Tvardi Therapeutics Announces First Quarter 2026 Results and Provides Business Update

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Topline results from healthy volunteer study and clinical development strategy for next-generation STAT3 inhibitor, TTI-109, anticipated in June

Topline data from Phase 2 trial of TTI-101 in hepatocellular carcinoma (HCC) on track for 2H 2026

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

HOUSTON, May 08, 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 reported its financial and operating results for the first quarter ended March 31, 2026, and provided a business update.

Recent Progress and Upcoming Catalysts:

- TTI-109 (Healthy Volunteer Study): Study ongoing with topline data anticipated in June 2026. The Company plans to announce the clinical development strategy based on these results.
- TTI-101 (HCC – REVERT LIVER CANCER study): Phase 1b/2 trial remains on track to report topline results in 2H 2026.
- TTI-101 (IPF – REVERT IPF study additional analyses): Phase 2 trial showed that TTI-101 was associated with a 9.4% baseline-weighted reduction in fibrosis score compared to 2.4% for placebo. Treatment with TTI-101 was also associated with a 4.5-fold greater decline in IL-6, a central STAT3-driven inflammatory cytokine.

Imran Alibhai, Ph.D., Chief Executive Officer of Tvardi, stated, "We are approaching a key inflection point with topline data from our next-generation STAT3 inhibitor, TTI-109, expected in June. These results are expected to inform our future clinical development strategy."

"TTI-109 is designed to build on the preclinical and clinical activity observed with TTI-101 while potentially offering improved tolerability through its prodrug profile and enabling broader development across inflammatory and proliferative diseases driven by STAT3."

"In parallel, we remain on track to report topline data from our ongoing Phase 2 REVERT LIVER CANCER trial in the second half of this year. Prior interim findings demonstrated clinically meaningful activity across treatment settings, and we look forward to evaluating the full dataset."

"We continue to make significant progress advancing both programs, providing line of sight to two near-term value inflection points," Dr. Alibhai concluded.

Key Upcoming Milestones:

- June 2026: TTI-109 Phase 1 healthy volunteer topline data and clinical development strategy
- 2H 2026: TTI-101 Phase 1b/2 HCC topline data

First Quarter 2026 Financial Results

Research and development expenses for the three months ended March 31, 2026, were $4.9 million as compared to $3.1 million for the comparable period in 2025. The increase was primarily driven by higher TTI-109 developmental costs, partly offset by declining clinical costs associated with TTI-101.

General and administrative expenses were $2.1 million for the three months ended March 31, 2026, as compared to $1.2 million for the three months ended March 31, 2025. The increase was primarily driven by higher personnel costs, including

stock-based compensation, and professional fees, including costs associated with being a publicly traded company.

Net loss for the three months ended March 31, 2026, was $6.8 million, as compared to a net loss of $9.6 million for the comparable period in 2025.

Basic and diluted net loss per share attributable to common shareholders for the three months ended March 31, 2026, were a net loss of $(0.73), compared to a net loss of $(3.72) for the comparable period in 2025.

Cash, cash equivalents and short-term investments as of March 31, 2026, were $25.0 million, as compared to $30.8 million as of December 31, 2025. 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-109 in healthy volunteers and TTI-101 in hepatocellular carcinoma (NCT05440708). 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 Annual Report on Form 10-K for the year ended December 31, 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 March 31, 2026	As of December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 19,851	$ 20,734
Short-term investments	5,130	10,077
Prepaid expenses and other current assets	345	727
Total current assets	25,326	31,538
Property and equipment, net	44	52
Intangible assets, net	306	322
Operating lease right-of-use assets	124	144
Other non-current assets	17	17
Total assets	$ 25,817	$ 32,073
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,620	$ 3,219
Accrued expenses	6,518	7,707
Operating lease liabilities, current portion	120	116
Total current liabilities	11,258	11,042
Operating lease liabilities, net of current portion	54	85
Total liabilities	11,312	11,127
Commitments and contingencies (Note 12)		
Stockholders' Equity:		
Common stock, $0.001 par value; 150,000,000 shares authorized as of March 31, 2026 and December 31, 2025; 9,381,344 shares issued and outstanding as of March 31, 2026 and December 31, 2025	9	9
Additional paid-in capital	131,749	131,379
Accumulated other comprehensive income	1	8
Accumulated deficit	(117,254)	(110,450)
Total stockholders' equity	14,505	20,946
Total liabilities and stockholders' equity	$ 25,817	$ 32,073

TVARDI THERAPEUTICS
Consolidated Statement of Operations
(unaudited)

	For the Three Months Ended March 31,	
	2026	2025
Operating expenses:		
Research and development	$ 4,911	$ 3,111
General and administrative	2,140	1,243
Total operating expenses	7,051	4,354
Loss from operations	(7,051)	(4,354)
Interest income	247	275
Other expense	—	(5,500)
Net loss	$ (6,804)	$ (9,579)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.73)	$ (3.72)
Weighted-average common shares outstanding, basic and diluted	9,381,344	2,575,462

Comprehensive loss:		
Net loss	$ (6,804)	$ (9,579)
Unrealized (loss) gain on short-term investments	(7)	2
Comprehensive loss	$ (6,811)	$ (9,577)

Source: Tvardi Therapeutics