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

FORM 10-Q

(Mark One)

☒ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2025

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

COMMISSION FILE NUMBER 001-36279

TVARDI THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware **(State or other jurisdiction of incorporation or organization)**	**75-3175693** **(I.R.S. Employer Identification No.)**
3 Sugar Creek Ctr. Blvd. **Suite 525** **Sugar Land, Texas** **(Address of registrant's principal executive offices)**	**77478** **(Zip Code)**

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

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

Title of each class	Trading Symbol	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 (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☒Yes ☐ No.

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). ☒Yes ☐ No.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer", "accelerated filer", "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		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. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). ☐Yes ☒ No.

The number of outstanding shares of the registrant's common stock, par value $0.001 per share, as of November 10, 2025 was: 9,381,344.

TVARDI THERAPEUTICS, INC.

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FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2025

PART I —FINANCIAL INFORMATION

Item 1. Financial Statements

TVARDI THERAPEUTICS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited, amounts in thousands, except share and per share amounts)

	As of September 30, 2025	As of December 31, 2024
Assets		
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	$ 39,021	$ 35,199
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	11,155	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 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	9	2
Additional paid-in capital	131,025	1,103
Accumulated other comprehensive income	7	—
Accumulated deficit	(103,175)	(92,236)
Total stockholders' equity (deficit)	27,866	(91,131)
Total liabilities, redeemable convertible preferred stock, and stockholders' equity (deficit)	$ 39,021	$ 35,199

The accompanying notes are an integral part of these condensed consolidated financial statements.

TVARDI THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Unaudited, amounts in thousands, except share and per share amounts)

	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	$ (5,527)	$ (5,513)	$ (10,939)	$ (16,690)
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)

The accompanying notes are an integral part of these condensed consolidated financial statements.

TVARDI THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
(Unaudited, amounts in thousands, except share amounts)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated	Accumulated Other Comprehensive	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Capital	Deficit	Income (Loss)	(Deficit)
Balances as of December 31, 2024	29,555,538	$ 85,503	19,197,914	$ 19	$ 1,086	$ (92,236)	$ —	$ (91,131)
Retroactive application of reverse recapitalization	(25,591,628)	—	(16,623,147)	(17)	17	—	—	—
Adjusted balance, beginning of period	3,963,910	85,503	2,574,767	2	1,103	(92,236)	—	(91,131)
Exercise of stock options	—	—	727	—	3	—	—	3
Stock-based compensation	—	—	—	—	80	—	—	80
Unrealized gain on short-term investments	—	—	—	—	—	—	2	2
Net loss	—	—	—	—	—	(9,579)	—	(9,579)
Balances as of March 31, 2025	3,963,910	$ 85,503	2,575,494	$ 2	$ 1,186	$ (101,815)	$ 2	$ (100,625)
Exercise of stock options	—	—	17,891	—	421	—	—	421
Stock-based compensation	—	—	—	—	627	—	—	627
Conversion of redeemable convertible preferred stock into common stock in connection with the Merger	(3,963,910)	(85,503)	3,963,910	4	85,499	—	—	85,503
Issuance of common stock upon the conversion of Convertible Notes	—	—	1,265,757	1	23,099	—	—	23,100
Issuance of common stock in connection with the Merger	—	—	1,550,381	2	23,871	—	—	23,873
Transaction costs in connection with the Merger	—	—	—	—	(4,124)	—	—	(4,124)
Unrealized loss on short-term investments	—	—	—	—	—	—	(15)	(15)
Net income	—	—	—	—	—	4,167	—	4,167
Balances as of June 30, 2025	—	$ —	9,373,433	$ 9	$ 130,579	$ (97,648)	$ (13)	$ 32,927
Exercise of stock options	—	—	5,899	—	107	—	—	107
Stock-based compensation	—	—	—	—	339	—	—	339
Unrealized gain on short-term investments	—	—	—	—	—	—	20	20
Net loss	—	—	—	—	—	(5,527)	—	(5,527)
Balances as of September 30, 2025	—	$ —	9,379,332	$ 9	$ 131,025	$ (103,175)	$ 7	$ 27,866
Balances as of December 31, 2023	29,555,538	$ 85,503	19,134,164	$ 19	$ 762	$ (62,839)	$ —	$ (62,058)
Retroactive application of reverse recapitalization	(25,591,628)	—	(16,567,945)	(17)	17	—	—	—
Adjusted balance, beginning of period	3,963,910	85,503	2,566,219	2	779	(62,839)	—	(62,058)
Exercise of stock options	—	—	8,548	—	5	—	—	5
Stock-based compensation	—	—	—	—	81	—	—	81
Net loss	—	—	—	—	—	(4,202)	—	(4,202)
Balances as of March 31, 2024	3,963,910	$ 85,503	2,574,767	$ 2	$ 865	$ (67,041)	$ —	$ (66,174)
Stock-based compensation	—	—	—	—	79	—	—	79
Net loss	—	—	—	—	—	(6,975)	—	(6,975)
Balances as of June 30, 2024	3,963,910	$ 85,503	2,574,767	$ 2	$ 944	$ (74,016)	$ —	$ (73,070)
Stock-based compensation	—	—	—	—	80	—	—	80
Net loss	—	—	—	—	—	(5,513)	—	(5,513)
Balances as of September 30, 2024	3,963,910	$ 85,503	2,574,767	$ 2	$ 1,024	$ (79,529)	$ —	$ (78,503)

The accompanying notes are an integral part of these condensed consolidated financial statements.

TVARDI THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited, amounts in thousands)

	For the Nine Months Ended September 30,	
	2025	2024
Cash flows from operating activities:		
Net loss	$ (10,939)	$ (16,690)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	71	71
Stock-based compensation expense	1,046	240
Change in fair value of Convertible Notes	(7,810)	—
Non-cash lease expense	53	44
Accretion of discounts on short-term investments	(166)	—
Interest accrued on Convertible Notes	651	—
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(1,564)	1,974
Accounts payable and accrued expenses	919	958
Operating lease liabilities	(75)	(69)
Net cash used in operating activities	(17,814)	(13,472)
Cash flows from investing activities:		
Purchases of short-term investments	(31,486)	—
Maturities of short-term investments	16,402	—
Net cash used in investing activities	(15,084)	—
Cash flows from financing activities:		
Cash acquired in connection with the Merger	24,992	—
Payments for Merger transaction costs	(2,821)	(14)
Proceeds from exercise of stock options	531	5
Net cash provided by (used in) financing activities	22,702	(9)
Net decrease in cash and cash equivalents	(10,196)	(13,481)
Cash and cash equivalents - beginning of period	31,614	22,919
Cash and cash equivalents - end of period	$ 21,418	$ 9,438
Non-cash investing and financing activities		
Merger transaction costs included in accounts payable	$ —	$ 1,069
Conversion of redeemable convertible preferred stock to common stock	$ 85,503	$ —
Conversion of Convertible Notes to common stock	$ 23,100	$ —

The accompanying notes are an integral part of these condensed consolidated financial statements.

TVARDI THERAPEUTICS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

1. Nature of the Business and Basis of Presentation

Tvardi Therapeutics, Inc. and subsidiaries (Tvardi or the Company) is a Delaware corporation headquartered in Houston, Texas. The Company 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. Based upon its founder's seminal work and deep understanding of the transcription factor STAT3, the Company has designed an innovative approach to directly inhibit STAT3, a highly validated, yet historically undruggable target. Leveraging this expertise, the Company is developing a pipeline of STAT3 inhibitors with a differentiated mechanism of action and convenient oral dosing. The Company's lead product candidate, TTI-101, is currently in Phase 2 clinical development for hepatocellular carcinoma (HCC). The Company's second product candidate, TTI-109, is also an oral, small molecule STAT3 inhibitor that is structurally related to, yet chemically distinct from, TTI-101 and is designed to enhance the Company's ability to target STAT3. The Company submitted an Investigational New Drug application for TTI-109 in June 2025. A Phase 1 trial of TTI-109 in healthy volunteers to evaluate safety, tolerability, and pharmacokinetics, as well as bioequivalence to TTI-101 is ongoing.

Merger

On December 17, 2024, the Delaware corporation formerly known as Tvardi Therapeutics, Inc. (Legacy Tvardi) entered into an agreement and plan of merger and reorganization (the Merger Agreement) with Cara Therapeutics, Inc. (Cara), and CT Convergence Merger Sub, Inc., a wholly-owned subsidiary of Cara (Merger Sub), pursuant to which Merger Sub merged with and into Legacy Tvardi, with Legacy Tvardi surviving the Merger as a wholly-owned subsidiary of Cara (such transaction, the Merger). Upon the closing of the Merger on April 15, 2025, Cara changed its corporate name to Tvardi Therapeutics, Inc. and Legacy Tvardi's business continued as the business of the Company. Unless otherwise indicated or the context otherwise requires, references in these notes to condensed consolidated financial statements to "Tvardi" and "the Company" refer to the business and operations of Legacy Tvardi prior to the Merger and to Tvardi Therapeutics, Inc. and its consolidated subsidiaries following the Merger. See Note 3, *Merger Agreement*, for additional information on the Merger.

Risks and Uncertainties

The Company is subject to risks and uncertainties common to early-stage companies in the biopharmaceutical industry, including, but not limited to, successful development of TTI-101 and TTI-109, the development of new technological innovations by competitors, dependence on key personnel, the ability to attract and retain qualified employees, protection of proprietary technology, compliance with governmental regulations and the ability to secure additional capital to fund operations and commercial success of TTI-101 and TTI-109. There can be no assurance that the Company's research and development will be successfully completed, that adequate protection for the Company's intellectual property will be maintained, that any therapeutic products developed will obtain required regulatory approval or that any approved or consumer products will be commercially viable. Even if the Company's development efforts are successful, it is uncertain when, if ever, the Company will generate significant product sales.

Additionally, the Company is subject to risks and uncertainties as a result of global business, political and macroeconomic events and conditions, including increasing financial market volatility and uncertainty, inflation, interest rate fluctuations, uncertainty with respect to the federal budget and debt ceiling, as well as the potential for future potential government shutdowns related thereto, potential instability in the global banking system, cybersecurity events, the impact of war or military conflict, including regional conflicts around the world, and public health pandemics. The extent to which business, political and macroeconomic factors, including increasing financial market volatility and uncertainty, will impact the Company's business will depend on future developments that are highly uncertain and cannot be predicted at this time.

Liquidity and Going Concern

The accompanying condensed consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business.

As of September 30, 2025, the Company had cash and cash equivalents and short-term investments of $21.4 million and $15.0 million, respectively, which included approximately $23.9 million in net assets acquired from the consummation of the Merger Agreement (as further discussed in Note 3, *Merger Agreement*) in April 2025. Since inception, the Company has incurred net operating losses and negative cash flows from operations. During the three and nine months ended September 30, 2025, the Company incurred net losses of $5.5 million and $10.9 million, respectively, and used $17.8 million of cash in operating activities during the nine months ended September 30, 2025. As of September 30, 2025, the Company had an accumulated deficit of $103.2 million. The Company expects to continue to incur significant operating losses for the foreseeable future and may never become profitable. Losses are expected to continue as the Company continues to invest in research and development activities. The assessment of the Company's ability to meet its future obligations is inherently judgmental, subjective and susceptible to change. Given the inherent uncertainties in the forecast, the Company considered both quantitative and qualitative factors that are known or reasonably knowable as of the date that these condensed consolidated financial statements are issued and concluded that there are conditions present in the aggregate that raise substantial doubt about the Company's ability to continue as a going concern.

To date, the Company has no products approved for marketing and sale and it has not yet recorded any revenue from product sales. The Company's ability to achieve profitability is dependent on its ability to successfully develop its compounds, conduct clinical trials, obtain regulatory approvals, and support commercialization activities for its product candidates. Any products developed will require approval of the U.S. Food and Drug Administration (FDA) or a foreign regulatory authority prior to commercial sale.

Since inception, the Company has relied primarily on sales of redeemable convertible preferred stock and issuance of convertible debt to fund its operations. The Company's product candidates are still in the early stages of development, and substantial additional financing will be needed by the Company to fund its operations and ongoing research and development efforts prior to the commercialization of its product candidates.

The Company also completed the Merger in April 2025. Significant additional funding is necessary to maintain current operations and to advance the Company's research and development activities. The Company plans to seek additional funding through equity offerings or debt financings, credit or loan facilities, and strategic alliances and licensing arrangements. The Company's ability to access capital when and in the amount needed is not assured. As a result, the Company has concluded that management's plans do not alleviate substantial doubt about the Company's ability to continue as a going concern.

The accompanying condensed consolidated financial statements do not reflect any adjustments relating to the recoverability and reclassifications of assets and liabilities that might be necessary if the Company is unable to continue as a going concern.

Basis of Presentation

The accompanying condensed consolidated financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States of America (GAAP). The accompanying condensed consolidated financial statements represent the accounts of the Company as a result of the consummation of the Merger in April 2025. All intercompany balances and transactions have been eliminated.

The condensed consolidated financial statements reflect all adjustments (consisting of normal recurring adjustments) necessary to present fairly the financial position of the Company as of September 30, 2025, and results of operations and

cash flows for all periods presented. The interim results presented are not necessarily indicative of results that can be expected for the full year ending December 31, 2025.

2. Summary of Significant Accounting Policies

Other than policies noted below, there have been no significant changes from the significant accounting policies and estimates disclosed in Note 2 of the "Notes to financial statements" in the Company's audited annual financial statements as of and for the years ended December 31, 2024 and 2023, as filed as Exhibit 99.1 to Cara's Current Report on Form 8-K, which was filed with the U.S. Securities and Exchange Commission (SEC) on April 1, 2025.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, and expenses as of and during the reporting period. The Company bases estimates and assumptions on historical experience when available and on various factors that it believes to be reasonable under the circumstances. The Company assesses estimates on an ongoing basis; however, actual results could materially differ from those estimates. Significant estimates and assumptions reflected within these condensed consolidated financial statements include, but are not limited to, prepaid and accrued research and development expenses, including those related to contract research organizations (CROs), contract development manufacturing organizations (CDMOs), and other third-party vendors, and the valuation of the Company's common stock prior to the Merger, stock-based awards, and the fair value of Convertible Notes (as defined in Note 4, *Fair Value Measurements*), which converted to common stock upon close of the Merger. Changes in estimates are recorded in the period in which they become known.

Concentration of Credit Risk and of Significant Suppliers

The Company's cash and cash equivalents represent potential concentrations of credit risk. The Company deposits its cash and cash equivalents in financial institutions in amounts that may exceed federally insured limits, has not experienced any losses on such accounts and does not believe it is exposed to any unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

The following table presents information about the Company's significant suppliers:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,		As of September 30,	As of December 31,
	2025	2024	2025	2024	2025	2024
	% of operating expenses		% of operating expenses		% of accounts payable	
Vendor A	35 %	64 %	39 %	62 %	75 %	43 %

The Company's preclinical studies and clinical trials and testing could be adversely affected by a significant interruption in the supply chain from its significant suppliers.

Cash and Cash Equivalents

The Company considers all highly liquid investments, with an original maturity of three months or less, to be cash equivalents. Cash equivalents include amounts held in money market funds in the amount of $18.7 million and $31.3 million as of September 30, 2025 and December 31, 2024, respectively.

The Company recorded interest income on its cash equivalents of $0.3 million and $0.2 million for the three months ended September 30, 2025 and 2024, respectively, and $0.6 million for each of the nine months ended September 30, 2025 and 2024, on its condensed consolidated statements of operations and comprehensive loss.

Short-term Investments

The Company invests excess cash in short-term investments with high credit ratings. These securities consist primarily of U.S. Treasury Notes that are classified as "available-for-sale." The Company classifies any investments as

short-term if the maturity date is less than or equal to one year from the balance sheet date or as long-term if the maturity date is in excess of one year from the balance sheet date.

The Company's short-term investments are carried at fair value, with the unrealized gains and losses reported as a component of accumulated other comprehensive income (loss) in stockholders' equity (deficit). Realized gains and losses and declines in fair value due to credit-related factors are based on the specific identification method and would be included within the non-operating section of the condensed consolidated statements of operations and comprehensive loss, as needed. The Company recorded interest income on short-term investments, inclusive of accretion of its discounts on its short-term investments, of $0.1 million and $0.5 million during the three and nine months ended September 30, 2025, respectively, which is classified as interest income in the condensed consolidated statements of operations and comprehensive loss. There was no interest income on short-term investments for the three and nine months ended September 30, 2024.

At each balance sheet date, the Company assesses available-for-sale debt securities in an unrealized loss position to determine whether the unrealized loss or any potential credit losses should be recognized within the non-operating section of the condensed consolidated statement of operations and comprehensive loss. The Company evaluates whether it intends to sell, or it is more likely than not that it will be required to sell, the security before recovery of its amortized cost basis. The credit-related portion of unrealized losses, and any subsequent improvements, would be recorded in the condensed consolidated statement of operations and comprehensive loss accordingly. The portion that is not credit-related is treated in accordance with other unrealized losses as a component of accumulated other comprehensive income (loss) in stockholders' equity (deficit). There have been no impairment or credit losses recognized during any of the periods presented.

Deferred Offering Costs

The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with in process equity financings as deferred offering costs until such financings are consummated. After consummation of the equity financing, these costs are recorded as a reduction of the proceeds from the offering, either as a reduction of the carrying value of the preferred stock or in stockholders' equity (deficit) as a reduction of additional paid-in-capital generated as a result of the offering. The Company recorded deferred offering costs of $2.8 million as of December 31, 2024. With the addition of the Company's deferred costs incurred in 2025 prior to the Merger closing, a total of $4.1 million in deferred offering costs were reclassified as a reduction of additional paid-in-capital upon the close of the Merger.

Net Loss Per Share

Prior to the close of the Merger, as further described in Note 3, *Merger Agreement*, the Company calculated net loss per share using the two-class method required for participating securities. The Company's redeemable convertible preferred stock was considered participating as the holders were entitled to receive dividends in preference and priority to the holders of common stock. The two-class method determines net loss per share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income available to common stockholders for the period to be allocated between common and participating securities based upon their respective rights to receive dividends as if all income for the period has been distributed. There was no allocation required under the two-class method during periods of loss prior to the close of the Merger since the participating securities did not have a contractual obligation to share in the losses of the Company. Upon close of the Merger in April 2025, the Company's redeemable convertible preferred stock converted into shares of the Company's common stock, and as such, there were no remaining participating securities as of September 30, 2025.

Basic net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common shares outstanding for the period, excluding potentially dilutive common shares. Diluted net loss per share is computed by: (i) adjusting net loss attributable to common stockholders to (a) reallocate undistributed earnings based on the potential impact of dilutive securities and (b) reverse any current period change in fair value of convertible debt securities and add back any related interest expense (in accordance with the if-converted method) and (ii) dividing the diluted net loss attributable to

common stockholders by the weighted-average number of shares of common stock outstanding for the period, including potential dilutive shares of common stock.

In periods in which the Company reports a net loss available to common stockholders, diluted net loss per share available to common stockholders is generally the same as basic net loss per share available to common stockholders, since dilutive common shares are not assumed to have been issued as their effect is anti-dilutive. However, in periods where the Company has a change in fair value of convertible debt securities, any numerator and denominator adjustments, as described above, are applied accordingly.

As such, although the Company had a net loss for the nine months ended September 30, 2025, diluted earnings per share was computed by dividing net loss attributable to common stockholders, as adjusted by removing the $7.8 million net gain on the fair value remeasurement of its Convertible Notes and adding back the $0.7 million of interest expense, by the weighted-average number of shares of common stock outstanding, adjusted to give effect to potentially dilutive elements.

Comprehensive Income (Loss)

Comprehensive income (loss) is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from nonowner sources, including unrealized gains and losses on short-term investments held as available-for-sale. For each of the three and nine months ended September 30, 2025, comprehensive loss includes net loss and a net unrealized gain on short-term investments. There was no difference between net loss and comprehensive loss for the three and nine months ended September 30, 2024.

Recently Adopted Accounting Pronouncements

In November 2023, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*, or ASU 2023-07. ASU 2023-07 expands public entities' segment disclosures by requiring disclosure of significant segment expenses that are regularly provided to the chief operating decision maker (CODM) and included within each reported measure of segment profit or loss, an amount and description of its composition for other segment items, and interim disclosures of a reportable segment's profit or loss and assets. All disclosure requirements under ASU 2023-07 are also required for public entities with a single reportable segment. The Company adopted the guidance in the fiscal year beginning January 1, 2024. There was no impact on the Company's reportable segments identified and additional required disclosures have been included in Note 16, *Segment Reporting*.

Recently Issued Accounting Pronouncements Not Yet Adopted

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures,* or ASU 2023-09. ASU 2023-09 requires public business entities to disclose additional information in specified categories with respect to the reconciliation of the effective tax rate to the statutory rate (the rate reconciliation) for federal, state, and foreign income taxes. It also requires greater detail about individual reconciling items in the rate reconciliation to the extent the impact of those items exceeds a specified threshold (if the effect of those reconciling items is equal to or greater than 5% of the amount computed by multiplying pretax income or loss by the applicable statutory income tax rate). In addition to new disclosures associated with the rate reconciliation, ASU 2023-09 requires information pertaining to taxes paid (net of refunds received) to be disaggregated for federal, state, and foreign taxes and further disaggregated for specific jurisdictions to the extent the related amounts exceed a quantitative threshold. The amendments are effective for public business entities for annual periods beginning after December 15, 2024. Early adoption is permitted. As of September 30, 2025, the Company has not yet adopted this new ASU, however the Company expects no impact to its operations, cash flows, financial condition, or any related disclosures, upon adoption for the year ended December 31, 2025.

In November 2024, the FASB issued ASU 2024-03, *Income Statement — Reporting Comprehensive Income — Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses,* or ASU 2024-03. The amendments in ASU 2024-03 address investor requests for more detailed expense information and require additional disaggregated disclosures in the notes to financial statements for certain categories of expenses that are included in the statement of operations. This guidance is effective for fiscal years beginning after December 15, 2026,

and interim periods within fiscal years beginning after December 15, 2027, with early adoption permitted. The Company is currently evaluating the provisions of this guidance and the potential impact on its condensed consolidated financial statements and disclosures.

3. Merger Agreement

As discussed in Note 1, *Nature of the Business and Basis of Presentation*, on April 15, 2025, pursuant to the terms of the Merger Agreement entered into on December 17, 2024, Merger Sub merged with and into Legacy Tvardi, with Legacy Tvardi surviving as a wholly-owned subsidiary of Cara.

Upon the closing of the Merger:

- Cara changed its corporate name to Tvardi Therapeutics, Inc.
- the business of Legacy Tvardi continued as the business of the Company.
- the outstanding shares of common stock of Legacy Tvardi (including the shares of common stock issuable upon conversion of all shares of preferred stock of Legacy Tvardi prior to the Merger), $0.001 par value per share (Legacy Tvardi common stock), were converted into 6,539,404 shares of the Company's common stock in the aggregate, based on an exchange ratio calculated in accordance with the Merger Agreement (the Exchange Ratio);
- the Company acquired approximately $23.9 million in net assets in accordance with the Merger Agreement.
- the outstanding Convertible Notes (as defined in Note 4, *Fair Value Measurements*) of Legacy Tvardi were converted into 1,265,757 shares of the Company's common stock in the aggregate, pursuant to the terms of the Convertible Notes.
- all outstanding and unexercised options to purchase shares of Legacy Tvardi common stock immediately prior to Closing were assumed by the Company and converted into options to purchase the Company's common stock based on the Exchange Ratio.

Immediately following the Merger, the equity holders of Legacy Tvardi prior to the Merger, including the holders of Convertible Notes, owned approximately 84.5% of the outstanding common stock of the combined company on a fully diluted basis.

In addition, on April 15, 2025, immediately prior to the closing of the Merger, Cara (i) effected a 1-for-3 reverse stock split of its common stock and (ii) increased its authorized shares of common stock to 150,000,000.

Upon the closing of the Merger, the Company's 2025 Equity Incentive Plan (the 2025 Plan) and 2025 Employee Stock Purchase Plan (the 2025 ESPP), both approved during a special meeting of Cara's stockholders on April 1, 2025, also became effective, following the reverse stock split. Refer to Note 10, *Stock-based Compensation*, for further information on the 2025 Plan and the 2025 ESPP.

The Merger was accounted for as an in-substance reverse recapitalization of Cara by Legacy Tvardi. Under this method of accounting, Legacy Tvardi was considered the accounting acquirer for financial reporting purposes. A reverse recapitalization does not result in a new basis of accounting, and the consolidated financial statements of the combined entity represent the continuation of the financial statements of Legacy Tvardi in many respects. Accordingly, the assets, liabilities and results of operations of Legacy Tvardi became the historical financial statements of the Company. At the effective time of the Merger, substantially all of the assets of Cara consisted of cash and cash equivalents, as well as other nominal non-operating assets. Under such reverse recapitalization accounting, the assets and liabilities of Cara were recorded at their fair value in the Company's financial statements at the effective time of the Merger, which approximated book value due to the short-term nature. No goodwill or intangible assets were recognized. Consequently, the condensed consolidated financial statements of the Company reflect the historical operations of Legacy Tvardi for accounting purposes together with the equity transactions of Cara and Legacy Tvardi noted above. The Exchange Ratio

was retroactively applied to all outstanding common shares, redeemable convertible preferred stock, Convertible Notes and stock options of Legacy Tvardi.

As part of the recapitalization, the Company obtained the assets and liabilities listed below (in thousands):

Cash and cash equivalents	$ 24,992
Prepaid expenses and other current assets	132
Accounts payable	(228)
Accrued expenses and other current liabilities	(1,023)
Net assets acquired	$ 23,873

The Company incurred total capitalizable transaction costs of $4.1 million, all of which was paid in cash as of September 30, 2025. Of the $4.1 million in transaction costs paid in cash as of September 30, 2025, $1.3 million was paid during fiscal 2024. The total amount of $4.1 million was recorded as a reduction to additional paid-in capital in the condensed consolidated statements of redeemable convertible preferred stock and stockholders' equity (deficit) for the nine months ended September 30, 2025.

4. Fair Value Measurements

The following tables present information about the Company's financial assets and liabilities measured at fair value on a recurring basis and indicate the level of the fair value hierarchy used to determine such fair values (in thousands):

	Fair Value Measurements as of September 30, 2025			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Cash equivalents:				
Money market funds	$ 18,725	$ —	$ —	$ 18,725
Short-term investments:				
U.S. Treasury Notes	15,042	—	—	15,042
Total financial assets	$ 33,767	$ —	$ —	$ 33,767

	Fair Value Measurements as of December 31, 2024			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Cash equivalents:				
Money market funds	$ 31,303	$ —	$ —	$ 31,303
Total financial assets	$ 31,303	$ —	$ —	$ 31,303
Financial liabilities:				
Convertible Notes	$ —	$ —	$ 30,259	$ 30,259
Total financial liabilities	$ —	$ —	$ 30,259	$ 30,259

There were no transfers between Levels during the periods presented.

The unrealized loss on the Company's short-term investments for the three and nine months ended September 30, 2025 was not material.

Convertible Notes

In December 2024, Legacy Tvardi entered into a note purchase agreement to issue and sell convertible notes (the Convertible Notes) in an aggregate principal amount of $28.3 million. The Convertible Notes accrued interest at 8% per annum and had a maturity date of December 31, 2026 (the Maturity Date). As further discussed in Note 3, *Merger Agreement*, the Company completed its Merger with Cara in April 2025. Upon the closing of the Merger, the

Convertible Notes converted into 1,265,757 shares of the Company's common stock, $0.001 par value per share, in the aggregate.

The fair value of the Convertible Notes as of December 31, 2024 was estimated based on significant inputs not observable in the market, which represented Level 3 measurements within the fair value hierarchy. The Convertible Notes were valued using a scenario-based valuation analysis requiring a probability of inputs including the probability of occurrence of events that would trigger conversion of the Convertible Notes and the expected timing of such events.

In addition to the estimated probabilities of the occurrence of events that would trigger conversion, the following table presents the other assumptions, estimates, and contractual features incorporated into the valuation of the Convertible Notes as of December 31, 2024:

	As of December 31, 2024
Time to Qualified/non-Qualified financing (in years)	0.25
Time to IPO (in years)	0.25
Time to reverse merger (in years)	0.33
Time to dissolution (in years)	n/a
Interest rate (risk-free)	4.37 %
Conversion discount rate	20.00 %

Since the Company elected the fair value option to account for the Convertible Notes, at the time of conversion, the fair value was measured as the quoted market price of the Company's common shares into which the Convertible Notes were exchanged. The fair value was determined to be the closing market trading price of the Company's common stock on April 16, 2025, the first day of trading for the Company's common stock following the closing of the Merger.

Under the fair value option, any change in fair value was recorded to the Company's condensed consolidated statements of operations and comprehensive loss as a gain or loss from a fair value measurement. At the time of conversion, the fair value of the Convertible Notes was $23.1 million, calculated as 1,265,757 shares of common stock at the closing market trading price on April 16, 2025. The $12.8 million change in fair value when comparing the $23.1 million at the time of conversion to the $35.9 million recorded value of the Convertible Notes immediately prior to the conversion date was recorded to the Company's condensed consolidated statements of operations and comprehensive loss as a gain within other income, net during the second quarter of 2025. For the nine months ended September 30, 2025, the net change in fair value recorded to the Company's condensed consolidated statements of operations and comprehensive loss within other income, net was $7.8 million.

The following table presents the changes in the fair value of the Level 3 Convertible Notes (in thousands):

	Amounts
Balance as of December 31, 2024	$ 30,259
Interest accrued during the three months ended March 31, 2025	558
Change in fair value of the Convertible Notes	4,942
Balance as of March 31, 2025	35,759
Interest accrued during the three months ended June 30, 2025 [(1)]	93
Balance immediately prior to the date of conversion	35,852
Change in fair value of the Convertible Notes	(12,752)
Conversion of the Convertible Notes	(23,100)
Balance as of June 30, 2025 and thereafter	$ —

(1) Includes interest accrued from April 1, 2025 until closing of the Merger.

5. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following as of September 30, 2025 and December 31, 2024 (in thousands):

	As of September 30, 2025	As of December 31, 2024
Prepaid research and development expenses	$ 1,388	$ 18
Prepaid insurance	368	—
Other prepaid expenses	227	54
Total prepaid expenses and other current assets	$ 1,983	$ 72

6. Intangible Assets

Intangible assets consisted of the following as of September 30, 2025 and December 31, 2024 (in thousands):

	As of September 30, 2025	As of December 31, 2024
Licensed patent rights	$ 826	$ 826
Less: accumulated amortization	(488)	(441)
Total intangible assets, net	$ 338	$ 385

As of September 30, 2025, the expected remaining amortization expense is as follows (in thousands):

Year Ended December 31,	Amount
2025 (remaining three months)	$ 16
2026	63
2027	63
2028	63
2029	63
Thereafter	70
Total	$ 338

The Company recognized less than $0.1 million for amortization expense for each of the three and nine months ended September 30, 2025 and 2024. Amortization expense is included in research and development expense in the condensed consolidated statements of operations and comprehensive loss.

7. Accrued Expenses

Accrued expenses consisted of the following as of September 30, 2025 and December 31, 2024 (in thousands):

	As of September 30, 2025	As of December 31, 2024
Accrued research and development expenses	$ 5,047	$ 5,172
Accrued employee compensation and benefits	1,014	1,142
Accrued professional fees	336	1,756
Other accrued expenses	452	8
Total accrued expenses	$ 6,849	$ 8,078

8. Leases

The Company has one operating lease pertaining to 5,969 square feet of corporate office space in Sugar Land, Texas pursuant to a lease agreement that commenced April 1, 2022. As of September 30, 2025 the remaining term of lease was 1.83 years. The lease requires monthly lease payments that are subject to annual increases throughout the lease term.

The components of lease costs, which are included within general and administrative expenses in the Company's condensed consolidated statements of operations and comprehensive loss were as follows (in thousands):

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2025	2024	2025	2024
Lease costs:				
Operating lease cost	$ 24	$ 22	$ 72	$ 67
Variable lease cost	21	21	61	59
Total lease costs	$ 45	$ 43	$ 133	$ 126

Supplemental disclosure of cash flow information related to the lease were as follows (in thousands):

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2025	2024	2025	2024
Operating cash flows from operating leases	$ 50	$ 50	$ 150	$ 148

The weighted-average discount rate and remaining lease term were as follows:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2025	2024	2025	2024
Weighted-average discount rate	9.50 %	9.50 %	9.50 %	9.50 %
Weighted-average remaining lease term	1.83	2.83	1.83	2.83

As of September 30, 2025, the maturities of the Company's operating lease liabilities were as follows (in thousands):

Year Ended December 31,	Amount
2025 (remaining three months)	$ 32
2026	129
2027	88
Total lease payments	249
Less: imputed interest	(21)
Present value of lease liabilities	228
Less: operating lease liabilities, current portion	$ 113
Operating lease liabilities, net of current portion	$ 115

9. Stockholders' Equity (Deficit)

Redeemable Convertible Preferred Stock

Prior to the conversion upon the closing of the Merger, Legacy Tvardi issued Series A preferred stock and Series B preferred stock (the Preferred Stock). Prior to the completion of the Merger, Legacy Tvardi classified the Preferred Stock outside of permanent equity as the shares had redemption features that were not entirely within the control of Legacy Tvardi. As discussed in Note 3, *Merger Agreement*, upon the closing of the Merger, Legacy Tvardi's Preferred Stock converted into 3,963,910 shares of the Company's common stock.

Preferred Stock

As of September 30, 2025, the Company had 5,000,000 shares of preferred stock authorized, $0.001 par value, pursuant to its amended and restated certificate of incorporation. However, no such shares were issued or outstanding as of September 30, 2025.

Common Stock

As discussed in Note 3, *Merger Agreement*, the Company completed its Merger with Cara in April 2025. Upon the closing of the Merger, the following shares of common stock were received by Legacy Tvardi shareholders:

- Legacy Tvardi common stock converted into 2,575,494 shares of the Company's common stock in the aggregate.
- Legacy Tvardi preferred stock converted into 3,963,910 shares of the Company's common stock in the aggregate.
- Legacy Tvardi Convertible Notes converted into 1,265,757 shares of the Company's common stock in the aggregate.

Further, after effecting the reverse stock split discussed in Note 3, *Merger Agreement*, Legacy Cara shareholders received 1,550,381 shares of the Company's common stock in the aggregate as a result of the Merger.

As of September 30, 2025 and as a result of the Merger, the Company's amended and restated certificate of incorporation authorized the issuance of 150,000,000 shares of $0.001 par value common stock, of which 9,379,332 shares were issued and outstanding.

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are entitled to receive dividends, as may be declared by the Board, if any. As of September 30, 2025, no dividends were declared.

10. Stock-based Compensation

2018 Equity Incentive Plan

Legacy Tvardi's 2018 Stock Incentive Plan (the 2018 Plan) provided employees, consultants and advisors and non-employee members of the Board of Directors and its affiliates with the opportunity to receive grants of stock options, stock awards and equity awards. Since inception, Legacy Tvardi only issued stock options. The Company assumed, effective as of the closing of the Merger, the 2018 Plan, as well as the outstanding awards granted thereunder and the award agreements evidencing the grants of such awards, including any awards granted to Tvardi's named executive officers, in each case subject to applicable adjustments in the manner set forth in the Merger Agreement to such awards. No further awards will be granted under the 2018 Plan following the Merger.

2025 Equity Incentive Plan

The Company's 2025 Plan became effective at the closing of the Merger. As of the effective time of the Merger, there were 935,554 shares of the Company's common stock available for grant under the 2025 Plan. In addition, the number of shares initially reserved and available for issuance under the 2025 Plan may be increased at the discretion of the Company's Board of Directors (and without any further action by the Company's stockholders) on January 1 of each year for a period of five years, commencing on January 1, 2026 and ending on January 1, 2030, in an amount not to exceed 5% of the total number of shares of the Fully Diluted Common Stock (as defined in the 2025 Plan) determined on December 31 of the preceding year, if the Company's Board of Directors acts prior to January 1 of a given year to provide that the increase for such year will occur and to determine the applicable number of additional shares of the Company's common stock. In the absence of action by the Company's Board of Directors, no such increase will automatically occur.

Shares of unused common stock underlying any Awards that are forfeited, canceled or reacquired by the Company prior to vesting will again be available for the grant of Awards under the 2025 Plan. Shares underlying any Awards that are forfeited, canceled, or reacquired by the Company prior to vesting, satisfied without the issuance of stock or otherwise terminated and shares that are withheld upon exercise of an option of settlement of an award to cover the exercise price or tax withholding shall be added back to the shares available for issuance under the 2025 Plan. As of September 30, 2025, the Company had 551,221 shares remaining available for grant under the 2025 Plan.

2025 Employee Stock Purchase Plan

The Company's 2025 ESPP became effective at the closing of the Merger. As of the effective time of the Merger, there were 93,555 shares of the Company's common stock reserved for issuance under the 2025 ESPP (the Initial Share Reserve). Additionally, the number of shares of common stock reserved for issuance under the 2025 ESPP will automatically increase on January 1 of each year for a period of up to ten years, beginning on January 1, 2026 and continuing through and including January 1, 2035, by an amount equal to the lesser of (i) 1% of the total number of shares of the Fully Diluted Common Stock (as defined in the 2025 ESPP) determined on December 31 of the preceding year, and (ii) a number of shares equal to three times the Initial Share Reserve. Notwithstanding the foregoing, the Company's Board of Directors may act prior to January 1st of a given year to provide that the increase for such year will be a lesser number of shares. No offering periods under the 2025 ESPP had been initiated as of September 30, 2025.

Fair Value Inputs

The fair value of stock option grants is estimated using the Black-Scholes option-pricing model. The Company historically had been a private company prior to the Merger and lacked company-specific historical and implied volatility information. Therefore, it estimated its expected stock volatility based on the historical volatility of a publicly traded set of peer companies and expects to continue to do so after the Merger until such time as it has adequate historical data regarding the volatility of its own publicly traded stock price. The expected option term is calculated based on the simplified method for awards with service-based conditions, which uses the midpoint between the vesting date and the contractual term, as the Company does not have sufficient historical data to develop an estimate based on participant behavior. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

The following table presents, on a weighted-average basis, the assumptions used in the Black-Scholes option-pricing model to determine the fair value of stock options granted. For options granted after the Merger in April 2025, the Company's closing stock price on the grant date was used.

