



Tvardi Therapeutics Announces Second Quarter 2025 Results and Provides Business Update

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On track for multiple Phase 2 data readouts with STAT3 inhibitor, TTI-101, with lead program in IPF expected in Q4 2025

Cash runway anticipated to be sufficient to fund operations into Q4 2026

HOUSTON--(BUSINESS WIRE)--Aug. 14, 2025-- 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 fibrosis-driven diseases, today announced its financial and operating results for the second quarter ended June 30, 2025, and provided a business update.

Second Quarter 2025 Highlights:

- Announced completion of enrollment in its REVERT IPF clinical trial, a Phase 2 trial of TTI-101, for patients with idiopathic pulmonary fibrosis (IPF); topline data on track for Q4 2025.
- Submitted an Investigational New Drug (IND) application for its second clinical candidate, TTI-109, with the U.S. Food and Drug Administration (FDA) in June 2025.
- Announced that an abstract, entitled *Single Cell Transcriptomics in A Treatment Status Segregated Cohort Exposes a STAT-3-Regulated Therapeutic Gap in Idiopathic Pulmonary Fibrosis*, was presented at the American Thoracic Society (ATS) 2025 Annual Conference.
- Completed its merger with Cara Therapeutics, transitioning Tvardi into a publicly traded company.

Imran Alibhai, Ph.D., Chief Executive Officer of Tvardi, stated, "We are on track for topline data in the fourth quarter from our fully enrolled REVERT IPF Phase 2 clinical trial. These data will offer important additional insights into the safety and efficacy of TTI-101, and, if positive, we believe will further validate our approach of targeting STAT3, a central mediator of fibrosis, to treat patients with IPF.

"In parallel, our Phase 2 REVERT Liver Cancer trial continues to enroll patients, and we remain on track to report topline results in the first half of 2026. Prior interim data from this ongoing study demonstrated clinically meaningful activity of TTI-101 as both monotherapy and in combination with established anti-cancer agents across treatment lines.

"Importantly, we are well-financed through these potential value inflection points, and into Q4 of next year. We believe we are very well positioned to bring meaningful innovation to patients living with fibrosis driven-diseases while creating significant value for our company."

Upcoming Milestones:

- Data from the company's ongoing REVERT IPF Phase 2 clinical trial of TTI-101 anticipated in 4Q 2025
- Preliminary topline data from the company's ongoing REVERT Liver Cancer Phase 1b/2 clinical trial of TTI-101 anticipated in 1H 2026

Second Quarter 2025 Financial Results

Research and development expenses for the three months ended June 30, 2025, were \$5.8 million as compared to \$6.5 million for the comparable period in 2024. The decrease of \$0.7 million was primarily driven by clinical, pre-clinical, and CMC costs associated with TTI-101.

General and administrative expenses for the three months ended June 30, 2025, were \$3.1 million as compared to \$650,000 for the comparable period in 2024. The increase of \$2.4 million was primarily driven by increases in professional fees of \$1.6 million, attributable to increased legal, accounting and audit fees incurred as a result of the merger. The remaining increase was attributable to increases in personnel costs, insurance costs, and other costs.

Net income for the three months ended June 30, 2025, was \$4.2 million as compared to a net loss of \$7.0 million for the comparable period in 2024. The improvement in net income was due primarily to a \$12.8 million remeasurement gain on Tvardi's Convertible Notes recognized in the second quarter of 2025.

Basic and diluted net income (loss) per share attributable to common shareholders for the three months ended June 30, 2025,

were a net gain of \$0.51 and net loss of \$1.00, respectively, compared to a net loss of \$2.71 on a basic and diluted basis for the comparable period in 2024.

Cash, cash equivalents and short-term investments as of June 30, 2025, were \$41.0 million, as compared to \$31.6 million as of December 31, 2024.

About Tvardi Therapeutics

Tvardi is a clinical-stage biopharmaceutical company focused on the development of novel, oral small molecule therapies targeting STAT3 to treat fibrosis-driven diseases with significant unmet need. STAT3 is a central mediator across critical fibrotic signaling pathways that drive uncontrolled deposition, proliferation, survival and immune suppression. 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 Phase 2 clinical trials in fibrosis-driven diseases with high unmet need: idiopathic pulmonary fibrosis ([NCT05671835](#)) and 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; 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 June 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 combined 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.

TVARDI THERAPEUTICS Consolidated Balance Sheets (Unaudited)

	<u>As of June 30,</u> <u>2025</u>	<u>As of December</u> <u>31,</u> <u>2024</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 20,648	\$ 31,614
Short-term investments	20,346	—
Prepaid expenses and other current assets	2,136	72
Total current assets	43,130	31,686
Property and equipment, net	68	84
Intangible assets, net	354	385
Operating lease right-of-use assets	181	216
Deferred offering costs	—	2,811
Other non-current assets	17	17

Total assets	\$ 43,750	\$ 35,199
Liabilities, Redeemable Convertible Preferred Stock, and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	\$ 2,425	2,186
Accrued expenses	8,144	8,078
Operating lease liabilities, current portion	109	103
Total current liabilities	10,678	10,367
Operating lease liabilities, net of current portion	145	201
Convertible Notes	—	30,259
Total liabilities	10,823	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 June 30, 2025 and December 31, 2024, respectively; 0 shares and 3,963,910 shares issued and outstanding as of June 30, 2025 and December 31, 2024, respectively; aggregate liquidation preference of \$0 and \$85,902 as of June 30, 2025 and December 31, 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 June 30, 2025 and December 31, 2024, respectively; 9,373,433, and 2,574,767 shares issued and outstanding as of June 30, 2025 and December 31, 2024, respectively	9	2
Additional paid-in capital	130,579	1,103
Accumulated other comprehensive loss	(13)	—
Accumulated deficit	(97,648)	(92,236)
Total stockholders' equity (deficit)	32,927	(91,131)
Total liabilities, redeemable convertible preferred stock, and stockholders' equity (deficit)	\$ 43,750	\$ 35,199

TVARDI THERAPEUTICS
Consolidated Statement of Operations
(Unaudited)

	For the Three Months Ended June 30,	
	2025	2024
Operating expenses:		
Research and development	\$ 5,806	\$ 6,531
General and administrative	3,063	650
Total operating expenses	8,869	7,181
Loss from operations	(8,869)	(7,181)
Interest income	377	206
Other income, net	12,659	—
Net income (loss)	\$ 4,167	\$ (6,975)
Net income (loss) per share attributable to common stockholders:		
Basic	\$ 0.51	\$ (2.71)
Diluted	\$ (1.00)	\$ (2.71)
Weighted-average common shares outstanding:		
Basic	8,246,582	2,574,767

Diluted	8,455,223	2,574,767
Comprehensive income (loss):		
Net income (loss)	\$ 4,167	\$ (6,975)
Unrealized loss on short-term investments	(15)	—
Comprehensive income (loss)	<u>\$ 4,152</u>	<u>\$ (6,975)</u>

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