



## Tvardi Therapeutics Announces Third Quarter 2025 Results and Provides Business Update

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*On track for topline data from Phase 2 trial of TTI-101 in hepatocellular carcinoma (HCC) in H1 2026*

*Results from healthy volunteer study of its next-generation STAT3 inhibitor, TTI-109, expected in H1 2026*

*Cash runway sufficient to fund operations into Q4 2026*

HOUSTON--(BUSINESS WIRE)--Nov. 13, 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 third quarter ended September 30, 2025, and provided a business update.

### Third Quarter 2025 and Recent Highlights:

- Continued to progress its Phase 2 study of TTI-101 in HCC, with topline data anticipated in the first half of 2026.
- Announced that the IND for its next-generation STAT3 inhibitor, TTI-109, is in effect and that a healthy volunteer study has been initiated, results of which are anticipated in the first half of 2026.
- In October, the company reported preliminary data from the Phase 2 REVERT IPF trial and concluded that the study did not meet its goals. Tvardi is conducting additional analyses to further understand these results and inform next steps.

Imran Alibhai, Ph.D., Chief Executive Officer of Tvardi, stated, "While we continue to analyze the results from our REVERT IPF clinical trial to determine the most appropriate path forward, we remain confident in the potential of STAT3 inhibition to address fibrosis-driven diseases. We believe our lead program, TTI-101, has demonstrated encouraging clinical activity in oncology and continues to hold promise across a range of indications where STAT3 is a key driver.

"To that end, we eagerly await data from our ongoing Phase 2 REVERT Liver Cancer trial in the first half of next year. 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.

"At the same time, we are also advancing our next-generation STAT3 inhibitor, TTI-109, through a healthy volunteer study. TTI-109 is designed to rapidly convert to TTI-101 and lessen the exposure of the active drug to the intestinal lining. We believe TTI-109 strengthens our STAT3-targeted approach by providing a more efficient delivery mechanism for TTI-101 that has the potential to improve tolerability.

"With a balance sheet extending into the fourth quarter of next year, we remain focused on fully realizing the therapeutic potential of STAT3 inhibition across fibrotic diseases."

### Upcoming Milestones:

- Preliminary topline data from the company's ongoing REVERT Liver Cancer Phase 1b/2 clinical trial of TTI-101 anticipated in the first half of 2026
- Preliminary topline data from a healthy volunteer study of its next-generation STAT3 inhibitor, TTI-109, also anticipated in the first half of 2026

### Third Quarter 2025 Financial Results

**Research and development expenses** for the three months ended September 30, 2025, were \$3.6 million as compared to \$4.8 million for the comparable period in 2024. The decrease of \$1.2 million was primarily driven by lower costs associated with TTI-101, including decreases of \$1.4 million and \$1.0 million related to Tvardi's HCC and IPF trials, respectively. The decrease in Tvardi's HCC trial expense was primarily attributable to the changes in patient enrollments and estimated study costs, while the decrease in Tvardi's IPF trial expense was attributable to the trial being completed in the second quarter of 2025. These declines were partly offset by an increase of \$2.0 million related to the ongoing healthy volunteer study of TTI-109, which began in the third quarter of 2025, as well as related CMC costs.

**General and administrative expenses** were \$2.3 million for the three months ended September 30, 2025, compared to \$0.9 million for the three months ended September 30, 2024. The increase of approximately \$1.5 million was primarily driven by

increases in professional fees of \$0.7 million, attributable to higher legal fees and ongoing accounting and audit fees. The remaining increase was attributable to higher personnel costs, insurance costs and rent and other related costs.

**Net loss** for the three months ended September 30, 2025 was \$5.5 million, roughly flat with the comparable period in 2024.

**Basic and diluted net loss per share** attributable to common shareholders for the three months ended September 30, 2025 were a net loss of \$0.59 on a basic and diluted basis, compared to a net loss of \$2.14 on a basic and diluted basis for the comparable period in 2024.

**Cash, cash equivalents and short-term investments** as of September 30, 2025, were \$36.5 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, 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 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 clinical trials with TTI-101 in hepatocellular carcinoma ([NCT05440708](https://clinicaltrials.gov/ct2/show/study/NCT05440708)) and TTI-109 in healthy volunteers. To learn more, please visit [tvarditherapeutics.com](https://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; the final results of its clinical trial of TTI-101 in IPF; 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](https://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.