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2025	2024	2025	2024
Per share fair value of common stock	$ 36.32	n/a	$ 17.14	$ 4.62
Expected volatility	67.72 %	n/a	67.72 - 68.86 %	73.79 %
Expected dividends	— %	n/a	— %	— %
Expected term (in years)	6.25	n/a	5.50 - 6.25	5.94
Risk-free rate	3.8 %	n/a	3.8 - 4.0 %	3.9 %

Stock Options

The Company granted 2,000 stock options during the three months ended September 30, 2025. The Company granted 399,940 stock options during the nine months ended September 30, 2025. The Company granted 3,352 stock options during the nine months ended September 30, 2024. There were no stock options granted during the three months ended September 30, 2024.

The weighted-average grant date fair value per share of options granted to one employee during the three months ended September 30, 2025 was $23.54. The weighted-average grant date fair value per share of options granted to employees, non-employee members of the Company's Board of Directors and consultants during the nine months ended September 30, 2025 was $11.20. The weighted-average grant date fair value per share of options granted to one employee during the nine months ended September 30, 2024 was $4.62. Forfeitures of stock options are recorded as incurred.

Both the stock option grant detail above and the option activity below reflect the retroactive application of the Exchange Ratio as discussed in Note 3, *Merger Agreement*.

The following table summarizes option activity during the nine months ended September 30, 2025:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (In Years)	Intrinsic Value (In Thousands)
Outstanding as of January 1, 2025	729,010	$ 3.21	6.06	$ 2,914
Granted	399,940	17.14		
Exercised [1]	(24,517)	21.66		
Forfeited/expired [2]	(109,162)	319.57		
Options assumed from Cara upon Merger closing	113,487	319.80		
Outstanding as of September 30, 2025	1,108,758	$ 9.09	6.78	$ 34,081
Options exercisable as of September 30, 2025 [3]	686,194	$ 4.85	5.23	$ 24,366
Vested and expected to vest as of September 30, 2025	1,108,758	$ 9.09	6.78	$ 34,081

(1) Includes 21,665 of exercises of assumed Cara options after the Merger closed.
(2) Includes 83,293 of assumed Cara options that expired after the Merger closed.

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying stock options and the estimated fair value of the Company's common stock for those stock options that had exercise prices lower than the estimated fair value of the Company's common stock. The aggregate intrinsic value of stock options exercised during the three and nine months ended September 30, 2025 was $0.1 million and $0.2 million, respectively. The aggregate intrinsic value of stock options exercised during the nine months ended September 30, 2024 was less than $0.1 million. There were no exercises of stock options during the three months ended September 30, 2024.

The following table illustrates the classification of stock-based compensation in the condensed consolidated statements of operations and comprehensive loss (in thousands):

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2025	2024	2025	2024
Research and development	$ 79	$ 29	$ 255	$ 86
General and administrative	260	51	791	154
Total stock-based compensation	$ 339	$ 80	$ 1,046	$ 240

As of September 30, 2025, there was $3.7 million of total unrecognized compensation cost related to unvested stock options, which is expected to be recognized over a weighted-average period of 2.87 years.

11. Income Taxes

For the three and nine months ended September 30, 2025 and 2024, there was no current or deferred income tax expense or benefit due to the Company's current year losses and full valuation allowance. As of September 30, 2025, the Company evaluated all available evidence and concluded that a valuation allowance is still required against its net deferred tax assets because it is more likely than not they will not be realized in the foreseeable future.

On July 4, 2025, the One Big Beautiful Bill Act (OBBBA) was signed into law. The OBBBA introduced multiple U.S. federal income tax changes such as deductibility of domestic research and development expenses, deductibility of certain property additions and limitations on interest expense deductions. The Company has considered the impact of these provisions on its condensed consolidated financial statements for the period ended September 30, 2025, however, the changes in tax law did not result in a change in the Company's tax provision.

12. Net Loss Per Share

Basic and diluted net loss per share attributable to common stockholders was calculated as follows (dollar amounts in thousands):

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2025	2024	2025	2024
Numerator:				
Net loss for basic net loss per share attributable to common stockholders	$ (5,527)	$ (5,513)	$ (10,939)	$ (16,690)
Reversal of fair market value remeasurement net gain on Convertible Notes [1]	—	—	(7,810)	—
Add back of interest expense from the Convertible Notes [1]	—	—	651	—
Net loss for diluted net loss per share attributable to common stockholders	$ (5,527)	$ (5,513)	$ (18,098)	$ (16,690)
Denominator:				
Weighted-average common shares outstanding, basic	9,377,079	2,574,767	6,757,955	2,574,054
Effect of potentially dilutive securities:				
Convertible Notes	—	—	486,830	—
Weighted-average common shares outstanding, diluted	9,377,079	2,574,767	7,244,785	2,574,054
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)

[1] As the Company recorded its Convertible Notes at fair value, when calculating the diluted net loss per share for the nine months ended September 30, 2025, the respective fair value remeasurement net gain of $7.8 million recognized in the condensed consolidated statement of operations and comprehensive loss during the nine months ended September 30, 2025 should be reversed and treated as an adjustment to the numerator. In addition, the $0.7 million of interest expense from the Convertible Notes recognized in the condensed consolidated statement of operations and comprehensive loss during the nine months ended September 30, 2025 should be added back as an adjustment to the numerator.

The Company's potentially dilutive securities include its stock options to purchase common stock, Preferred Stock, and Convertible Notes. For the nine months ended September 30, 2025, the Company's Convertible Notes has been included in the computation of diluted net loss per share as the effect for the period was determined to be dilutive while its stock options to purchase common stock and Preferred Stock were excluded from the diluted net loss per share computation as the effect was determined to be anti-dilutive. All of the Company's potentially dilutive securities have been excluded from the computation of diluted net loss per share for the three months ended September 30, 2025 and the three and nine months ended September 30, 2024, as the effect would be anti-dilutive. Therefore, the weighted-average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders for the three months ended September 30, 2025 and the three and nine months ended September 30, 2024 is the same.

The following potentially dilutive securities have been excluded from the calculation of diluted net loss per share due to their anti-dilutive effect:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2025	2024	2025	2024
Preferred Stock (as converted to common stock)	—	3,963,910	—	3,963,910
Stock options to purchase common stock	1,108,758	731,063	1,108,758	731,063

13. Commitments and Contingencies

Legal Matters

The Company is subject to contingent liabilities, such as legal proceedings and claims, that arise in the ordinary course of business activities. The Company accrues for loss contingencies when losses become probable and are reasonably estimable. If the reasonable estimate of the loss is a range and no amount within the range is a better estimate, the minimum amount of the range is recorded as a liability on the condensed consolidated balance sheets. The Company does not accrue for contingent losses that, in its judgment, are considered to be reasonably possible, but not probable; however, it discloses the range of reasonably possible losses. As of September 30, 2025 and December 31, 2024, the Company was not a party to any material legal proceedings or claims other than those described below.

Merger Proceedings

Between December 20, 2024, and March 19, 2025, Cara received 13 demands (and three draft complaints) from purported stockholders of Cara (collectively, the Demands) challenging the disclosures in the proxy statement/prospectus (the Proxy Statement/Prospectus) included in the Registration Statement on Form S-4 related to the Merger and asserting claims for violations of Sections 14(a) and 20(a) of the Securities Exchange Act of 1934. In addition, on March 5 and March 6, 2025, two lawsuits were filed by purported stockholders of Cara in the Supreme Court of the State of New York, County of New York. The lawsuits are captioned Joseph Clark v. Cara Therapeutics, Inc., et al., No. 651260/2025 and Michael Kent v. Cara Therapeutics, Inc., et al., No. 651272/2025 (collectively, the Complaints). The Complaints named Cara and the members of the Cara board of directors as defendants, and, like the Demands, challenged the disclosures (under New York state law) in the Proxy Statement/Prospectus.

Cara and the other named defendants deny that they violated any laws or breached any duties to stockholders of Cara, and they believe that no supplemental disclosure was required to the Proxy Statement/Prospectus under any applicable law, rule or regulation. Nevertheless, solely to eliminate the burden and expense of litigation and to avoid any possible disruption to the Merger that could result from such litigation, Cara filed certain supplemental disclosures on March 24, 2025 to moot the disclosure claims alleged in the Demands and the Complaints. On April 15, 2025, the Merger closed. Thereafter, counsel for the purported stockholders (that sent the Demands or filed the Complaints) reached out to counsel for the Company to discuss a potential mootness fee in connection with the supplemental disclosures filed by Cara. On August 15, 2025, the Company resolved the fee demand and the matter is now closed.

Contracts

The Company enters into contracts in the normal course of business with various third parties for preclinical research studies, clinical trials, testing, manufacturing, and other services. These contracts generally provide for termination upon notice and are cancellable without significant penalty or payment, and do not contain any minimum purchase commitments.

Guarantees and Indemnifications

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with all members of the Board that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or

service as directors. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company is not aware of any claims under indemnification arrangements that could have a material effect on its financial position, results of operations or cash flows, and it has not accrued any liabilities related to such obligations in its condensed consolidated financial statements as of September 30, 2025 and December 31, 2024.

Other Commitments

In addition to the Company's obligation to make potential royalty payments under the BCM First Agreement and BCM Second Agreement (both as discussed and defined in Note 14, *License Agreements*), the Company is also obligated to pay royalties to each of its founders in an amount equal to 1% each on the worldwide net sales of TTI-101 and any derivative formulations, or any Royalty Bearing Products. These royalty obligations last, on a country-by-country basis, for the later of (i) the date on which the sale of any Royalty Bearing Products are no longer covered by a Covered Patent (as defined below) in such country, or (ii) 15 years after the first commercial sale of royalty bearing product in such country. The timing of when these royalty payments will actually be made is uncertain as the payments are contingent upon future activities, including the successful development, regulatory approval and commercialization of any Royalty Bearing Products. A Covered Patent means, subject to certain customary exceptions, an issued patent that is owned by the Company or an affiliate, or for which all rights to develop and commercialize pharmaceutical products for the treatment of any human disorder, are exclusively licensed to the Company or an affiliate by the owner of such patent, with the Company's right or its affiliate's right to grant sublicenses.

14. License Agreements

In July 2012, Stem Med Limited Partnership (StemMed) entered into a license agreement (the BCM First Agreement) with Baylor College of Medicine (BCM) for the exclusive, worldwide, sublicensable license to certain patents and patent applications related to STAT3 inhibitors in oncology and certain non-oncology indications (the BCM Patent Rights), which are referred to together with certain cell lines, biological materials, compounds, know-how and technologies as the BCM Technology, in all fields of use. Under the license for the BCM First Agreement, the Company is permitted to make, have made, use, market, sell, offer to sell, lease and import products, processes or services that incorporate, utilize, or are made with the use of the BCM Patent Rights or BCM Technology, which is referred to together as the BCM1 Licensed Products, in all fields of use.

In June 2015, StemMed entered into a second license agreement with BCM (the BCM Second Agreement), which is referred to together with the BCM First Agreement as the BCM License Agreements, for the exclusive, worldwide, sublicensable license to certain patents and patent applications co-owned by BCM and the National Institutes of Health (NIH) related to methods and compositions for the use of STAT3 inhibitors in certain conditions like anaphylaxis (the Licensed Patent Rights). Under the license for the Second BCM Agreement, the Company is permitted to make, have made, use, market, sell, offer to sell, lease and import products, processes or services that incorporate, utilize or are made with the use of the Licensed Patent Rights (the BCM2 Licensed Products), in all fields of use.

StemMed assigned the BCM First Agreement and the BCM Second Agreement to the Company in connection with the transfer of all or substantially all of the assets and businesses to which the BCM License Agreements relate to in January and February 2018.

In accordance with BCM License Agreements, and in consideration for the rights and licenses granted to the Company, the Company agreed to pay BCM the following:

a. Annual maintenance fees, ranging from $30,000 to $50,000 per year, per license.
b. Milestone payments, up to a low-seven digit figure in the aggregate.
c. Royalty fees, set at a low-single-digit percentage of net sales of any BCM1 Licensed Products or BCM2 Licensed Products.

Milestones include new drug filings, clinical trial stages, and New Drug Application approval by the FDA.

As of September 30, 2025, the full amount of $50,000 in annual maintenance fees had already been paid and thus no accrual was needed. As a result, the Company had $12,500 remaining in prepaid expenses as of September 30, 2025. As of December 31, 2024, the full amount of $50,000 in annual maintenance fees had already been paid and thus no accrual was needed. To date, no royalty fees have been incurred. All related license costs are expensed as incurred within research and development on the condensed consolidated statements of operations and comprehensive loss.

15. Retirement Savings Plan

The Company maintains a 401(k) Plan which is available to all employees. Under the terms of the 401(k) Plan, participants may elect to contribute up to 80% of their compensation or the statutory prescribed limits. The Company does not make any matching contributions to deferrals made by participants.

16. Segment Reporting

The Company has one reportable segment relating to the discovery and development of novel orally bioavailable, small molecule therapies across a broad range of diseases driven by STAT3 with high unmet need.

The Company's CODM, its Chief Executive Officer and Chief Financial Officer, manages the Company's operations on company-wide level for the purpose of allocating resources. The key measure of segment profit or loss that the CODM uses to allocate resources and assess financial performance is the Company's net income (loss), which is utilized to evaluate the progress of its research and development programs and other expense categories. The CODM makes decisions using this information on a company-wide basis.

The table below shows a reconciliation of the Company's net loss, including the significant expense categories regularly provided to and reviewed by the CODM, as computed under GAAP, to the Company's net loss in the condensed consolidated statements of operations and comprehensive loss (in thousands):

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2025	2024	2025	2024
Direct research and development expenses by program:				
TTI-101:				
HCC	$ 597	$ 1,980	$ 2,001	$ 4,996
IPF	—	1,023	3,863	2,991
mBC	—	683	(268)	2,771
Pre-clinical, CMC, and other (unallocated) [1]	112	130	427	715
TTI-109	1,991	19	3,171	697
Unallocated research and development expense:				
Personnel costs	741	718	2,516	2,273
Consultant fees and other costs [2]	162	242	810	604
General and administrative expense:				
Personnel costs	1,012	492	2,659	1,501
Other general and administrative expenses [3]	1,323	389	3,982	757
Interest income	(411)	(163)	(1,063)	(615)
Other income, net	—	—	(7,159)	—
Net loss	$ (5,527)	$ (5,513)	$ (10,939)	$ (16,690)

[1] Pre-clinical, chemistry, manufacturing and control (CMC), and other (unallocated) costs include pre-clinical testing, CMC, and other direct research and development expenses that are not allocated to a specific program.

[2] Consultant fees and other costs include expenses incurred for research and development consultants as well as payroll costs for employees within the research and development function.

(3) Other general and administrative expenses include professional fees, accounting services, rent, and other overhead and administrative expenses.

Assets provided to the CODM are consistent with those reported on the condensed consolidated balance sheets.

17. Related-party Transactions

During the three and nine months ended September 30, 2025 and 2024, the Company did not have any transactions with related parties. The Company evaluates transactions with counterparties who may be considered related parties, including owners, members of management or affiliates and then discloses the nature and amounts of those transactions in the notes to its condensed consolidated financial statements.

18. Subsequent Event

Phase 2 REVERT Clinical Trial of TTI-101 in IPF

On October 13, 2025, the Company reported preliminary data from its Phase 2 clinical trial of TTI-101 in idiopathic pulmonary fibrosis (IPF), concluding that the study did not meet its goals. The Company is conducting additional analyses to further understand the results and inform next steps.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion of Tvardi Therapeutics, Inc.'s financial condition and results of operations in conjunction with Tvardi Therapeutics, Inc.'s unaudited condensed consolidated financial statements and the related notes included elsewhere in this Quarterly Report. In addition to historical financial information, the following discussion contains forward-looking statements based upon current expectations that involve risks and uncertainties. Tvardi Therapeutics, Inc.'s actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors. Factors that could cause or contribute to these differences include, but are not limited to, those discussed below and elsewhere in this Quarterly Report. Unless otherwise indicated or the context otherwise requires, references in this "Management's Discussion and Analysis of Financial Condition and Results of Operations" section to "Tvardi," "the Company," "we," "us," "our" and other similar terms refer to the business and operations of Legacy Tvardi prior to the Merger and to Tvardi Therapeutics, Inc. and its consolidated subsidiaries following the Merger.

Overview

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. Based upon Tvardi's founder's seminal work and deep understanding of the transcription factor STAT3, Tvardi has designed an innovative approach to directly inhibit STAT3, a highly validated, yet historically undruggable target. Leveraging this expertise, Tvardi is developing a pipeline of STAT3 inhibitors with a differentiated mechanism of action and convenient oral dosing. Tvardi's lead product candidate, TTI-101, is currently in Phase 2 clinical development in hepatocellular carcinoma (HCC). Tvardi expects to report preliminary topline data from its Phase 1b/2 HCC clinical trial in the first half of 2026. Tvardi's second product candidate, TTI-109, is also an oral, small molecule STAT3 inhibitor that is structurally related to, yet chemically distinct from, TTI-101 and is designed to enhance Tvardi's ability to target STAT3. Tvardi submitted an Investigational New Drug (IND) application for TTI-109 in June 2025. After U.S. Food and Drug Administration (FDA) acceptance of the IND, Tvardi has initiated a Phase 1 trial of TTI-109 in healthy volunteers to evaluate safety, tolerability, and pharmacokinetics, as well as bioequivalence to TTI-101. The study is ongoing and Tvardi expects to report out topline data from this trial in the first half of 2026. In October 2025, Tvardi reported preliminary data from its Phase 2 clinical trial of TTI-101 in idiopathic pulmonary fibrosis (IPF) and concluded that the study did not meet its goals. Tvardi is conducting additional analyses to further understand these results and inform next steps.

Since commencing operations in 2017, Tvardi has devoted substantially all of its efforts and financial resources to developing its product candidates, organizing and staffing its company, business planning, raising capital, establishing its intellectual property portfolio and performing research and development of its product candidates, signaling and biology, medicinal chemistry and clinical insights to discover and develop novel therapies for the treatment of fibrosis-driven diseases. Through the date of this filing, Tvardi has historically financed its operations principally through the issuance and sale of its preferred stock and convertible debt. Legacy Tvardi has received $28.3 million from the sale and issuance of its Convertible Notes (as defined below) in December 2024 and $83.4 million from the issuance and sale of its preferred stock and historical convertible debt, which was converted into preferred stock, in 2018 and 2021.

As of September 30, 2025, Tvardi had $21.4 million in cash and cash equivalents and $15.0 million in short-term investments. As further discussed below, in April 2025, Legacy Tvardi completed its Merger (as defined below) with Cara Therapeutics, Inc. (Cara), through which Legacy Tvardi acquired approximately $23.9 million in net assets. Tvardi has incurred net losses since inception. As of September 30, 2025 and December 31, 2024, its accumulated deficit was $103.2 million and $92.2 million, respectively. For the three and nine months ended September 30, 2025, Tvardi reported net losses of $5.5 million and $10.9 million, respectively. For the three and nine months ended September 30, 2024, Legacy Tvardi reported net losses of $5.5 million and $16.7 million, respectively. Tvardi's net loss may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of its clinical development activities and other research and development activities. Tvardi expects to continue to incur significant operating losses for the foreseeable future and may never become profitable. Losses are expected to continue as Tvardi continues to invest in research and development activities. The assessment of Tvardi's ability to meet its future obligations is inherently judgmental, subjective and susceptible to change. Given the inherent uncertainties in the forecast, Tvardi considered both quantitative and qualitative factors that are known or reasonably knowable as of the date that these condensed consolidated financial statements are issued and concluded that there are conditions present in the aggregate that raise substantial doubt about Tvardi's ability to continue as a going concern. Tvardi has based this estimate on assumptions

that may prove to be wrong, and it could exhaust its capital resources sooner than it expects. See the subsection titled "— *Liquidity and Capital Resources*" below for further discussion.

Tvardi will require additional funding in order to finance operations and complete its ongoing and planned clinical trials. Access to such funding on acceptable terms cannot be assured.

Tvardi expects that its expense and capital requirements will increase substantially in connection with its ongoing activities and for the foreseeable future, particularly if Tvardi, among other things:

- advances TTI-101, TTI-109 and its other product candidates through clinical development and, if successful, later-stage clinical trials;
- discovers and develops additional product candidates;
- advances its preclinical development programs into clinical development;
- experiences delays or interruptions to preclinical studies, clinical trials, receipt of services from its third-party service providers on whom it relies, or its supply chain;
- seeks and maintains regulatory approvals for any product candidates that successfully complete clinical trials;
- commercializes TTI-101, TTI-109, its other product candidates and any future product candidates, if approved;
- hires additional clinical development, quality control, scientific and management personnel;
- expands its operational, financial and management systems and increase personnel, including personnel to support its clinical development and manufacturing efforts and operations as a public company;
- establishes a sales, marketing, medical affairs and distribution infrastructure to commercialize any products for which Tvardi may obtain marketing approval and intend to commercialize on its own or jointly with third parties;
- maintains, expands and protects its intellectual property portfolio;
- invests in or in-licenses other technologies or product candidates;
- continues to build out its organization to engage in such activities; and
- incurs additional legal, accounting, investor relations and other general and administrative expenses associated with operating as a public company.

Given Tvardi's stage of development, to date it has not had any products approved for sale and has not generated any revenue. Tvardi does not expect to generate any revenues from product sales unless and until it successfully completes development and obtains regulatory approval for one or more of its product candidates, which may not be for several years, if ever. If Tvardi obtains regulatory approval for any of its product candidates, it expects to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. As a result, until such time, if ever, that Tvardi can generate substantial product revenue, it expects to finance its cash needs through equity offerings, debt financings or other capital sources, including collaborations, licenses or similar arrangements. However, Tvardi may be unable to raise additional funds or enter into such other arrangements when needed or on favorable terms, if at all. If Tvardi does raise additional capital through public or private equity offerings, the ownership interest of its existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect its stockholders' rights. If Tvardi raises additional capital through debt financing, it may be subject to covenants or other restrictions limiting its ability to engage in specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any failure to raise capital as and when needed could have a negative impact on its financial condition and on its ability to pursue its business plans and strategies, including its

research and development activities. If Tvardi is unable to raise capital, Tvardi will need to delay, reduce or terminate planned activities, including its ongoing and planned clinical trials, to reduce costs.

Additionally, Tvardi is subject to risks and uncertainties as of result of global business, political and macroeconomic events and conditions, including increasing financial market volatility and uncertainty, inflation, interest rate fluctuations, uncertainty with respect to the federal budget and debt ceiling, as well as the potential for future potential government shutdowns related thereto, potential instability in the global banking system, cybersecurity events, the impact of war or military conflict, including regional conflicts around the world, and public health pandemics. Tvardi's business, financial condition and results of operations could be materially and adversely affected by further negative impact on the global economy and capital markets resulting from these global economic conditions, particularly if such conditions are prolonged or worsen.

Although, to date, Tvardi's business has not been materially impacted by these global economic and geopolitical conditions, it is impossible to predict the extent to which its operations will be impacted in the short and long term, or the ways in which such instability could impact its business and results of operations. The extent and duration of these market disruptions, other geopolitical tensions, record inflation, tariffs or otherwise, are impossible to predict, but could be substantial. Any such disruptions may also magnify the impact of other risks described in this Quarterly Report.

Recent Developments

Unblinded Data from Phase 2 Clinical Trial

We reported preliminary data from our REVERT IPF Phase 2 clinical trial of TTI-101 in IPF in October 2025. After reviewing the preliminary safety data and exploratory efficacy results, including changes in forced vital capacity (FVC), we concluded that the study did not meet its goals. We are conducting additional analyses to further understand these results and inform next steps.

The trial was a Phase 2, multicenter, randomized, double-blind, placebo-controlled clinical trial of TTI-101 to evaluate safety, tolerability and PK in patients suffering from IPF. In addition to safety and PK endpoints, we evaluated established Phase 3 efficacy endpoints including pulmonary function tests (PFTs), providing measurements for FVC and diffusing capacity of the lung for carbon monoxide (DLCO), six-minute walk test (6MWT), and imaging, including Quantitative Lung Fibrosis High Resolution CT (HRCT). Additionally, we evaluated validated biomarkers and patient reported outcomes (PROs). The clinical trial was conducted in 26 sites across the United States and enrolled patients with mild and moderate IPF who had been on a stable dose of nintedanib or were not on anti-fibrotic therapy.

Overall, 88 patients were randomized to TTI-101 400mg per day (n=30), 800mg per day (n=29) or placebo (n=29), and stratified by nintedanib use, with 58% of patients receiving concomitant therapy. Preliminary data demonstrated patients' baseline characteristics were similar across treatment arms, with the exception of percent predicted FVC, which was lower in the placebo-treated patients (70.1%) compared to the TTI-101-treated arms (74.1% and 81.1%, respectively).

Discontinuation rates across treatment arms were imbalanced, with lower discontinuation rates observed in the placebo group (10.3%) compared to treated arms (400mg and 800mg; 56.7% vs 62.1%, respectively). Discontinuation rates among the TTI-101 population were primarily driven by gastrointestinal adverse events, with higher rates of events and discontinuations among patients on concurrent nintedanib. Deaths across treatment arms were balanced, with one event observed in each arm.

The number of efficacy evaluable patients with at least one baseline and on-treatment FVC measurement was placebo (n=29), 400mg (n=23), and 800mg (n=27). The numbers, however, declined by the 12-week timepoint to placebo (n=24), 400mg (n=8), or 800mg (n=13). The preliminary analysis was performed on actual FVC values; values were not modeled or imputed.

Preliminary analysis of exploratory efficacy showed no statistically significant differences between placebo and treatment arms; though, the study was not powered to evaluate exploratory endpoints. Overall, from baseline to

last visit on treatment, the proportion of patients who demonstrated FVC improvement from baseline was 41% for the placebo, and 39% and 44% for the 400mg and 800mg arms, respectively.

FVC change from baseline overlapped between treatment arms, with large variability within each cohort. Notably, the placebo-treated patients' FVC decline was lower than expected compared to historical controls.

Preliminary Summary of Change from Baseline in FVC (mL) at 12 Weeks While on Treatment

	Placebo	TTI-101 – 400mg	TTI-101 – 800mg
n	24	8	13
Mean in mL (standard deviation)	-22.2 (126.0)	-61.1 (190.7)	-102.8 (238.3)

We believe the IPF patient population is less tolerant to gastrointestinal treatment emergent adverse events (TEAEs) than the oncology patient population. We previously reported gastrointestinal TEAEs from our TTI-101 trials in oncology. As of August 2024, we observed similar incidence and grade in both the Phase 1 oncology study and the ongoing Phase 2 HCC study with diarrhea being the most commonly reported TEAE, mostly grade 1 or 2.

The incidence of discontinuations due to gastrointestinal events was unexpectedly higher in the IPF study than previously observed in the oncology studies with TTI-101, at similar doses. The overall discontinuation rate in the IPF study was primarily driven by gastrointestinal adverse events, with higher rates of events and discontinuations among patients on concurrent nintedanib.

Our second product candidate, TTI-109, is an oral, small-molecule, prodrug of, and mechanistically identical to, TTI-101. TTI-109 itself does not inhibit STAT3 but rapidly converts to TTI-101 in the blood. TTI-109 is designed to rapidly convert to TTI-101 and lessen the exposure of the active drug to the intestinal lining. We therefore believe that TTI-109 enhances our ability to target STAT3 with a more efficient delivery vehicle for TTI-101 that has the potential to improve tolerability. A Phase 1 trial of TTI-109 in healthy volunteers to evaluate safety, tolerability, and pharmacokinetics, as well as bioequivalence to TTI-101, is ongoing and Tvardi expects to report out topline data from this trial in the first half of 2026.

Reverse Merger

On December 17, 2024, Legacy Tvardi entered into an agreement and plan of merger and reorganization (the Merger Agreement) with Cara and CT Convergence Merger Sub, Inc., a wholly-owned subsidiary of Cara (Merger Sub), pursuant to which, on April 15, 2025, Merger Sub merged with and into Legacy Tvardi, with Legacy Tvardi surviving as a wholly-owned subsidiary of Cara (the Merger). Upon completion of the Merger, Cara changed its name to Tvardi Therapeutics, Inc., and Legacy Tvardi's business continued as the business of Tvardi.

Pursuant to the terms and conditions of the Merger Agreement, at the effective time of the Merger (the Effective Time):

- the outstanding shares of Legacy Tvardi's common stock (including the shares of common stock issuable upon conversion of all shares of Legacy Tvardi's preferred stock prior to the Merger), $0.001 par value per share (Legacy Tvardi common stock), were converted into 6,539,404 shares of Tvardi's common stock, $0.001 par value per share (Tvardi common stock) in the aggregate, based on an exchange ratio calculated in accordance with the Merger Agreement (the Exchange Ratio);

- Tvardi acquired approximately $23.9 million in net assets in accordance with the Merger Agreement;

- Legacy Tvardi's outstanding Convertible Notes converted into 1,265,757 shares of Tvardi common stock in the aggregate, pursuant to the terms of the Convertible Notes; and

- all outstanding and unexercised options to purchase shares of Legacy Tvardi common stock were assumed by Tvardi and converted into options to purchase shares of Tvardi common stock based on the Exchange Ratio.

Immediately following the Merger, equity holders of Legacy Tvardi prior to the Merger, including the holders of Convertible Notes, owned approximately 84.5% of the outstanding Tvardi common stock on a fully diluted basis.

The Merger was accounted for as a reverse recapitalization in accordance with accounting principles generally accepted in the United States (U.S. GAAP). Legacy Tvardi was deemed to be the accounting acquirer for financial reporting purposes. Refer to Note 3, *Merger Agreement*, in the Notes to Condensed Consolidated Financial Statements included elsewhere in this Quarterly Report.

In addition, on April 15, 2025, immediately prior to the closing of the Merger, Cara (i) effected a 1-for-3 reverse stock split of its common stock and (ii) increased its authorized shares of common stock to 150,000,000.

Upon the closing of the Merger, Tvardi's 2025 Equity Incentive Plan (the 2025 Plan) and 2025 Employee Stock Purchase Plan (the 2025 ESPP), both approved during a special meeting of Cara's stockholders on April 1, 2025, also became effective, following the reverse stock split.

As of the Effective Time, there were 935,554 and 93,555 shares of Tvardi's common stock available for grant under the 2025 Plan and 2025 ESPP, respectively. As of September 30, 2025, there was 551,221 shares of Tvardi's common stock remaining available for grant under the 2025 Plan. As of September 30, 2025, no offering periods under the 2025 ESPP had been initiated.

Convertible Notes

In December 2024, Legacy Tvardi entered into a note purchase agreement, pursuant to which it issued and sold convertible promissory notes (the Convertible Notes) in an aggregate principal amount of approximately $28.3 million. The Convertible Notes accrued interest at 8% per annum and had a maturity date of December 31, 2026 (the Maturity Date).

Upon the closing of the Merger, pursuant to the terms of the Convertible Notes, the outstanding principal balance of the Convertible Notes and all unpaid accrued interest automatically converted into 1,265,757 shares of Tvardi common stock in the aggregate. Utilizing the fair value option to account for the Convertible Notes, Tvardi recorded a gain of $12.8 million during the second quarter of 2025 and a net gain of $7.8 million for the nine months ended September 30, 2025 in its condensed consolidated statements of operations and comprehensive loss as a result of the net changes in fair value over the year-to-date 2025 period. There was no change in fair value recorded during the three months ended September 30, 2025 as the Convertible Notes were fully converted during the second quarter of 2025.

License Agreements

In July 2012 and June 2015, Stem Med Limited Partnership (StemMed) entered into license agreements with Baylor College of Medicine (BCM) referred to herein as the BCM First Agreement and BCM Second Agreement, respectively. StemMed assigned the BCM First Agreement and BCM Second Agreement to Legacy Tvardi in connection with the transfer of all or substantially all of the assets and businesses to which BCM First Agreement and BCM Second Agreement relate in January 2018 and February 2018, respectively. Under both the BCM First Agreement and BCM Second Agreement, Legacy Tvardi obtained exclusive, worldwide, sublicense licenses under certain of BCM's patents and patent applications and additionally in the case of the BCM First Agreement, certain BCM technology. Under these licenses, Tvardi is permitted to make, have made, use, market, sell, offer to sell, lease and import products, processes or services that incorporate, utilize or are made with the use such patents and patent applications or technologies (respectively, the BCM1 Licensed Products and BCM2 Licensed Products) in all fields of use. The licenses, patents and patent applications and technologies applicable to the BCM First Agreement and BCM Second Agreement are further discussed below.

First License Agreement with Baylor College of Medicine

Under the BCM First Agreement, Legacy Tvardi obtained an exclusive, worldwide, sublicensable license under BCM's rights to certain patents and patent applications related to STAT3 inhibitors in oncology and certain non-oncology indications, which Tvardi refers to as the BCM Patent Rights, together with certain cell lines, biological

materials, compounds, know-how and technologies, which Tvardi collectively refers to as the BCM Technology, to make, have made, use, market, sell, offer to sell, lease and import BCM1 Licensed Products, in all fields of use.

Pursuant to the terms of the BCM First Agreement, StemMed owed an initial license fee of $75,000 as consideration for the license rights. Upon the assignment of the agreement to Legacy Tvardi, Legacy Tvardi became responsible for the payment of annual maintenance fees on the anniversary of the agreement, which range from $30,000 to $50,000. Tvardi is also required to pay BCM royalties in the amount of a low-single-digit percent of net sales of BCM1 Licensed Products during the term, which expires, on a country-by-country basis, on the later of (i) the date of expiration of the last-to-expire of the BCM Patent Rights, or, (ii) if no BCM Patent Rights issued in such country, the tenth anniversary of the first commercial sale of the BCM1 Licensed Product in such country. Tvardi currently expects the BCM Patent Rights to expire April 18, 2039. Upon the initiation of the Phase 2 clinical trials for two BCM1 Licensed Products, Legacy Tvardi paid BCM development milestone payments of $250,000 in the aggregate. Upon the achievement of additional specified development and regulatory milestones, Tvardi is required to pay BCM one-time milestone payments of up to $2,200,000 in the aggregate for the first BCM1 Licensed Product in an oncology indication and for the first BCM1 Licensed Product in a non-oncology indication to achieve such milestones. Further, in connection with the initiation of the Phase 3 clinical trial, Tvardi would expect to incur approximately $400,000 of oncology-related costs and approximately $300,000 of non-oncology-related costs. Tvardi is additionally required to pay BCM a tiered low-double-digit percentage of sublicensing revenue obtained in connection with any sublicense granted by Tvardi under the BCM Patent Rights or BCM Technology.

Tvardi may terminate the BCM First Agreement at its convenience following a specified notice period upon advance written notice to BCM. The BCM First Agreement may also be terminated by BCM for Tvardi's default or failure to perform any of terms of the BCM First Agreement, following a specified notice and cure period. Additionally, BCM may terminate the BCM First Agreement if Tvardi undergoes specified bankruptcy or insolvency events, following the expiration of a specified period. Upon expiration of the term of the BCM First Agreement in a given country, the license grant from BCM to Tvardi will be fully-paid and perpetual in such country.

The BCM First Agreement was amended in April 2015 to update the schedule of BCM Patent Rights and description of description of BCM Technology covered by the license for immaterial consideration. The BCM First Agreement was further amended in August 2019 to amend Legacy Tvardi's diligence and insurance obligations as well as to further update the schedule of BCM Patent Rights.

Under the BCM First Agreement, the full amount of $50,000 in annual maintenance fees had already been paid as of September 30, 2025, and thus no accrual was needed. As a result, Tvardi had $12,500 remaining in prepaid expenses as of September 30, 2025. As of December 31, 2024, the full amount of $50,000 in annual maintenance fees had already been paid and thus no accrual was needed. No royalty fees have been incurred to date. All related license costs are expensed as incurred within research and development on the condensed consolidated statements of operations and comprehensive loss.

Second License Agreement with Baylor College of Medicine

Under the BCM Second Agreement, Legacy Tvardi obtained an exclusive, worldwide, sublicensable license under certain patents and patent applications co-owned by BCM and the National Institutes of Health (NIH), related to methods and compositions for the use of STAT3 inhibitors in certain conditions like anaphylaxis, which rights Tvardi refers to as the Licensed Patent Rights, to make, have made, use, market, sell, offer to sell, lease and import the BCM2 Licensed Products, in all fields of use.

Pursuant to the terms of the BCM Second Agreement, StemMed owed an initial license fee of $5,000 in consideration for the license rights. Upon the assignment of the agreement to Legacy Tvardi, it became responsible for the payment of maintenance fees on the anniversary of the agreement, which range from $30,000 to $50,000. Tvardi is also required to pay BCM royalties in the amount of a low-single-digit percent of net sales of BCM2 Licensed Products during the term, which expires, on a country-by-country basis, on the later (i) of the date of expiration of the last to expire of the Licensed Patent Rights, or, (ii) if no Licensed Patent Rights issued in such country, the tenth anniversary of the first commercial sale of the BCM2 Licensed Product in such country. Tvardi currently expects the Licensed Patent Rights to expire July 18, 2034. Upon the achievement of additional specified development and regulatory milestones, Tvardi is required to pay BCM one-time milestone payments of up to $1,225,000 in the aggregate for the first BCM2

Licensed Product to achieve such milestones. Further, in connection with the initiation of the Phase 3 clinical trial, Tvardi would expect to incur approximately $300,000 in costs. Tvardi is additionally required to pay BCM a tiered low-double-digit percentage of sublicensing revenue obtained in connection with any sublicense granted by Tvardi under the Licensed Patent Rights.

