UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 OR 15(d) of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported) **August 14, 2026**

TVARDI THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-36279**	**75-3175693**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)
3 Sugar Creek Ctr. Blvd. **Suite 525** **Sugar Land, Texas** (Address of principal executive offices)		**77478** (Zip Code)

Registrant's telephone number, including area code: **(713) 489-8654**

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2.):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.001 per share	TVRD	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02. Results of Operations and Financial Condition.

On August 14, 2026, Tvardi Therapeutics, Inc. (the "Company") issued a press release announcing its financial results and business highlights for the fiscal quarter ended June 30, 2026. A copy of the Company's press release dated August 14, 2026 is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

The information contained herein and the accompanying Exhibit 99.1 is being furnished under "Item 2.02 Results of Operations and Financial Condition" and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended, nor shall it be deemed incorporated by reference in any filing with the Securities and Exchange Commission made by us, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued on August 14, 2026.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

TVARDI THERAPEUTICS, INC.

Date: August 14, 2026

By: /s/ Imran Alibhai
Name: Imran Alibhai
Title: Chief Executive Officer

Exhibit 99.1

Tvardi Therapeutics Announces Second Quarter 2026 Results and Provides Business Update

Reported topline healthy volunteer results for next-generation STAT3 inhibitor TTI-109, confirming the prodrug design, improved tolerability and reductions in disease-relevant immune cell populations

Announced ulcerative colitis (UC) as the initial disease indication for TTI-109 and will host a KOL webinar on the clinical potential of TTI-109 in UC on August 19, 2026, at 11:00 a.m. ET

HOUSTON, TX – August 14, 2026 – Tvardi Therapeutics, Inc. ("Tvardi" or the "Company") (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 second quarter ended June 30, 2026, and provided a business update.

Recent Developments

- Reported topline results from the healthy volunteer study of its next-generation STAT3 inhibitor, TTI-109, confirming prodrug design, improved tolerability and pharmacodynamic evidence of STAT3 target engagement.
    - TTI-109 delivered TTI-101-equivalent exposure with improved tolerability and, across the active dose range, reductions in cellular and humoral immune populations known to correlate with UC disease severity.
- Selected UC as the initial disease indication for TTI-109, based on its ability to modulate multiple pathogenic pathways downstream of STAT3 simultaneously.
    - In UC, STAT3 acts as a single convergent node downstream of multiple signaling pathways implicated in disease progression, integrating immune dysregulation, inflammation and tissue remodeling.
    - These findings are further supported by published clinical studies linking reductions in activated STAT3 with higher rates of clinical remission across multiple UC therapeutic classes.
    - UC represents a large, underserved market, with more than 1.25 million patients diagnosed in the U.S. and an addressable market of approximately $3 billion in the U.S. and $9 billion globally.
- Announced that the Company will host a KOL webinar on the clinical potential of TTI-109 in UC featuring Randy Longman, MD, PhD (Weill Cornell Medicine) on August 19, 2026, at 11:00 a.m. ET.

Imran Alibhai, Ph.D., Chief Executive Officer of Tvardi, stated, "Since our last quarterly report, we have made significant progress in the clinical development of our STAT3 inhibitors. Regarding our next-generation STAT3 inhibitor, TTI-109, we were enthusiastic to see modulation of disease-relevant immune cell population even in healthy volunteers. We believe this bodes well for the development of TTI-109 in inflammatory and proliferative diseases, like UC."

Key Upcoming Milestones

- August 19, 2026: KOL webinar with Randy Longman, M.D., Ph.D., on the UC treatment landscape and TTI-109. To register, please click here
- 4Q 2026: TTI-101 Phase 1b/2 HCC topline data
- 2027: Initiation of clinical trial of TTI-109 in UC, subject to clearance of Investigational New Drug (IND) application and additional funding

Second Quarter 2026 Financial Results

Research and development expenses for the three months ended June 30, 2026, were $4.0 million as compared to $5.8 million for the comparable period in 2025. The decrease was primarily driven by lower clinical costs associated with TTI-101, partially offset by higher development costs associated with TTI-109.

