



Tvardi Therapeutics Announces First Quarter 2025 Results and Provides Business Update

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Completed merger with Cara Therapeutics; cash, cash equivalents and short-term investments at closing anticipated to be sufficient to fund operations into 2H 2026

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

HOUSTON--(BUSINESS WIRE)--May 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 first quarter ended March 31, 2025, and provided a business update.

First Quarter 2025 and Subsequent Period Highlights:

- Tvardi completed its merger with Cara Therapeutics.
 - Tvardi received approximately \$23.8 million in net cash from Cara in connection with the closing of the merger. This capital augments the previously announced December 2024 private placement financing of approximately \$28.3 million from a syndicate of new and existing institutional investors.
- 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*, will be presented at the upcoming American Thoracic Society 2025 Annual Conference, which is being held May 16-21, 2025 in San Francisco.
- Announced that results from the first-in-human Phase 1 study of TTI-101 in patients with advanced solid tumors were published in the journal [Clinical Cancer Research](#).

Dr. Imran Alibhai, Chief Executive Officer of Tvardi, stated, "While it has only been a few weeks since we completed our merger with Cara Therapeutics, our Nasdaq listing has heightened our visibility and potential access to capital. With the cash on our balance sheet, we believe we are well financed through meaningful value inflection points, including anticipated Phase 2 readouts of our lead program in idiopathic pulmonary fibrosis (IPF) as well as our hepatocellular carcinoma program. We expect that our anticipated cash runway, as of the closing of the merger, will be sufficient to fund our operations approximately one year post data readouts in IPF, into the second half of 2026."

Upcoming Milestones:

- Investigational New Drug (IND) submission planned for its second clinical candidate, TTI- 109, in 1H 2025
- Data from the company's ongoing REVERT IPF Phase 2 clinical trial of TTI-101 anticipated in 2H 2025
- Preliminary topline data from the company's ongoing REVERT Liver Cancer Phase 1b/2 clinical trial of TTI-101 anticipated in 1H 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 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 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 Registration Statement on Form S-4, as amended (File No. 333-283900) initially filed with the Securities and Exchange Commission (the "SEC") on December 18, 2024 and declared effective by the SEC on February 14, 2025, and Tvardi's other documents subsequently filed with or furnished to the SEC. 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.

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