Tvardi may terminate the BCM Second Agreement at its convenience following a specified notice period upon advance written notice to BCM. The BCM Second Agreement may also be terminated by BCM for Tvardi's default or failure to perform any of terms of the BCM Second Agreement, following a specified notice and cure period. Additionally, BCM may terminate the BCM Second Agreement if Tvardi undergoes specified bankruptcy or insolvency events, following the expiration of a specified period. The NIH may terminate its license to BCM if Tvardi fails to fulfill certain obligations. Upon expiration of the term of the BCM Second Agreement in a given country, the license grant from BCM to Tvardi will be fully paid and perpetual in such country.

The BCM Second Agreement was amended in June 2019 to amend Legacy Tvardi's diligence and insurance obligations. Legacy Tvardi entered into a second amendment in April 2023 to further amend its diligence obligations and to terminate the obligation to pay annual maintenance fees until the first anniversary of the achievement of certain patent milestones and annually thereafter.

Under the BCM Second Agreement, no payments were made or incurred during the three and nine months ended September 30, 2025 and 2024. No royalty fees have been incurred to date.

Components of Operating Results

Revenue

Legacy Tvardi has not generated any revenue since its inception and Tvardi does not expect to generate any revenue from the sale of products in the near future, if at all. If Tvardi's development efforts for TTI-101, TTI-109 or additional product candidates that it may develop in the future are successful and result in marketing approval, or if Tvardi enters into collaboration or license agreements with third parties, it may generate revenue in the future from a combination of product sales or payments from such collaboration or license agreements.

Operating Expenses

Legacy Tvardi's operating expenses since inception have consisted primarily of research and development expenses and general and administrative costs.

Research and Development Expenses

Tvardi's research and development expenses consist primarily of direct and indirect costs incurred in performing clinical and preclinical development activities.

Direct costs include:

- expenses incurred under agreements with consultants and third-party contract research organizations (CROs) that conduct research and development activities on Tvardi's behalf;
- costs related to production of preclinical and clinical materials, including fees paid to contract manufacturers; and
- costs associated with license agreements.

Indirect costs include:

- personnel costs, which includes salaries, benefits, stock-based compensation expense and travel expenses, for personnel engaged in research and development functions;

- facilities, amortization and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance and other supplies; and

- costs related to compliance with quality and regulatory requirements.

Pursuant to U.S. GAAP and Tvardi's internal policies, including its clinical trial accrual policy, Tvardi expenses all research and development costs in the periods in which they are incurred, including the costs of treatment center start-up activities, patient enrollment, and study reporting. Costs for certain other research and development activities are recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to Tvardi by its vendors and third-party service providers. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and are reflected in Tvardi's unaudited condensed consolidated financial statements as prepaid or accrued research and development expenses.

The majority of Tvardi's clinical spending in the three and nine months ended September 30, 2025 and Legacy Tvardi's clinical spending in the three and nine months ended September 30, 2024 was on TTI-101, for which certain direct research and development costs are tracked by clinical trial. Spending for the development of TTI-109 began in 2023 and costs incurred for TTI-109 related to chemistry, manufacturing and control (CMC) and clinical operations for the three and nine months ended September 30, 2025, and CMC and pre-clinical operations for the three and nine months ended September 30, 2024.

Tvardi expects its research and development expenses to increase substantially for the foreseeable future as it continues to invest in the development of TTI-101 and TTI-109, support its ongoing preclinical programs and discover any new product candidates, as well as increase its headcount. In particular, clinical development, as opposed to preclinical development, generally has higher development costs, primarily due to the increased size and duration of later-stage clinical trials. Moreover, the costs associated with Tvardi's clinical activities, which are managed by its CROs, and Contract Development and Manufacturing Organizations (CDMOs), to manufacture materials for Tvardi's product candidates and future commercial products, are much more costly as compared to early-stage preclinical development. Tvardi cannot determine with certainty the timing of initiation, the duration or the completion costs of current or future preclinical studies and clinical trials of its current and future candidates due to the inherently unpredictable nature of preclinical and clinical development. Preclinical and clinical development timelines, the probability of success and development costs can differ materially from expectations. Tvardi anticipates that it will make determinations as to which therapeutic candidates to pursue and how much funding to direct to each therapeutic candidate on an ongoing basis in response to the results of ongoing and future preclinical studies and clinical trials, regulatory developments and Tvardi's ongoing assessments as to each therapeutic candidate's commercial potential. Tvardi will need substantial additional capital in the future to support these efforts. In addition, Tvardi cannot forecast which therapeutic candidates may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect its development plans and capital requirements.

At this time, Tvardi cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete the development of any of its product candidates. Tvardi is also unable to predict when, if ever, material net cash inflows will commence from sales or licensing of its product candidates. This is due to the numerous risks and uncertainties associated with drug development, including:

- negative or inconclusive results from Tvardi's preclinical studies or clinical trials or the clinical trials of others for product candidates similar to Tvardi's, leading to a decision or requirement to conduct additional preclinical testing or clinical trials or abandon a program;

- undesirable product-related side effects experienced by subjects in Tvardi's clinical trials or by individuals using drugs or therapeutics similar to its product candidates;

- poor efficacy of Tvardi's product candidates during clinical trials;

- delays in submitting IND applications or comparable foreign applications or delays or failure in obtaining the necessary approvals from the FDA or other comparable foreign regulatory authorities to commence a clinical trial, or a suspension or termination of a clinical trial once commenced;

- conditions imposed by the FDA or comparable foreign regulatory authorities regarding the scope or design of Tvardi's clinical trials;
- delays in enrolling subjects in clinical trials, including due to operational challenges or competition with other clinical trials;
- high drop-out rates or screening failures of subjects from clinical trials;
- inadequate supply or quality of product candidates or other materials necessary for the conduct of Tvardi's clinical trials;
- greater than anticipated clinical trial costs;
- inability to compete with other therapies;
- failure to secure or maintain orphan designation in some jurisdictions;
- unfavorable FDA or other regulatory agency inspection and review of a clinical trial site;
- failure of Tvardi's third-party contractors or investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner, or at all;
- delays and changes in regulatory requirements, policy and guidelines, including the imposition of additional regulatory oversight around clinical testing generally or with respect to Tvardi's technology in particular; or
- varying interpretations of data by the FDA and other comparable foreign regulatory authorities.

A change in the outcome of any of these variables with respect to the development of any of Tvardi's product candidates or potential future product candidates could mean a significant change in the costs and timing associated with the development of that product candidate or potential future product candidate. For example, if the FDA or another regulatory authority were to require Tvardi to conduct clinical trials beyond those that it anticipates would be required for the completion of clinical development of a product candidate or potential future product candidate, or if Tvardi experiences significant delays in its clinical trials due to slower than expected patient enrollment or other reasons, it would be required to expend significant additional financial resources and time on the completion of clinical development. Tvardi may never obtain regulatory approval for any of its product candidates, and, even if Tvardi does, drug commercialization takes several years and millions of dollars in development costs.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel costs, including salaries, benefits and stock-based compensation, for personnel in Tvardi's executive, finance, corporate and business development and administrative functions. General and administrative expenses also include outside professional services, such as legal, audit and accounting services, insurance costs and facility-related expenses, which includes direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs.

Tvardi expects its general and administrative expenses to increase over the next several years as it continues its research and development activities, prepares for potential commercialization of its current and future product candidates, as well as expands its operations and continues operating as a public company following the Merger. These increases will likely include increases related to the hiring of additional personnel and legal, regulatory and other fees and services associated with maintaining compliance with listing rules and SEC requirements, director and officer insurance premiums and investor relations costs associated with being a public company.

Interest Income

Interest income for the three and nine months ended September 30, 2025 consisted of interest earned on Tvardi's cash equivalents as well as interest earned on short-term investments and the accretion of the discount of its short-term investments. Interest income for the three and nine months ended September 30, 2024 consisted of interest earned on Legacy Tvardi's cash equivalents.

Other Income, Net

Other income, net consists of the net changes in fair value of Legacy Tvardi's Convertible Notes, for which it elected the fair value option as well as interest accrued on the Convertible Notes. See "—Recent Developments—Convertible Notes" for further discussion of Legacy Tvardi's Convertible Notes.

Income Taxes

For the three and nine months ended September 30, 2025 and 2024, there was no current or deferred income tax expense or benefit due to Tvardi's current year losses and full valuation allowance. As of September 30, 2025, Tvardi evaluated all available evidence and concluded that a valuation allowance is still required against its net deferred tax assets because it is more likely than not they will not be realized in the foreseeable future.

On July 4, 2025, the One Big Beautiful Bill Act (OBBBA) was signed into law. The OBBBA introduced multiple U.S. federal income tax changes such as deductibility of domestic research and development expenses, deductibility of certain property additions and limitations on interest expense deductions. Tvardi has considered the impact of these provisions on its condensed consolidated financial statements for the period ended September 30, 2025, however, the changes in tax law did not result in a change in Tvardi's tax provision.

Results of Operations

Comparison of the Three and Nine Months Ended September 30, 2025 and 2024

The following table sets forth Tvardi's results of operations for the three and nine months ended September 30, 2025 and 2024 (in thousands, except percentages):

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2025	2024	Amount	Percent	2025	2024	Amount	Percent
Operating expenses:								
Research and development	$ 3,603	$ 4,795	$ (1,192)	(24.9)%	$ 12,520	$ 15,047	$ (2,527)	(16.8)%
General and administrative	2,335	881	1,454	165.0 %	6,641	2,258	4,383	194.1 %
Total operating expenses	5,938	5,676	262	4.6 %	19,161	17,305	1,856	10.7 %
Loss from operations	(5,938)	(5,676)	(262)	4.6 %	(19,161)	(17,305)	(1,856)	10.7 %
Interest income	411	163	248	152.1 %	1,063	615	448	72.8 %
Other income, net	—	—	—	—	7,159	—	7,159	n/a
Net loss	$ (5,527)	$ (5,513)	$ (14)	0.3 %	$ (10,939)	$ (16,690)	$ 5,751	(34.5)%

Research and Development Expenses

Research and development expenses for the three and nine months ended September 30, 2025 and 2024 were comprised of the following (in thousands, except percentages):

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2025	2024	Amount	Percent	2025	2024	Amount	Percent
Direct research and development expenses by program:								
TTI-101:								
HCC	$ 597	$ 1,980	$ (1,383)	(69.8)%	$ 2,001	$ 4,996	$ (2,995)	(59.9)%
IPF	—	1,023	(1,023)	(100.0)%	3,863	2,991	872	29.2 %
mBC	—	683	(683)	(100.0)%	(268)	2,771	(3,039)	(109.7)%
Pre-clinical, CMC, and other (unallocated)	112	130	(18)	(13.8)%	427	715	(288)	(40.3)%
TTI-109	1,991	19	1,972	10,378.9 %	3,171	697	2,474	354.9 %
Unallocated research and development expense:								
Personnel costs (including stock-based compensation)	741	718	23	3.2 %	2,516	2,273	243	10.7 %
Consultant fees and other costs	162	242	(80)	(33.1)%	810	604	206	34.1 %
Total research and development expenses	$ 3,603	$ 4,795	$ (1,192)	(24.9)%	$ 12,520	$ 15,047	$ (2,527)	(16.8)%

Research and development expenses were $3.6 million for the three months ended September 30, 2025, compared to $4.8 million for the three months ended September 30, 2024. The decrease of $1.2 million was primarily driven by costs associated with Tvardi's product candidate TTI-101, including decreases of $1.4 million, $1.0 million and $0.7 million related to Tvardi's HCC, IPF and metastatic breast cancer (mBC) trials, respectively. The decrease in Tvardi's HCC trial was primarily attributable to the changes in patient enrollments and estimated study costs. The decrease in Tvardi's IPF trial was attributable to the trial being completed in the second quarter of 2025, with no additional expenses expected to be incurred until the fourth quarter of 2025. The decrease in Tvardi's mBC trial was due to the discontinuation of the trial in January 2024.

The increase of $2.0 million related to Tvardi's product candidate TTI-109 was primarily driven by the healthy volunteer study, which began in the third quarter of 2025, as well as related CMC costs.

Research and development expenses were $12.5 million for the nine months ended September 30, 2025, compared to $15.0 million for the nine months ended September 30, 2024. The decrease of $2.5 million was primarily driven by costs associated with Tvardi's product candidate TTI-101, including decreases of $3.0 million and $3.0 million related to Tvardi's HCC and mBC trials, respectively. The decrease in Tvardi's HCC trial was attributable to the changes in patient enrollments and estimated study costs, while the decrease in Tvardi's mBC trial was due to the discontinuation of the trial in January 2024 and a related true-up recorded during the second quarter of 2025 due to the negotiation of wind-down costs. These decreases in costs were partially offset by a $0.9 million increase in costs related to Tvardi's IPF trial, due to the timing of patient enrollment prior to the trial ending in the second quarter of 2025.

The increase of $2.5 million related to Tvardi's product candidate TTI-109 was primarily driven by the healthy volunteer study, which began in the third quarter of 2025, as well as related CMC costs.

The increase of personnel costs of $0.2 million was primarily related to increases in compensation across the research and development functions. The $0.2 million increase in consultant fees and other costs was primarily related to other research and development costs such as costs to maintain intellectual property and prepare regulatory filings.

General and Administrative Expenses

General and administrative expenses for the three and nine months ended September 30, 2025 and 2024 were comprised of the following (in thousands, except percentages):

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2025	2024	Amount	Percent	2025	2024	Amount	Percent
Personnel costs	$ 1,012	$ 492	$ 520	105.7 %	$ 2,659	$ 1,501	$ 1,158	77.1 %
Professional fees	1,001	269	732	272.1 %	3,131	410	2,721	663.7 %
Insurance costs	177	16	161	1,006.3 %	342	46	296	643.5 %
Rent and other costs	145	104	41	39.4 %	509	301	208	69.1 %
Total general and administrative expenses	$ 2,335	$ 881	$ 1,454	165.0 %	$ 6,641	$ 2,258	$ 4,383	194.1 %

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 increased legal fees and ongoing accounting and audit fees. The remaining increase was attributable to increases in personnel costs, insurance costs, and rent and other related costs.

General and administrative expenses were $6.6 million for the nine months ended September 30, 2025, compared to $2.3 million for the nine months ended September 30, 2024. The increase of approximately $4.4 million was primarily driven by increases in professional fees of $2.7 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 rent and other related costs.

Interest Income

Interest income was $0.4 million for the three months ended September 30, 2025, compared to $0.2 million for the three months ended September 30, 2024. The $0.4 million of interest income for the three months ended September 30, 2025 includes $0.3 million of interest earned on Tvardi's cash and cash equivalents and $0.1 million of interest from its short-term investments, as well as the accretion of the discount on its short-term investments. The $0.2 million of interest income for the three months ended September 30, 2024 was driven by interest income earned on Legacy Tvardi's cash equivalents.

Interest income was $1.1 million for the nine months ended September 30, 2025, compared to $0.6 million for the nine months ended September 30, 2024. The $1.1 million of interest income for the nine months ended September 30, 2025 includes $0.6 million of interest earned on Tvardi's cash and cash equivalents and $0.5 million of interest from its short-term investments, as well as the accretion of the discount on its short-term investments. The $0.6 million of interest income for the nine months ended September 30, 2024 was driven by interest income earned on Legacy Tvardi's cash equivalents.

Other Income, Net

For the three months ended September 30, 2025 and 2024, there was no other income, net recorded within the condensed consolidated statements of operations and comprehensive loss, as there were no financial instruments requiring valuation or interest expense for the respective periods. The Convertible Notes were fully converted during the second quarter of 2025, and there was no remeasurement gain or loss recorded for the three months ended September 30, 2025.

Other income, net of $7.2 million for the nine months ended September 30, 2025 was primarily attributable to the $12.8 million remeasurement gain on Legacy Tvardi's Convertible Notes recorded during the second quarter of 2025, partially offset by a $4.9 million remeasurement loss recorded during the first quarter of 2025, as well as $0.7 million in interest accrued on the Convertible Notes during those respective periods. See "—Recent Developments" above for

further discussion of the Convertible Notes. There were no financial instruments requiring valuation or interest expense for the nine months ended September 30, 2024.

Liquidity and Capital Resources

Sources of Liquidity

Since inception, Tvardi has not generated any revenue from product sales or any other sources and has incurred significant operating losses. Tvardi has not yet commercialized any products and does not expect to generate revenue from sales of any product candidates for several years, if ever. To date, Tvardi has financed its operations primarily through the (i) issuance and sale of its Convertible Notes in December 2024 for gross proceeds of $28.3 million (ii) the issuance and sale of preferred stock and historical convertible debt (which converted into preferred stock in 2018 and 2021) for total gross proceeds of $83.4 million, and (iii) as discussed above in "—Recent Developments," its Merger with Cara in April 2025. To date, Tvardi has devoted substantially all of its efforts and financial resources to developing its product candidates, organizing and staffing its company, business planning, raising capital, establishing its intellectual property portfolio and performing research and development of its product candidates, signaling and biology, medicinal chemistry and clinical insights to discover and develop novel therapies for the treatment of fibrosis-driven diseases. As of September 30, 2025, Tvardi had $21.4 million in cash and cash equivalents and $15.0 million in short-term investments. In April 2025, Tvardi acquired approximately $23.9 million of net assets in connection with the closing of the Merger.

See "—Recent Developments" above for further discussion of the Merger and Convertible Notes.

Funding Requirements

Tvardi's primary uses of cash are to fund its operations, which consist primarily of research and development costs related to the development of its product candidates, and, to a lesser extent, general and administrative costs. Tvardi has incurred significant operating losses since its inception, and as of September 30, 2025, had an accumulated deficit of $103.2 million. Management has determined that its present capital resources as of September 30, 2025 will not be sufficient to fund its planned operations for at least one year from the issuance date of the unaudited condensed consolidated financial statements, included elsewhere in this Quarterly Report, which raises substantial doubt as to Tvardi's ability to continue as a going concern. In April 2025, as further discussed above, Legacy Tvardi completed its Merger with Cara, through which it acquired approximately $23.9 million in net assets. Subsequent to the completion of the Merger, Tvardi plans to seek additional funding through equity offerings or debt financings, credit or loan facilities, and strategic alliances and licensing arrangements. However, there can be no assurance that such funding will be available to Tvardi, will be obtained on terms favorable to Tvardi, or will provide Tvardi with sufficient funds to meet its objectives.

Tvardi anticipates that it will continue to incur significant and potentially increasing expenses for the foreseeable future as it continues to advance its product candidates, expand its corporate infrastructure, including the costs associated with being a public company following the Merger, further Tvardi's research and development initiatives for its product candidates and incur costs associated with the potential commercialization of its product candidates, if approved. Tvardi is subject to all of the risks typically related to the development of new drug candidates, and may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect its business. Tvardi anticipates that it will need substantial additional funding in connection with its continuing operations. However, Tvardi may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. If Tvardi raises additional capital through public or private equity offerings, the ownership interest of its existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect its stockholders' rights. If Tvardi raises additional capital through debt financing, it may be subject to covenants or other restrictions limiting its ability to engage in specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any failure to raise capital as and when needed could have a negative impact on Tvardi's financial condition and on its ability to pursue its business plans and strategies. If Tvardi is unable to raise capital, it will need to delay, reduce or terminate planned activities to reduce costs.

Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products, Tvardi is unable to estimate the exact amount of its operating capital requirements.

Tvardi's future funding requirements will depend on many factors, including, but not limited to:

- the initiation, progress, timing, costs and results of preclinical studies and clinical trials for its potential future product candidates;
- the clinical development plans Tvardi establishes for its product candidates;
- the timelines of its clinical trials and the overall costs to conduct and complete the clinical trials, including any increased costs due to disruptions caused by marketplace conditions, including the effects of health epidemics, or other geopolitical and macroeconomic conditions;
- the cost and capital commitments required for manufacturing its product candidates at clinical and if, approved, commercial scales;
- the number and characteristics of product candidates that Tvardi develops;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA and other comparable foreign regulatory authorities;
- whether Tvardi is able to enter into future collaboration agreements and the terms of any such agreements;
- the ability to achieve and timing of achieving a favorable pricing and reimbursement decision by the pricing authorities in the markets of interest;
- the cost of filing, prosecuting, defending and enforcing its patent claims and other intellectual property rights, including patent infringement actions brought by third parties against Tvardi or its product candidates;
- the effect of competing technological and market developments;
- the cost and timing of completion of commercial-scale outsourced manufacturing activities; and
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which Tvardi may receive regulatory approval in regions where it chooses to commercialize its products on its own.

A change in the outcome of any of these or other variables with respect to the development of any of Tvardi's current and future product candidates could significantly change the costs and timing associated with the development of that product candidate. See the section titled "Risk Factors" set forth in this Quarterly Report for additional risks associated with Tvardi's substantial capital requirements.

Cash Flows

The following table summarizes Tvardi's cash flows for the periods indicated (in thousands):

	Nine Months Ended September 30,	
	2025	2024
Net cash used in operating activities	$ (17,814)	$ (13,472)
Net cash used in investing activities	(15,084)	—
Net cash provided by (used in) financing activities	22,702	(9)
Net decrease in cash and cash equivalents	$ (10,196)	$ (13,481)

Operating Activities

Net cash used in operating activities was $17.8 million for the nine months ended September 30, 2025, reflecting a net loss of $10.9 million, non-cash changes of $6.2 million, and changes in operating assets and liabilities of $0.7 million. The changes of $6.2 million in non-cash expenses were primarily driven by $7.8 million related to the net change in fair value of Legacy Tvardi's Convertible Notes, partially offset by $1.0 million related to stock-based compensation expense and $0.7 million in interest accrued on its Convertible Notes until conversion during the second quarter of 2025. The net changes in operating assets and liabilities of $0.7 million were primarily driven by a $1.6 million increase in prepaid expenses and other current assets, attributable to payments for pre-clinical activities and prepaid insurance, partially offset by a $0.9 million increase in accounts payable and accrued expenses, driven by the timing of invoices and payments.

Net cash used in operating activities was $13.5 million for the nine months ended September 30, 2024, reflecting a net loss of $16.7 million and net changes in operating assets and liabilities of $2.8 million, partially offset by non-cash charges for depreciation and amortization, stock-based compensation expense, and non-cash lease expense of $0.4 million. The net change in operating assets and liabilities of $2.8 million was primarily driven by (i) a $2.0 million decrease in prepaid expenses and other current assets, attributable to the timing of patient enrollments, and (ii) a $0.9 million increase in accounts payable and accrued expenses, driven by the timing of invoices and payments.

Investing Activities

Net cash used in investing activities was $15.1 million for the nine months ended September 30, 2025, attributable to purchases of short-term investments of $31.5 million, partially offset by maturities of short-term investments of $16.4 million.

There was no net cash provided by investing activities for the nine months ended September 30, 2024.

Financing Activities

The net cash provided by financing activities for the nine months ended September 30, 2025 was primarily due to approximately $25.0 million of cash acquired in connection with the Merger and proceeds of $0.5 million from the exercise of stock options, partially offset by payments of $2.8 million related to Merger transaction costs.

The net cash used in financing activities for the nine months ended September 30, 2024 was due to the payments of deferred offering costs, partially offset by proceeds from the exercise of stock options.

Contractual Obligations and Commitments

Lease Obligations

Tvardi leases space under one operating lease agreement for corporate office space in Sugar Land, Texas, which expires in August 2027. As of September 30, 2025, Tvardi had future operating lease liabilities of $0.2 million, of which $0.1 million is included within operating lease liabilities, current portion on its condensed consolidated balance sheet.

License Agreements

As discussed above, Tvardi has license agreements with BCM for exclusive use of patent rights of TTI-101. The license agreements contain terms for annual maintenance fees, milestone payments and net revenue royalties. Annual maintenance fees range from $30,000 to $50,000 per year, per license. Potential milestone payments are up to $1,225,000 in the aggregate per license. Milestones include new drug filings, clinical trial stages, and NDA approval by the FDA. Tvardi is obligated to pay BCM royalties in the amount of a low-single-digit percent of net sales of BCM1 Licensed Products or BCM2 Licensed Products during the term, which expire, on a country-by-country basis, on the later of (i) the date of expiration of BCM Patent Rights or Licensed Patent Rights, whichever is the last to expire, or, (ii) if no BCM Patent Rights or Licensed Patent Rights are issued in such country, the tenth anniversary the first commercial sale of the BCM1 Licensed Products or BCM2 Licensed Products in such country. License fees are expensed as incurred within research and development within Tvardi's condensed consolidated statements of operations

and comprehensive loss. Under the BCM First Agreement, the full amount of $50,000 in annual maintenance fees had already been paid as of September 30, 2025, and thus no accrual was needed. As a result, Tvardi had $12,500 remaining in prepaid expenses as of September 30, 2025. As of December 31, 2024, the full amount of $50,000 in annual maintenance fees had already been paid and thus no accrual was needed. No royalty fees have been incurred to date.

Other Capital Requirements and Additional Royalty Obligations

Tvardi enters into agreements in the normal course of business with various third-party providers for the provision of research and development services, which include preclinical studies and clinical trial services with CROs and the manufacturing of product candidates for use in its preclinical studies and clinical trials with CDMOs. These agreements may include certain provisions for purchase obligations and termination obligations that could require payments for the cancellation of committed purchase obligations or for early termination of the agreements. The amount of the cancellation or termination payments vary and are based on the timing of the cancellation or termination and the specific terms of the agreement. These obligations and commitments are not presented separately.

In addition to Tvardi's obligation to make potential royalty payments under the BCM First Agreement and BCM Second Agreement discussed above, pursuant to Legacy Tvardi's founder restricted stock purchase agreements with each of its founders, David J. Tweardy, M.D. and Ron DePinho, M.D., Tvardi is also obligated to pay royalties to each such founder in an amount equal to 1% each on the worldwide net sales of TTI-101 and any derivative formulations (a Royalty Bearing Product). These royalty obligations last, on a country-by-country basis, for the later of (i) the date on which the sale of Royalty Bearing Product is no longer covered by a Covered Patent (as defined below) in such country, or (ii) 15 years after the first commercial sale of Royalty Bearing Product in such country. The timing of when Tvardi's royalty payments will actually be made is uncertain as the payments are contingent upon future activities, including the successful development, regulatory approval and commercialization of Royalty Bearing Product. A Covered Patent means, subject to certain customary exceptions, an issued patent that is owned by us or an affiliate, or for which all rights to develop and commercialize pharmaceutical products for the treatment of any human disorder, are exclusively licensed to Tvardi or an affiliate by the owner of such patent, with Tvardi's right or Tvardi's affiliate's right to grant sublicenses.

Critical Accounting Estimates

Tvardi's unaudited condensed consolidated financial statements are prepared in accordance with U.S. GAAP. The preparation of the unaudited condensed consolidated financial statements and related disclosures requires management to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses in Tvardi's unaudited condensed consolidated financial statements. Tvardi bases its estimates on historical experience, known trends and events and various other factors that management believes are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Management evaluates estimates and assumptions on a periodic basis. Tvardi's actual results may differ from these estimates.

While Tvardi's significant accounting policies are described in more detail in Note 2 to the unaudited condensed consolidated financial statements for the three and nine months ended September 30, 2025 and 2024, included elsewhere within this Quarterly Report, management believes that the following accounting policies are critical to understanding Tvardi's historical and future performance, as the policies relate to the more significant areas involving management's judgments and estimates used in the preparation of the unaudited condensed consolidated financial statements.

Prepaid and Accrued Research and Development Costs

Accounting for preclinical studies and clinical trials relating to activities performed by CROs and other external vendors requires management to exercise significant estimates in regard to the timing and accounting for these expenses. Tvardi estimates costs of research and development activities conducted by service providers, which include costs to properly initiate and manage ongoing preclinical studies and clinical trials. The diverse nature of services being provided under contracts with Tvardi's CROs, CDMOs and other arrangements, the different compensation arrangements that exist for each type of service and the lack of timely information related to certain pre-clinical and clinical activities complicates the estimation of accruals for services rendered by the CROs, CDMOs and other vendors in connection with preclinical studies and clinical trials.

Examples of estimated accrued research and development expenses include:

- expenses incurred under agreements with third parties, including Tvardi's CROs that conducts research, preclinical studies and clinical trials on its behalf;
- expenses incurred under agreements with third parties, including its CDMOs, that develop and manufacture its product candidate for use in Tvardi's preclinical studies and clinical trials; and
- other providers and vendors in connection with research and development activities.

Tvardi bases its expenses related to preclinical studies and clinical trials on its estimates of the services received and efforts expended pursuant to quotes and contracts with its CROs, CDMOs and other third-party vendors that conduct research, preclinical studies and clinical trials on its behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to Tvardi's vendors will exceed the level of services provided and result in a prepayment of the expense.

Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing fees, Tvardi estimates the time period over which services will be performed, the enrollment of patients and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from Tvardi's estimate, or if Tvardi receives any change orders from its third-party providers, it adjusts the accrual or amount of prepaid expense accordingly. Although Tvardi does not expect its estimates to be materially different from amounts actually incurred, its understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in Tvardi reporting amounts that are too high or too low in any particular period. To date, Tvardi has not made any material adjustments to its prior estimates of accrued research and development expenses.

Tvardi also records advance payments to service providers as prepaid expenses and other current assets, which are expensed when the contracted services are performed. If the actual timing of the performance of services varies from the estimate, then Tvardi adjusts the amount of the accrued expense or the prepaid expense accordingly.

Convertible Notes

Historically, Legacy Tvardi elected to account for its Convertible Notes pursuant to the fair value option under Accounting Standards Codification (ASC) 825, *Financial Instruments* (ASC 825). In accordance with ASC 825 and the fair value option, Legacy Tvardi recorded its Convertible Notes at fair value with changes in fair value recorded as component of other income (expense), net in its condensed consolidated statements of operations and comprehensive loss. As a result of the fair value option, any issuance costs related to the Convertible Notes were expensed as incurred and were not deferred.

The fair value of the Convertible Notes was determined using a scenario-based valuation analysis that requires a probability of inputs, including the probability of occurrence of events that would trigger conversion of the Convertible Notes and the expected timing of such events.

Prior to the Merger with Cara in April 2025, Legacy Tvardi assessed the probability of (i) an automatic conversion of the Convertible Notes into equity securities upon a Qualified or non-Qualified Financing, (ii) an automatic conversion of the Convertible Notes into shares of Legacy Tvardi's common stock upon an IPO, (iii) an automatic conversion of the Convertible Notes into the combined company's common stock upon a reverse merger, and (iv) an event of default, dissolution, or liquidation, weighted with 2.5%, 0%, 95%, and 2.5%, respectively.

Additional assumptions and estimates used to estimate the fair value of the Convertible Notes included the: (i) fixed price conversion option, which was valued using a Black-Scholes option model, (ii) aggregate call value of each scenario, which was synthesized using a bond plus call option model, (iii) expected volatility, (iv) risk-free interest rate, and (v) the fair value of the Convertible Notes under the reverse merger scenario, which was estimated using a forward contract structure.

Since Tvardi elected the fair value option for the Convertible Notes, at the time of conversion, the fair value was measured as the quoted market price of Tvardi's common shares into which the Convertible Notes were exchanged. The fair value was determined to be the closing market trading price on April 16, 2025, the first day of trading for Tvardi's common shares.

Under the fair value option, any change in fair value was recorded to Tvardi's condensed consolidated statements of operations and comprehensive loss as a gain or loss from a fair value measurement. At the time of conversion, the fair value of the Convertible Notes was $23.1 million, calculated as 1,265,757 shares of common stock at the closing market trading price on April 16, 2025. The $12.8 million change in fair value when comparing the $23.1 million at the time of conversion to the $35.9 million recorded value of the Convertible Notes immediately prior to the conversion date was recorded to Tvardi's condensed consolidated statements of operations and comprehensive loss within other income, net for the second quarter of 2025. Net fair value changes of $7.8 million were recorded to Tvardi's condensed consolidated statements of operations and comprehensive loss within other income, net for the nine months ended September 30, 2025.

As discussed above, upon the closing of the Merger, the Convertible Notes converted into 1,265,757 shares of Tvardi common stock in the aggregate. As a result, there were no Convertible Notes as of September 30, 2025.

Stock-Based Compensation Expense and Fair Value of Stock-Based Awards

Stock-Based Compensation Expense

Tvardi measures and records the expense related to stock-based awards granted to employees, directors, consultants and advisors based upon their respective fair value at the date of grant. Generally, Tvardi issues stock option awards with service-based vesting conditions and records the expense for these awards using the straight-line method such that the aggregate amount of expense recognized is at least the fair value of what has legally vested. Tvardi estimates the grant date fair value of each common stock option using the Black-Scholes option-pricing model, which requires the input of highly subjective assumptions and management's best estimates. These estimates involve inherent uncertainties and management's judgement. If factors change and different assumptions are used, Tvardi's stock-based compensation could be materially different in the future.

These assumptions are estimated as follows:

- *Fair Value* — Because Legacy Tvardi's common stock was not yet publicly traded prior to the Merger, it had to estimate the fair value of its common stock. Tvardi's board of directors considered numerous objective and subjective factors to determine the fair value of its common stock at each meeting in which awards were approved. Subsequent to the Merger, Tvardi's common stock is publicly traded.

- *Expected Volatility* — Because Legacy Tvardi did not have any trading history for its common stock prior to the Merger, the expected volatility was estimated using averages of the historical volatility of its peer group of companies for a period equal to the expected term of the stock options granted. Legacy Tvardi's peer group of publicly traded companies was chosen based on their similar size, stage in the life cycle or area of specialty. Subsequent to the Merger, Tvardi intends to continue to consistently apply this process using the same or a similar peer group of public companies, until a sufficient amount of historical information regarding the volatility of its own common stock price becomes available.

- *Expected Term* — Derived from the life of the options granted under the option plan and is based on the simplified method which is essentially the weighted average of the vesting period and contractual term.

- *Risk-Free Interest Rate* — The risk-free interest rate is based on the implied yield currently available on U.S. Treasury zero-coupon issues with a term that is equal to the options' expected term at the grant date.

- *Dividend Yield* — Legacy Tvardi had not declared or paid dividends, and Tvardi does not anticipate declaring dividends. As such, the dividend yield has been estimated to be zero.

Changes in the foregoing assumptions can materially affect the estimate of grant date fair value and ultimately how much share-based compensation expense is recognized; and the resulting change in fair value, if any, is recognized in Tvardi's condensed consolidated statements of operations during the period the related services are rendered. These inputs are subjective and generally require significant analysis and judgment to develop.

Fair Value of Stock-Based Awards

As a privately held company prior to the Merger, there had been no public market for Legacy Tvardi's common stock. The estimated fair value of Legacy Tvardi's common stock had been determined by its board of directors as of the date of each option grant, with input from management, considering the most recently available third-party valuations of its common stock and its board of directors' assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent valuation through the date of the grant. These third-party valuations were performed in accordance with the guidance outlined in the *American Institute of Certified Public Accountants' Accounting and Valuation Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation*.

Legacy Tvardi's third-party valuations of common stock were prepared using the option-pricing method (OPM), which used a market approach to estimate Legacy Tvardi's enterprise value. The OPM treats common stock as call options on the total equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company's securities changes. Under this method, the common stock has value only if the funds available for distribution to stockholders exceeded the value of the preferred stock liquidation preferences at the time of the liquidity event, such as a strategic sale or a merger.

These third-party valuations resulted in a valuation of Legacy Tvardi's common stock of $0.92 (pre-application of the Exchange Ratio) as of June 30, 2023. Legacy Tvardi used this information to calculate the grant date fair value per share of stock options granted in January 2024 ($4.62 post-Exchange Ratio). In addition to considering the results of these third-party valuations, Legacy Tvardi's board of directors considered various objective and subjective factors to determine the fair value of its common stock as of each grant date, including:

- the prices at which Legacy Tvardi sold shares of its preferred stock and the superior rights and preferences of the preferred stock relative to its common stock at the time of each grant;
- the lack of an active public market, for Legacy Tvardi's common stock and preferred stock;
- the progress of Legacy Tvardi's research and development programs, including the status and results of preclinical studies and clinical trials for its product candidates;
- Legacy Tvardi's stage of development and commercialization and its business strategy, and material risks to its business;
- external market conditions affecting the pharmaceutical and biopharmaceutical industry and trends within each industry;
- Legacy Tvardi's financial position, including cash on hand, and its historical and forecasted performance and operating results;
- the likelihood of achieving a liquidity event, such as an initial public offering or sale of Legacy Tvardi in light of prevailing market conditions; and
- the analysis of initial public offerings and the market performance of similar companies in the biopharmaceutical industry.

The assumptions underlying these valuations represented management's best estimate, which involved inherent uncertainties and the application of management's judgment. As a result, if Legacy Tvardi had used significantly different assumptions or estimates prior, the fair value of its common stock and its stock-based compensation expense could have been materially different.

Recently Issued and Adopted Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact Tvardi's financial position and results of operations is disclosed in Note 2 to the unaudited condensed consolidated financial statements for the three and nine months ended September 30, 2025 and 2024, included elsewhere within this Quarterly Report.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

As of September 30, 2025, Tvardi had $21.4 million in cash and cash equivalents and $15.0 million in short-term investments. As of December 31, 2024, Legacy Tvardi had $31.6 million in cash and cash equivalents. Tvardi's cash, cash equivalents and short-term investments are primarily maintained in accounts with multiple financial institutions in the United States. Tvardi may maintain cash and cash equivalent balances in excess of Federal Deposit Insurance Corporation limits. Tvardi does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships, particularly because Tvardi's investments are in short-term marketable securities. Tvardi's primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. Due to the short-term duration and low risk profile of Tvardi's cash equivalents and short-term investments, it believes an immediate 10% change in interest rates would not have a material effect on their fair market value. Tvardi has the ability to hold its investments until maturity, and therefore, would not expect its operating results or cash flows to be affected to any significant degree by the effect of a change in market interest rates on its investment portfolio.

Effects of Inflation

Inflation generally affects Tvardi by increasing the cost of labor and research and development contract costs. Tvardi does not believe inflation has had a material effect on its results of operations during the periods presented in its unaudited condensed consolidated financial statements included elsewhere within in this Quarterly Report.

