticipated cash runway; and other statements regarding management’s intentions, plans, beliefs, expectations or forecasts for the future, and, therefore, you are cautioned not to place undue reliance on them.

Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. These forward-looking statements are subject to a number of risks, including, among other things: the uncertainties associated with Tvardi’s product candidates, as well as risks associated with the clinical development and regulatory approval of product candidates, including potential delays in the completion of clinical trials; the significant net losses Tvardi has incurred since inception; Tvardi’s ability to initiate and complete ongoing and planned preclinical studies and clinical trials and advance its product candidates through clinical development; the timing of the availability of data from Tvardi’s clinical trials; the outcome of preclinical testing and clinical trials of the Tvardi’s product candidates, including the ability of those trials to satisfy relevant governmental or regulatory requirements; Tvardi’s plans to research, develop and commercialize its current and future product candidates; the clinical utility, potential benefits and market acceptance of Tvardi’s product candidates; the requirement for additional capital to continue to advance these product candidates, which may not be available on favorable terms or at all; Tvardi’s anticipated cash runway; Tvardi’s ability to attract, hire, and retain skilled executive officers and employees; Tvardi’s ability to protect its intellectual property and proprietary technologies; Tvardi’s reliance on third parties, contract manufacturers, and contract research organizations; the possibility that Tvardi may be adversely affected by other economic, business, or competitive factors; risks associated with changes in applicable laws or regulations; those factors discussed in Tvardi’s filings with the Securities and Exchange Commission, including the “Risk Factors” section of the Quarterly Report on Form 10-Q for the quarter ended September 30, 2025, and Tvardi’s other documents subsequently filed with or furnished to the SEC, all of which are available on the SEC’s website at www.sec.gov. All forward-looking statements contained in this press release speak only as of the date on which they were made. The company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law.

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TVARDI THERAPEUTICS
Consolidated Balance Sheets
(unaudited)

	As of December 31,	
	2025	2024
Assets		
Current assets:		
Cash and cash equivalents	\$ 20,734	\$ 31,614
Short-term investments	10,077	—
Prepaid expenses and other current assets	727	72
Total current assets	31,538	31,686
Property and equipment, net	52	84
Intangible assets, net	322	385
Operating lease right-of-use assets	144	216
Deferred offering costs	—	2,811
Other non-current assets	17	17
Total assets	\$ 32,073	\$ 35,199
Liabilities, Redeemable Convertible Preferred Stock, and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	\$ 3,219	2,186
Accrued expenses	7,707	8,078
Operating lease liabilities, current portion	116	103
Total current liabilities	11,042	10,367
Operating lease liabilities, net of current portion	85	201
Convertible Notes	—	30,259
Total liabilities	11,127	40,827
Commitments and contingencies (Note 13)		
Redeemable convertible preferred stock (Series A, B), \$0.001 par value; 0 shares and 29,723,540 shares authorized as of December 31, 2025 and 2024, respectively; 0 shares and 3,963,910 shares issued and outstanding as of December 31, 2025 and 2024, respectively; aggregate liquidation preference of \$0 and \$85,902 as of December 31, 2025 and 2024, respectively	—	85,503
Stockholders' Equity (Deficit):		
Common stock, \$0.001 par value; 150,000,000 shares and 58,251,629 shares authorized as of December 31, 2025 and 2024, respectively; 9,381,344, and 2,574,767 shares issued and outstanding as of December 31, 2025 and 2024, respectively	9	2
Additional paid-in capital	131,379	1,103
Accumulated other comprehensive income	8	—
Accumulated deficit	(110,450)	(92,236)
Total stockholders' equity (deficit)	20,946	(91,131)
Total liabilities, redeemable convertible preferred stock, and stockholders' equity (deficit)	\$ 32,073	\$ 35,199

TVARDI THERAPEUTICS
Consolidated Statement of Operations
(unaudited)

	For the Three Months Ended December 31,		For the Twelve Months Ended December 31,	
	2025	2024	2025	2024
Operating expenses:				
Research and development	\$ 5,491	\$ 8,603	\$ 18,011	\$ 23,650
General and administrative	2,096	2,199	8,737	4,457
Total operating expenses	<u>7,587</u>	<u>10,802</u>	<u>26,748</u>	<u>28,107</u>
Loss from operations	(7,587)	(10,802)	(26,748)	(28,107)
Interest income	312	132	1,375	747
Other income, net	-	(2,037)	7,159	(2,037)
Net loss	<u>\$ (7,275)</u>	<u>\$ (12,707)</u>	<u>\$ (18,214)</u>	<u>\$ (29,397)</u>
Net loss per share attributable to common stockholders:				
Basic	\$ (0.78)	\$ (4.94)	\$ (2.46)	\$ (11.42)
Diluted	\$ (0.78)	\$ (4.94)	\$ (3.26)	\$ (11.42)
Weighted-average common shares outstanding:				
Basic	9,380,819	2,574,233	7,419,060	2,574,233
Diluted	9,380,819	2,574,767	7,783,182	2,574,233
Comprehensive loss:				
Net loss	\$ (7,275)	\$ (12,707)	\$ (18,214)	\$ (29,397)
Unrealized gain on short-term investments	1	-	8	-
Comprehensive loss	<u>\$ (7,274)</u>	<u>\$ (12,707)</u>	<u>\$ (18,206)</u>	<u>\$ (29,397)</u>



Source: Tvardi Therapeutics