General and administrative expenses were $2.6 million for the three months ended June 30, 2026, as compared to $3.1 million for the three months ended June 30, 2025. The decrease was primarily driven by lower professional fees, reflecting higher accounting and consulting costs in the comparable 2025 period associated with the Company's April 2025 merger, partially offset by higher legal and investor relations costs associated with operating as a public company.

Net loss for the three months ended June 30, 2026, was $6.5 million, compared to net income of $4.2 million for the three months ended June 30, 2025. Net income in the prior-year period reflected a $12.7 million non-cash gain from the change in fair value of the Company's convertible notes, which converted into common stock in connection with the Company's merger with Cara Therapeutics in April 2025.

Basic and diluted net loss per share attributable to common shareholders for the three months ended June 30, 2026, were both $(0.69). Basic net income per share attributable to common shareholders for the three months ended June 30, 2025 was $0.51, and diluted net loss per share for the same period was $(1.00), reflecting the dilutive impact of the Company's convertible notes prior to their conversion into common stock in April 2025.

Cash, cash equivalents and short-term investments as of June 30, 2026, were $15.8 million, as compared to $30.8 million as of December 31, 2025. Tvardi anticipates that its existing cash, cash equivalents and short-term investments will be sufficient to fund operations, as currently planned, through the HCC topline readout into the third quarter of 2027. Advancing TTI-109 into UC and additional indications will require additional funding and IND clearance.

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 or safety or other complications related to its product candidates; the ability to obtain IND clearance for TTI-109 in UC on the timelines expected or at all; the requirement for additional capital to continue to advance these product candidates, which may not be available on favorable terms or at all; 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 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; 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
(in thousands, unaudited)

	June 30, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 15,765	$ 20,734
Short-term investments	—	10,077
Prepaid expenses and other current assets	1,304	727
Total current assets	**17,069**	**31,538**
Property and equipment, net	36	52
Intangible assets, net	291	322
Operating lease right-of-use assets	104	144
Other non-current assets	17	17
Total assets	**$ 17,517**	**$ 32,073**
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,638	$ 3,219
Accrued expenses	4,352	7,707
Operating lease liabilities, current portion	123	116
Total current liabilities	**9,113**	**11,042**
Operating lease liabilities, net of current portion	22	85
Total liabilities	**9,135**	**11,127**
Stockholders' equity:		
Common stock	9	9
Additional paid-in capital	132,084	131,379
Accumulated other comprehensive income	—	8
Accumulated deficit	(123,711)	(110,450)
Total stockholders' equity	**8,382**	**20,946**
Total liabilities and stockholders' equity	**$ 17,517**	**$ 32,073**

TVARDI THERAPEUTICS
Consolidated Statements of Operations
(in thousands, except share and per share data, unaudited)

	Three Months Ended		Six Months Ended	
	June 30, 2026	**June 30, 2025**	**June 30, 2026**	**June 30, 2025**
Operating expenses:				
Research and development	$ 4,002	$ 5,806	$ 8,913	$ 8,917
General and administrative	2,627	3,063	4,767	4,306
Total operating expenses	**6,629**	**8,869**	**13,680**	**13,223**
Loss from operations	(6,629)	(8,869)	(13,680)	(13,223)
Interest income	172	377	419	652
Other income, net	—	12,659	—	7,159
Net (loss) income	**$ (6,457)**	**$ 4,167**	**$ (13,261)**	**$ (5,412)**
Net (loss) income per share attributable to common stockholders:				
Basic	$ (0.69)	$ 0.51	$ (1.41)	$ (1.00)
Diluted	$ (0.69)	$ (1.00)	$ (1.41)	$ (2.04)
Weighted-average common shares outstanding:				
Basic	9,381,344	8,246,582	9,381,344	5,426,688
Diluted	9,381,344	8,455,223	9,381,344	6,160,967