Foreign Currency Exchange Risk

All of Tvardi's employees and its operations are currently located in the United States, and expenses are generally denominated in U.S. dollars. As such, Tvardi is not exposed to financial risks from exchange rate fluctuations between U.S. dollars and other currencies.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Tvardi maintains "disclosure controls and procedures," (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act) to provide reasonable assurance that information required to be disclosed by Tvardi in the reports that it files or submits under the Exchange Act is (1) recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC, and (2) accumulated and communicated to Tvardi's management, including its principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosures. Pursuant to Rules 13a-15(e) and 15d-15(e) under the Exchange Act, Tvardi's management, with the participation of its principal executive officer and principal financial officer, has evaluated the effectiveness of its disclosure controls and procedures as of September 30, 2025. See below "*Material Weakness in Internal Control Over Financial Reporting Related to Legacy Tvardi*".

Based on its evaluation, Tvardi's principal executive officer and principal financial officer have concluded that, as of September 30, 2025, Tvardi's disclosure controls and procedures were not effective at a reasonable assurance level as a result of material weaknesses that existed in Legacy Tvardi's internal control over financial reporting as described below.

Changes in Internal Control Over Financial Reporting

There was no change in Tvardi's internal control over financial reporting that occurred during the quarter ended September 30, 2025 that has materially affected, or is reasonably likely to materially affect, Tvardi's internal control over financial reporting.

Limitations on Controls and Procedures

Management, including Tvardi's principal executive officer and principal financial officer, recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost benefit relationship of possible controls and procedures. Because of the inherent limitations of the effectiveness of all control systems, no evaluation of controls and procedures can provide absolute assurance that all control issues and instances of fraud, if any, within Tvardi have been detected.

Material Weaknesses in Internal Control Over Financial Reporting Related to Legacy Tvardi

In connection with the preparation of Legacy Tvardi's financial statements for the years ended December 31, 2024 and 2023, material weaknesses were identified in the design and operating effectiveness of Legacy Tvardi's internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis.

Two of these material weaknesses are related to the fact that Legacy Tvardi lacked a sufficient number of professionals to consistently establish appropriate authorities and responsibilities in pursuit of Legacy Tvardi's financial reporting objectives. The lack of sufficient number of finance and accounting professionals contributed to the inadequate design and Legacy Tvardi's inability to maintain effective controls over the segregation of duties related to journal entries. In addition, Legacy Tvardi identified a material weakness in its financial reporting related to inadequate review of financial statements and disclosures. The third material weakness pertains to the prepaid and accrued research and development expenses related to the CRO. The lack of formal documentation and timely communication of applicable updates to these expenses contributed to Legacy Tvardi's inability to maintain effective controls over the CRO accrual process.

Management's Plan to Remediate the Legacy Tvardi Material Weaknesses

To remediate the material weaknesses, Tvardi has begun a formal risk assessment process to identify control gaps and design new procedures and controls to remediate the identified weaknesses. Tvardi has added additional experienced accounting and financial reporting personnel and resources and is formalizing the design and implementation of internal controls over the financial reporting process. The material weaknesses will not be considered remediated until management completes the design and implementation of the measures described above and the controls operate for a sufficient period of time and management has concluded, through testing, that these controls are effective. The measures Tvardi has taken to date, and is continuing to design and implement, may not be sufficient to remediate the material weaknesses Legacy Tvardi identified or avoid potential future material weaknesses. If the steps Tvardi takes do not correct these material weaknesses in a timely manner, Tvardi will be unable to conclude that it maintains effective internal control over financial reporting. Accordingly, there could continue to be a reasonable possibility that a material misstatement of Tvardi's financial statements would not be prevented or detected on a timely basis.

During the remainder of fiscal year 2025, management will test and evaluate the related internal controls to ascertain whether they are designed and operating effectively to provide reasonable assurance that they will prevent or detect a material error in the financial statements.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings

Merger Proceedings

Between December 20, 2024, and March 19, 2025, Cara received 13 demands (and three draft complaints) from purported stockholders of Cara (collectively, the Demands) challenging the disclosures in the proxy statement/prospectus (the Proxy Statement/Prospectus) included in the Registration Statement on Form S-4 related to the Merger and asserting claims for violations of Sections 14(a) and 20(a) of the Securities Exchange Act of 1934. In addition, on March 5 and March 6, 2025, two lawsuits were filed by purported stockholders of Cara in the Supreme Court of the State of New York, County of New York. The lawsuits are captioned Joseph Clark v. Cara Therapeutics, Inc., et al., No. 651260/2025 and Michael Kent v. Cara Therapeutics, Inc., et al., No. 651272/2025 (collectively, the Complaints). The Complaints named Cara and the members of the Cara board of directors as defendants, and, like the Demands, challenged the disclosures (under New York state law) in the Proxy Statement/Prospectus.

Cara and the other named defendants deny that they violated any laws or breached any duties to stockholders of Cara, and they believe that no supplemental disclosure was required to the Proxy Statement/Prospectus under any applicable law, rule or regulation. Nevertheless, solely to eliminate the burden and expense of litigation and to avoid any possible disruption to the Merger that could result from such litigation, Cara filed certain supplemental disclosures on March 24, 2025 to moot the disclosure claims alleged in the Demands and the Complaints. On April 15, 2025, the Merger closed. Thereafter, counsel for the purported stockholders (that sent the Demands or filed the Complaints) reached out to counsel for Tvardi to discuss a potential mootness fee in connection with the supplemental disclosures filed by Cara. On August 15, 2025, Tvardi resolved the fee demand and the matter is now closed.

Other Proceedings

From time to time, Tvardi may be subject to legal proceedings and claims arising in the ordinary course of its business. Tvardi is not currently a party or aware of any proceedings that it believes will have, individually or in the aggregate, a material adverse effect on Tvardi's business, financial condition or results of operations.

Item 1A. Risk Factors

You should carefully consider the risks described below, as well as the other information in this Quarterly Report on Form 10-Q, including the unaudited condensed consolidated financial statements and related notes and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations," and in Tvardi's other public filings in evaluating Tvardi's business. The occurrence of any of the events or developments described below could harm Tvardi's business, financial condition, results of operations and growth prospects. In such an event, the market price of Tvardi's common stock could decline. Additional risks and uncertainties not presently known to Tvardi or that Tvardi currently deems immaterial also may impair Tvardi's business operations and the market price of Tvardi's common stock.

Summary Risk Factors

- Tvardi has a limited operating history, which may make it difficult to evaluate Tvardi's prospects and likelihood of success.
- Tvardi has not generated any revenue to date and Tvardi may never become or remain profitable.
- Tvardi's financial condition raises substantial doubt as to its ability to continue as a going concern.
- Tvardi will require substantial additional capital to fund its operations. If Tvardi is unable to raise such capital when needed, or on acceptable terms, it may be forced to delay, reduce and/or eliminate one or more of its research and drug development programs, future commercialization efforts or other operations.
- Tvardi's business is highly dependent on the success of its product candidates, TTI-101, TTI-109 and any other product candidates that it advances into the clinic. All of Tvardi's product candidates will require significant

additional preclinical and clinical development before Tvardi may be able to seek regulatory approval for and launch a product commercially.

- Preclinical and clinical development involves a lengthy, complex and expensive process, with an uncertain outcome.

- Tvardi's ongoing and future clinical trials may reveal significant adverse events or unexpected drug-drug interactions not seen in preclinical studies and may result in a safety profile that could delay or prevent regulatory approval or market acceptance of any of its product candidates.

- Interim, blinded and preliminary data from Tvardi's clinical trials that it announces or publishes from time to time may change as more patient data become available or as additional analyses are conducted and as the data are subject to audit and verification procedures that could result in material changes in the final data.

- Positive results from early preclinical studies and clinical trials of Tvardi's current or future product candidates are not necessarily predictive of the results of later preclinical studies and clinical trials of Tvardi's current or future product candidates. If Tvardi cannot replicate the positive results from its preclinical studies or early clinical trials of current or future product candidates in future clinical trials, it may be unable to successfully develop, obtain regulatory approval for and commercialize any current or future product candidates.

- Although Tvardi has received U.S. orphan drug designation for TTI-101 for IPF and HCC, it may be unable to obtain and maintain orphan drug designation for its other product candidates and, even if Tvardi obtains such designation, it may not be able to realize the benefits of such designation, including potential marketing exclusivity of its product candidates, if approved.

- Although Tvardi has received a Fast Track designation from the FDA for TTI-101 for HCC, it may not benefit from a faster development or regulatory review or approval process and a Fast Track designation does not increase the likelihood that its product candidates will receive marketing approval.

- The regulatory approval process is highly uncertain, and Tvardi may be unable to obtain, or may be delayed in obtaining, U.S. or foreign regulatory approval and, as a result, unable to commercialize TTI-101, TTI-109 or any current or future product candidates. Even if Tvardi believes that its current, or planned clinical trials are successful, regulatory authorities may not agree that they provide adequate data on safety or efficacy.

- Tvardi does not currently own or in-license any composition of matter patent protection for the TTI-101 molecule. As such, Tvardi relies solely upon patents related to methods of use, manufacturing and pharmaceutical compositions.

- It is difficult and costly to protect Tvardi's intellectual property and its proprietary technologies, and Tvardi may not be able to ensure their protection.

- Tvardi relies on third parties to conduct certain aspects of its preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, Tvardi may not be able to obtain regulatory approval of or commercialize any potential product candidates.

- Legacy Tvardi identified material weaknesses in its internal control over financial reporting, and, following the Merger, such material weaknesses must be remediated by Tvardi. If Tvardi fails to remediate these material weaknesses, or if it experiences additional material weaknesses in the future or otherwise fails to maintain effective internal control over financial reporting in the future, Tvardi may not be able to accurately or timely report its financial condition or results of operations, which may adversely affect investor confidence in Tvardi and, as a result, the value of its common stock.

- The market price of Tvardi's common stock is expected to be volatile.

- Tvardi will incur costs and demands upon management as a result of complying with the laws, rules and regulations affecting public companies.

- An active trading market for Tvardi's common stock may not develop and its stockholders may not be able to resell their shares of common stock for a profit, if at all.

- Future sales of shares by existing stockholders could cause Tvardi's stock price to decline.

- If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about Tvardi, its business or its market, its stock price and trading volume could decline.

Risks Related to Tvardi's Financial Position and Need for Additional Capital

Tvardi has incurred significant net losses since inception, and Tvardi expects to continue to incur significant net losses for the foreseeable future.

Development of biopharmaceutical product candidates is a highly speculative undertaking and involves a substantial degree of risk. Tvardi is still in the early stages of development of its product candidates and its lead product candidate, TTI-101, is only in a Phase 2 clinical trial for hepatocellular carcinoma (HCC). Tvardi reported preliminary data from its Phase 2 clinical trial of TTI-101 in IPF in October 2025 and concluded that the study did not meet its goals. Tvardi is conducting additional analyses to further understand these results and inform next steps. Tvardi has no products approved for commercial sale and has not generated any revenue to date. Tvardi has incurred significant net losses since its inception and has financed operations principally through equity and debt financing. Tvardi continues to incur significant research and development and other expenses related to its ongoing operations. Tvardi's net losses were $5.5 million and $10.9 million for the three and nine months ended September 30, 2025, respectively. As of September 30, 2025, Tvardi had an accumulated deficit of $103.2 million. Tvardi has devoted substantially all of its resources and efforts to research and development, and expects that it will be several years, if ever, before Tvardi has a commercialized product candidate and generates revenue from sales. Even if Tvardi receives marketing approval for and commercializes one or more of its product candidates, Tvardi expects that it will continue to incur substantial research and development and other expenses in order to further develop and, if approved, market additional potential product candidates.

Tvardi expects to continue to incur significant losses for the foreseeable future, and anticipates that its expenses will increase substantially if, and as, it:

- advances TTI-101, TTI-109 and its other product candidates through clinical development, and, if successful, later-stage clinical trials;

- discovers and develops additional product candidates;

- advances its preclinical development programs into clinical development;

- experiences delays or interruptions to preclinical studies, clinical trials, receipt of services from its third-party service providers on whom Tvardi relies or its supply chain;

- seeks and maintains regulatory approvals for any product candidates that successfully complete clinical trials;

- commercializes TTI-101, TTI-109, any other product candidates and any future product candidates, if approved;

- increases the amount of research and development activities to identify and develop product candidates;

- hires additional clinical development, quality control, scientific and management personnel;
- expands its operational, financial and management systems and increases personnel, including personnel to support its clinical development and manufacturing efforts and operations as a public company;
- establishes a sales, marketing, medical affairs and distribution infrastructure to commercialize any products for which it may obtain marketing approval and intends to commercialize on its own or jointly with third parties;
- maintains, expands and protects its intellectual property portfolio;
- invests in or in-licenses other technologies or product candidates;
- continues to build out its organization to engage in such activities; and
- incurs additional legal, accounting, investor relations and other general and administrative expenses associated with operating as a public company.

Tvardi has a limited operating history, which may make it difficult to evaluate Tvardi's prospects and likelihood of success.

Tvardi is a clinical-stage biopharmaceutical company with a limited operating history. Tvardi was incorporated in 2017, has no products approved for commercial sale and has not generated any revenue to date. Tvardi's operations to date have been limited to organizing and staffing its company, business planning, raising capital, establishing its intellectual property portfolio and performing research and development of its product candidates, signaling and biology, medicinal chemistry and clinical insights to discover and develop novel therapies for the treatment of fibrosis-driven diseases. Tvardi's most advanced product candidate, TTI-101, is in clinical development for the treatment of HCC, and in preclinical development for the treatment of other indications. Tvardi's second product candidate, TTI-109, is in clinical development. Both programs will require substantial additional development and clinical research time and resources before Tvardi would be able to apply for or receive regulatory approvals and begin generating revenue from product sales. All of Tvardi's product candidates are still in preclinical and early clinical development and may be unable to obtain regulatory approval, manufacture a commercial scale product or arrange for a third party to do so on Tvardi's behalf, or conduct sales and marketing activities necessary for successful product commercialization. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval and become commercially viable. In addition, as a business with a limited operating history, Tvardi may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by early-stage biopharmaceutical companies in rapidly evolving fields. Consequently, Tvardi has no meaningful history of operations upon which to evaluate its business, and predictions about any future success or viability may not be as accurate as they could be if Tvardi had a longer operating history or a history of successfully developing and commercializing drug products.

Tvardi has not generated any revenue to date and may never become or remain profitable.

Tvardi's ability to become profitable depends upon its ability to generate revenue. To date, Tvardi has not generated any revenue. Tvardi does not expect to generate significant product revenue unless or until it successfully completes clinical development and obtains regulatory approval of, and then successfully commercializes, at least one of its product candidates. All of its product candidates will require additional preclinical studies or clinical development as well as regulatory review and approval, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before it can generate any revenue from product sales. Tvardi will face significant development risk as its product candidate advances

through clinical development. Tvardi's ability to generate revenue depends on a number of factors, including, but not limited to:

- timely completion of its preclinical studies and current and future clinical trials, which may be significantly slower or more costly than currently anticipated and will depend substantially upon the performance of third-party contractors;
- Tvardi's ability to complete IND application-enabling studies and successfully submit INDs or comparable applications to allow it to initiate clinical trials for current or any future product candidates;
- whether Tvardi is required by the FDA or similar foreign regulatory authorities to conduct additional clinical trials or other studies beyond those planned to support the approval and commercialization of its product candidates or any future product candidates;
- Tvardi's ability to demonstrate to the satisfaction of the FDA or similar foreign regulatory authorities the safety, potency, purity and acceptable risk-to-benefit profile of its product candidates or any future product candidates;
- the prevalence, duration and severity of potential side effects or other safety issues experienced with its product candidates or future product candidates;
- the timely receipt of necessary marketing approvals from the FDA or similar foreign regulatory authorities;
- the willingness of physicians, operators of clinics and patients to utilize or adopt any of Tvardi's product candidates or future product candidates as potential cancer treatments;
- Tvardi's ability and the ability of third parties with whom it contracts to manufacture adequate clinical and commercial supplies of its product candidates or any future product candidates, remain in good standing with regulatory authorities and develop, validate and maintain commercially viable manufacturing processes that are compliant with current good manufacturing practices (cGMPs);
- Tvardi's ability to successfully develop a commercial strategy and thereafter commercialize its product candidates or any future product candidates in the United States and internationally, if licensed for marketing, reimbursement, sale and distribution in such countries and territories, whether alone or in collaboration with others; and
- Tvardi's ability to establish and enforce intellectual property rights in and to its product candidates or any future product candidates.

To become and remain profitable, Tvardi must develop and eventually commercialize products with significant market potential. This will require it to be successful in a range of challenging activities, including completing preclinical studies and clinical trials, obtaining marketing approval for product candidates, manufacturing, marketing and selling products for which it may obtain marketing approval and satisfying any post-marketing requirements. Tvardi may never succeed in any or all of these activities and, even if it does, it may never generate revenue that is significant enough to achieve profitability. If Tvardi does achieve profitability, it may not be able to sustain or increase profitability on a quarterly or annual basis. Tvardi's failure to become and remain profitable would decrease the value of the Company and could impair its ability to raise capital, maintain research and development efforts, expand its business or continue its operations.

Tvardi's financial condition raises substantial doubt as to its ability to continue as a going concern.

As a result of the Merger, Cara's historic business operations ceased, and Tvardi's go-forward business operations are Legacy Tvardi's. Tvardi's primary uses of cash are to fund its operations, which consist primarily of research and development costs related to the development of its product candidates, and, to a lesser extent, general and administrative costs. Tvardi's net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of its clinical development activities and other research and development activities. Tvardi expects to continue to incur significant operating losses for the foreseeable future and may never become profitable. Losses are expected to continue as Tvardi continues to invest in research and development activities. The assessment of Tvardi's ability to meet its future obligations is inherently judgmental, subjective and susceptible to change. Given the inherent uncertainties in the forecast, Tvardi considered both quantitative and qualitative factors that are known or reasonably knowable as of the date that these condensed consolidated financial statements are issued and concluded that there are conditions present in the aggregate that raise substantial doubt about Tvardi's ability to continue as a going concern. Tvardi has based this estimate on assumptions that may prove to be wrong.

In April 2025, as further discussed above, Tvardi completed its Merger with Cara, through which it acquired approximately $23.9 million in net assets. Tvardi will require additional funding in order to finance operations and complete its ongoing and planned clinical trials. Tvardi plans to seek additional funding through equity offerings or debt financings, credit or loan facilities, and strategic alliances and licensing arrangements. However, there can be no assurance that such funding will be available to Tvardi, will be obtained on terms favorable to Tvardi, or will provide Tvardi with sufficient funds to meet its objectives.

Tvardi will require substantial additional capital to fund its operations. If Tvardi is unable to raise such capital when needed, or on acceptable terms, it may be forced to delay, reduce and/or eliminate one or more of its research and drug development programs, future commercialization efforts or other operations.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. Tvardi's operations have consumed substantial amounts of cash since inception. Tvardi expects its expenses to increase in connection with its ongoing activities, particularly as it conducts its planned clinical trials of TTI-101, TTI-109 and any future product candidates that it may develop, seek regulatory approvals for its product candidates and launch and commercialize any products for which it receives regulatory approval. Tvardi also expects to incur additional costs associated with operating as a public company. Accordingly, it will need to obtain substantial additional funding in order to maintain its continuing operations. If Tvardi is unable to raise capital when needed or on acceptable terms, it may be forced to delay, reduce or eliminate one or more of its research and drug development programs or future commercialization efforts.

As of September 30, 2025, Tvardi had cash and cash equivalents and short-term investments of approximately $21.4 million and $15.0 million, respectively, and Tvardi will require additional capital in order to complete clinical development of any of its current programs. Tvardi's monthly spending levels will vary based on new and ongoing development and corporate activities. Because the length of time and activities associated with development of its product candidates is highly uncertain, Tvardi is unable to estimate the actual funds it will require for development, marketing and commercialization activities. Tvardi's future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the initiation, progress, timing, costs and results of preclinical studies and clinical trials for its product candidates;
- the clinical development plans Tvardi establishes for its product candidates;
- the timelines of its clinical trials and the overall costs to conduct and complete the clinical trials, including any increased costs due to disruptions caused by marketplace conditions, including the effects of health epidemics, or other geopolitical and macroeconomic conditions;

- the cost and capital commitments required for manufacturing its product candidates at clinical and, if approved, commercial scales;
- the number and characteristics of product candidates that Tvardi develops;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA and other comparable foreign regulatory authorities;
- whether Tvardi is able to enter into future collaboration agreements and the terms of any such agreements;
- the ability to achieve and timing of achieving a favorable pricing and reimbursement decision by the pricing authorities in the markets of interest;
- the cost of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights, including patent infringement actions brought by third parties against Tvardi or its product candidates;
- the effect of competing technological and market developments;
- the cost and timing of completion of commercial-scale outsourced manufacturing activities; and
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which Tvardi may receive regulatory approval in regions where it chooses to commercialize its products on its own.

Tvardi does not have any committed external source of funds or other support for its development efforts and cannot be certain that additional funding will be available on acceptable terms, or at all. Until Tvardi can generate sufficient revenue to finance its cash requirements, which it may never do, it expects to finance future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing or distribution arrangements. If Tvardi raises additional funds through public or private equity offerings, the terms of these securities may include liquidation or other preferences that adversely affect the rights of its common stockholders. Further, to the extent that Tvardi raises additional capital through the sale of common stock or securities convertible or exchangeable into common stock, your ownership interest will be diluted. In addition, any debt financing may subject Tvardi to fixed payment obligations and covenants limiting or restricting its ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If Tvardi raises additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, Tvardi may have to relinquish certain valuable intellectual property or other rights to its product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to Tvardi. Tvardi also may be required to seek collaborators for any of its product candidates at an earlier stage than otherwise would be desirable or relinquish its rights to product candidates or technologies that it otherwise would seek to develop or commercialize alone. Market volatility resulting from challenging financial markets factors, including the effects of health epidemics and geopolitical conflicts or other factors, could also adversely impact Tvardi's ability to access capital when and in the amounts needed. If Tvardi is unable to raise additional capital in sufficient amounts or on terms acceptable to it, it may have to significantly delay, scale back or discontinue the development or commercialization of one or more of its product candidates or one or more of its other research and development initiatives. Any of the above events could significantly harm its business, prospects, financial condition and results of operations and cause the price of its common stock to decline.

The amount of Tvardi's future losses is uncertain, and its quarterly and annual operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause its stock price to fluctuate or decline.

Tvardi's quarterly and annual operating results may fluctuate significantly in the future due to a variety of factors, many of which are outside of its control and may be difficult to predict, including the following:

- the timing and success or failure of clinical trials for its product candidates or competing product candidates;
- Tvardi's ability to successfully recruit and retain subjects for clinical trials, and any delays caused by difficulties in such efforts;
- Tvardi's ability to obtain marketing approval for its product candidates, and the timing and scope of any such approvals it may receive;
- the timing and cost of, and level of investment in, research and development activities relating to its product candidates, which may change from time to time;
- the cost of manufacturing its product candidates, which may vary depending on the difficulty of manufacturing, quantity of production and the terms of its agreements with manufacturers;
- Tvardi's ability to attract, hire and retain qualified personnel;
- expenditures that Tvardi will or may incur to develop additional product candidates;
- the level of demand for its product candidates should they receive approval, which may vary significantly;
- the risk/benefit profile, cost and reimbursement policies with respect to its product candidates, if approved;
- existing and potential future therapeutics that compete with its product candidates;
- changes in the competitive landscape of Tvardi's industry, including consolidation among competitors or partners;
- general market conditions or extraordinary external events, such as recessions or the effects of health epidemics;
- the changing and volatile U.S. and global economic and political environments; and
- future accounting pronouncements or changes in its accounting policies.

The cumulative effects of these factors could result in large fluctuations and unpredictability in Tvardi's quarterly and annual operating results. As a result, comparing Tvardi's operating results on a period-to-period basis may not be meaningful. This variability and unpredictability could also result in it failing to meet the expectations of industry or financial analysts or investors for any period. If Tvardi's revenue or operating results fall below the expectations of analysts or investors or below any forecasts Tvardi may provide to the market, or if the forecasts Tvardi provides to the market are below the expectations of analysts or investors, the price of its common stock could decline substantially. Such a stock price decline could occur even when Tvardi has met any previously publicly stated guidance it may provide.

Risks Related to Research and Development and the Biopharmaceutical Industry

Tvardi's business is highly dependent on the success of its product candidates, TTI-101, TTI-109 and any other product candidates that it advances into the clinic. All of Tvardi's product candidates will require significant additional preclinical and clinical development before Tvardi may be able to seek regulatory approval for and launch a product commercially.

Tvardi is currently conducting a Phase 2 clinical trial of TTI-101 in HCC, has no products that are approved for commercial sale and may never be able to develop marketable products. Tvardi is early in its development efforts and has only two product candidates, TTI-101 and TTI-109, in early clinical development. If TTI-101, TTI-109 or any of its other product candidates encounter safety or efficacy problems, development delays, regulatory issues or other problems, Tvardi's development plans and business would be significantly harmed. For example, Tvardi reported preliminary data from its Phase 2 clinical trial of TTI-101 in IPF in October 2025 and concluded that the study did not meet its goals, and Tvardi is conducting additional analyses to further understand these results and inform next steps.

Before Tvardi can generate any revenue from sales of its product candidates, TTI-101, TTI-109 or any of its other product candidates, it must undergo additional preclinical and clinical development, regulatory review and approval in one or more jurisdictions. In addition, if one or more of its product candidates are approved, it must ensure access to sufficient commercial manufacturing capacity and conduct significant marketing efforts in connection with any commercial launch. These efforts will require substantial investment, and Tvardi may not have the financial resources to continue development of its product candidates.

Tvardi may experience setbacks that could delay or prevent regulatory approval of the extent of regulatory protection for or its ability to commercialize, its product candidates, including:

- negative or inconclusive results from preclinical studies or clinical trials or the clinical trials of others for product candidates similar to Tvardi's, leading to a decision or requirement to conduct additional preclinical testing or clinical trials or abandon a program;
- undesirable product-related side effects experienced by subjects in Tvardi's clinical trials or by individuals using drugs or therapeutics similar to its product candidates;
- poor efficacy of Tvardi's product candidates during clinical trials;
- delays in submitting IND applications or comparable foreign applications or delays or failure in obtaining the necessary approvals from FDA or other comparable foreign regulatory authorities to commence a clinical trial, or a suspension or termination of a clinical trial once commenced;
- conditions imposed by the FDA or comparable foreign regulatory authorities regarding the scope or design of Tvardi's clinical trials;
- delays in enrolling subjects in clinical trials, including due to operational challenges or competition with other clinical trials;
- high drop-out rates or screening failures of subjects from clinical trials;
- inadequate supply or quality of product candidates or other materials necessary for the conduct of Tvardi's clinical trials;
- greater than anticipated clinical trial costs;
- inability to compete with other therapies;
- failure to secure or maintain orphan designation in some jurisdictions;

- unfavorable FDA or other regulatory agency inspection and review of a clinical trial site;
- failure of its third-party contractors or investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner, or at all;
- delays and changes in regulatory requirements, policy and guidelines, including the imposition of additional regulatory oversight around clinical testing generally or with respect to Tvardi's technology in particular; or
- varying interpretations of Tvardi's clinical and preclinical data by the FDA and other comparable foreign regulatory authorities.

In addition, because Tvardi's other product candidates, in particular TTI-109, are based on similar mechanisms of action, if TTI-101 encounters safety or efficacy problems, manufacturing or supply interruptions, developmental delays, regulatory issues or other problems, its development plans and business related to those other indications for TTI-101 as well as other product candidates could be significantly harmed. Tvardi does not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats to its intellectual property rights and its manufacturing, marketing, distribution and sales efforts or that of any future collaborator.

Preclinical and clinical development involves a lengthy, complex and expensive process, with an uncertain outcome.

To obtain the requisite regulatory approvals to commercialize any product candidates, Tvardi must demonstrate through extensive preclinical studies and clinical trials that its product candidates are safe and effective in humans. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. In particular, the general approach for FDA approval of a new drug is dispositive data from two well-controlled, Phase 3 clinical trials of the relevant drug in the relevant patient population. Phase 3 clinical trials typically involve hundreds of patients, have significant costs and take years to complete. A product candidate can fail at any stage of testing, even after observing promising signals of activity in earlier preclinical studies or earlier stage clinical trials. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. For example, Tvardi reported preliminary data from its Phase 2 clinical trial of TTI-101 in IPF in October 2025 and concluded that the study did not meet its goals. A large number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier clinical trials. Most product candidates that commence clinical trials are never approved as products and there can be no assurance that any of Tvardi's future clinical trials will ultimately be successful or support further clinical development of TTI-101, TTI-109 or any of Tvardi's other product candidates. Product candidates that appear promising in the early phases of development may fail to reach the market for several reasons, including:

- later stage clinical trials may show the product candidates to be less effective than expected or to have unacceptable side effects or toxicities;
- failure to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful;
- failure to receive the necessary regulatory approvals;
- development of competing products in the same indication;
- manufacturing costs, formulation issues, pricing or reimbursement issues or other factors that make a product candidate uneconomical; and

- the proprietary rights of others and their competing products and technologies that may prevent one of Tvardi's product candidates from being commercialized.

Moreover, clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in clinical trials have nonetheless failed to obtain marketing approval of their products. Additionally, some of Tvardi's clinical trials are open-label, where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most typically, open-label clinical trials test only the investigational product candidate and sometimes do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. In addition, open-label clinical trials may be subject to an "investigator bias," where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. Therefore, it is possible that positive results observed in open-label clinical trials will not be replicated in later placebo-controlled clinical trials.

In addition, the standards that the FDA and comparable foreign regulatory authorities use when regulating Tvardi require judgment and can change, which makes it difficult to predict with certainty how they will be applied. Although Tvardi is initially focusing its efforts on development of small molecule drug products, it may in the future pursue development of other products, which could make it subject to additional regulatory requirements. Any analysis Tvardi performs of data from preclinical and clinical activities is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. Tvardi may also encounter unexpected delays or increased costs due to new government regulations. Examples of such regulations include future legislation or administrative action, or changes in FDA policy during the period of product development and FDA regulatory review. It is impossible to predict whether legislative changes will be enacted, or whether FDA or foreign regulations, guidance or interpretations will be changed, or what the impact of such changes, if any, may be. The FDA may also require a panel of experts, referred to as an Advisory Committee, to deliberate on the adequacy of the safety and efficacy data to support approval. The opinion of the Advisory Committee, although not binding, may have a significant impact on Tvardi's ability to obtain approval of any product candidates that it develops.

Successful completion of clinical trials is a prerequisite to submitting a new drug application (NDA), to the FDA and similar marketing applications to comparable foreign regulatory authorities, for each product candidate, and, consequently, the ultimate approval and commercial marketing of any product candidates. Tvardi may experience negative or inconclusive results, which may result in it deciding, or being required by regulators, to conduct additional preclinical studies or clinical trials or abandon some or all of its product development programs, which could have a material adverse effect on its business.

Tvardi's ongoing and future clinical trials may reveal significant adverse events or unexpected drug-drug interactions not seen in preclinical studies and may result in a safety profile that could delay or prevent regulatory approval or market acceptance of any of its product candidates.

To obtain the requisite regulatory approvals to market and sell TTI-101 or TTI-109 for any indication, or any of Tvardi's future product candidates, it must demonstrate through clinical trials that such product candidates are safe and effective for use in each targeted indication. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization. Unforeseen side effects could arise either during clinical development, or, if such side effects are more rare, after Tvardi's products have been approved by regulatory authorities and the approved product has been marketed, resulting in the exposure of additional patients than if such side effect had arisen during a clinical trial. Further, Tvardi may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful, and a clinical trial can fail at any stage of testing.

Tvardi completed clinical trials of its lead product candidate, TTI-101, in healthy volunteers and in patients with advanced malignancies, where TTI-101 was observed to be generally well-tolerated. However, if significant adverse events or other side effects are observed in any of its ongoing or future clinical trials, Tvardi may have difficulty recruiting patients to its clinical trials, patients may drop out of its clinical trials or it may be required to abandon the clinical trials or development efforts altogether. For example, in Tvardi's Phase 2 clinical trial in IPF, Tvardi observed discontinuation rates of 56.7% in the 400 mg arm and 62.1% in the 800 mg arm, as compared to 10.3% in the placebo arm. The discontinuation rates in the TTI-101 arms were primarily driven by gastrointestinal adverse events, with higher rates of events and discontinuations among patients on concurrent nintedanib. In addition, in Tvardi's ongoing Phase 2 clinical trial, Tvardi is evaluating TTI-101 administered alone or in addition to standard of care (SoC) HCC agents. Tvardi may encounter unexpected drug-drug interactions in planned clinical trials and may be required to further test these product candidates, including additional drug-drug interaction studies, which may be expensive and time-consuming and result in delays to Tvardi's programs.

Additionally, in Tvardi's Phase 1b/2 clinical trial in HCC, Tvardi explored escalating dosages of TTI-101 up to 1200 mg/day and determined 800 mg/day as the recommended monotherapy Phase 2 dose (RP2D). Based upon the HCC RP2D determination as well as other early data, Tvardi requested that the Safety Monitoring Committee of the Phase 2 clinical trial in IPF convene to consider discontinuation of enrollment to 1200 mg/day arm. The Safety Monitoring Committee agreed with Tvardi's recommendation to discontinue enrollment to the 1200 mg/day arm. In addition, after reviewing the benefit-risk of the remaining arms of the clinical trial, they recommended to continue enrollment to the 400 mg/day, 800 mg/day and placebo arms of the clinical trial.

Separately, early safety data from the combination arms (TTI-101 + pembrolizumab or TTI-101 + atezolizumab + bevacizumab) of the Phase 1b/2 clinical trial in HCC revealed a higher-than-expected incidence of pulmonary-related treatment-emergent adverse events, which are known side effects of treatment with standard of care. Based upon this information, and after consultations with thought leaders and investigators, the protocol was modified to explore lower dosages and intermittent schedules of TTI-101 in combination with pembrolizumab or atezolizumab + bevacizumab.

Clinical trials of Tvardi's product candidates must be conducted in carefully defined subsets of patients who have agreed to enter into clinical trials. Consequently, it is possible that Tvardi's clinical trials, or those of any potential future collaborator, may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects. If one or more of Tvardi's product candidates receives marketing approval and Tvardi, or others, discover that it is less effective than previously believed or causes undesirable side effects that were not previously identified, including during any long-term follow-up observation period recommended or required for patients who receive treatment using Tvardi's products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product, seize the product or seek an injunction against its manufacture or distribution;
- Tvardi, or any future collaborators, may be required to recall the product, change the way such product is administered to patients or conduct additional clinical trials;
- additional restrictions may be imposed on the marketing of, or the manufacturing processes for, the particular product;
- regulatory authorities may require additional warnings on the label, such as a "black box" warning or a contraindication, or impose distribution or use restrictions;
- Tvardi, or any future collaborators, may be required to create a Risk Evaluation and Mitigation Strategy (REMS), which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers and/or other elements to assure safe use;

- Tvardi, or any future collaborators, may be subject to fines, injunctions or the imposition of civil or criminal penalties;
- Tvardi, or any future collaborators, could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- Tvardi's reputation may suffer.

Any of the foregoing could prevent Tvardi from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm its business, results of operations and prospects, and could adversely impact Tvardi's financial condition, results of operations or the market price of its common stock.

Tvardi may be subject to additional risks because it intends to evaluate its product candidates in combination with the standard of care for the indications that Tvardi is pursuing.

Tvardi intends to evaluate its product candidates in combination with other compounds, specifically the standard of care for the indications that Tvardi is pursuing. The use of Tvardi's product candidates in combination with such other compounds may subject it to risks that Tvardi would not face if its product candidates were being administered as monotherapy. The outcome and cost of developing a product candidate to be used with other compounds is difficult to predict and dependent on a number of factors that are outside its control. If Tvardi experiences efficacy or safety issues in its clinical trials in which its product candidates are being administered with other compounds, Tvardi may not receive regulatory approval for its product candidates, which could prevent it from ever generating revenue or achieving profitability.

Tvardi may experience delays in initiating, completing or ultimately be unable to complete, the development and commercialization of TTI-101, TTI-109 or any other product candidates.

Tvardi may experience delays in initiating or completing clinical trials. Tvardi also may experience numerous unforeseen events during, or as a result of, any future clinical trials that could delay or prevent its ability to receive marketing approval or commercialize TTI-101, TTI-109 or any other product candidates, including:

- regulators or institutional review boards (IRBs), or ethics committees may not authorize Tvardi and its investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- the FDA or other comparable regulatory authorities may disagree with Tvardi's clinical trial design, including with respect to dosing levels administered in its planned clinical trials, which may delay or prevent Tvardi from initiating its clinical trials with its originally intended trial design;
- Tvardi may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective contract research organizations (CROs), which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- patient enrollment in Tvardi's clinical trials may be slower than anticipated;
- the number of subjects required for clinical trials of any product candidates may be larger than Tvardi anticipates, or subjects may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than Tvardi anticipates;
- Tvardi's third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to Tvardi in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the clinical trial, which may require that Tvardi add new clinical trial sites or investigators;

- Tvardi may experience delays or interruptions to its manufacturing supply chain, or it could suffer delays in reaching, or may fail to reach, agreement on acceptable terms with third-party service providers on whom it relies;

- additional delays and interruptions to Tvardi's clinical trials could extend the duration of the clinical trials and increase the overall costs to finish the clinical trials as its fixed costs are not substantially reduced during delays;

- Tvardi may elect to, or regulators, IRBs, Data Safety Monitoring Boards (DSMBs), or ethics committees may require that it or its investigators suspend or terminate clinical research or trials for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;

- Tvardi may not have the financial resources available to begin and complete the planned clinical trials, or the cost of clinical trials of any product candidates may be greater than it anticipates;

- the supply or quality of its product candidates or other materials necessary to conduct clinical trials of its product candidates may be insufficient or inadequate to initiate or complete a given clinical trial; and

- the FDA or other comparable foreign regulatory authorities may require Tvardi to submit additional data such as long-term toxicology studies or impose other requirements before permitting it to initiate a clinical trial.