## TVARDI THERAPEUTICS Consolidated Balance Sheets (Unaudited)

|                           | As of<br>September<br>30,<br>2025 | As of<br>December<br>31,<br>2024 |
|---------------------------|-----------------------------------|----------------------------------|
| <b>Assets</b>             |                                   |                                  |
| Current assets:           |                                   |                                  |
| Cash and cash equivalents | \$ 21,418                         | \$ 31,614                        |
| Short-term investments    | 15,042                            | —                                |

|                                           |                  |                  |
|-------------------------------------------|------------------|------------------|
| Prepaid expenses and other current assets | 1,983            | 72               |
| Total current assets                      | 38,443           | 31,686           |
| Property and equipment, net               | 60               | 84               |
| Intangible assets, net                    | 338              | 385              |
| Operating lease right-of-use assets       | 163              | 216              |
| Deferred offering costs                   | —                | 2,811            |
| Other non-current assets                  | 17               | 17               |
| Total assets                              | <u>\$ 39,021</u> | <u>\$ 35,199</u> |

**Liabilities, Redeemable Convertible Preferred Stock, and Stockholders' Equity (Deficit)**

Current liabilities:

|                                                     |               |               |
|-----------------------------------------------------|---------------|---------------|
| Accounts payable                                    | \$ 4,078      | 2,186         |
| Accrued expenses                                    | 6,849         | 8,078         |
| Operating lease liabilities, current portion        | 113           | 103           |
| Total current liabilities                           | 11,040        | 10,367        |
| Operating lease liabilities, net of current portion | 115           | 201           |
| Convertible Notes                                   | —             | 30,259        |
| Total liabilities                                   | <u>11,155</u> | <u>40,827</u> |

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 September 30, 2025 and December 31, 2024, respectively; 0 shares and 3,963,910 shares issued and outstanding as of September 30, 2025 and December 31, 2024, respectively; aggregate liquidation preference of \$0 and \$85,902 as of September 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 September 30, 2025 and December 31, 2024, respectively; 9,379,332, and 2,574,767 shares issued and outstanding as of September 30, 2025 and December 31, 2024, respectively

|                                                                                               |                  |                  |
|-----------------------------------------------------------------------------------------------|------------------|------------------|
| Additional paid-in capital                                                                    | 9                | 2                |
| Accumulated other comprehensive income                                                        | 131,025          | 1,103            |
| Accumulated deficit                                                                           | 7                | —                |
|                                                                                               | (103,175)        | (92,236)         |
| Total stockholders' equity (deficit)                                                          | 27,866           | (91,131)         |
| Total liabilities, redeemable convertible preferred stock, and stockholders' equity (deficit) | <u>\$ 39,021</u> | <u>\$ 35,199</u> |

**TVARDI THERAPEUTICS**  
**Consolidated Statement of Operations**  
**(Unaudited)**

|                            | For the Three Months Ended September 30, |                   | For the Nine Months Ended September 30, |                    |
|----------------------------|------------------------------------------|-------------------|-----------------------------------------|--------------------|
|                            | 2025                                     | 2024              | 2025                                    | 2024               |
| Operating expenses:        |                                          |                   |                                         |                    |
| Research and development   | \$ 3,603                                 | \$ 4,795          | \$ 12,520                               | \$ 15,047          |
| General and administrative | 2,335                                    | 881               | 6,641                                   | 2,258              |
| Total operating expenses   | 5,938                                    | 5,676             | 19,161                                  | 17,305             |
| Loss from operations       | (5,938)                                  | (5,676)           | (19,161)                                | (17,305)           |
| Interest income            | 411                                      | 163               | 1,063                                   | 615                |
| Other income, net          | —                                        | —                 | 7,159                                   | —                  |
| Net loss                   | <u>\$ (5,527)</u>                        | <u>\$ (5,513)</u> | <u>\$ (10,939)</u>                      | <u>\$ (16,690)</u> |

Net loss per share attributable to common stockholders:

|                                             |            |            |             |             |
|---------------------------------------------|------------|------------|-------------|-------------|
| Basic                                       | \$ (0.59)  | \$ (2.14)  | \$ (1.62)   | \$ (6.48)   |
| Diluted                                     | \$ (0.59)  | \$ (2.14)  | \$ (2.50)   | \$ (6.48)   |
| Weighted-average common shares outstanding: |            |            |             |             |
| Basic                                       | 9,377,079  | 2,574,767  | 6,757,955   | 2,574,054   |
| Diluted                                     | 9,377,079  | 2,574,767  | 7,244,785   | 2,574,054   |
| Comprehensive loss:                         |            |            |             |             |
| Net loss                                    | \$ (5,527) | \$ (5,513) | \$ (10,939) | \$ (16,690) |
| Unrealized gain on short-term investments   | 20         | —          | 7           | —           |
| Comprehensive loss                          | \$ (5,507) | \$ (5,513) | \$ (10,932) | \$ (16,690) |

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