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) **November 13, 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**	**77478**
(Address of principal executive offices)	(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 November 13, 2026, Tvardi Therapeutics, Inc. (the "Company") issued a press release announcing its financial results and business highlights for the fiscal quarter ended September 30, 2026. A copy of the Company's press release dated November 13, 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 November 13, 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: November 13, 2026

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

Tvardi Therapeutics Announces Third Quarter 2026 Results and Provides Business Update

HOUSTON, TX – November 13, 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 third quarter ended September 30, 2026, and provided a business update.

Business and Clinical Program Updates:

TTI-109 – Ulcerative Colitis (UC)

- **Advancing development plans for TTI-109 in UC.** Building on positive Phase 1 healthy volunteer results reported in July and the subsequent selection of UC as its initial target indication, Tvardi is preparing to advance TTI-109 into clinical development in UC, subject to clearance of our Investigational New Drug (IND) application and additional funding.
    - The Phase 1 results confirmed the prodrug design, with TTI-109 delivering TTI-101-equivalent exposure with improved tolerability and, across the active dose range, demonstrated reductions in cellular and humoral immune populations known to correlate with UC disease severity, providing pharmacodynamic evidence of STAT3 target engagement.

- **Published additional preclinical data supporting STAT3 inhibition in UC.** New findings published in the *International Journal of Molecular Sciences* demonstrated that, in a preclinical model of chronic colitis, TTI-101 achieved colon tissue exposure approximately eightfold higher than in plasma, normalized disease-associated changes in colon gene expression, muted colitis-associated changes in the gut microbiome and prevented the formation of colon adenocarcinomas, a long-term consequence of chronic colitis.
    - The preclinical data highlights the potential of STAT3 inhibition to address immune dysregulation, inflammation and fibrosis that drive UC progression. These findings build on prior preclinical studies in which TTI-101 and TTI-109 significantly reduced disease activity across three acute colitis models representing distinct immune axes.

TTI-101 – Hepatocellular Carcinoma (HCC)

- **Advancing Phase 1b/2 REVERT LIVER CANCER study toward topline readout in early first quarter of 2027.** The ongoing REVERT LIVER CANCER study is evaluating TTI-101 as monotherapy and in combination with established therapies in patients with HCC. The Company expects to report topline data early in the first quarter of 2027 to allow for complete cohort evaluation.

Imran Alibhai, Ph.D., Chief Executive Officer of Tvardi, stated, "We continue to make meaningful progress across our pipeline. Positive Phase 1 results for TTI-109 have strengthened our confidence in its potential as we prepare to advance this next-generation STAT3 inhibitor into clinical development in ulcerative colitis and potentially other inflammatory bowel diseases in 2027, subject to the availability of additional funding. In HCC, we remain encouraged by the previously reported interim results for TTI-101 and look forward to the topline readout in early first quarter of 2027, which will help inform our next steps."

Key Upcoming Milestones

- 2027: Initiation of clinical trial of TTI-109 in UC, subject to IND clearance and additional funding
- Early first quarter of 2027: TTI-101 Phase 1b/2 HCC topline data

Third Quarter 2026 Financial Results

Research and development expenses for the three months ended September 30, 2026, were $4.5 million, compared to $3.6 million for the comparable period in 2025. The increase was primarily driven by higher clinical costs associated with TTI-101.

General and administrative expenses were $1.9 million for the three months ended September 30, 2026, compared to $2.3 million for the three months ended September 30, 2025. The decrease was primarily driven by lower professional fees.

Net loss for the three months ended September 30, 2026, was $6.1 million, compared to a net loss of $5.5 million for the three months ended September 30, 2025.

Basic and diluted net loss per share attributable to common stockholders for the three months ended September 30, 2026, were both $(0.48), compared to basic and diluted net loss per share of $(0.59) for the three months ended September 30, 2025.

Cash and cash equivalents as of September 30, 2026, were $22.3 million, compared to cash, cash equivalents and short-term investments of $30.8 million as of December 31, 2025. Tvardi anticipates that its existing cash and cash equivalents will be sufficient to fund operations, as currently planned, into the third quarter of 2027. Advancing TTI-109 into UC and additional indications remain subject to 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 immune dysregulation, inflammation, and proliferation. STAT3 is also positioned at the intersection of many signaling pathways integral to the survival and immune evasion of cancer cells. The Company has completed a Phase 1 healthy volunteer study of TTI-109 and plans to initiate clinical trials of TTI-109 in ulcerative colitis pending IND clearance and the availability of additional funding. The Company is also conducting a Phase 1b/2 clinical trial of 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 ability to replicate results for preclinical studies and early clinical trials in later trials; 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
(Unaudited, amounts in thousands, except share and per share amounts)

	As of September 30, 2026	As of December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 22,275	$ 20,734
Short-term investments	—	10,077
Prepaid expenses and other current assets	855	727
Total current assets	23,130	31,538
Property and equipment, net	28	52
Intangible assets, net	275	322
Operating lease right-of-use assets	83	144
Other non-current assets	17	17
Total assets	$ 23,533	$ 32,073
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,076	$ 3,219
Accrued expenses	5,885	7,707
Operating lease liabilities, current portion	116	116
Total current liabilities	8,077	11,042
Operating lease liabilities, net of current portion	—	85
Total liabilities	8,077	11,127
Stockholders' Equity:		
Common stock, $0.001 par value; 150,000,000 shares authorized as of September 30, 2026 and December 31, 2025; 13,345,956 shares and 9,381,344 shares issued and outstanding as of September 30, 2026 and December 31, 2025, respectively	13	9
Additional paid-in capital	145,278	131,379
Accumulated other comprehensive income	—	8
Accumulated deficit	(129,835)	(110,450)
Total stockholders' equity	15,456	20,946
Total liabilities and stockholders' equity	$ 23,533	$ 32,073

TVARDI THERAPEUTICS
Consolidated Statements of Operations
(Unaudited, amounts in thousands, except share and per share amounts)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2026	**2025**	**2026**	**2025**
Operating expenses:				
Research and development	$ 4,474	$ 3,603	$ 13,387	$ 12,520
General and administrative	1,854	2,335	6,621	6,641
Total operating expenses	6,328	5,938	20,008	19,161
Loss from operations	(6,328)	(5,938)	(20,008)	(19,161)
Interest income	204	411	623	1,063
Other income, net	—	—	—	7,159
Net loss	$ (6,124)	$ (5,527)	$ (19,385)	$ (10,939)
Net loss per share attributable to common stockholders:				
Basic	$ (0.48)	$ (0.59)	$ (1.85)	$ (1.62)
Diluted	$ (0.48)	$ (0.59)	$ (1.85)	$ (2.50)
Weighted-average common shares outstanding:				
Basic	12,653,836	9,377,079	10,484,162	6,757,955
Diluted	12,653,836	9,377,079	10,484,162	7,244,785
Comprehensive loss:				
Net loss	$ (6,124)	$ (5,527)	$ (19,385)	$ (10,939)
Unrealized (loss) gain on short-term investments	—	20	(8)	7
Comprehensive loss	$ (6,124)	$ (5,507)	$ (19,393)	$ (10,932)