Tvardi's product development costs will increase if it experiences additional delays in clinical testing or in obtaining marketing approvals. Tvardi does not know whether any of its clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. If Tvardi does not achieve product development goals in the timeframes it announces and expects, the approval and commercialization of its product candidates may be delayed or prevented entirely. Significant clinical trial delays also could shorten any periods during which it may have the exclusive right to commercialize product candidates and may allow competitors to bring products to market before Tvardi does, potentially impairing its ability to successfully commercialize product candidates and harming its business and results of operations. Any delays in Tvardi's clinical development programs may harm its business, financial condition and results of operations significantly

Interim, blinded and preliminary data from Tvardi's clinical trials that it announces or publishes from time to time may change as more patient data become available or as additional analyses are conducted and as the data are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, Tvardi may publish interim, blinded or preliminary data from clinical trials. Interim data from clinical trials that it may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more or longer-term patient data become available. For example, Tvardi previously reported the preliminary, blinded safety data review of 45 patients in its Phase 2 clinical trial in patients suffering from IPF, which represented a small sample size relative to Tvardi's enrollment for the overall clinical trial. The purpose of this blinded data review was to enable an assessment of the overall management and conduct of the clinical trial, without unblinding any individual patient data. Tvardi reported preliminary data from this trial in October 2025 and concluded that the study did not meet its goals. Tvardi is conducting additional analyses to further understand these results and inform next steps. Preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data previously published. As a result, interim and preliminary blinded data should be viewed with caution until the final data are available, as initial clinical trial results as necessarily indicative of results that will be obtained in subsequent clinical trials or clinical practice. Differences between preliminary or interim data and final data could significantly harm Tvardi's business prospects.

Positive results from early preclinical studies and clinical trials of Tvardi's current or future product candidates are not necessarily predictive of the results of later preclinical studies and clinical trials of Tvardi's current or future product candidates. If Tvardi cannot replicate the positive results from preclinical studies or early clinical trials of its current or future product candidates in future clinical trials, Tvardi may be unable to successfully develop, obtain regulatory approval for and commercialize current or future product candidates.

Positive results from Tvardi's preclinical studies of current or future product candidates, and any positive results it may obtain from early clinical trials of its current or future product candidates, including the ongoing and future clinical trials of TTI-101, may not necessarily be predictive of the results from required later preclinical studies and clinical trials. Similarly, even if Tvardi is able to complete its planned preclinical studies or clinical trials of current or future product candidates according to its current development timeline, the positive results from such preclinical studies and/or clinical trials of current or future product candidates, including TTI-101 and TTI-109, may not be replicated in subsequent preclinical studies or clinical trials. In particular, while Tvardi has conducted certain preclinical studies of TTI-109 and Phase 1 clinical trials of TTI-101, it does not know whether either of these product candidates will perform in planned clinical trials as it has performed in these prior preclinical studies or early clinical trials. For example, Tvardi reported preliminary data from its Phase 2 clinical trial of TTI-101 in IPF in October 2025 and concluded that the study did not meet its goals.

There is no guarantee that preclinical results or early clinical results will be replicated in later clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development, and Tvardi cannot be certain that it will not face similar setbacks. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway or safety or efficacy observations made in preclinical studies and clinical trials, including previously unreported adverse events. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain approval from the FDA or comparable foreign regulatory authority. If Tvardi fails to produce positive results in planned preclinical studies or clinical trials of any of its current or future product candidates, the development timeline and regulatory approval and commercialization prospects for its current or future product candidates, and, correspondingly, its business and financial prospects, would be materially adversely affected.

If Tvardi encounters difficulties enrolling patients in clinical trials, its clinical development activities could be delayed or otherwise adversely affected.

Tvardi may experience difficulties in patient enrollment in clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on Tvardi's ability to enroll a sufficient number of patients who remain in the clinical trial until its conclusion. The enrollment of patients depends on many factors, including:

- the patient eligibility and exclusion criteria defined in the protocol;
- the size of the patient population required for analysis of the clinical trial's primary endpoints and the process for identifying patients;
- the willingness or availability of patients to participate in Tvardi's clinical trials;
- the proximity of patients to clinical trial sites;
- the design of the clinical trial;
- Tvardi's ability to recruit clinical trial investigators with the appropriate competencies and experience;

- clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new products that may be approved for the indications Tvardi is investigating or other preclinical studies or clinical trials enrolling for similar diseases;

- the availability of competing commercially available therapies and other competing product candidates' clinical trials;

- Tvardi's ability to obtain and maintain patient informed consents; and

- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

For example, Tvardi is initially developing a pipeline of STAT3 inhibitors for the treatment of fibrosis-driven diseases. A number of fibrosis-driven diseases are estimated to only affect approximately <200,000 patients in the United States. As a result, Tvardi may encounter difficulties enrolling subjects in its clinical trials due, in part, to the small size of these patient populations. Tvardi's clinical trials compete with other clinical trials for product candidates that are in the same therapeutic areas as its product candidates, and this competition will reduce the number and types of patients available to Tvardi, because some patients who might have opted to enroll in Tvardi's clinical trials may instead opt to enroll in a clinical trial being conducted by one of its competitors. Since the number of qualified clinical investigators is limited, Tvardi expects to conduct some of its clinical trials at the same clinical trial sites that some of its competitors use, which will reduce the number of patients who are available for Tvardi's clinical trials in such clinical trial site. Certain of Tvardi's planned clinical trials may also involve invasive procedures such as bronchoscopy and broncho-alveolar lavage, which may lead some patients to drop out of clinical trials to avoid these follow-up procedures.

Additionally, the FDA may modify or enhance clinical trial requirements, which may affect enrollment. For example, in August 2023, the FDA published a guidance document, "Informed Consent, Guidance for IRBs, Clinical Investigators, and Sponsors," which supersedes past guidance and finalizes draft guidance on informed consent. The FDA's new guidance presents evolving requirements for informed consent which may affect recruitment and retention of patients in clinical trials. Effects on recruitment and retention of patients may hinder or delay a clinical trial and could cause a significant setback to an applicable program.

The design or execution of Tvardi's ongoing and future clinical trials may not support marketing approval.

The design or execution of a clinical trial can determine whether its results will support marketing approval, and flaws in the design or execution of a clinical trial may not become apparent until the clinical trial is well advanced. Tvardi is currently conducting a Phase 2 clinical trial of TTI-101 in HCC as monotherapy and combination with SoC therapy. In some instances, there can be significant variability in safety or efficacy results between different clinical trials with the same product candidate due to numerous factors, including differences in clinical trial protocols, size and type of the patient populations, variable adherence to the dosing regimen or other protocol requirements and the rate of dropout among clinical trial participants. Tvardi does not know whether any clinical trials it conducts will demonstrate consistent or adequate efficacy and safety to obtain marketing approval to market its product candidates.

Further, the FDA and comparable foreign regulatory authorities have substantial discretion in the approval process and in determining when or whether marketing approval will be obtained for any of Tvardi's product candidates. Tvardi's product candidates may not be approved even if they achieve their primary endpoints in future Phase 3 clinical trials or registrational trials. The FDA or comparable foreign regulatory authorities may disagree with Tvardi's clinical trial designs and its interpretation of data from preclinical studies or clinical trials. Further, requirements regarding clinical trial data may evolve. Changes to data requirements may cause the FDA or comparable foreign regulatory authorities to disagree with data from preclinical studies or clinical trials and may require further studies.

In addition, any of these regulatory authorities may change requirements for the approval of a product candidate even after reviewing and providing comments or advice on a protocol for a pivotal Phase 3 or registrational clinical trial. In addition, any of these regulatory authorities may also approve a product candidate for fewer or more limited indications than Tvardi requests or may grant approval contingent on the performance of costly post-marketing clinical trials. The FDA or comparable foreign regulatory authorities may not approve the labeling claims that Tvardi believes would be necessary or desirable for the successful commercialization of its product candidates, if approved.

Tvardi may not be successful in its efforts to identify or discover additional product candidates in the future.

Tvardi's research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for a number of reasons, including:

- Tvardi's inability to design such product candidates with the pharmacological properties that it desires or attractive PK; or
- potential product candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be medicines that will receive marketing approval and achieve market acceptance.

Research programs to identify new product candidates require substantial technical, financial, and human resources. If Tvardi is unable to identify suitable compounds for preclinical and clinical development, it will not be able to obtain product revenue in future periods, which likely would result in significant harm to its financial position and adversely impact its stock price.

Due to Tvardi's limited resources and access to capital, it must make decisions on the allocation of resources to certain programs and product candidates; these decisions may prove to be wrong and may adversely affect its business.

Tvardi has limited financial and human resources and intends to initially focus on research programs and product candidates for a limited set of indications. As a result, it may forgo or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential or a greater likelihood of success. In addition, Tvardi seeks to accelerate its development timelines, including by initiating certain clinical trials of its product candidates before earlier-stage studies have been completed. This approach may cause Tvardi to commit significant resources to prepare for and conduct later-stage clinical trials for one or more product candidates that subsequently fail earlier-stage clinical testing. Therefore, resource allocation decisions may cause Tvardi to fail to capitalize on viable commercial products or profitable market opportunities or expend resources on product candidates that are not viable.

There can be no assurance that Tvardi will ever be able to identify additional therapeutic opportunities for its product candidates or to develop suitable potential product candidates through internal research programs, which could materially adversely affect its future growth and prospects. Tvardi may focus its efforts and resources on potential product candidates or other potential programs that ultimately prove to be unsuccessful.

Tvardi may in the future conduct clinical trials for current or future product candidates outside the United States, and the FDA and comparable foreign regulatory authorities may not accept data from such clinical trials.

Tvardi may in the future choose to conduct one or more clinical trials outside the United States. The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice, (ii) the clinical trials were performed by clinical investigators of recognized competence and (iii) the data may be considered valid without the need for an on-site inspection by the FDA, or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the

data through an on-site inspection or other appropriate means. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign clinical trials would be subject to the applicable local laws of the foreign jurisdictions where the clinical trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from clinical trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional clinical trials, which could be costly and time-consuming, and which may result in current or future product candidates that Tvardi may develop not receiving approval for commercialization in the applicable jurisdiction.

Although Tvardi has received U.S. orphan drug designation for TTI-101 for IPF and HCC, it may be unable to obtain and maintain orphan drug designation for other product candidates and, even if Tvardi obtains such designation, it may not be able to realize the benefits of such designation, including potential marketing exclusivity of its product candidates, if approved.

Regulatory authorities in some jurisdictions, including the United States and other major markets, may designate drugs intended to treat conditions or diseases affecting relatively small patient populations as orphan drugs. Under the Orphan Drug Act of 1983, the FDA, may designate a product candidate as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as having a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. Although Tvardi has received U.S. orphan drug designation for TTI-101 for IPF and HCC, the designation of any of its product candidates as an orphan drug does not mean that any regulatory agency will accelerate regulatory review of, or ultimately approve, that product candidate, nor does it limit the ability of any regulatory agency to grant orphan drug designation to product candidates of other companies that treat the same indications as Tvardi's product candidates.

Generally, if a product candidate with an orphan drug designation receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or foreign regulatory authorities from approving another marketing application for a product that constitutes a similar medicinal product treating the same indication for that marketing exclusivity period, except in limited circumstances. The applicable period is seven years in the United States. Orphan drug exclusivity may be revoked if any regulatory agency determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of patients with the rare disease or condition.

Although Tvardi received orphan drug designation for TTI-101 for IPF and HCC, that exclusivity may not effectively protect the product candidate from competition because different drugs with different active moieties can be approved for the same condition in the United States. Even after an orphan drug is approved, the FDA may subsequently approve another drug with the same active moiety for the same condition if the FDA concludes that the latter drug is not a similar medicinal product or is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. Any legislative changes to the orphan drug provisions could change Tvardi's opportunities for, or likelihood of success in obtaining, orphan drug exclusivity and would materially adversely affect Tvardi's business, results of operations, financial condition and prospects.

Although Tvardi has received a Fast Track designation from the FDA for TTI-101 for HCC, it may not benefit from a faster development or regulatory review or approval process, and a Fast Track designation does not increase the likelihood that its product candidates will receive marketing approval.

If a drug product is intended for the treatment of a serious or life-threatening disease or condition and it demonstrates the potential to address unmet medical needs for such a disease or condition, the drug sponsor may apply for FDA Fast Track designation for a particular indication. Tvardi has received Fast Track designation for TTI-101 for the treatment of relapsed/refractory locally advanced, unresectable or metastatic HCC but may never receive Fast Track designation for its pipeline programs. Marketing applications submitted by sponsors of products

in Fast Track development may qualify for priority review under the policies and procedures offered by the FDA, but the Fast Track designation does not assure any such qualification or ultimate marketing licensure by the FDA. Although Tvardi received Fast Track designation for TTI-101, it may not experience a faster development process, review or licensure compared to conventional FDA procedures or pathways, and receiving a Fast Track designation does not provide assurance of ultimate FDA licensure. In addition, the FDA may withdraw any Fast Track designation granted to Tvardi if it believes that the designation is no longer supported by data from Tvardi's clinical development program. The FDA may also withdraw any Fast Track designation at any time.

Even if a product candidate Tvardi develops receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

Even if TTI-101, TTI-109 or any other product candidate Tvardi develops receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors, such as Medicare and Medicaid programs and managed care organizations, and others in the medical community. In addition, the availability of coverage by third-party payors may be affected by existing and future healthcare reform measures designed to reduce the cost of health care. If the product candidates Tvardi develops do not achieve an adequate level of acceptance, Tvardi may not generate significant product revenues and Tvardi may not become profitable.

The degree of market acceptance of any product candidate, if approved for commercial sale, will depend on a number of factors, including:

- efficacy and potential advantages compared to alternative treatments;
- the ability to offer Tvardi's products, if approved, for sale at competitive prices;
- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the recommendations with respect to Tvardi's product candidates in guidelines published by various scientific organizations applicable to Tvardi and its product candidates;
- the strength of marketing and distribution support;
- the ability to obtain sufficient third-party coverage and adequate reimbursement; and
- the prevalence and severity of any side effects.

If government and other third-party payors do not provide coverage and adequate reimbursement levels for any products Tvardi commercializes, market acceptance and commercial success would be reduced.

Tvardi faces substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than Tvardi.

The development and commercialization of new drug products is highly competitive. Tvardi may face competition with respect to any product candidates that it seeks to develop or commercialize in the future from major biopharmaceutical companies, specialty biopharmaceutical companies and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

There are a number of biopharmaceutical and biotechnology companies that are currently pursuing the development of products for the treatment of fibrosis-driven diseases. Companies that Tvardi is aware of that are targeting the treatment of various fibrosis indications include companies with significantly more financial resources such as AbbVie Inc., AstraZeneca plc, Bristol Myers Squibb Co., Merck & Co., Inc., Novartis AG, Scholar Rock Inc. and Takeda Pharmaceutical Company. Companies that Tvardi is aware of that are targeting the treatment of the HCC indication include large companies such as Novartis AG, Bristol Myers Squibb Co., Roche AG, AstraZeneca plc, AbbVie Inc. and Bayer AG.

Many of Tvardi's current or potential competitors, either alone or with their strategic partners, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than Tvardi does.

Mergers and acquisitions in the biopharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with Tvardi in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, its programs. Tvardi's commercial opportunity could be reduced or eliminated if competitors develop and commercialize products that are safer, more effective, more convenient or less expensive than any products that Tvardi may develop. Furthermore, products currently approved for other indications could be discovered to be effective treatments of fibrosis as well, which could give such products significant regulatory and market timing advantages over TTI-101, TTI-109 or other product candidates that Tvardi may identify. Tvardi's competitors also may obtain FDA or other regulatory approval for their products more rapidly than Tvardi may obtain approval for its product candidates, which could result in Tvardi's competitors establishing a strong market position before Tvardi is able to enter the market. Additionally, products or technologies developed by Tvardi's competitors may render its potential product candidates uneconomical or obsolete, and Tvardi may not be successful in marketing any product candidates it may develop against competitors. The availability of competitive products could limit the demand, and the price Tvardi is able to charge, for any products that it may develop and commercialize.

Compliance with governmental regulations regarding the treatment of animals used in research could increase Tvardi's operating costs, which would adversely affect the commercialization of its products.

The Animal Welfare Act (AWA), is the federal law that covers the treatment of certain animals used in research. Currently, the AWA imposes a wide variety of specific regulations that govern the humane handling, care, treatment and transportation of certain animals by producers and users of research animals, most notably relating to personnel, facilities, sanitation, cage size and feeding, watering and shipping conditions. Third parties with whom Tvardi contracts are subject to registration, inspections and reporting requirements under the AWA. Furthermore, some states have their own regulations, including general anti-cruelty legislation, which establish certain standards in handling animals. Comparable rules, regulations and/or obligations exist in many foreign jurisdictions. If Tvardi or its contractors fail to comply with regulations concerning the treatment of animals used in research, Tvardi may be subject to fines and penalties and adverse publicity, and its operations could be adversely affected.

If product liability lawsuits are brought against Tvardi, it may incur substantial financial or other liabilities and may be required to limit commercialization of its product candidates.

Tvardi faces an inherent risk of product liability as a result of testing TTI-101, TTI-109 and any of its other product candidates in clinical trials and will face an even greater risk if it commercializes any products. For example, Tvardi may be sued if its product candidates cause, or are perceived to cause, injury or are found to be otherwise unsuitable during clinical trials, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer

protection acts. If Tvardi cannot successfully defend itself against product liability claims, it may incur substantial liabilities or be required to limit commercialization of its product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- inability to bring a product candidate to the market;
- decreased demand for Tvardi products;
- injury to Tvardi's reputation;
- withdrawal of clinical trial participants and inability to continue clinical trials;
- initiation of investigations by regulators;
- fines, injunctions or criminal penalties;
- costs to defend the related litigation;
- diversion of management's time and its resources;
- substantial monetary awards to trial participants;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and Tvardi's capital resources;
- the inability to commercialize any product candidate, if approved; and
- decline in Tvardi's share price.

Tvardi's inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products it develops. Tvardi will need to obtain additional insurance for clinical trials as TTI-101 and TTI-109 continue clinical development. However, Tvardi may be unable to obtain, or may obtain on unfavorable terms, clinical trial insurance in amounts adequate to cover any liabilities from any of its clinical trials. Tvardi's insurance policies may also have various exclusions, and Tvardi may be subject to a product liability claim for which it has no coverage. Tvardi may have to pay any amounts awarded by a court or negotiated in a settlement that exceed its coverage limitations or that are not covered by its insurance, and Tvardi may not have, or be able to obtain, sufficient capital to pay such amounts. Even if Tvardi's agreements with any future corporate collaborators entitle it to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

Risks Related to Marketing, Reimbursement, Healthcare Regulations and Ongoing Regulatory Compliance

The regulatory approval process is highly uncertain, and Tvardi may be unable to obtain, or may be delayed in obtaining, U.S. or foreign regulatory approval and, as a result, unable to commercialize TTI-101, TTI-109 or any current or future product candidates. Even if Tvardi believes its current, or planned clinical trials are successful, regulatory authorities may not agree that they provide adequate data on safety or efficacy.

TTI-101, TTI-109 and any other current or future product candidates Tvardi develops are subject to extensive governmental regulations relating to, among other things, research, testing, development, manufacturing, approval, recordkeeping, reporting, labeling, storage, packaging, advertising and promotion, pricing, post-approval

monitoring, marketing and distribution of products. Rigorous preclinical studies and clinical trials and an extensive regulatory approval process are required to be completed successfully in the United States and in many foreign jurisdictions before a new product can be marketed. Satisfaction of these and other regulatory requirements is costly, time-consuming, uncertain and subject to unanticipated delays. It is possible that none of Tvardi's product candidates will obtain the regulatory approvals necessary for Tvardi to begin selling them.

As a company, Tvardi has no prior experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA. The time required to obtain FDA and other approvals is unpredictable but typically takes many years following the commencement of clinical trials, depending upon the type, complexity and novelty of the product candidate. The standards that the FDA and its foreign counterparts use when regulating Tvardi require judgment and can change, which makes it difficult to predict with certainty their application. Any analysis Tvardi performs of data from preclinical studies and clinical trials is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. Tvardi may also encounter unexpected delays or increased costs due to new government regulations, for example, from future legislation or administrative action, or from changes in FDA policy during the period of product development, clinical trials and FDA regulatory review. It is impossible to predict whether additional legislative changes will be enacted, or whether FDA or foreign regulations, guidance or interpretations will be changed, or the impact of such changes, if any. Any elongation or de-prioritization of preclinical studies or clinical trials or delay in regulatory review resulting from such disruptions could adversely affect the development and clinical testing of TTI-101, TTI-109 or other current or future product candidates.

Further, the FDA and its foreign counterparts may respond to any NDA that Tvardi may file by defining requirements that Tvardi does not anticipate. Such responses could delay clinical development of TTI-101, TTI-109 or any other current or future product candidates.

Any delay or failure in obtaining required approvals could adversely affect Tvardi's ability to generate revenue from the particular product candidate for which Tvardi is seeking approval. Furthermore, any regulatory approval to market a product may be subject to limitations on the approved uses for which Tvardi may market the product or on the labeling or other restrictions.

Tvardi is also subject to or may in the future become subject to numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. The foreign regulatory approval process varies among countries and may include all of the risks associated with the FDA approval process described above, as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval may differ from that required to obtain FDA approval. FDA approval does not ensure approval by regulatory authorities outside the United States and vice versa. Any delay or failure to obtain U.S. or foreign regulatory approval for a product candidate could have a material and adverse effect on Tvardi's business, financial condition, results of operations and prospects.

Even if Tvardi receives regulatory approval for its product candidates, it will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, Tvardi's product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal. The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Tvardi may be subject to penalties if it fails to comply with regulatory requirements or experience unanticipated problems with its product candidates.

Any regulatory approvals that Tvardi or its future collaborators obtain for its product candidates may also be subject to limitations on the approved indicated uses for which a product may be marketed or to the conditions of approval or contain requirements for potentially costly post-marketing testing and surveillance to monitor the safety and efficacy of the product candidate.

In addition, if the FDA, the European Medicines Agency (EMA), or a comparable foreign regulatory authority approves Tvardi's product candidates, the manufacturing processes, labeling, packaging, distribution, post-

approval monitoring and AE reporting, storage, import, export, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. The FDA has significant post-market authority, including the authority to require labeling changes based on new safety information and to require post-market studies or clinical trials to evaluate safety risks related to the use of a product or to require withdrawal of the product from the market. The FDA also has the authority to require a REMS plan after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug. The manufacturing facilities Tvardi uses to make a future product, if any, will also be subject to periodic review and inspection by the FDA and other regulatory agencies, including for continued compliance with cGMPs requirements. The discovery of any new or previously unknown problems with Tvardi's third-party manufacturers, manufacturing processes or facilities may result in restrictions on the product, manufacturer or facility, including withdrawal of the product from the market. As Tvardi expects to rely on third-party manufacturers, it will not have control over compliance with applicable rules and regulations by such manufacturers.

Any product promotion and advertising will also be subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates marketing, labeling, advertising and promotion of prescription drugs. These regulations include standards and restrictions for direct-to-consumer advertising, industry-sponsored scientific and educational activities, promotional activities involving the internet and off-label promotion. Any regulatory approval that the FDA grants is limited to those specific diseases and indications for which a product is deemed to be safe and effective by FDA. Although clinicians may prescribe products for off-label uses as the FDA and other regulatory agencies do not regulate a physician's choice of drug treatment made in the physician's independent medical judgment, Tvardi's ability to promote any products will be narrowly limited to those indications that are specifically approved by the FDA. In addition, as Tvardi does not intend to conduct head-to-head comparative clinical trials for its product candidates, it will be unable to make comparative claims regarding any other products in the promotional materials for its product candidates.

If Tvardi promotes its approved products in a manner inconsistent with FDA-approved labeling or otherwise not in compliance with FDA regulations, it may be subject to significant liability and enforcement action. If Tvardi or its collaborators, manufacturers or service providers fail to comply with applicable continuing regulatory requirements in the United States or foreign jurisdictions in which Tvardi seeks to market its product candidates, Tvardi or its collaborators, manufacturers or service providers may be subject to, among other things, fines, warning or untitled letters, holds on clinical trials, delay of approval or refusal by the FDA or comparable foreign regulatory bodies to approve pending applications or supplements to approved applications, suspension or withdrawal of regulatory approval, product recalls and seizures, administrative detention of products, refusal to permit the import or export of products, operating restrictions, injunction, civil penalties and criminal prosecution. The U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If Tvardi cannot successfully manage the promotion of any product candidates, if approved, it could become subject to significant liability, which would materially adversely affect its business and financial condition.

Subsequent discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with Tvardi's third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines, warning or untitled letters or holds on clinical trials;
- refusal by the Medicines and Healthcare Products Regulatory Agency or the FDA to approve pending applications or supplements to approved applications filed by Tvardi or its strategic partners;
- suspension or revocation of product license approvals;

- product seizure or detention or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

Tvardi also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. Changes in FDA staffing could result in delays in the FDA's responsiveness or in its ability to review submissions or applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion or at all.

Coverage and reimbursement may be limited or unavailable or pricing unfavorable in certain market segments for Tvardi's product candidates, if approved, which could make it difficult for Tvardi to sell any product candidates profitably.

Significant uncertainty exists as to the coverage and reimbursement status of any products for which Tvardi may obtain regulatory approval. In the United States, sales of any products for which Tvardi may receive regulatory marketing approval will depend, in part, on the availability of coverage and adequacy of reimbursement from third-party payors. Third-party payors include government authorities such as Medicare, Medicaid, TRICARE and the Veterans Administration, managed care providers, private health insurers, and other organizations. Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Patients are unlikely to use Tvardi's product candidates unless coverage is provided, and reimbursement is adequate to cover a significant portion of the cost. Tvardi cannot be sure that coverage and reimbursement will be available for, or accurately estimate the potential revenue from, its product candidates or assure that coverage and adequate reimbursement will be available for any product that Tvardi may develop and, if reimbursement is available, what the level of reimbursement will be.

Government authorities and other third-party payors decide which drugs and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

In the United States, as well as foreign jurisdictions, no uniform policy of coverage and reimbursement for products exists among third-party payors.

Coverage and reimbursement for products may vary depending on the payor, the insurance plan and other factors. As a result, obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require Tvardi to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of Tvardi products on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. Even if Tvardi obtains coverage for a given product, the resulting reimbursement payment rates might not be adequate for it to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payors may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of product candidates, once approved. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for Tvardi's product candidates, if approved.

A primary trend in the United States and European healthcare industries is toward cost containment, as legislative bodies, government authorities, third-party payors, and others have attempted to control costs by limiting coverage, pricing and the amount of reimbursement available for certain treatments. Such third-party payors, including Medicare, may question the coverage of, and challenge or seek to lower the prices charged for medical products, and many third-party payors limit coverage and reimbursement for newly approved health care products. Moreover, reimbursement, if available, may vary according to the use of the product and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost products and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors or by future laws, regulations or guidance seeking to limit prescription drug prices. Further, coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which Tvardi receives regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. If Tvardi is unable to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved products that Tvardi develops, or if net prices are reduced by mandatory discounts or rebates, there could be a material adverse effect on Tvardi's operating results, its ability to raise capital needed to commercialize products and overall financial condition.

Changes to current healthcare laws and state and federal healthcare reform measures that may be adopted in the future that impact coverage and reimbursement for drug or biologic products may result in additional payment reductions in Medicare and other healthcare funding and otherwise affect the prices Tvardi may obtain for any product candidates for which it may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

Recently enacted legislation, future legislation and other healthcare reform measures may increase the difficulty and cost for Tvardi to obtain marketing approval for and commercialize product candidates and may affect the prices Tvardi may set.

In the United States and some foreign jurisdictions, there have been, and Tvardi expects there will continue to be, a number of legislative and regulatory changes to the healthcare system, including cost-containment measures that may reduce or limit coverage and reimbursement for newly approved drugs and affect Tvardi's ability to profitably sell any product candidates for which it obtains marketing approval. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare.

For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the ACA), was enacted in the United States, which resulted in delays in the implementation of, and action taken to repeal or replace, certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. In addition, there have been a number of health reform initiatives by the Biden administration that have impacted the ACA. For example, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (IRA), into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and through a newly established manufacturer discount program. It is possible that the ACA will be subject to judicial or congressional challenges in the future. Additionally, on July 4, 2025, the annual reconciliation bill, the One Big Beautiful Bill Act (OBBBA), was signed into law which is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. OBBBA also narrows access to ACA marketplace exchange enrollment and declines to extend the ACA enhanced advanced premium tax credits, set to expire in 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. Moreover, the American Taxpayer Relief Act of 2021, effective January 1, 2024, eliminated the

statutory cap on rebate amounts owed by drug manufacturers under the MDRP, previously capped at 100% of the Average Manufacturer Price for a covered outpatient drug.

Further, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. For example, the IRA, among other things, (1) directs the Department of Health & Human Services (HHS), to negotiate the price of certain single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions began to take effect progressively starting in fiscal year 2023. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented. On August 15, 2024, HHS announced the agreed-upon reimbursement prices of the first ten drugs that were subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. On January 17, 2025, HHS selected 15 additional products covered under Part D for price negotiation in 2025. Each year thereafter more Part B and Part D products will become subject to the Medicare Drug Price Negotiation Program. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework.

The current Trump administration is pursuing policies to reduce regulations and expenditures across government including at HHS, the FDA, the Centers for Medicare & Medicaid Services (CMS) and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. These actions, for example, include (1) directives to reduce agency workforce; (2) rescinding a Biden administration executive order tasking the Center for Medicare and Medicaid Innovation (CMMI) to consider new payment and healthcare models to limit drug spending; (3) eliminating the Biden administration's executive order that directed HHS in establishing an AI task force and developing a strategic plan; (4) directing HHS and other agencies to lower prescription drug costs through a variety of initiatives, including by improving upon the Medicare Drug Price Negotiation Program and establishing Most-Favored-Nation pricing for pharmaceutical products; (5) imposing tariffs on imported pharmaceutical products; (6) directing certain federal agencies to enforce existing law regarding hospital and plan price transparency and by standardizing prices across hospitals and health plans; and (7) as part of the Make America Healthy Again (MAHA) Commission's recent Strategy Report, working across government agencies to increase enforcement on direct-to-consumer pharmaceutical advertising. Additionally, in its June 2024 decision in Loper Bright Enterprises v. Raimondo (Loper Bright), the U.S. Supreme Court overturned the longstanding Chevron doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The Loper Bright decision could result in additional legal challenges to current regulations and guidance issued by federal agencies applicable to our operations, including those issued by the FDA. Congress may introduce and ultimately pass health care related legislation that could, among others, impact the drug approval process, modify the Medicare Drug Price Negotiation Program, expand the orphan drug exclusion in the IRA, and reduce Medicaid enrollment and funding. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payors. The implementation of current and future cost containment measures or other healthcare reforms may adversely affect Tvardi's operations and prevent it from being able to generate revenue, attain profitability, or commercialize Tvardi's product candidates.

Tvardi's ability to develop and market new drug products may be impacted if litigation challenging the FDA's approval of another company's drug continues. In April 2023, the U.S. District Court for the Northern District of Texas invalidated the approval by the FDA of mifepristone, a drug product, which was originally approved in 2000, and whose distribution is governed by various measures adopted under a REMS. The Court of Appeals for the Fifth Circuit declined to order the removal of mifepristone from the market but did hold that plaintiffs were

likely to prevail in their claim that changes allowing for expanded access of mifepristone, which the FDA authorized in 2016 and 2021, were arbitrary and capricious. In June 2024, the Supreme Court reversed and remanded that decision after unanimously finding that the plaintiffs did not have standing to bring this legal action against the FDA. Depending on the outcome of this litigation, if it continues, Tvardi's ability to develop TTI-101, TTI-109 or future product candidates Tvardi may develop may be at risk and could be delayed, undermined or subject to protracted litigation. Finally, Tvardi could be adversely affected by several significant administrative law cases decided by the U.S. Supreme Court in 2024. In *Loper Bright Enterprises v. Raimondo*, for example, the court overruled *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, which for 40 years required federal courts to defer to permissible agency interpretations of statutes that are silent or ambiguous on a particular topic. The Supreme Court stripped federal agencies of this presumptive deference and held that courts must exercise their independent judgment when deciding whether an agency such as FDA acted within its statutory authority under the Administrative Procedure Act (the APA). Additionally, in *Corner Post, Inc. v. Board of Governors of the Federal Reserve System*, the court held that actions to challenge a federal regulation under the APA can be initiated within six years of the date of injury to the plaintiff, rather than the date the rule is finalized. The decision appears to give prospective plaintiffs a personal statute of limitations to challenge longstanding agency regulations. These decisions could introduce additional uncertainty into the regulatory process and may result in additional legal challenges to actions taken by federal regulatory agencies, including the FDA and the Centers for Medicare & Medicaid Services that Tvardi relies on. In addition to potential changes to regulations as a result of legal challenges, these decisions may result in increased regulatory uncertainty and delays and other impacts, any of which could adversely impact Tvardi's business and operations.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints. Tvardi expects that the ACA, the IRA, and any other healthcare reform measures that may be adopted in the future may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that Tvardi receives for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent Tvardi from being able to generate revenue, attain profitability or commercialize its product candidates, if approved.

Tvardi's operations and relationships with healthcare providers, healthcare organizations, customers and third-party payors will be subject to applicable anti-bribery, anti-kickback, fraud and abuse, transparency and other healthcare laws and regulations, which could expose Tvardi to, among other things, enforcement actions, criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.

Tvardi's future arrangements with healthcare providers, healthcare organizations, third-party payors and customers will expose Tvardi to broadly applicable anti-bribery, fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which Tvardi researches, markets, sells and distributes its products, if approved. Restrictions under applicable federal and state anti-bribery and healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, individuals and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal and state healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the federal criminal and civil false claims laws, including the federal False Claims Act, which can be enforced through civil whistleblower or qui tam actions against individuals or entities, and the Federal Civil Monetary Penalties Laws, which prohibit, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent, knowingly

making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. Moreover, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act;

- Health Insurance Portability and Accountability Act (HIPAA), which imposes criminal and civil liability, prohibits, among other things, knowingly and willfully executing, or attempting to execute a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), and their respective implementing regulations, which impose obligations on certain healthcare providers, health plans and healthcare clearinghouses, known as covered entities, as well as their business associates that perform certain services involving the storage, use or disclosure of individually identifiable health information for or on behalf of a covered entity and their covered subcontractors, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information, and require notification to affected individuals and regulatory authorities of certain breaches of security of individually identifiable health information;

- the federal legislation commonly referred to as the Physician Payments Sunshine Act, enacted as part of the ACA, and its implementing regulations, which requires certain manufacturers of covered drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid or the Children's Health Insurance Program, with certain exceptions, to report annually to CMS, information on certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), teaching hospitals and certain other health care providers (such as physician assistants and nurse practitioners), as well as ownership and investment interests held by physicians and their immediate family members;

- the U.S. Foreign Corrupt Practices Act of 1977, as amended (FCPA), which prohibits, among other things, U.S. companies and their employees and agents from authorizing, promising, offering or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations and foreign government owned or affiliated entities, candidates for foreign political office and foreign political parties or officials thereof;

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; and

- certain state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to clinicians and other healthcare providers or marketing expenditures and drug pricing information, and state and local laws that require the registration of pharmaceutical sales representatives.

If Tvardi or its collaborators, manufacturers or service providers fail to comply with applicable federal, state or foreign laws or regulations, it could be subject to enforcement actions, which could affect Tvardi's ability to

develop, market and sell its product candidates successfully and could harm its reputation and lead to reduced acceptance of its products, if approved by the market.

Efforts to ensure that Tvardi's current and future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that Tvardi's business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If Tvardi's operations are found to be in violation of any such requirements, it may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, the curtailment or restructuring of its operations, loss of eligibility to obtain approvals from the FDA, exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, integrity oversight and reporting obligations or reputational harm, any of which could adversely affect its financial results. These risks cannot be entirely eliminated. Any action against Tvardi for an alleged or suspected violation could cause it to incur significant legal expenses and could divert management's attention from the operation of its business, even if the defense is successful. In addition, achieving and sustaining compliance with applicable laws and regulations may be costly to Tvardi in terms of money, time and resources.

If Tvardi fails to comply with environmental, health and safety laws and regulations, it could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of its business.

Tvardi is subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Tvardi's research and development activities involve the use of biological and hazardous materials and produce hazardous waste products. Tvardi generally contracts with third parties for the disposal of these materials and wastes. Tvardi cannot eliminate the risk of contamination or injury from these materials, which could cause an interruption of its commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although Tvardi believes that the safety procedures utilized by its third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, it cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, Tvardi may be held liable for any resulting damages and such liability could exceed its resources and state or federal or other applicable authorities may curtail its use of certain materials and/or interrupt its business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. Tvardi cannot predict the impact of such changes and cannot be certain of its future compliance. In addition, Tvardi may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair its research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Although Tvardi maintains workers' compensation insurance to cover costs and expenses it may incur due to injuries to its employees resulting from the use of hazardous materials or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities. Tvardi does not carry specific biological waste or hazardous waste insurance coverage, workers' compensation or property and casualty and general liability insurance policies that include coverage for damages and fines arising from biological or hazardous waste exposure or contamination.

Tvardi's future growth may depend, in part, on its ability to penetrate foreign markets, where it would be subject to additional regulatory burdens and other risks and uncertainties that could materially adversely affect its business.

Tvardi is not permitted to market or promote any of its current or future product candidates before it receives regulatory approval from the applicable regulatory authority in that foreign market, and Tvardi may never receive such regulatory approval for any of its current or future product candidates. To obtain separate regulatory approval in many other countries, Tvardi must comply with numerous and varying regulatory requirements of such countries

regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of its current or future product candidates, and Tvardi cannot predict success in these jurisdictions. If it obtains approval of its current or future product candidates and ultimately commercializes its current or future product candidates in foreign markets, Tvardi would be subject to additional risks and uncertainties, including:

- differing regulatory requirements in foreign countries, such that obtaining regulatory approvals outside of the United States may take longer and be more costly than obtaining approval in the United States;
- Tvardi's customers' ability to obtain reimbursement for current or future product candidates in foreign markets;
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- import or export licensing requirements;
- longer accounts receivable collection times;
- longer lead times for shipping;
- language barriers for technical training;
- reduced protection of intellectual property rights in some foreign countries;
- the existence of additional potentially relevant third-party intellectual property rights;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the FCPA or comparable foreign regulations;
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism.

Foreign sales of current or future product candidates could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs.

Governments outside the United States tend to impose strict price controls, which may adversely affect Tvardi's revenue, if any.

In some countries, particularly in the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a drug. To obtain coverage and reimbursement or pricing approval in some countries, Tvardi may be required to conduct a clinical trial that compares the cost-effectiveness of its product candidate to other available therapies. In addition, many countries outside the United States have limited government support programs that provide for reimbursement of drugs such as Tvardi's product candidates, with an emphasis on private payors for access to commercial products. If reimbursement of Tvardi's products, if approved, is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, Tvardi's business could be materially harmed.

Inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of Tvardi's business may rely, which could negatively impact its business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the FDA and other government agencies on which Tvardi's operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect Tvardi's business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical employees and stop critical activities, including the most recent shutdown in October and November 2025. If another prolonged government shutdown occurs, or if global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process Tvardi's regulatory submissions, which could have a material adverse effect on Tvardi's business. Further, in Tvardi's operations as a public company, future government shutdowns could impact its ability to access the public markets and obtain necessary capital in order to properly capitalize and continue its operations.

Tvardi is subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations. Tvardi can face serious consequences for violations.

Among other matters, U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations, which are collectively referred to as Trade Laws, prohibit companies and their employees, agents, contract research organizations, legal counsel, accountants, consultants, contractors and other partners from authorizing, promising, offering, providing, soliciting or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences. Tvardi has direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. Tvardi also expects its non-U.S. activities to increase in time. Tvardi plans to engage third parties for clinical trials and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals and it can be held liable for the corrupt or other illegal activities of its

personnel, agents or partners, even if Tvardi does not explicitly authorize or have prior knowledge of such activities.

Risks Related to Tvardi's Intellectual Property

Tvardi's commercial success depends in part on its and its current or future licensors', including Baylor College of Medicine (BCM), ability to obtain, maintain, enforce, and otherwise protect its intellectual property and proprietary technology, and if the scope of the intellectual property protection obtained is not sufficiently broad, Tvardi's competitors or other third parties could develop and commercialize similar products and product candidates and Tvardi's ability to successfully develop and commercialize its product candidates may be adversely affected.

Tvardi's commercial success depends, in large part, on its ability and the ability of its current and future licensors to obtain and maintain intellectual property rights protection through patents, trademarks and trade secrets in the United States and other countries with respect to its product candidates. If Tvardi and its current and future licensor do not adequately protect Tvardi's intellectual property rights, competitors or other third parties may be able to erode, negate or preempt any competitive advantage Tvardi may have, which could harm its business and ability to achieve profitability.

If the scope of the patent protection Tvardi obtains is not sufficiently broad, it may not be able to prevent others from developing and commercializing technology and products similar or identical to Tvardi's product candidates. The degree of patent protection Tvardi requires to successfully compete in the marketplace may be unavailable or severely limited in some cases and may not adequately protect its rights or permit Tvardi to gain or keep any competitive advantage. Tvardi cannot provide any assurances that any of its own or its licensor's patents have, or that any of its own or its licensor's pending patent applications that mature into issued patents will include claims with a scope sufficient to protect its product candidates or otherwise provide any competitive advantage. Other parties may develop technologies that may be related or competitive with Tvardi's approach and may have filed or may file patent applications and may have been issued or may be issued patents with claims that overlap or conflict with Tvardi's patent portfolio, either by claiming the same compounds, formulations or methods or by claiming subject matter that could dominate its patent position. In addition, the laws of foreign countries may not protect its rights to the same extent as the laws of the United States.

Tvardi's patent portfolio may not provide it with any meaningful protection or prevent competitors from designing around its patent claims, enabling its competitors to circumvent Tvardi's patent portfolio by developing similar or alternative pharmaceutical products in a non-infringing manner. For example, a third party may develop a pharmaceutical product that provides benefits similar to Tvardi's pharmaceutical products but falls outside the scope of its patent protection or licensed rights. If the patent protection provided by the patent and patent applications Tvardi holds or pursues with respect to its product candidates is not sufficiently broad to impede such competition, its ability to successfully commercialize its product candidates could be negatively affected, which would harm its business.

It is possible that defects of form in the preparation or filing of Tvardi's patent portfolio may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope or requests for patent term adjustments. If Tvardi or its future partners or collaborators fail to establish, maintain or protect Tvardi's patents and other intellectual property rights, such rights may be reduced or eliminated. In addition, while Tvardi has the right to provide input, it does not have the right to control prosecution or maintain certain patents and patent applications that Tvardi has in-licensed from BCM. If BCM is not fully cooperative or disagrees with Tvardi as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation, prosecution or enforcement of Tvardi's patent portfolio, such patents may be invalid and/or unenforceable, and such applications may never result in valid, enforceable patents. Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and/or applications will be due to be paid to the U.S. Patent and Trademark Office (USPTO), and various government patent agencies outside of the United States over the lifetime of Tvardi's owned or licensed patents and patent applications. Tvardi currently relies on its outside counsel and BCM to pay these fees due to U.S. and non-U.S. patent agencies. The USPTO and various non-U.S. government patent agencies require compliance with

several procedural, documentary, fee payment and other similar provisions during the patent application process. Any of these outcomes could impair Tvardi's ability to prevent competition from third parties, which may have an adverse impact on its business.

The patent position of biotechnology and pharmaceutical companies carries uncertainty. In addition, the determination of patent rights with respect to pharmaceutical products commonly involves complex legal and factual questions, which are dependent upon the current legal and intellectual property context, extant legal precedent and interpretations of the law by individuals. As a result, the issuance, scope, validity, enforceability and commercial value of Tvardi's patent rights are characterized by uncertainty.

Tvardi's competitors may seek approval to market their own products similar to or otherwise competitive with Tvardi's products. In these circumstances, Tvardi may need to defend or assert its own and in-licensed patents, or both, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find Tvardi's patents invalid or unenforceable, or that Tvardi's competitors do not infringe its own and licensed patents. As such, even if Tvardi has valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve its business objectives.

Tvardi also maintains certain information as company trade secrets. This information may relate to inventions that are not patentable or not optimally protected with patents. Tvardi uses commercially acceptable practices to protect this information, including, for example, limiting access to the information and requiring passwords for its computers. Additionally, Tvardi executes confidentiality agreements with any third parties to whom Tvardi may provide access to the information and with its employees, consultants, scientific advisors, collaborators, vendors, contractors and advisors. Tvardi cannot provide any assurances that all such agreements have been duly executed, and third parties may still obtain this information or may come upon this or similar information independently. It is possible that technology relevant to Tvardi's business will be independently developed by a person who is not a party to such a confidentiality or invention assignment agreement. If any of Tvardi's trade secrets were to be independently developed by a competitor or other third party, Tvardi would have no right to prevent such competitor or third party, or those to whom they communicate such independently developed information, from using that information to compete with Tvardi. Tvardi may not be able to prevent the unauthorized disclosure or use of its technical knowledge or trade secrets by contract manufacturers, consultants, collaborators, vendors, advisors, former employees and current employees. Monitoring unauthorized uses and disclosures is difficult and Tvardi does not know whether the steps Tvardi has taken to protect its proprietary technologies will be effective. Furthermore, if the parties to Tvardi's confidentiality agreements breach or violate the terms of these agreements, Tvardi may not have adequate remedies for any such breach or violation, and it could lose its trade secrets as a consequence of such breaches or violations. Tvardi's trade secrets could otherwise become known or be independently discovered by its competitors. Additionally, if the steps taken to maintain its trade secrets are deemed inadequate, Tvardi may have insufficient recourse against third parties for misappropriating its trade secrets. If any of these events occur or if Tvardi otherwise loses protection for its trade secrets, its business, financial condition, results of operation and prospects may be materially and adversely harmed.

Pending patent applications cannot be enforced against third parties unless and until a patent issues. Even if Tvardi obtains any patents covering its product candidates or its technology, they could nonetheless be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad.

Pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Assuming the other requirements for patentability are met, currently, the first to file a patent application is generally entitled to the patent. However, prior to March 16, 2013, in the United States, the first to invent was entitled to the patent. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are not published until 18 months after filing, or in some cases not at all. Therefore, Tvardi cannot be certain that it or its licensor were the first to make the inventions claimed in its own or in-licensed patents and patent applications, or that Tvardi or its licensor were the first to file for patent protection of such inventions. If third parties have filed prior patent applications on inventions claimed in Tvardi's patent

portfolio that were filed on or before March 15, 2013, an interference proceeding in the United States can be initiated by such third parties to determine who was the first to invent any of the subject matter covered by Tvardi's patent portfolio. If third parties have filed such prior applications after March 15, 2013, a derivation proceeding in the United States can be initiated by such third parties to determine whether Tvardi's invention was derived from theirs.

Moreover, because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, the patents of Tvardi's patent portfolio may be challenged in the courts or patent offices in the United States and abroad. There is no assurance that all the potentially relevant prior art relating to Tvardi's patent portfolio has been found. If such prior art exists, it may be used to invalidate a patent or may prevent a patent from issuing from a pending patent application. For example, such patent filings may be subject to a third-party submission of prior art to the USPTO, or to other patent offices around the world. There also may be prior art of which Tvardi is aware, but which it does not believe affects the validity or enforceability of a claim, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. Alternately or additionally, Tvardi may become involved in post-grant review procedures, oppositions, derivation proceedings, *ex parte* reexaminations, *inter partes* review, supplemental examinations or interference proceedings or challenges before the USPTO or in district court in the United States, or similar proceedings in various foreign jurisdictions, including both national and regional, challenging patents or patent applications in which Tvardi has rights, including patents on which Tvardi relies to protect its business. An adverse determination in any such challenges may result in loss of the patent or claims in the patent portfolio being narrowed, invalidated or held unenforceable, in whole or in part, or in denial of the patent application or loss or reduction in the scope of one or more claims of the patent portfolio, any of which could limit Tvardi's ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of Tvardi's technology and products.

Pending and future patent applications may not result in patents being issued that protect Tvardi's business, in whole or in part, or which effectively prevent others from commercializing competitive products. Competitors may also be able to design around Tvardi's own and in-licensed patents. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of Tvardi's own and in-licensed patents or narrow the scope of its own and in-licensed patent protection. In addition, the laws of foreign countries may not protect Tvardi's rights to the same extent or in the same manner as the laws of the United States. For example, patent laws in various jurisdictions, including jurisdiction covering significant commercial markets, such as the European Patent Office, China and Japan, restrict the patentability of methods of treatment of the human body more than U.S. law does. If these developments were to occur, they could have a material adverse effect on Tvardi's ability to generate revenue.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that Tvardi, its licensor or any future collaborators or partners will be successful in protecting Tvardi's product candidates by obtaining and defending patents.

The patent application process is subject to numerous risks and uncertainties, including that:

- the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance, whether intentional or not, can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case;

- patent applications may not result in any patents being issued;

- Tvardi's own or in-licensed patents that have been issued or may be issued in the future may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;

- Tvardi's competitors, many of whom may have substantially greater resources and many of whom may have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or eliminate Tvardi's ability to make, use and sell its product candidates;

- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns;

- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing products;

- countries other than the United States may, under certain circumstances, force Tvardi to grant a license under its patents to a competitor, allowing the competitor to compete with Tvardi in that jurisdiction or forcing it to lower the price of its drug in that jurisdiction; and

- Tvardi, its licensor, and any future partners or collaborators, as the case may be, may fail to meet Tvardi's obligations to the U.S. government in regards to any co-owned or in-licensed patents and patent applications that are funded or may be funded by U.S. government grants, leading to the loss of patent rights.

Tvardi does not currently own or in-license any composition of matter patent protection for the TTI-101 molecule. As such, Tvardi relies solely upon patents related to methods of use, manufacturing and pharmaceutical compositions.

Composition-of-matter patents on the active pharmaceutical ingredient (API), in prescription drug products are generally considered to be the strongest form of intellectual property protection for drug products because those types of patents provide protection without regard to any particular method of use or manufacture or formulation of the API used. Tvardi does not own or in-license any patents or patent applications in the United States or any other jurisdiction with respect to the TTI-101 molecule. As the compound was made public before a patent application could be filed, Tvardi will not be able to obtain patents or patent applications in the United States or any other jurisdiction with respect to TTI-101 molecule.

Instead, Tvardi has filed patent applications and in-licensed patents and patent applications covering methods-of-use of TTI-101 and pharmaceutical composition of TTI-101. Method-of-use patents protect the use of a compound for the specified method. Pharmaceutical composition patents protect the compositions of TTI-101 with other components. Method-of-use patents do not prevent a competitor or other third party from developing or marketing TTI-101 for an indication that is outside the scope of Tvardi's patented methods of use. Pharmaceutical composition patents do not prevent a competitor or other third party from developing or marketing a different formulation of TTI-101 that is outside the scope of Tvardi's patented formulations. Moreover, with respect to method-of-use patents, even if competitors or other third parties do not actively promote their product for Tvardi's targeted indications or uses for which Tvardi may obtain patents, physicians may recommend that patients use these products off-label, or patients may do so themselves. Although off-label use may infringe or contribute to the infringement of method-of-use patents, the practice is common, and this type of infringement is difficult to prevent or prosecute.

There may be publications and other prior art that may be relevant to Tvardi's patent portfolio and may be used to challenge the validity of these owned or in-licensed patents and patent applications in litigation or other intellectual property-related proceedings. If these types of challenges are successful, the scope of Tvardi's patent portfolio may be narrowed or found to be invalid, and Tvardi may lose valuable intellectual property rights. Any of the foregoing could have a material adverse effect on Tvardi's business, financial conditions, prospects and results of operations.

It is difficult and costly to protect Tvardi's intellectual property and Tvardi's proprietary technologies, and Tvardi may not be able to ensure their protection.

Tvardi's commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection for its product candidates, as well as on its ability to successfully defend these patents against potential third-party challenges. Tvardi's ability to protect its product candidates from unauthorized making, using, selling, offering to sell or importing by third parties is dependent on the extent to which Tvardi has rights under valid and enforceable patents that cover these activities.

The patent positions of pharmaceutical, biotechnology and other life sciences companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved and have in recent years been the subject of much litigation. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of Tvardi's intellectual property. Over the past decade, U.S. federal courts have increasingly invalidated pharmaceutical and biotechnology patents during litigation often based on changing interpretations of patent law. Further, the determination that a patent application or patent claim meets all the requirements for patentability is a subjective determination based on the application of law and jurisprudence. The ultimate determination by the USPTO or by a court or other trier of fact in the United States, or corresponding foreign national patent offices or courts, on whether a claim meets all requirements of patentability cannot be assured. Although Tvardi has conducted searches for third-party publications, patents and other information that may affect the patentability of certain claims in Tvardi's patent portfolio, it cannot be certain that all relevant information has been identified. Accordingly, Tvardi cannot predict the breadth of claims that may be allowed or enforced in its own patent portfolio.

Tvardi cannot provide assurances that any of the patent applications in its patent portfolio will be found to be patentable, including over its own prior art publications or patent literature, or will issue as patents. Neither can Tvardi make assurances as to the scope of any claims that may issue from the patent applications of its patent portfolio, nor to the outcome of any proceedings by any potential third parties that could challenge the patentability, validity or enforceability of its patent portfolio in the United States or foreign jurisdictions. Any such challenge, if successful, could limit patent protection for its product candidates and/or materially harm its business.

In addition to challenges during litigation, third parties can challenge the validity of Tvardi's and its licensor's patents in the United States using post-grant review and *inter partes* review proceedings, which some third parties have been using to cause the cancellation of selected or all claims of issued patents of competitors. For a patent filed March 16, 2013, or later, a petition for post-grant review can be filed by a third party in a nine-month window from issuance of the patent. A petition for *inter partes* review can be filed immediately following the issuance of a patent if the patent has an effective filing date prior to March 16, 2013. A petition for *inter partes* review can be filed after the nine-month period for filing a post-grant review petition has expired for a patent with an effective filing date of March 16, 2013, or later. Post-grant review proceedings can be brought on any ground of invalidity, whereas *inter partes* review proceedings can only raise an invalidity challenge based on published prior art and patents. These adversarial actions at the USPTO review patent claims without the presumption of validity afforded to U.S. patents in lawsuits in U.S. federal courts and use a lower burden of proof than used in litigation in U.S. federal courts. Therefore, it is generally considered easier for a competitor or third party to have a U.S. patent invalidated in a USPTO post-grant review or *inter partes* review proceeding than invalidated in a litigation in a U.S. federal court. If any of Tvardi's own or in-licensed patents are challenged by a third party in such a USPTO proceeding, there is no guarantee that Tvardi will be successful in defending the patent, which may result in a loss of the challenged patent right to Tvardi.

The degree of future protection for Tvardi's proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect its rights or permit Tvardi to gain or keep its competitive advantage. For example:

- Tvardi may not be able to generate sufficient data to support full patent applications that protect the entire breadth of developments in one or more of Tvardi's programs;

- it is possible that one or more of the patent applications in Tvardi's patent portfolio will not become an issued patent or, if issued, that the patent(s) claims will have sufficient scope to protect its technology, provide Tvardi with commercially viable patent protection or provide it with any competitive advantages;

- if the pending applications in Tvardi's patent portfolio issue as patents, they may be challenged by third parties as invalid or unenforceable under United States or foreign laws;

- Tvardi may not successfully commercialize its product candidates, if approved, before the relevant patents in its patent portfolio expire;

- Tvardi may not be the first to make the inventions covered by its patent portfolio;

- Tvardi may not develop additional proprietary technologies or inventions on its product candidates that are separately patentable; or

- it is possible that there are unpublished patent applications maintained in secrecy that may later issue with claims related to its product candidates or products or technology similar to Tvardi's.

In addition, to the extent that Tvardi is unable to obtain and maintain patent protection for its product candidates, or in the event that such patent protection expires, it may no longer be cost-effective to extend Tvardi's portfolio by pursuing additional development of any of its product candidates for follow-on indications.

Tvardi's intellectual property licensed from third parties may be subject to retained rights.

Tvardi's licensors may retain certain rights under the relevant agreements with Tvardi, including the right to use the underlying product candidates for academic and research use, to publish general scientific findings from research related to the product candidates, to make customary scientific and scholarly disclosures of information relating to the product candidates. For example, Tvardi depends on its license agreements with the BCM for the development of its product candidates, pursuant to which Tvardi has an exclusive, worldwide, sublicensable license under BCM's rights to certain patents and patent applications related to STAT3 inhibitors in various indications. BCM has retained rights under the license agreements to grant a non-exclusive license to other academic or research institutions for non-commercial research purposes, and, if required by law, to grant a non-exclusive license to the U.S. government or to a foreign state pursuant to a treaty with the United States; BCM's rights to make or use the licensed patents and technology for non-commercial research, patient care and educational purposes; and additional rights reserved by the government of the United States. BCM has retained rights under the license agreements to the extent necessary to carry out its obligations for manufacturing under the license agreements with BCM. It is difficult to monitor whether BCM will limit its use of the intellectual property exclusively licensed to Tvardi for these permitted uses, and Tvardi could incur substantial expenses to enforce its rights to its licensed product candidates in the event of misuse.

In addition, the U.S. federal government retains certain rights in inventions produced with its financial assistance under Patent and Trademark Law Amendments Act (the Bayh-Dole Act). The U.S. federal government retains a "nonexclusive, nontransferable, irrevocable, paid-up license" for its own benefit. The Bayh-Dole Act also provides federal agencies with "march-in rights." March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a "nonexclusive, partially exclusive, or exclusive license" to a "responsible applicant or applicants." If the patent owner refuses to do so, the government may grant the license itself. Tvardi may at times choose to collaborate with academic institutions to accelerate its preclinical research or development. If Tvardi engages with university partners in projects where there is a risk that federal funds may be commingled, it cannot be sure that any co-developed intellectual property will be free from government rights pursuant to the Bayh-Dole Act. If the federal government chooses to exercise its march-in rights with respect to any patents or technology Tvardi in-licensed and which is critical to its business that is developed in whole or in part with federal funds subject to the Bayh-Dole Act, Tvardi's ability to enforce or otherwise exploit patents covering such patents or technology may be adversely affected.

Patent terms may be inadequate to protect Tvardi's competitive position on its products for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. The patent term of a U.S. patent may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the USPTO in granting a patent or may be shortened if a patent is terminally disclaimed over an earlier-filed patent.

Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review of new pharmaceutical products, patents protecting such pharmaceutical products might expire before or shortly after such pharmaceutical products are commercialized.

In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a Patent Term Extension (PTE), of up to five years beyond the normal expiration of the patent to compensate patent owners for loss of enforceable patent term due to the lengthy regulatory approval process. A PTE grant cannot extend the remaining term of a patent beyond a total of 14 years from the date of the product approval. Further, PTE may only be applied once per product, and only with respect to an approved indication - in other words, only one patent (for example, covering the product itself, an approved use of said product, or a method of manufacturing said product) can be extended by PTE. Tvardi anticipates applying for PTE in the United States. Similar extensions may be available in other countries where Tvardi is prosecuting patents, and Tvardi likewise anticipates applying for such extensions.

In the United States, Tvardi's broadest patent, 8,779,001, which protects the use of TTI-101 for inhibiting STAT3, is set to expire on November 13, 2030. Tvardi may potentially apply PTE and Orphan Drug Exclusivity to the 8,779,001 patent, extending the patent term of the 8,779,001 patent by up to seven years. After expiration of the 8,779,001 patent, Tvardi's commercial use of TTI-101 will be protected by formulation patents and manufacturing patents that Tvardi owns; however these patents provide narrower protection than the 8,779,001 patent. If a competitor designs a formulation of TTI-101 that is not covered by any of Tvardi's formulation or manufacturing patents, then Tvardi may not be able to prevent them from selling their formulation of TTI-101 to inhibit STAT3.

The granting of patent term extensions is not guaranteed and is subject to numerous requirements. Tvardi might not be granted an extension because of, for example, failure to apply within applicable periods, failure to apply prior to the expiration of relevant patents or otherwise failure to satisfy any of the numerous applicable requirements. In addition, to the extent Tvardi wishes to pursue patent term extension based on a patent that it has in-licensed from BCM or another third party, Tvardi would need the cooperation of BCM or the other third party. Moreover, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with Tvardi's assessment of whether such extensions are available, and may refuse to grant extensions to its patents, or may grant more limited extensions than Tvardi requests. If this occurs, Tvardi's competitors may be able to obtain approval of competing products following the patent expiration by referencing Tvardi's clinical and preclinical data and launch their product earlier than might otherwise be the case. If this were to occur, it could have a material adverse effect on Tvardi's ability to generate revenue.

In the context of the European Union, the Court of Justice of the European Union has recently restricted grant of supplementary protection certificate (SPC), for new medical uses of existing products, thus narrowing the availability of patent term extension for second medical uses. Therefore, any development of Tvardi's product candidates with respect to second medical uses may be adversely affected in the European Union. In addition, within the European Union, regulatory protections afforded to medicinal products such as data exclusivity, marketing protection, market exclusivity for orphan indications and pediatric extensions are currently under review and may likely be curtailed in future years. On April 26, 2023, the European Commission adopted a proposal for a new Regulation set to replace Regulation (EC) No 726/2004 and a new Directive replacing Directive 2001/83 on

the Community Code relating to medicinal products for human use. If made into law, this proposal will revise and replace the existing general pharmaceutical legislation and will affect the existing period of regulatory protection afforded to medicinal products in the European Union and Northern Ireland. If Tvardi is unable to obtain patent term extension or the term of any such extension is less than it requests, or if data exclusivity or other regulatory protections are reduced, Tvardi's competitors may obtain approval of competing products following Tvardi's patent expiration, and its business, financial condition, results of operations and prospects could be materially harmed.

Changes in the interpretation of patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing Tvardi's ability to protect its products.

The United States Congress is responsible for passing laws establishing patentability standards. As with any laws, implementation is left to federal agencies and the federal courts based on their interpretations of the laws. Interpretation of patent standards can vary significantly within the USPTO, and across the various federal courts, including the U.S. Supreme Court. Recently, the U.S. Supreme Court has ruled on several patent cases, generally limiting the types of inventions that can be patented. Further, there are open questions regarding interpretation of patentability standards that the Supreme Court has yet to decisively address. Absent clear guidance from the Supreme Court, the USPTO has become increasingly conservative in its interpretation of patent laws and standards.

In addition to increasing uncertainty with regard to Tvardi's ability to obtain patents in the future, the legal landscape in the U.S. has created uncertainty with respect to the value of patents. Depending on any actions by Congress, and future decisions by the lower federal courts and the U.S. Supreme Court, along with interpretations by the USPTO, the laws and regulations governing patents could change in unpredictable ways and could weaken Tvardi's ability to obtain new patents or to enforce its existing patents and patents that it might obtain in the future.

The U.S. Supreme Court has ruled on several patent cases in recent years; these cases often narrow the scope of patent protection available to inventions in the biotechnology and pharmaceutical spaces. For example, in *Amgen Inc. v. Sanofi* (Amgen), the U.S. Supreme Court held that certain of Amgen's patent claims defined a class of antibodies by their function of binding to a particular antigen. The U.S. Supreme Court further wrote that because the patent claims defined the claimed class of antibodies only by their function of binding to a particular antigen, a skilled artisan would have to use significant trial and error to identify and make all of the molecules in that class. The U.S. Supreme Court ultimately held that Amgen failed to properly enable its patent claims. Tvardi's patent portfolio does not relate to any broad class of antibodies as in Amgen; however, Tvardi has claimed broad classes of compounds related to its lead products. To the extent that a court finds that the skilled artisan would need significant trial and error to identify all of the compounds covered by any of its claims, the court may find the claims invalid under Amgen. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken its ability to obtain new patents or to enforce its existing patents and patents that it might obtain in the future.

Further, a new court system recently became operational in the European Union. The Unified Patent Court (UPC), began accepting patent cases on June 1, 2023. The UPC is a common patent court with jurisdiction over patent infringement and revocation proceedings effective for multiple member states of the European Union. The broad geographic reach of the UPC could enable third parties to seek revocation of any of Tvardi's European patents in a single proceeding at the UPC rather than through multiple proceedings in each of the individual European Union member states in which the European patent is validated. Under the UPC, a successful revocation proceeding for a European Patent under the UPC would result in loss of patent protection in those European Union countries. Accordingly, a single proceeding under the UPC could result in the partial or complete loss of patent protection in numerous European Union countries. Such a loss of patent protection could have a material adverse impact on Tvardi's business and its ability to commercialize its technology and product candidates and, resultantly, on its business, financial condition, prospects and results of operations. Moreover, the controlling laws and regulations of the UPC will develop over time and Tvardi cannot predict what the outcomes of cases tried before the UPC will be. The case law of the UPC may adversely affect Tvardi's ability to enforce or defend the validity of

its European patents. Patent owners have the option to opt-out their European Patents from the jurisdiction of the UPC, defaulting to pre-UPC enforcement mechanisms. Tvardi has decided to opt out certain European patents and patent applications from the UPC. However, if certain formalities and requirements are not met, its European patents and patent applications could be subject to the jurisdiction of the UPC. Tvardi cannot be certain that its European patents and patent applications will avoid falling under the jurisdiction of the UPC, if it decides to opt out of the UPC.

Tvardi may not be able to seek or obtain patent protection throughout the world or enforce such patent protection once obtained.

Filing, prosecuting, enforcing and defending patents protecting Tvardi's product candidates in all countries throughout the world would be prohibitively expensive, and its intellectual property rights in some countries outside the United States can be less extensive than those in the United States. The requirements for patentability may differ in certain countries, particularly in developing countries; thus, even in countries where it does pursue patent protection, there can be no assurance that any patents will issue with claims that cover its products.

Moreover, Tvardi's ability to protect and enforce its own and in-licensed intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. Additionally, laws of some countries outside of the United States and Europe do not afford intellectual property protection to the same extent as the laws of the United States and Europe. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. This could make it difficult for Tvardi to stop the infringement of its patents or the misappropriation of its other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. Consequently, Tvardi may not be able to prevent third parties from practicing its inventions in certain countries outside the United States and Europe or from selling or importing products made from its inventions in and into the United States or other jurisdictions. Competitors may use its technologies in jurisdictions where Tvardi has not obtained patent protection to develop and market their own products and, further, may export otherwise infringing products to territories where Tvardi has patent protection, if its ability to enforce its patents to stop infringing activities is inadequate. These products may compete with Tvardi's products, and its patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Further, the standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. As such, Tvardi does not know the degree of future protection that it will have on its product candidates. While Tvardi will endeavor to try to protect its product candidates with intellectual property rights, such as patents, as appropriate, the process of obtaining patents is time consuming, expensive and unpredictable.

Proceedings to enforce Tvardi's own or in-licensed patent rights, whether successful or not, could result in substantial costs and divert its efforts and resources from other aspects of its business. Further, such proceedings could put its own and in-licensed patents at risk of being invalidated, held unenforceable or interpreted narrowly; put its own or in-licensed pending patent applications at risk of not issuing; and provoke third parties to assert claims against Tvardi. Tvardi may not prevail in any lawsuits that it initiates, and the damages or other remedies awarded, if any, may not be commercially meaningful. Furthermore, while Tvardi intends to protect its intellectual property rights in major markets for its products, it cannot ensure that it will be able to initiate or maintain similar efforts in all jurisdictions in which Tvardi may wish to market its products, if approved. Accordingly, its efforts to protect its intellectual property rights in such countries may be inadequate.

In addition, geopolitical actions in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of Tvardi's patent applications or those of any current or future licensors and the maintenance, enforcement or defense of its issued patents or those of any current or future licensors. For example, the United States and foreign government actions related to Russia's conflict in Ukraine may limit or prevent filing, prosecution and maintenance of patent applications in Russia. Government actions may also prevent maintenance of issued patents in Russia. These actions could result in abandonment or lapse of Tvardi's patents or patent applications, resulting in partial or complete loss of patent rights in Russia. If such an

event were to occur, it could have a material adverse effect on Tvardi's business. In addition, a decree was adopted by the Russian government in March 2022, allowing Russian companies and individuals to exploit inventions owned by patentees from the United States without consent or compensation. Consequently, Tvardi would not be able to prevent third parties from practicing its inventions in Russia or from selling or importing products made using its inventions in and into Russia. Accordingly, Tvardi's competitive position may be impaired, and its business, financial condition, results of operations and prospects may be adversely affected.

In order to protect Tvardi's competitive position around its product candidates, Tvardi may become involved in lawsuits to enforce its patents or other intellectual property, which could be expensive, time consuming and unsuccessful and which may result in its own or in-licensed patents being found invalid or unenforceable.

Competitors may seek to commercialize competitive products to Tvardi's product candidates. In order to protect its competitive position, Tvardi may become involved in lawsuits asserting infringement of its own or in-licensed patents, or misappropriation or other violations of other of its intellectual property rights. Litigation is expensive and time consuming and would likely divert the time and attention of its management and scientific personnel. There can be no assurance that Tvardi will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if Tvardi ultimately prevails in such claims, the monetary cost of such litigation and the diversion of the attention of its management and scientific personnel could outweigh any benefit it receives as a result of the proceedings.

If Tvardi files a patent infringement lawsuit against a perceived infringer, such a lawsuit could provoke the defendant to counterclaim that it infringes their patents and/or that its own or in-licensed patents are invalid and/or unenforceable. In patent litigation in the United States, it is commonplace for a defendant to counterclaim alleging invalidity and/or unenforceability. In any patent litigation there is a risk that a court will decide that the asserted patents are invalid or unenforceable, in whole or in part, and that Tvardi does not have the right to stop the defendant from using the invention at issue. With respect to a counterclaim of invalidity, Tvardi cannot be certain that there is no invalidating prior art of which it and the patent examiner were unaware during prosecution. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent claims narrowly or decide that Tvardi does not have the right to stop the other party from using the invention at issue on the grounds that its patent claims do not cover the invention. If any of Tvardi's own or in-licensed patents are found invalid or unenforceable, or construed narrowly, its ability to stop the other party from launching a competitive product would be materially impaired. Further, such adverse outcomes could limit Tvardi's ability to assert those patents against future competitors. Loss of patent protection would have a material adverse impact on its business.

Even if Tvardi establishes infringement of any of its own or in-licensed patents by a competitive product, a court may decide not to grant an injunction against further infringing activity, thus allowing the competitive product to continue to be marketed by the competitor. It is difficult to obtain an injunction in U.S. litigation and a court could decide that the competitor should instead pay Tvardi a "reasonable royalty" as determined by the court, and/or other monetary damages. A reasonable royalty or other monetary damages may or may not be an adequate remedy. Loss of exclusivity and/or competition from a related product would have a material adverse impact on its business.

Litigation often involves significant amounts of public disclosures. Such disclosures could have a materially adverse impact on Tvardi's competitive position or its stock prices. During any litigation Tvardi would be required to produce voluminous records related to its patents and its research and development activities in a process called discovery. The discovery process may result in the disclosure of some of its confidential information. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could adversely affect the price of its common shares.

Litigation is inherently expensive, and the outcome is often uncertain. Any litigation likely would substantially increase Tvardi's operating losses and reduce its resources available for development activities. Further, Tvardi may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of its competitors may be able to sustain the costs of such litigation or proceedings more effectively than Tvardi can

because of their substantially greater financial resources. As a result, Tvardi may conclude that even if a competitor is infringing any of its patents, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of it or its stockholders. In such cases, Tvardi may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution.

For any in-licensed patent rights, Tvardi may not have the right to file a lawsuit for infringement and may have to rely on its licensor to enforce these rights for Tvardi. If Tvardi is not able to directly assert its licensed patent rights against infringers or if a licensor does not vigorously prosecute any infringement claims on its behalf, Tvardi may have difficulty competing in certain markets where such potential infringers conduct their business, and Tvardi's commercialization efforts may suffer as a result.

Concurrently with an infringement litigation, third parties may also be able to challenge the validity of Tvardi's patents before administrative bodies in the United States or abroad. Such mechanisms include re-examination, post grant review and equivalent proceedings in foreign jurisdictions, e.g., opposition proceedings. Such proceedings could result in revocation or amendment of Tvardi's patents in such a way that they no longer cover its products, potentially negatively impacting any concurrent litigation.

If Tvardi is sued for infringing intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay Tvardi from developing or commercializing its product candidates.

Tvardi's commercial success depends in part on its ability to develop, manufacture, market and sell its product candidates without infringing, misappropriating or otherwise violating the intellectual property and other proprietary rights of third parties. However, Tvardi's research, development and commercialization activities may be subject to claims that it infringes, misappropriates or otherwise violates patents or other intellectual property rights owned or controlled by third parties. Third parties may have U.S. and non-U.S. issued patents and pending patent applications relating to compositions, formulations, methods of manufacturing compounds or formulations and/or methods of use for the treatment of the disease indications for which Tvardi is developing. If any third-party patents or patent applications are found to cover its product candidates, their compositions, formulations or their methods of use or manufacture, Tvardi may not be free to manufacture or market such product candidates as planned without obtaining a license, which may not be available on commercially reasonable terms, or at all.

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and Tvardi may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to its product candidates, including patent infringement lawsuits in the U.S. or abroad. There may be third-party patents or patent applications with claims to compositions, formulations, methods of manufacture or methods for treatment related to the compositions or formulations and use or manufacture of Tvardi's product candidates. Third parties may assert infringement claims against Tvardi based on existing patents that they own or in-license or patents that may grant to them (or which they may in-license) in the future, regardless of the merit of such patents or infringement claims. If Tvardi's defenses to such assertions of infringement were unsuccessful, it could be liable for a court-determined reasonable royalty on its existing sales and further damages to the patent owner (or licensee), such as lost profits. Such royalties and damages could be significant. If Tvardi is found to have willfully infringed the claims of a third party's patent, the third party could be awarded treble damages and attorney's fees. Further, unless Tvardi obtains a license to such patent, it may be precluded from commercializing the infringing product candidate. Any of the aforementioned could have a material adverse effect on its business, financial condition, results of operations and prospects.

Tvardi cannot guarantee the completeness or thoroughness of any of its patent searches or analyses including, but not limited to, the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, nor can it be certain that it has identified each and every patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of any of its product candidates in any jurisdiction. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that any of Tvardi's product candidates may be accused of infringing. In addition, third parties may obtain patents in the future and claim that use of Tvardi's technologies

infringes upon these patents. Accordingly, third parties may assert infringement claims against Tvardi based on intellectual property rights that exist now or arise in the future. The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. The pharmaceutical and biotechnology industries have produced a significant number of patents, and it may not always be clear to industry participants, including Tvardi, which patents cover various types of products or methods of use or manufacture. The scope of protection afforded by a patent is subject to interpretation by the courts, and the interpretation is not always uniform. If Tvardi were sued for patent infringement, it would need to demonstrate that the relevant product or methods of using the product either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and Tvardi may not be able to do this. Proving invalidity is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if Tvardi is successful in these proceedings, Tvardi may incur substantial costs and the time and attention of its management and scientific personnel could be diverted in pursuing these proceedings, which could significantly harm its business and operating results. In addition, parties making claims against Tvardi may be able to sustain the costs of complex patent litigation more effectively than it can because they have substantially greater resources, and Tvardi may not have sufficient resources to bring these actions to a successful conclusion.

If Tvardi is found to infringe, misappropriate or otherwise violate a third party's intellectual property rights, it could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product. Alternatively, Tvardi may be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing product. If Tvardi were required to obtain a license to continue to manufacture or market the affected product, Tvardi may be required to pay substantial royalties or grant cross-licenses to its patents. Even if Tvardi were able to obtain a license, it could be nonexclusive, thereby giving its competitors and other third parties access to the same technologies licensed to Tvardi. Tvardi cannot make assurances that any such license will be available on acceptable terms, if at all. Ultimately, Tvardi could be prevented from commercializing a product, or be forced to cease some aspect of its business operations as a result of claims of patent infringement or violation of other intellectual property rights, Further, the outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance, including the demeanor and credibility of witnesses and the identity of any adverse party. This is especially true in intellectual property cases that may turn on the testimony of experts as to technical facts upon which experts may reasonably disagree. Furthermore, Tvardi may not be able to obtain any required license on commercially reasonable terms or at all. Even if Tvardi were able to obtain a license, it could be non-exclusive, thereby giving its competitors access to the same technologies licensed to it; alternatively or additionally it could include terms that impede or destroy its ability to compete successfully in the commercial marketplace. A finding of infringement could prevent Tvardi from commercializing a product or force Tvardi to cease some of its business operations, which could harm its business. Claims that Tvardi has misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on its business. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of Tvardi's confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have material adverse effect on its ability to raise additional funds or otherwise have a material adverse effect on its business, results of operations, financial condition and prospects.

Others may challenge inventorship or claim an ownership interest in Tvardi's intellectual property which could expose it to litigation and have a significant adverse effect on its prospects.

Determinations of inventorship can be subjective. While Tvardi undertakes to accurately identify correct inventorship of inventions made on its behalf by its employees, consultants and contractors, an employee, consultant or contractor may disagree with its determination of inventorship and assert a claim of inventorship. Any disagreement over inventorship could result in Tvardi being forced to defend its determination of inventorship in a legal action which could result in substantial costs and be a distraction to its senior management and scientific personnel.

While Tvardi typically requires employees, consultants and contractors who may develop intellectual property on its behalf to execute agreements assigning such intellectual property to Tvardi, Tvardi may be unsuccessful in obtaining execution of assignment agreements with each party who in fact develops intellectual property that it regards as its own. Moreover, even when Tvardi obtains agreements assigning intellectual property to it, the assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached. In either case, Tvardi may be forced to bring claims against third parties, or defend claims that they may bring against Tvardi, to determine the ownership of what it regards as its intellectual property. Furthermore, individuals executing agreements with Tvardi may have preexisting or competing obligations to a third party, such as an academic institution, and thus an agreement with Tvardi may be ineffective in perfecting ownership of inventions developed by that individual. If Tvardi is unsuccessful in obtaining assignment agreements from an employee, consultant or contractor who develops intellectual property on its behalf, the employee, consultant or contractor may later claim ownership of the invention. Any disagreement over ownership of intellectual property could result in Tvardi losing ownership, or exclusive ownership, of the contested intellectual property, paying monetary damages and/or being enjoined from clinical testing, manufacturing and marketing of the affected product candidate(s). Even if Tvardi is successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to its senior management and scientific personnel.

Tvardi may be subject to claims by third parties asserting that its employees or it has misappropriated their intellectual property or claiming ownership of what it regards as its own intellectual property.

Many of Tvardi's current and former employees, including its senior management, were previously employed at universities or at other biotechnology or pharmaceutical companies, including some which may be competitors or potential competitors. Although Tvardi takes commercially reasonable steps to ensure that its employees do not use the proprietary information, know-how or trade secrets of others in their work for Tvardi, including incorporating such intellectual property into its product candidates, Tvardi may be subject to claims that it or these employees have misappropriated the intellectual property of a third party.

If Tvardi or any of its employees are accused of misappropriating the proprietary information, know-how or trade secrets of a third party, Tvardi may be forced to defend such claims in litigation. If Tvardi is found to have misappropriated the intellectual property rights of a third party, Tvardi may be forced to pay monetary damages, sustain reputational damage, lose key personnel or lose valuable intellectual property rights. Further, it may become necessary for Tvardi to obtain a license from such third party to commercialize its product candidates. Such a license may not be available on commercially reasonable terms or at all. Any of the aforementioned could materially affect the commercialization of Tvardi's product candidates. Even if Tvardi is successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

If Tvardi is unable to protect the confidentiality of its trade secrets, its business and competitive position would be harmed.

Tvardi considers proprietary trade secrets or confidential know-how and unpatented know-how to be important to its business. Tvardi may rely on trade secrets or confidential know-how to protect its technology, especially where patent protection is believed by Tvardi to be of limited value. Tvardi expects to rely on third parties for future manufacturing of its product candidates. Tvardi also expects to collaborate with third parties on the development of its product candidates. As a result of the aforementioned collaborations, Tvardi must, at times, share trade secrets with its collaborators. Tvardi may also conduct joint research and development programs that may require Tvardi to share trade secrets under the terms of its research and development partnerships or similar agreements.

Trade secrets or confidential know-how can be difficult to maintain as confidential. To protect this type of information against disclosure or appropriation by competitors, Tvardi's policy is to require its employees, consultants, contractors and advisors to enter into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with Tvardi prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose Tvardi's confidential information, including its trade secrets. However, current or former employees, consultants, contractors and advisers may unintentionally or willfully disclose Tvardi's confidential information to competitors,

and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. The need to share trade secrets and other confidential information increases the risk that such trade secrets become known by Tvardi's competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that Tvardi's proprietary position is based, in part, on its know-how and trade secrets, a competitor's discovery of its trade secrets or other unauthorized use or disclosure would impair its competitive position and may have an adverse effect on its business and results of operations. Enforcing a claim that a third party obtained illegally and is using trade secrets or confidential know-how is expensive, time consuming and unpredictable. The enforceability of confidentiality agreements may vary from jurisdiction to jurisdiction.

In addition, these agreements typically restrict the ability of Tvardi's advisors, employees, third-party contractors and consultants to publish data potentially relating to its trade secrets, although its agreements may contain certain limited publication rights. Despite Tvardi's efforts to protect its trade secrets, its competitors may discover its trade secrets, either through breach of its agreements with third parties, independent development or publication of information by any of its third-party collaborators. A competitor's discovery of Tvardi's trade secrets would impair its competitive position and have an adverse impact on its business.

Furthermore, courts outside the United States are sometimes less willing to protect trade secrets. If Tvardi chooses to go to court to stop a third party from using any of its trade secrets, Tvardi may incur substantial costs. These lawsuits may consume Tvardi's time and other resources even if Tvardi is successful. Although Tvardi takes steps to protect its proprietary information and trade secrets, including through contractual means with its employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to Tvardi's trade secrets or disclose its technology.

Tvardi may need to acquire or license additional intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.

A third party may hold intellectual property, including patent rights that are important or necessary to the development of Tvardi's product candidates. It may be necessary for Tvardi to use the patented or proprietary technology of one or more third parties to commercialize its current and future product candidates.

The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies may pursue strategies to license or acquire third-party intellectual property rights that Tvardi may consider attractive. These established companies may have a competitive advantage over Tvardi due to their size, cash resources and greater clinical development. If Tvardi is unable to acquire such intellectual property outright or obtain licenses to such intellectual property from such third parties when needed or on commercially reasonable terms, its ability to commercialize its product candidates, if approved, would likely be delayed or Tvardi may have to abandon development of that product candidate or program and its business and financial condition could suffer.

If Tvardi in-licenses additional product candidates in the future, it might become dependent on proprietary rights from third parties with respect to those product candidates. Any termination of such licenses could result in the loss of significant rights and would cause material adverse harm to Tvardi's ability to develop and commercialize any product candidate subject to such licenses. Even if Tvardi is able to in-license any such necessary intellectual property, it could be on nonexclusive terms, including with respect to the use, field or territory of the licensed intellectual property, thereby giving Tvardi's competitors and other third parties access to the same intellectual property licensed to Tvardi. In-licensing intellectual property rights could require Tvardi to make substantial licensing and royalty payments. For example, upon commercialization of certain of its product candidates, if ever, Tvardi is obligated to make certain royalty payments to each of BCM and certain of its founders. Patents licensed to Tvardi could be put at risk of being invalidated or interpreted narrowly in litigation filed by or against Tvardi's licensors or another licensee or in administrative proceedings. If any in-licensed patents are invalidated or held unenforceable, Tvardi may not be able to prevent competitors or other third parties from developing and commercializing competitive products.

Disputes may also arise between Tvardi and its current or future licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- Tvardi's financial or other obligations under the license agreement;
- whether and the extent to which Tvardi's technology and processes infringe intellectual property of the licensor that is not subject to the licensing agreement;
- Tvardi's right to sublicense patent and other rights to third parties under collaborative development relationships;
- Tvardi's diligence obligations with respect to the use of licensed technology in relation to its development and commercialization of its product candidates and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by Tvardi's licensors and Tvardi and its partners; and
- the priority of invention of patented technology.

If disputes over intellectual property that Tvardi has licensed or in the future have licensed prevent or impair Tvardi's ability to maintain its current licensing arrangements on acceptable terms, Tvardi may be unable to successfully develop and commercialize the affected product candidates.

The risks described elsewhere pertaining to Tvardi's intellectual property rights also apply to the intellectual property rights that Tvardi may own or in-license now or in the future, and any failure by Tvardi or its licensors to obtain, maintain, defend and enforce these rights could have an adverse effect on its business. In some cases Tvardi may not have control over the prosecution, maintenance or enforcement of the patents that it licenses, and may not have sufficient ability to provide input into the patent prosecution, maintenance and defense process with respect to such patents, and potential future licensors may fail to take the steps that it believes are necessary or desirable in order to obtain, maintain, defend and enforce the licensed patents.

If Tvardi's trademarks and trade names are not adequately protected, then Tvardi may not be able to build name recognition in its trademarks of interest and its business may be adversely affected.

Tvardi's trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. Tvardi relies on both registration and common law protection for its trademarks. As a means to enforce its trademark rights and prevent infringement, Tvardi may be required to file trademark claims against third parties or initiate trademark opposition proceedings. This can be expensive and time-consuming, particularly for a company of Tvardi's size. Tvardi may not be able to protect its rights to these trademarks and trade names or may be forced to stop using these names, which it needs for name recognition by potential partners or customers in its markets of interest. At times, competitors may adopt trade names or trademarks similar to Tvardi's, thereby impeding its ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of Tvardi's registered or unregistered trademarks or trade names. Over the long term, if Tvardi is unable to establish name recognition based on its trademarks and trade names, then Tvardi may not be able to compete effectively, and its business may be adversely affected. During trademark registration proceedings, Tvardi may receive rejections. Although Tvardi would be given an opportunity to respond to those rejections, Tvardi may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against Tvardi's trademarks, and its trademarks may not survive such proceedings.

Moreover, any name Tvardi proposes to use for its products in the United States must be approved by the FDA, regardless of whether Tvardi has registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA objects to any of Tvardi's proposed product names, Tvardi may be required to expend significant additional resources in an effort to identify a usable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. If Tvardi is unable to establish name recognition based on its trademarks and trade names, Tvardi may not be able to compete effectively, and its business may be adversely affected.

Intellectual property rights do not necessarily address all potential threats to its business.

The degree of future protection afforded by Tvardi's intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect its business, or permit Tvardi to maintain its competitive advantage. The following examples are illustrative:

- others may be able to make products that are competitive to Tvardi's product candidates or any of its product candidates but that are not covered by the claims of its patent portfolio;
- others may independently develop similar or alternative technologies or otherwise circumvent any of Tvardi's technologies without infringing its patent portfolio;
- Tvardi or any of its collaborators might not have been the first to invent the inventions covered by its patent portfolio;
- Tvardi or any of its collaborators might not have been the first to file patent applications covering certain of the patents or patent applications that it or they own or have obtained a license, or will own or will have obtained a license;
- it is possible that Tvardi's own and in-licensed pending patent applications or those that Tvardi may file in the future will not lead to issued patents;
- others may have access to the same intellectual property rights licensed to Tvardi on a non-exclusive basis in the future;
- issued patents that Tvardi owns or in-licensed may not provide Tvardi with any competitive advantage, or may be held invalid or unenforceable, including as a result of legal challenges by its competitors;
- Tvardi's competitors might conduct research and development activities in countries where it does not have patent rights, or in countries where research and development safe harbor laws exist, and then use the information learned from such activities to develop competitive products for sale in its major commercial markets;
- ownership of Tvardi's patent portfolio may be challenged by third parties;
- the patents of third parties or pending or future applications of third parties, if issued, may have an adverse effect on its business;
- patent enforcement is expensive and time-consuming and difficult to predict; thus, Tvardi may not be able to enforce any of its patents against a competitor; and
- Tvardi may choose not to file a patent application for certain inventions, instead choosing to rely on trade secret protection, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could significantly harm Tvardi's business, financial condition, results of operations and prospects.

Risks Related to Tvardi's Reliance on Third Parties

Tvardi relies on third parties to conduct certain aspects of its preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, Tvardi may not be able to obtain regulatory approval of or commercialize any potential product candidates.

Tvardi depends upon third parties to conduct certain aspects of its preclinical studies and clinical trials, under agreements with universities, medical institutions, CROs, strategic collaborators and others. Tvardi expects to have to negotiate budgets and contracts with such third parties, which may result in delays to its development timelines and increased costs.

Tvardi will rely especially heavily on third parties over the course of its clinical trials, and, as a result, will have limited control over the clinical investigators and limited visibility into their day-to-day activities, including with respect to their compliance with the approved clinical protocol. Nevertheless, Tvardi is responsible for ensuring that each of its clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and Tvardi's reliance on third parties does not relieve Tvardi of its regulatory responsibilities. Tvardi and these third parties are required to comply with Good Clinical Practice (GCP), requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of clinical trial sponsors, clinical investigators and clinical trial sites. If Tvardi or any of these third parties fail to comply with applicable GCP requirements, the clinical data generated in its clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require Tvardi to suspend or terminate these clinical trials or perform additional preclinical studies or clinical trials before approving its marketing applications. Tvardi cannot be certain that, upon inspection, such regulatory authorities will determine that any of its clinical trials comply with the GCP requirements.

Tvardi's failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require Tvardi to repeat clinical trials, which would delay the regulatory approval process. Moreover, Tvardi's business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting aspects of Tvardi's preclinical studies or clinical trials will not be its employees and, except for remedies that may be available to Tvardi under its agreements with such third parties, it cannot control whether or not they devote sufficient time and resources to its preclinical studies and clinical programs. These third parties may also have relationships with other commercial entities, including Tvardi's competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on its behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the preclinical or clinical data they obtain is compromised due to the failure to adhere to Tvardi's protocols or regulatory requirements or for other reasons or if due to federal or state orders or absenteeism due to global conditions, including health epidemics and pandemics, they are unable to meet their contractual and regulatory obligations, Tvardi's development timelines, including clinical development timelines, may be extended, delayed or terminated and Tvardi may not be able to complete development of, obtain regulatory approval of or successfully commercialize its product candidates. As a result, Tvardi's financial results and the commercial prospects for its product candidates would be harmed, its costs could increase and its ability to generate revenue could be delayed.

If any of Tvardi's relationships with these third-party CROs or others terminate, Tvardi may not be able to enter into arrangements with alternative CROs or other third parties or to do so on commercially reasonable terms.

Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO begins work. As a result, delays may occur, which can materially impact Tvardi's ability to meet its desired development timelines. Though Tvardi carefully manages its relationships with its CROs, there can be no assurance that it will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on its business, financial condition and prospects.

Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates progress through preclinical to late-stage clinical trials to marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize yield, manufacturing batch size, minimize costs and achieve consistent quality and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause Tvardi's product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of Tvardi's product candidates and jeopardize Tvardi's ability to commercialize its product candidates and generate revenue.

In addition, there are risks associated with large scale manufacturing for clinical trials or commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, compliance with good manufacturing practices, lot consistency and timely availability of raw materials. Even if Tvardi obtains marketing approval for any of its product candidates, there is no assurance that its manufacturers will be able to manufacture the approved product to specifications acceptable to the FDA or other comparable foreign regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential commercial launch of the product or to meet potential future demand. If Tvardi's manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization, its development and commercialization efforts would be impaired, which would have an adverse effect on its business, financial condition, results of operations and growth prospects.

Because Tvardi relies on third-party manufacturing and supply vendors, including single-source vendors and vendors in foreign jurisdictions, its supply of research and development, preclinical and clinical development materials may become limited or interrupted or may not be of satisfactory quantity or quality.

Tvardi relies on third-party contract manufacturers to manufacture its product candidates for preclinical studies and clinical trials. Tvardi does not own manufacturing facilities for producing any clinical trial product supplies. There can be no assurance that its preclinical and clinical development product supplies will not be limited, interrupted or of satisfactory quality or continue to be available at acceptable prices, including due to challenging macroeconomic conditions. Because Tvardi is dependent on limited third-party suppliers and manufacturers for the manufacturing of its product candidates, so long as it remains dependent on them, the loss of any of these suppliers and manufacturers, or any difficulties encountered by these suppliers and manufacturers in the production of its product candidates, could materially delay the conduct of its clinical trials and adversely impact its business.

In addition, Tvardi relies on vendors in foreign jurisdictions for its clinical drug supply for TTI-101, TTI-109 and future drug formulations. If this supply is interrupted for business or geopolitical reasons, the development of TTI-101 or TTI-109 could be materially delayed. In particular, any replacement of Tvardi's manufacturers could require significant time, effort and expertise because there may be a limited number of qualified replacements and the process to transfer technology and initiate manufacturing is complex and time consuming. Moreover, there is currently significant uncertainty about the future relationship between the United States and various other countries, including China, with respect to trade policies, treaties, government regulations and tariffs. It is possible further tariffs may be imposed that could affect imports of APIs used in Tvardi's product candidates or any other potential future product candidates, or its business may be adversely impacted by retaliatory trade measures taken by China or other countries, including restricted access to such raw materials used in its current or any other potential future product candidates.

The manufacturing process for a product candidate is subject to FDA and foreign regulatory authority review. Suppliers and manufacturers must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with regulatory standards, such as cGMPs. In the event that any of Tvardi's manufacturers fails to comply with such requirements or to perform its obligations to Tvardi in relation to quality, timing or otherwise, or if its supply of components or other materials becomes limited or interrupted for other reasons, Tvardi may be forced to manufacture the materials itself, for which it currently does not have the capabilities or resources, or enter into an agreement with another third party, which Tvardi may not be able to do on reasonable terms, if at all. In some cases, the technical skills or technology required to manufacture Tvardi's product candidates may be unique or proprietary to the original manufacturer and Tvardi may have difficulty transferring such skills or technology to another third party and a feasible alternative may not exist. These factors would increase Tvardi's reliance on such manufacturer or require Tvardi to obtain a license from such manufacturer in order to have another third party manufacture its product candidates. If Tvardi is required to change manufacturers for any reason, it will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. The delays associated with the verification of a new manufacturer could negatively affect Tvardi's ability to develop product candidates in a timely manner or within budget.

Tvardi expects to continue to rely on third-party manufacturers for commercial supply of drug product, if it receives regulatory approval for TTI-101, TTI-109 or any other product candidate. To the extent that Tvardi has existing, or enters into future, manufacturing arrangements with third parties, it will depend on these third parties to perform their obligations in a timely manner consistent with contractual and regulatory requirements, including those related to quality control and assurance. If Tvardi is unable to obtain or maintain third-party manufacturing for product candidates, or to do so on commercially reasonable terms, Tvardi may not be able to develop and commercialize its product candidates successfully. Tvardi's or a third party's failure to execute on its manufacturing requirements and comply with cGMP could adversely affect its business in a number of ways, including:

- an inability to initiate or continue clinical trials of product candidates under development;
- delay in submitting regulatory applications, or receiving regulatory approvals, for product candidates;
- loss of the cooperation of an existing or future collaborator;
- subjecting third-party manufacturing facilities or Tvardi's manufacturing facilities to additional inspections by regulatory authorities;
- requirements to cease distribution or to recall batches of Tvardi's product candidates; and
- in the event of approval to market and commercialize a product candidate, an inability to meet commercial demands for Tvardi's products.

Failure to maintain cGMP can result in a contractor receiving FDA sanctions, which can impact Tvardi's ability to operate or lead to delays in any clinical development programs. Tvardi believes that its current fill and finish contractor is operating in accordance with cGMP, but it can give no assurance that FDA or other regulatory agencies will not conclude that a lack of compliance exists. In addition, any delay in contracting for fill and finish services, or failure of the contract manufacturer to perform the services as needed, may delay any clinical trials, registration and launches, which could negatively affect its business.

If Tvardi is unable to enter into new collaborations, or if these collaborations are not successful, its business could be adversely affected.

A part of Tvardi's strategy is to selectively evaluate partnerships in indications and geographies where it believes partners can add significant commercial and/or development capabilities. Further, Tvardi has limited

capabilities for product development and does not yet have any capability for commercialization. Accordingly, Tvardi may in the future enter into collaborations with other companies to provide Tvardi with important technologies and funding for its programs and technology.

Any future collaborations Tvardi enters into may pose a number of risks, including the following:

- collaborators may have significant discretion in determining the efforts and resources that they will apply;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs or license arrangements based on clinical trial results, changes in the collaborators' strategic focus or available funding or external factors, such as a strategic transaction that may divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with Tvardi's products and product candidates if the collaborators believe that the competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than Tvardi's;
- product candidates discovered in collaboration with Tvardi may be viewed by its collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of Tvardi's product candidates;
- collaborators may fail to comply with applicable regulatory requirements regarding the development, manufacture, distribution or marketing of a product candidate or product;
- collaborators with marketing and distribution rights to one or more of Tvardi's product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product or products;
- collaborators may not provide Tvardi with timely and accurate information regarding development progress and activity under any future license agreement, which could adversely impact Tvardi's ability to report progress to Tvardi's investors and otherwise plan development of Tvardi's product candidates;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or terminations of the research, development or commercialization of product candidates, might lead to additional responsibilities for Tvardi with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend Tvardi's intellectual property rights or may use Tvardi's proprietary information in such a way as to invite litigation that could jeopardize or invalidate Tvardi's intellectual property or proprietary information or expose Tvardi to potential litigation;

- collaborators may infringe the intellectual property rights of third parties, which may expose Tvardi to litigation and potential liability;

- if a collaborator of Tvardi is involved in a business combination, the collaborator might deemphasize or terminate the development or commercialization of any product candidate licensed to it by Tvardi; and

- collaborations may be terminated by the collaborator, and, if terminated, Tvardi could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

If collaborations Tvardi enters into do not result in the successful discovery, development and commercialization of product candidates or if a future collaborator terminates its agreement with Tvardi, Tvardi may not receive any research funding or milestone or royalty payments under such collaboration. All of the risks relating to product development, regulatory approval and commercialization described in this Quarterly Report also apply to the activities of Tvardi's therapeutic collaborators.

Tvardi faces significant competition in seeking appropriate collaborators for its product candidates, and the negotiation process is time-consuming and complex. In order for Tvardi to successfully establish a collaboration for one or more of its product candidates, potential collaborators must view these product candidates as economically valuable in markets they determine to be attractive in light of the terms that Tvardi is seeking and other available products for licensing by other companies. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large biopharmaceutical companies that have resulted in a reduced number of potential future collaborators. Tvardi's ability to reach a definitive agreement for a collaboration will depend, among other things, upon its assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. If Tvardi is unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, Tvardi may have to curtail the development of a product candidate, reduce or delay its development program or one or more of Tvardi's other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase Tvardi's expenditures and undertake development or commercialization activities at Tvardi's own expense. If Tvardi elects to increase its expenditures to fund development or commercialization activities on its own, Tvardi may need to obtain additional expertise and additional capital, which may not be available to Tvardi on acceptable terms, or at all. If Tvardi fails to enter into future collaborations or does not have sufficient funds or expertise to undertake the necessary development and commercialization activities, Tvardi may not be able to further develop its product candidates, bring them to market and generate revenue from sales of drugs or continue to develop its technology, and its business may be materially and adversely affected. Even if Tvardi is successful in its efforts to establish new strategic collaborations, the terms that it agrees upon may not be favorable to it, and it may not be able to maintain such strategic collaborations if, for example, development or approval of a product candidate is delayed or sales of an approved product are disappointing. Any delay in entering into new strategic collaboration agreements related to Tvardi's product candidates could delay the development and commercialization of its product candidates and reduce their competitiveness even if they reach the market.

The operations of Tvardi's suppliers, some of which are located outside of the United States, are subject to additional risks that are beyond Tvardi's control and that could harm its business, financial condition, results of operations and prospects.

Currently, some of Tvardi's suppliers are located outside of the United States. As a result of its global suppliers, Tvardi is subject to risks associated with doing business abroad, including:

- political unrest, terrorism, labor disputes and economic instability resulting in the disruption of trade from foreign countries in which Tvardi's products are manufactured;

- the imposition of new laws and regulations, including those relating to labor conditions, quality, and safety standards, imports, duties, taxes and other charges on imports, as well as trade restrictions and

restrictions on currency exchange or the transfer of funds, particularly new or increased tariffs imposed on imports from countries where Tvardi's suppliers operate;

- greater challenges and increased costs with enforcing and periodically auditing or reviewing Tvardi's suppliers' and manufacturers' compliance with cGMPs or status acceptable to the FDA, EMA or comparable foreign regulatory authorities;
- reduced protection for intellectual property rights, including trademark protection, in some countries;
- disruptions in operations due to global, regional or local public health crises or other emergencies or natural disasters;
- disruptions or delays in shipments; and
- changes in local economic conditions in countries where Tvardi's manufacturers or suppliers are located.

These and other factors beyond Tvardi's control could interrupt Tvardi's suppliers' production, influence the ability of Tvardi's suppliers to export its clinical supplies cost-effectively or at all, and inhibit Tvardi's suppliers' ability to procure certain materials, any of which could harm its business, financial condition, results of operations and prospects.

Tvardi's suppliers and any future collaborators may need assurances that its financial resources and stability on a stand-alone basis are sufficient to satisfy their requirements for doing or continuing to do business with Tvardi.

Tvardi's suppliers and any future collaborators may need assurances that its financial resources and stability on a stand-alone basis are sufficient to satisfy their requirements for doing or continuing to do business with Tvardi. If these parties are not satisfied with its financial resources and stability, it could have a material adverse effect on Tvardi's ability to develop its drug candidates, enter into licenses or other agreements and on its business, financial condition or results of operations.

Risks Related to Managing Tvardi's Business and Operations

Tvardi may encounter difficulties in managing its growth, which could adversely affect its operations.

As of September 30, 2025, Tvardi had 12 full-time employees. As Tvardi's clinical development and commercialization plans and strategies develop, it will need to expand its managerial, clinical, regulatory, sales, marketing, financial, development, manufacturing and legal capabilities or contract with third parties to provide these capabilities for Tvardi. As Tvardi's operations expand, Tvardi expects that it will need to manage additional relationships with various strategic collaborators, suppliers and other third parties. Tvardi's future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, retaining and motivating additional employees;
- managing Tvardi's development and commercialization efforts effectively, including the clinical and FDA review process for TTI-101, TTI-109 and any other product candidates, while complying with Tvardi's contractual obligations to contractors and other third parties; and
- improving Tvardi's operational, financial and management controls, reporting systems and procedures.

Tvardi's ability to continue to develop and, if approved, commercialize its product candidates will depend, in part, on its ability to effectively manage its future growth. Tvardi's management may also have to divert a

disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

If Tvardi is not able to effectively expand its organization by hiring new employees and expanding its groups of consultants and contractors, Tvardi may not be able to successfully implement the tasks necessary to further develop and commercialize TTI-101, TTI-109 or any other product candidates and, accordingly, may not achieve its research, development and commercialization goals.

The Company may acquire additional technology and complementary businesses in the future. Acquisitions involve many risks, any of which could materially harm its business, including the diversion of management's attention from core business concerns, failure to effectively exploit acquired technologies, failure to successfully integrate the acquired business or realize expected synergies or the loss of key employees from either its business or the acquired businesses.

Tvardi currently has no marketing and sales organization and has no experience as a company in commercializing products, and Tvardi may have to invest significant resources to develop these capabilities. If Tvardi is unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell its products, Tvardi may not be able to generate product revenue.

Tvardi has no internal sales, marketing or distribution capabilities, nor has it commercialized a product. If any of Tvardi's product candidates ultimately receives regulatory approval, Tvardi expects to establish a marketing and sales organization with technical expertise and supporting distribution capabilities to commercialize each such product in major markets, which will be expensive and time consuming. Tvardi has no prior experience as a company in the marketing, sale and distribution of pharmaceutical products, and there are significant risks involved in building and managing a sales organization, including its ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of Tvardi's internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. Tvardi may also choose to collaborate with third parties that have direct sales forces and established distribution systems, either to augment its own sales force and distribution systems or in lieu of its own sales force and distribution systems. Tvardi may not be able to enter into collaborations or hire consultants or external service providers to assist Tvardi in sales, marketing and distribution functions on acceptable financial terms, or at all. In addition, its product revenues and its profitability, if any, may be lower if it relies on third parties for these functions than if it were to market, sell and distribute any products that it develops itself. Tvardi likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market its products effectively. If Tvardi is not successful in commercializing its products, either on its own or through arrangements with one or more third parties, Tvardi may not be able to generate any future product revenue and it would incur significant additional losses.

If Tvardi loses key management personnel, or if Tvardi fails to recruit additional highly skilled personnel, its ability to develop current product candidates or identify and develop new product candidates will be impaired, could result in loss of markets or market share and could make Tvardi less competitive.

Tvardi's ability to compete in the highly competitive biotechnology and biopharmaceutical industries depends upon its ability to attract and retain highly qualified managerial, scientific and medical personnel. Tvardi is highly dependent on its management, scientific and medical personnel, including key members of its senior management and executive team. Although Tvardi has employment agreements with its key employees, these employment agreements provide for at-will employment, which means that any of its employees could leave its employment at any time, with or without notice. Tvardi does not maintain "key person" insurance for any of its executives or other employees. The loss of the services of any of Tvardi's executive officers, other key employees and other scientific and medical advisors, and its inability to find suitable replacements could result in delays in product development and harm its business. Competition for skilled personnel in its market is intense and may limit its ability to hire and retain highly qualified personnel on acceptable terms or at all.

To induce valuable employees to remain in Tvardi, in addition to salary and cash incentives, Tvardi has provided equity awards that vest over time. The value to employees of equity awards that vest over time may be significantly affected by movements in its stock price that are beyond its control and may at any time be insufficient to counteract more lucrative offers from other companies. Despite Tvardi's efforts to retain valuable employees, members of its management, scientific and development teams may terminate their employment with Tvardi on short notice. Tvardi's key employees are at-will employees, which means that any of its employees could leave its employment at any time, with or without notice. Tvardi does not maintain "key person" insurance policies on the lives of these individuals or the lives of any of its other employees. Tvardi's success also depends on its ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior scientific and medical personnel.

Tvardi's employees, independent contractors, consultants, commercial partners, collaborators and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

Tvardi is exposed to the risk of employee fraud or other illegal activity by its employees, independent contractors, consultants, commercial partners, collaborators and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to comply with the laws of the FDA and other similar foreign regulatory bodies, provide true, complete and accurate information to the FDA and other similar foreign regulatory bodies, comply with manufacturing standards Tvardi has established, comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws, or report financial information or data accurately or to disclose unauthorized activities to Tvardi. If Tvardi obtains FDA approval of any of its product candidates and begins commercializing those products in the United States, its potential exposure under such laws will increase significantly, and its costs associated with compliance with such laws will also increase. These laws may impact, among other things, its current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. It is not always possible to identify and deter misconduct by Tvardi's employees, independent contractors, consultants, commercial partners and vendors, and the precautions Tvardi takes to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting Tvardi from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any actions are instituted against Tvardi and Tvardi is not successful in defending itself or asserting its rights, those actions could result in the imposition of civil, criminal and administrative penalties, damages, monetary fines, imprisonment, disgorgement, possible exclusion from participation in government healthcare programs, additional reporting obligations and oversight if Tvardi becomes subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm, diminished profits and future earnings and the curtailment of its operations.

Tvardi or the third parties upon whom it depends may be adversely affected by natural disasters, and its business continuity and disaster recovery plans may not adequately protect Tvardi from a serious disaster.

Tvardi's operations are located in its facilities in Sugar Land, Texas and it works with third-party CROs and CDMOs globally. Any unplanned event, such as flood, fire, explosion, tornadoes, extreme weather condition, medical epidemics, power shortage, telecommunication failure or other natural or man-made accidents or incidents that result in Tvardi being unable to fully utilize its facilities, or the manufacturing facilities of its third-party contract manufacturers, may have a material and adverse effect on its ability to operate its business and have significant negative consequences on its financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of Tvardi's product candidates or interruption of its business operations. Natural disasters could further disrupt its operations and have a material and adverse effect on its business, financial condition, results of operations and prospects. If a natural disaster, power outage or other event occurred that prevented Tvardi from using all or a significant portion of its headquarters, that damaged critical infrastructure, such as its research facilities or the manufacturing facilities of its third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for Tvardi to continue its business for a substantial period of time.

As part of its risk management policy, Tvardi maintains insurance coverage at levels that it believes are appropriate for its business. However, in the event of an accident or incident at these facilities, Tvardi cannot assure you that the amounts of insurance will be sufficient to satisfy any damages and losses. If Tvardi's facilities, or the manufacturing facilities of Tvardi's third-party contract manufacturers, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of Tvardi's research and development programs may be harmed.

Risks Related to Ownership of Tvardi's Common Stock

The market price of Tvardi's common stock is expected to be volatile.

The market price of Tvardi's common stock could be subject to significant fluctuations. Market prices for securities of early-stage pharmaceutical, biotechnology and other life sciences companies have historically been particularly volatile. Some of the factors that may cause the market price of Tvardi's common stock to fluctuate include:

- the ability of Tvardi to obtain regulatory approvals for its product candidates, and delays or failures to obtain such approvals (such as Tvardi's announcement regarding its Phase 2 trial of TTI-101 in IPF in October 2025);
- failure of any of Tvardi's product candidates, if approved, to achieve commercial success;
- failure by Tvardi to maintain its existing third-party license and supply agreements;
- failure by Tvardi or its licensors to prosecute, maintain, or enforce its intellectual property rights;
- changes in laws or regulations applicable to Tvardi's product candidates;
- any inability to obtain adequate supply of Tvardi's product candidates or the inability to do so at acceptable prices;
- adverse regulatory authority decisions;
- introduction of new products, services or technologies by Tvardi's competitors;
- failure to meet or exceed financial and development projections Tvardi may provide to the public;
- failure to meet or exceed the financial and development projections of the investment community;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by Tvardi or its competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and Tvardi's ability to obtain patent protection for its technologies;
- additions or departures of key personnel;
- significant lawsuits, including patent or stockholder litigation;
- if securities or industry analysts do not publish research or reports about Tvardi's business, or if they issue an adverse or misleading opinion regarding its business and stock;

- changes in the market valuations of similar companies;
- general market or macroeconomic conditions;
- sales of its common stock by Tvardi or its stockholders in the future;
- trading volume of Tvardi's common stock;
- failure to maintain compliance with the listing requirements of The Nasdaq Capital Market;
- announcements by commercial partners or competitors of new commercial products, clinical progress or the lack thereof, significant contracts, commercial relationships or capital commitments;
- adverse publicity generally, including with respect to other products and potential products in such markets;
- the introduction of technological innovations or new therapies that compete with potential products of Tvardi;
- changes in the structure of health care payment systems; and
- period-to-period fluctuations in Tvardi's financial results.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of Tvardi's common stock.

In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm Tvardi's profitability and reputation.

Additionally, a decrease in the stock price of Tvardi may cause Tvardi's common stock to no longer satisfy the continued listing standards of Nasdaq. If Tvardi is not able to maintain the requirements for listing on Nasdaq, it could be delisted, which could have a materially adverse effect on its ability to raise additional funds as well as the price and liquidity of its common stock.

Tvardi will incur costs and demands upon management as a result of complying with the laws, rules and regulations affecting public companies.

Tvardi will incur significant legal, accounting and other expenses that Legacy Tvardi did not incur as a private company, including costs associated with public company reporting requirements.

Tvardi will also incur costs associated with corporate governance requirements, including requirements under the laws, rules and regulations of the SEC as well as the Nasdaq rules. These laws, rules and regulations are expected to increase Tvardi's legal and financial compliance costs and to make some activities more time consuming and costly. For example, Tvardi's management team will include executive officers of Legacy Tvardi prior to the Merger, some of whom have not previously managed and operated a public company. These executive officers and other personnel will need to devote substantial time to gaining expertise regarding operations as a public company and compliance with applicable laws and regulations. These laws, rules and regulations also may make it difficult and expensive for Tvardi to obtain directors' and officers' liability insurance. As a result, it may be more difficult for Tvardi to attract and retain qualified individuals to serve on the board of directors or as

executive officers of Tvardi, which may adversely affect investor confidence in Tvardi and could cause Tvardi's business or stock price to suffer.

Anti-takeover provisions in Tvardi's charter documents and under Delaware law could make an acquisition of Tvardi more difficult and may prevent attempts by Tvardi stockholders to replace or remove Tvardi management.

Provisions in Tvardi's certificate of incorporation and bylaws may delay or prevent an acquisition or a change in management. In addition, because Tvardi is incorporated in Delaware, it is governed by the provisions of Section 203 of the DGCL, which prohibits stockholders owning in excess of 15% of the outstanding Tvardi voting stock from merging or combining with Tvardi. Although Tvardi believes these provisions collectively will provide for an opportunity to receive higher bids by requiring potential acquirors to negotiate with Tvardi's board of directors, they would apply even if the offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by Tvardi's stockholders to replace or remove then current management by making it more difficult for stockholders to replace members of the board of directors, which is responsible for appointing the members of management.

The amended and restated certificate of incorporation of Tvardi provides that the Court of Chancery of the State of Delaware is the exclusive forum for substantially all disputes between Tvardi and its stockholders, which could limit its stockholders' ability to obtain a favorable judicial forum for disputes with Tvardi or its directors, officers or other employees, and could make it more costly for stockholders to bring a claim against Tvardi.

The amended and restated certificate of incorporation and amended and restated bylaws of Tvardi provide, among other things, that that the Court of Chancery of the State of Delaware (or, in the event that the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware or other state courts of the State of Delaware) generally will be the exclusive forum for any derivative action or proceeding brought on Tvardi's behalf, any action asserting a claim of breach of fiduciary duty, any action asserting a claim against Tvardi arising pursuant to the DGCL, Tvardi's amended and restated certificate of incorporation or Tvardi's amended and restated bylaws, or any action asserting a claim against Tvardi that is governed by the internal affairs doctrine; provided that, the exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction; and provided further that, if and only if the Court of Chancery of the State of Delaware dismisses any such action for lack of subject matter jurisdiction, such action may be brought in another state or federal court sitting in the State of Delaware.

To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, the amended and restated certificate of incorporation and the amended and restated bylaws of Tvardi will further provide that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. However, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims, and investors cannot waive compliance with the federal laws and rules and regulations thereunder. While the Delaware courts have determined that such choice of forum provisions are facially valid and several state trial courts have enforced such provisions and required that suits asserting Securities Act claims be filed in federal court, there is no guarantee that courts of appeal will affirm the enforceability of such provisions and a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, Tvardi would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of its amended and restated certificate of incorporation and amended and restated bylaws. This may require significant additional costs associated with resolving such action in other jurisdictions and there is uncertainty that the provision would be enforced by a court in those other jurisdictions. If a court were to find either exclusive forum provision in Tvardi's amended and restated certificate of incorporation or amended and restated bylaws to be inapplicable or unenforceable in an action, Tvardi may incur further significant additional costs associated with litigating Securities Act claims in state court, or both state and federal court, which could seriously harm its business, financial condition, results of operations, and prospects. This exclusive forum provision may make it more expensive for stockholders to bring a claim than if the stockholders were permitted to

select another jurisdiction and may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with Tvardi or its directors, officers or other employees or stockholders, which may discourage such lawsuits against Tvardi and its directors, officers and other employees and stockholders. Alternatively, if a court were to find the choice of forum provision contained in Tvardi's amended and restated certificate of incorporation or amended and restated bylaws to be inapplicable or unenforceable in an action, Tvardi may incur additional costs associated with resolving such action in other jurisdictions, which could materially and adversely affect its business, financial condition and results of operations.

Tvardi does not anticipate paying any cash dividends in the foreseeable future.

The current expectation is that Tvardi will retain its future earnings, if any, to fund the development and growth of Tvardi's business. As a result, capital appreciation, if any, of the common stock of Tvardi will be its stockholders' sole source of gain, if any, for the foreseeable future.

An active trading market for Tvardi's common stock may not develop and its stockholders may not be able to resell their shares of common stock for a profit, if at all.

Prior to the Merger, there had been no public market for Legacy Tvardi's common stock. An active trading market for Tvardi's shares of common stock may never develop or be sustained. If an active market for its common stock does not develop or is not sustained, it may be difficult for its stockholders to sell their shares at an attractive price or at all.

Future sales of shares by existing stockholders could cause Tvardi's stock price to decline.

If existing stockholders of Tvardi sell, or indicate an intention to sell, substantial amounts of Tvardi's common stock in the public market after legal restrictions on resale lapse, including upon the expiration or release of lock-up restrictions pursuant to the terms of the Lock-Up Agreements, the trading price of the common stock of Tvardi could decline. Tvardi is not able to predict the effect that sales may have on the prevailing market price of Tvardi's common stock.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about Tvardi, its business or its market, its stock price and trading volume could decline.

The trading market for Tvardi's common stock is influenced by the research and reports that equity research analysts publish about it and its business. Equity research analysts may elect not to provide research coverage of Tvardi's common stock, and such lack of research coverage may adversely affect the market price of its common stock. In the event it does have equity research analyst coverage, Tvardi will not have any control over the analysts, or the content and opinions included in their reports. The price of Tvardi's common stock could decline if one or more equity research analysts downgrade its stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of Tvardi or fails to publish reports on it regularly, demand for its common stock could decrease, which in turn could cause its stock price or trading volume to decline.

If Tvardi fails to maintain proper and effective internal controls, its ability to produce accurate financial statements on a timely basis could be impaired.

Tvardi is subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the rules and regulations of Nasdaq. The Sarbanes-Oxley Act requires, among other things, that Tvardi maintain effective disclosure controls and procedures and internal control over financial reporting. Tvardi must perform system and process evaluation and testing of its internal control over financial reporting to allow management to report on the effectiveness of its internal controls over financial reporting in its Annual Report on Form 10-K filing for that year, as required by Section 404 of the Sarbanes-Oxley Act. As a private company, Legacy Tvardi was never required to test its internal controls within a specified period. This will require that Tvardi incur substantial professional fees and internal costs to expand its accounting and finance functions and that it expends significant management efforts. Tvardi may experience difficulty in meeting these reporting requirements in a timely manner.

Tvardi has discovered, and may discover in the future, weaknesses in its system of internal financial and accounting controls and procedures that could result in a material misstatement of its financial statements. Tvardi's internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If Tvardi is not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act, or if it is unable to maintain proper and effective internal controls, Tvardi may not be able to produce timely and accurate financial statements. If that were to happen, the market price of its common stock could decline and it could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities.

If Tvardi fails to attract and retain management and other key personnel, it may be unable to continue to successfully develop or commercialize its product candidates or otherwise implement its business plan.

Tvardi's ability to compete in the highly competitive pharmaceuticals industry depends on its ability to attract and retain highly qualified managerial, scientific, medical, legal, sales and marketing and other personnel. Tvardi is highly dependent on its management and scientific personnel. The loss of the services of any of these individuals could impede, delay, or prevent the successful development of Tvardi's product pipeline, completion of its planned clinical trials, commercialization of its product candidates or in-licensing or acquisition of new assets and could impact negatively its ability to implement successfully its business plan. If Tvardi loses the services of any of these individuals, it might not be able to find suitable replacements on a timely basis or at all, and its business could be harmed as a result. Tvardi might not be able to attract or retain qualified management and other key personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses.

Tvardi is expected to take advantage of reduced disclosure and governance requirements applicable to smaller reporting companies, which could result in its common stock being less attractive to investors.

Tvardi had a public float of less than $250 million as of June 30, 2025 and therefore qualifies as a smaller reporting company under the rules of the SEC. As a smaller reporting company, Tvardi is able to take advantage of reduced disclosure requirements, such as simplified executive compensation disclosures and reduced financial statement disclosure requirements in its SEC filings. Decreased disclosures in Tvardi's SEC filings due to its status as a smaller reporting company may make it harder for investors to analyze its results of operations and financial prospects. Tvardi cannot predict if investors will find its common stock less attractive if it relies on these exemptions. If some investors find its common stock less attractive as a result, there may be a less active trading market for its common stock and its stock price may be more volatile. Tvardi may take advantage of the reporting exemptions applicable to a smaller reporting company until it is no longer a smaller reporting company, which status would end once it has a public float greater than $250 million. In that event, Tvardi could still be a smaller reporting company if its annual revenues were below $100 million and it has a public float of less than $700 million.

Changes in tax laws may materially adversely affect Tvardi's business, prospects, financial condition and operating results.

New tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect Tvardi's business, prospects, financial condition and operating results. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to Tvardi. For example, the legislation commonly referred to as OBBBA, enacted in 2025, the Coronavirus Aid, Relief, and Economic Security Act enacted in 2020, and the Tax Cuts and Jobs Act enacted in 2017, and the IRA enacted many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to such legislation may affect Tvardi, and certain aspects of such legislation could be

repealed or modified in future legislation. Such tax law changes could have a material adverse impact on Tvardi. In addition, it is uncertain if and to what extent various states will conform to newly enacted federal tax legislation. While it is too early to assess the overall impact of these changes, as these and other tax laws and related regulations are revised, enacted, and implemented, Tvardi's financial condition, results of operations, and cash flows could be materially adversely impacted.

Tvardi's ability to use net operating loss carryforwards and other tax attributes may be limited, including as a result of the Merger.

Each of Cara and Legacy Tvardi has incurred losses during its history, and Tvardi does not expect to become profitable in the near future and may never achieve profitability. To the extent that Tvardi continues to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire, if at all. As of December 31, 2024, Cara had U.S. federal net operating loss (NOL) carryforwards and state NOL carryforwards of $475.4 million and $403.1 million, respectively, and Legacy Tvardi had U.S. federal NOL carryforwards of approximately $47.2 million. Under current law, U.S. federal NOL carryforwards generated in taxable periods beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such NOL carryforwards is limited to 80% of taxable income. It is uncertain if and to what extent various states will conform to federal law. In addition, under Sections 382 and 383 of the Code, federal NOL carryforwards and other tax attributes may become subject to an annual limitation in the event of certain cumulative changes in ownership. An "ownership change" pursuant to Section 382 of the Code generally occurs if one or more stockholders or groups of stockholders who own at least 5% of a company's stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. Tvardi's ability to utilize its NOL carryforwards and other tax attributes to offset future taxable income or tax liabilities may be limited as a result of ownership changes, including changes in connection with the Merger or other transactions. Similar rules may apply under state tax laws. If Tvardi earns taxable income, such limitations could result in increased future income tax liability to Tvardi, and Tvardi's future cash flows could be adversely affected.

The consummation of the Merger has made Tvardi subject to the SEC requirements applicable to reporting shell company business combinations. As a result, Tvardi is subject to more stringent reporting requirements, offering limitations and resale restrictions.

According to SEC guidance, the requirements applicable to reporting shell company business combinations apply to any company that sells or otherwise disposes of its historical assets or operations in connection with or as part of a plan to combine with a non-shell private company in order to convert the private company into a public one. Tvardi is subject to the SEC requirements applicable to reporting shell company business combinations, which are as follows:

- Tvardi was required file a Current Report on Form 8-K to report the Form 10 type information (the Super 8-K) after the closing of the Merger reflecting its status as an entity that is not a shell company;
- Tvardi will not be eligible to use a Form S-3 until 12 full calendar months after the closing of the Merger on April 15, 2025 (the Closing Date);
- Tvardi had to wait at least 60 calendar days after the filing of the Super 8-K to file a Form S-8 for any equity plans or awards, such as the 2025 Equity Plan and the 2025 Employee Stock Purchase Plan;
- Tvardi will be an "ineligible issuer" for three years following the Closing Date, which will prevent Tvardi from (i) incorporating by reference in its Form S-1 filings, (ii) using a free writing prospectus or (iii) taking advantage of the well-known seasoned issuer (WKSI) status despite its public float;
- investors who (i) were affiliates of Legacy Tvardi at the time the Merger was submitted for the vote or consent of Legacy Tvardi's stockholders, (ii) receive securities of Tvardi in the Merger and (iii) publicly offer or sell such securities will be deemed to be engaged in a distribution of such securities, and therefore would be underwriters with respect to resales of those securities; and

- Rule 144(i)(2) will limit the ability of holders of restricted securities and any affiliates of the public company to publicly resell Rule 145(c) securities per Rule 145(d), as well as any other "restricted" or "control" securities of Tvardi per Rule 144, until one year after the Form 10 information is filed with the SEC. Non-affiliate Cara Stockholders prior the Merger are not subject to such restrictions on public resales of their shares.

The foregoing SEC requirements will increase Tvardi's time and cost of raising capital, offering stock under equity plans, and complying with securities laws. Furthermore, such requirements will add burdensome restrictions on the resale of Tvardi's common stock by affiliates of Legacy Tvardi and any holders of "restricted" or "control" securities of Tvardi.

Tvardi may become involved in securities litigation that could divert management's attention and harm Tvardi's business and insurance coverage may not be sufficient to cover all costs and damages.

In the past, securities class action or stockholder derivative litigation often follows certain significant business transactions, such as the sale of a business division or announcement of a merger. Tvardi is involved and may continue to be involved in this type of litigation in connection with the Merger.

Between December 20, 2024, and March 19, 2025, Cara received 13 demands (and three draft complaints) from purported stockholders of Cara (collectively, the Demands) challenging the disclosures in the proxy statement/prospectus (the Proxy Statement/Prospectus) included in the Registration Statement on Form S-4 related to the Merger and asserting claims for violations of Sections 14(a) and 20(a) of the Securities Exchange Act of 1934. In addition, on March 5 and March 6, 2025, two lawsuits were filed by purported stockholders of Cara in the Supreme Court of the State of New York, County of New York. The lawsuits are captioned Joseph Clark v. Cara Therapeutics, Inc., et al., No. 651260/2025 and Michael Kent v. Cara Therapeutics, Inc., et al., No. 651272/2025 (collectively, the Complaints). The Complaints named Cara and the members of the Cara board of directors as defendants, and, like the Demands, challenged the disclosures (under New York state law) in the Proxy Statement/Prospectus.

Cara and the other named defendants deny that they violated any laws or breached any duties to stockholders of Cara, and they believe that no supplemental disclosure was required to the Proxy Statement/Prospectus under any applicable law, rule or regulation. Nevertheless, solely to eliminate the burden and expense of litigation and to avoid any possible disruption to the Merger that could result from such litigation, Cara filed certain supplemental disclosures on March 24, 2025 to moot the disclosure claims alleged in the Demands and the Complaints. On April 15, 2025, the Merger closed. Thereafter, counsel for the purported stockholders (that sent the Demands or filed the Complaints) reached out to counsel for the Company to discuss a potential mootness fee in connection with the supplemental disclosures filed by Cara. On August 15, 2025, Tvardi resolved the fee demand and the matter is now closed.

General Risk Factors

Legacy Tvardi identified material weaknesses in its internal control over financial reporting, and, following the Merger, such material weaknesses must be remediated by Tvardi. If Tvardi fails to remediate these material weaknesses, or if it experiences additional material weaknesses in the future or otherwise fails to maintain effective internal control over financial reporting in the future, Tvardi may not be able to accurately or timely report its financial condition or results of operations, which may adversely affect investor confidence in Tvardi and, as a result, the value of its common stock.

As of December 31, 2024, Legacy Tvardi had limited accounting personnel and other resources to address its internal control over financial reporting. In connection with the preparation of Legacy Tvardi's financial statements for the year ended December 31, 2024, material weaknesses were identified in the design and operating effectiveness of Legacy Tvardi's internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis.

These material weaknesses are related to the fact that Legacy Tvardi lacked a sufficient number of professionals to consistently establish appropriate authorities and responsibilities in pursuit of Legacy Tvardi's financial reporting objectives. The lack of sufficient number of finance and accounting professionals contributed to the inadequate design and Legacy Tvardi's inability to maintain effective controls over the segregation of duties

related to journal entries. In addition, Legacy Tvardi identified material weaknesses in its financial reporting related to inadequate review of financial statements and disclosures, as well as a lack of formal documentation and timely communication regarding prepaid and accrued research and development expenses related to the CRO.

However, these material weaknesses could result in a misstatement of substantially all of Tvardi's accounts or disclosures that would result in a material misstatement of its future annual or interim financial statements that would not be prevented or detected. Following the Merger, these material weaknesses must be remediated by Tvardi.

To remediate the material weaknesses, Tvardi has begun a formal risk assessment process to identify control gaps and design new procedures and controls to remediate the identified weaknesses. Tvardi has added additional experienced accounting and financial reporting personnel and resources and is formalizing the design and implementation of internal controls over the financial reporting process. The material weaknesses will not be considered remediated until management completes the design and implementation of the measures described above and the controls operate for a sufficient period of time and management has concluded, through testing, that these controls are effective. The measures Tvardi has taken to date, and is continuing to design and implement, may not be sufficient to remediate the material weaknesses Tvardi has identified or avoid potential future material weaknesses. If the steps Tvardi takes do not correct these material weaknesses in a timely manner, Tvardi will be unable to conclude that it maintains effective internal control over financial reporting. Accordingly, there could continue to be a reasonable possibility that a material misstatement of Tvardi's financial statements would not be prevented or detected on a timely basis.

If Tvardi fails to remediate its existing material weaknesses or identify new material weaknesses in its internal control over financial reporting, if Tvardi is unable to comply with the disclosure and attestation requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, if Tvardi is unable to conclude that its internal control over financial reporting is effective, or if its independent registered public accounting firm is unable to conclude that its internal control over financial reporting is effective, Tvardi may not be able to accurately or timely report its financial condition or results of operations, which may adversely affect investor confidence in Tvardi and the market price of its common stock could be negatively affected. As a result, Tvardi could also become subject to investigations by The Nasdaq Capital Market, the SEC or other regulatory authorities, and become subject to litigation from investors and stockholders, which could harm its reputation and financial condition or divert financial and management resources from its regular business activities.

Tvardi's disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

As a public reporting company, Tvardi is subject to certain reporting requirements of the Exchange Act. Tvardi's disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by Tvardi in reports Tvardi files or submits under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. Tvardi believes that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in Tvardi's control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected.

Tvardi's issuance of additional capital stock in connection with financings, acquisitions, investments, its stock incentive plans or otherwise will dilute all other stockholders.

Tvardi expects to issue additional capital stock in the future that will result in dilution to all other stockholders. Tvardi expects to grant equity awards to employees, directors, and consultants under its stock incentive plans. As part of its business strategy, Tvardi may acquire or make investments in complementary companies, products or technologies and issue equity securities to pay for any such acquisition or investment. Any

such issuances of additional capital stock may cause stockholders to experience significant dilution of their ownership interests and the per share value of Tvardi's common stock to decline.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about Tvardi's business, its stock price and trading volume could decline.

The trading market for Tvardi's common stock will depend in part on the research and reports that securities or industry analysts publish about Tvardi or its business. If one or more of the analysts who covers Tvardi downgrades its stock or publishes inaccurate or unfavorable research about its business, its stock price may decline. If one or more of these analysts ceases coverage of its company or fails to publish reports on Tvardi regularly, demand for its stock could decrease, which might cause its stock price and trading volume to decline.

Tvardi will incur significant increased costs as a result of operating as a public company, and its management is required to devote substantial time to new compliance initiatives.

As a public company, Tvardi incurs significant legal, accounting and other expenses. Tvardi is subject to the reporting requirements of the Exchange Act, which requires, among other things, that Tvardi file with the SEC annual, quarterly and current reports with respect to its business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and the Nasdaq Stock Market (Nasdaq), to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial reporting controls and changes in corporate governance practices. Further, there are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as "say on pay" and proxy access. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which Tvardi operates its business in ways it cannot currently anticipate.

Tvardi expects the rules and regulations applicable to public companies to substantially increase its legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of Tvardi's management and personnel from other business concerns, they could have an adverse effect on its business. The increased costs will decrease Tvardi's net income or increase Tvardi's net loss and may require Tvardi to reduce costs in other areas of its business or increase the prices of its products or services. For example, Tvardi expects these rules and regulations to make it more difficult and more expensive for Tvardi to obtain director and officer liability insurance and Tvardi may be required to incur substantial costs to maintain the same or similar coverage. Tvardi cannot predict or estimate the amount or timing of additional costs Tvardi may incur to respond to these requirements. The impact of these requirements could also make it more difficult for Tvardi to attract and retain qualified persons to serve on its board of directors, its board committees or as executive officers.

Tvardi and the third parties with whom it works, are or may be subject to stringent and evolving U.S. and foreign laws, regulations, rules, contractual obligations, and policies related to data privacy and security. Tvardi's (or the third parties with whom it works) actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; disruptions of its business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse business consequences.

In the ordinary course of business, Tvardi collects, receives, stores, processes, generates, uses, transfers, discloses, makes accessible, protects, secures, disposes of, transmits, and shares (collectively, process or processing) certain sensitive information, including proprietary and confidential business data, trade secrets, employee data, intellectual property, data it collects about clinical trial participants in connection with clinical trials, and other sensitive third-party data (collectively, sensitive data). The global data protection landscape is rapidly evolving and Tvardi is or may become subject to numerous data privacy and security obligations, such as various state, federal and foreign laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations governing the collection use, disclosure, retention, and security of

personal information or otherwise relating to data privacy and security, including as relates to information that Tvardi may collect in connection with clinical trials in the United States and abroad.

Various federal, state, local and foreign legislative and regulatory bodies, or self-regulatory organizations, may expand current laws, rules or regulations, enact new laws, rules or regulations or issue revised rules or guidance regarding data privacy and security. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and Tvardi cannot yet determine the impact future laws, regulations, standards, or perception of their requirements may have on its business. This evolution may create uncertainty in Tvardi's business, affect its ability to operate in certain jurisdictions or to collect, store, transfer use and share personal information, necessitate the acceptance of more onerous obligations in its contracts, result in liability or impose additional costs on Tvardi. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. Any actual or perceived failure by Tvardi to comply with federal, state or foreign laws or regulations, its internal policies and procedures or its contracts governing the processing of personal information could result in, among other things, negative publicity, government investigations and enforcement actions, claims by third parties and damage to Tvardi's reputation, any of which could have a material adverse effect on its business, results of operation, and financial condition.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, data privacy laws, and other similar laws. For example, HIPAA, as amended by HITECH (collectively, HIPAA), imposes among other things, certain requirements relating to the privacy, security, transmission, and breach of individually identifiable health information. Tvardi may obtain health information from third parties (including research institutions from which it obtains clinical trial data) that are subject to privacy and security requirements under HIPAA. Depending on the facts and circumstances, Tvardi could be subject to significant penalties if it violates HIPAA.

Certain states have also adopted comparable privacy and security laws and regulations, which govern the privacy, processing and protection of health-related and other personal information. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for Tvardi and its future customers and strategic partners. For example, the CCPA, went into effect on January 1, 2020 and applies to the personal information of consumers, business representatives, and employees who are California residents, and increases the privacy and security obligations of covered businesses under the CCPA that handle personal information subject to the CCPA, including among other things, requiring such businesses to provide specific disclosures in privacy notices and honor requests of California residents to exercise certain privacy rights, including the right to opt out of certain disclosures of their information. The CCPA provides for civil penalties as well as a private right of action with statutory damages for certain data breaches, thereby potentially increasing the likelihood of, and risks associated with, data breach litigation. Although the law includes limited exceptions, including for certain information collected as part of clinical trials, the CCPA may impact Tvardi's processing of personal information and increase its compliance costs. Additionally, the California Privacy Rights Act of 2020 (CPRA) went into effect on January 1, 2023, and significantly expands the CCPA, such as by granting additional rights to California residents, including the right to correct personal information and affording opt-out rights for certain uses of sensitive information, and imposes additional data protection obligations on covered businesses, including additional limitations on data uses and new audit requirements for higher risk sensitive information. The CPRA also established the California Privacy Protection Agency which is authorized to issue substantive regulations and could result in increased privacy and information security enforcement. Other states have also passed comprehensive privacy laws, and similar laws are being considered in several other states, as well as at the federal and local levels. While these state privacy laws, like the CCPA, may or do exempt some data processed in the context of clinical trials, these laws could have potentially conflicting requirements that further complicate compliance efforts, and increase legal risk and compliance costs for Tvardi and the third parties upon whom it relies.

In the event that Tvardi is subject to or affected by HIPAA, the CCPA, the CPRA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect its financial condition. In addition to government activity, privacy advocacy groups and technology and other industries are considering various new, additional or different self-regulatory standards that may place

additional burdens on Tvardi. In addition to data privacy and security laws, Tvardi is also bound by other contractual obligations related to data privacy and security, and its efforts to comply with such obligations may not be successful.

Each of these laws, rules, regulations and contractual obligations relating to data privacy and security, and any other such changes or new laws, rules, regulations or contractual obligations could impose significant limitations on Tvardi's business, require changes to Tvardi's business, or restrict its collection, use, storage or processing of personal information, which may increase its compliance expenses and make its business more costly or less efficient to conduct. In addition, any such changes could compromise Tvardi's ability to develop an adequate marketing strategy and pursue its growth strategy effectively or even prevent Tvardi from providing certain products in jurisdictions in which it currently operates and in which Tvardi may operate in the future or incur potential liability in an effort to comply with such legislation, which, in turn, could adversely affect its business, financial condition, results of operations and prospects.

Complying with these numerous, complex and often changing obligations is expensive and difficult, and failure to comply with any data privacy or security obligations, whether by Tvardi, one of its CROs, CMOs, partners or another third party, could adversely affect its business, financial condition, results of operations and prospects, including but not limited to: investigation costs; material fines and penalties; compensatory, special, punitive and statutory damages; litigation; consent orders regarding Tvardi's privacy and security practices; requirements that it provides notices, credit monitoring services and/or credit restoration services or other relevant services to impacted individuals; adverse actions against Tvardi's licenses to do business; reputational damage; and injunctive relief. In addition, new regulation or legislative actions regarding data privacy and security (together with applicable industry standards) may increase its costs of doing business.

In this regard, Tvardi expects that there will continue to be new proposed laws, regulations and industry standards relating to privacy and data protection in the United States, the EEA and other jurisdictions, and it cannot determine the impact such future laws, regulations and standards may have on its business. For example, the U.S. Department of Justice issued a rule entitled the Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons, which places additional restriction on certain data transactions involving countries of concern (e.g., China, Russia, Iran) and covered individuals (i.e., individuals and entities located in or controlled by individuals or entities located in those jurisdictions) that may impact certain business activities such as vendor engagements, sale or sharing of data, employment of certain individuals, and investor agreements. Violations of the rule could lead to significant civil and criminal fines and penalties. The rule applies regardless of whether data is anonymized, key-coded, pseudonymized, de-identified or encrypted, which presents particular challenges for companies like ours and may impact our ability to transfer data in connection with certain transactions or agreements.

Any actual or perceived failure by Tvardi or its third-party service providers to comply with any federal, state or foreign laws, rules, regulations, industry self-regulatory principles, industry standards or codes of conduct, regulatory guidance, orders to which Tvardi may be subject or other legal obligations relating to data privacy, data protection, security or consumer protection could adversely affect Tvardi's reputation, brand and business. Tvardi may also be contractually required to indemnify and hold harmless third parties from the costs or consequences of non-compliance with any laws, rules and regulations or other legal obligations relating to privacy or any inadvertent or unauthorized use or disclosure of data that Tvardi stores or handles as part of operating its business. Any of these events could adversely affect Tvardi's reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in its business operations (including clinical trials); inability to process personal information or to operate in certain jurisdictions; limited ability to develop or commercialize its products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to its business model or operations.

Tvardi cannot be certain that its CROs, CMOs or other third-parties with access to its or its suppliers', manufacturers', clinical trial participants' and employees' sensitive information in relation to which Tvardi is responsible will not breach contractual obligations imposed by Tvardi, or that they will not experience data security incidents, which could have a corresponding effect on its business, including putting Tvardi in breach of

its obligations under privacy laws and regulations and/or which could in turn adversely affect its business, financial condition, results of operations and prospects. Tvardi cannot be certain that its contractual measures and its own privacy and security-related safeguards will protect Tvardi from the risks associated with the third-party processing of such information. Any of the foregoing could adversely affect its business, financial condition, results of operations and prospects.

Tvardi posts certain of its privacy policies which describe its practices concerning its collection, use, disclosure and other processing of the personal information. Although it endeavors to comply with its public statements and documentation, Tvardi may at times fail to do so or be perceived to have failed to do so. Tvardi's publication of its privacy policies and other statements it publishes that provide promises and assurances about privacy and security can subject Tvardi to potential state and federal action if they are found to be deceptive, unfair or misrepresentative of its actual practices.

Any actual or perceived failure by Tvardi to comply with federal, state or foreign laws, rules or regulations, industry standards, contractual or other legal obligations relating to data privacy or security, or any actual, perceived or suspected cybersecurity incident, whether or not resulting in unauthorized access to, or acquisition, release or transfer of personal information or other data, may result in enforcement actions and prosecutions, private litigation, significant fines, penalties and censure, claims for damages by customers and other affected individuals, regulatory inquiries and investigations or adverse publicity and could cause its relevant stakeholders to lose trust in Tvardi, any of which could adversely affect its business, financial condition, results of operations and prospects.

The successful assertion of one or more large claims against Tvardi that exceeds its available insurance coverage, or results in changes to its insurance policies (including premium increases or the imposition of large deductible or co-insurance requirements), could have an adverse effect on its business. In addition, Tvardi cannot be sure that its existing insurance coverage will continue to be available on acceptable terms or that its insurers will not deny coverage as to any future claim.

Changes in U.S. tax law could adversely affect Tvardi's financial condition and results of operations.

The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the U.S. Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect Tvardi or holders of its common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. Future changes in U.S. tax laws could have a material adverse effect on its business, cash flow, financial condition or results of operations. Tvardi urges investors to consult with their legal and tax advisors regarding the implications of potential changes in U.S. tax laws on an investment in its common stock.

If Tvardi's information technology systems or those third parties with whom it works or its data, are or were compromised, Tvardi could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences.

Tvardi's information systems and those of its current and any future collaborators, contractors, consultants, and other third parties with whom it works (i.e., its supply chain) are vulnerable to a variety of evolving threats, including but not limited to malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks, credential stuffing attacks, credential harvesting, ransomware attacks, software bugs, software or hardware failures, personnel error or malfeasance, loss of data or other information technology assets, adware, earthquakes, fires, floods, attacks enhanced or facilitated by AI, malicious code (such as computer viruses and worms), unauthorized access, natural disasters, terrorism, war and telecommunication, electrical failures, and other similar threats. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors. We may expend significant resources or modify our business activities (including our clinical trial activities) to try

to protect against security incidents. Certain data privacy and security obligations have required us to implement and maintain specific security measures or industry-standard or reasonable security measures to protect our information technology systems and sensitive information.

Tvardi exercises little or no direct control over how the third parties with whom it works operate their information systems, which increases its vulnerability to problems with their systems. If Tvardi or third parties with whom it works have in the past or were in the future to experience any material system failure, accident, or security breach, it could result in a disruption of its development programs and its business operations, whether due to a loss of Tvardi's trade secrets or other proprietary information or other similar disruptions, as well as reputational harm and adverse legal and regulatory consequences. For example, the loss of clinical trial data from future clinical trials could result in delays in Tvardi's regulatory approval efforts and significantly increase its costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, Tvardi's data or applications, or inappropriate disclosure of confidential or proprietary information, it could incur liability, its competitive position could be harmed, and the further development and commercialization of its product candidates could be delayed.

Tvardi and the third parties with whom it works are also subject to cybersecurity risks caused by misappropriation, misuse, leakage, falsification or intentional or accidental release, exposure or loss of information maintained in the information systems and networks of Tvardi and the third parties with whom it works , including personal information of Tvardi's employees and clinical trial subjects, and Tvardi's confidential data. In addition, outside parties may attempt to penetrate Tvardi's systems or those of the third parties with whom it works or fraudulently induce its personnel or the personnel of the third parties with whom it works to disclose sensitive information in order to gain access to Tvardi's data and/or systems (or those of the third parties with whom it works). Tvardi may experience threats to its data and systems, including malicious code and viruses, supply chain attacks, phishing and other cyberattacks. The number and complexity of these threats continue to increase over time. In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, ability to provide our products or services, loss of sensitive data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but Tvardi may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. Remote work has increased risks to our information technology systems and data, as our employees utilize network connections, computers and devices outside our premises or network, including working at home, while in transit and in public locations. Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

If a material breach of, or accidental or intentional loss of data from, Tvardi's information technology systems or those of its vendors occurs, the market perception of the effectiveness of its security measures could be harmed and Tvardi's reputation and credibility could be damaged, and Tvardi could be subject to adverse legal and regulatory consequences. Tvardi could be required to expend significant amounts of money and other resources to repair or replace information systems or networks. Applicable data privacy and security obligations may require us, or we may voluntarily choose, to notify relevant stakeholders, including affected individuals, customers, regulators, and investors, of security incidents, or to take other actions, such as providing credit monitoring and identity theft protection services. Such disclosures and related actions can be costly, and the disclosure or the failure to comply with such applicable requirements could lead to adverse consequences.

Tvardi takes steps designed to detect, mitigate, and remediate vulnerabilities in our information systems (such as our hardware and/or software, including that of third parties with whom it works). Tvardi has not and may not in the future, however, detect and remediate all such vulnerabilities including on a timely basis. Further, Tvardi has and may in the future experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities.

Although Tvardi develops and maintains systems and controls designed to prevent these events from occurring and Tvardi has a process to identify and mitigate threats, the development and maintenance of these systems, controls and processes is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become increasingly sophisticated. It may be difficult and/or costly to detect, investigate, mitigate, contain, and remediate a security incident. Our efforts to do so may not be successful. Actions taken by us or the third parties with whom we work to detect, investigate, mitigate, contain, and remediate a security incident could result in outages, data losses, and disruptions of our business. Threat actors may also gain access to other networks and systems after a compromise of our networks and systems. Moreover, despite Tvardi's efforts, the possibility of these events occurring cannot be eliminated entirely. As Tvardi outsources more of its information systems to vendors, and relies more on cloud-based information systems, the related security risks will increase, and Tvardi will need to expend additional resources to protect its technology and information systems.

In addition, there can be no assurance that Tvardi's internal information technology systems or those of the third-parties with whom it works, or its consultants' efforts to implement adequate security and control measures, will be sufficient to protect Tvardi against breakdowns, service disruption, data deterioration or loss in the event of a system malfunction, or prevent data from being stolen or corrupted in the event of a cyberattack, security breach, industrial espionage attacks or insider threat attacks, which could result in financial, legal, business or reputational harm. In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveal competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position.

Any of the previously identified or similar threats have in the past and may in the future cause a security incident or other interruption that have in the past and may in the future result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information or our information technology systems, or those of the third parties with whom we work. For example, we have been the target of unsuccessful phishing attempts in the past and expect such attempts will continue in the future. A security incident or other interruption could disrupt our ability (and that of third parties with whom we work) to operate our business.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. In addition, while Tvardi maintains insurance policies that may cover certain liabilities in connection with a cybersecurity incident, it cannot be certain that the insurance coverage will be adequate for liabilities actually incurred, that insurance will continue to be available to Tvardi on commercially reasonable terms, or at all, or that any insurer will not deny coverage as to any future claim. The successful assertion of one or more large claims that exceed available insurance coverage, or the occurrence of changes in insurance policies, including premium increases or the imposition of large deductible or co-insurance requirements, could have a material adverse effect on its business, including its financial condition, results of operations and reputation.

Unfavorable global economic conditions could adversely affect Tvardi's business, financial condition or results of operations.

Tvardi's results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. Portions of Tvardi's future clinical trials may be conducted outside of the United States and unfavorable economic conditions resulting in the weakening of the U.S. dollar would make those clinical trials costlier to operate. Furthermore, the most recent global financial crisis caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn, due to factors including the effects of health epidemics and pandemics, geopolitical events, such as the Russian invasion of Ukraine, the conflict in the Middle East and related global escalation of geopolitical tensions, and inflationary pressures could result in a variety of risks to Tvardi's business, including a reduced ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy or international trade disputes could also strain its suppliers, some of which are located outside of the United States, possibly resulting in supply disruption. Any of

the foregoing could harm its business and Tvardi cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact its business.

Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults or non-performance by financial institutions or transactional counterparties, could adversely affect Tvardi's current and projected business operations and its financial condition and results of operations.

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems.

Since March 2023, several financial institutions have experienced failures and have been placed into receivership. In addition, if any of Tvardi's customers, suppliers or other parties with whom it conducts business are unable to access funds pursuant to such instruments or lending arrangements with such a financial institution, such parties' ability to pay their obligations to Tvardi or to enter into new commercial arrangements requiring additional payments to Tvardi could be adversely affected. Similar impacts have occurred in the past, such as during the 2008-2010 financial crisis.

Inflation and rapid increases in interest rates have led to a decline in the trading value of previously issued government securities with interest rates below current market interest rates. Although the U.S. Department of Treasury, Federal Deposit Insurance Corporation (FDIC), and Federal Reserve Board have announced a program to provide up to $25 billion of loans to financial institutions secured by certain of such government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments, widespread demands for customer withdrawals or other liquidity needs of financial institutions for immediately liquidity may exceed the capacity of such program. Additionally, there is no guarantee that the U.S. Department of Treasury, FDIC and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions, or that they would do so in a timely fashion.

Although Tvardi assesses its banking and customer relationships as it believes necessary or appropriate, its access to funding sources and other credit arrangements in amounts adequate to finance or capitalize its current and projected future business operations could be significantly impaired by factors that affect Tvardi, the financial institutions with whom Tvardi has credit agreements or arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could involve financial institutions or financial services industry companies with which Tvardi has financial or business relationships, but could also include factors involving financial markets or the financial services industry generally.

The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on Tvardi's current and projected business operations and its financial condition and results of operations. These could include, but may not be limited to, the following:

- delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets;
- delayed or lost access to working capital sources and/or delays, inability or reductions in its ability to enter into new credit facilities or other working capital resources;
- potential or actual breach of contractual obligations that require Tvardi to maintain letters of credit or other credit support arrangements;

- potential or actual breach of financial covenants in any credit agreements or credit arrangements; or
- potential or actual cross-defaults in other credit agreements, credit arrangements or operating or financing agreements.

In addition, investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for Tvardi to acquire financing on acceptable terms or at all.

Any decline in available funding or access to its cash and liquidity resources could, among other risks, adversely impact Tvardi's ability to meet its operating expenses, financial obligations or fulfill its other obligations, result in breaches of its financial and/or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on Tvardi's liquidity and its current and/or projected business operations and financial condition and results of operations.

In addition, any further deterioration in the macroeconomic economy or financial services industry could lead to losses or defaults by Tvardi's customers or suppliers, which in turn, could have a material adverse effect on its current and/or projected business operations and results of operations and financial condition. For example, a supplier may determine that it will no longer deal with Tvardi as a customer. In addition, a supplier could be adversely affected by any of the liquidity or other risks that are described above as factors that could result in material adverse impacts on Tvardi, including but not limited to delayed access or loss of access to uninsured deposits or loss of the ability to draw on existing credit facilities involving a troubled or failed financial institution. Any supplier bankruptcy or insolvency, or any breach or default by a supplier, or the loss of any significant supplier relationships, could result in material losses to Tvardi and may have a material adverse impact on its business.

The increasing use of social media platforms presents new risks and challenges.

Social media is increasingly being used to communicate about Tvardi's clinical development programs and the diseases its therapeutics are being developed to treat, and Tvardi intends to utilize appropriate social media in connection with its commercialization efforts following approval of its product candidates, if any. Social media practices in the biopharmaceutical industry continue to evolve and regulations and regulatory guidance relating to such use are evolving and not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to its business, resulting in potential regulatory actions against Tvardi, along with the potential for litigation related to off-label marketing or other prohibited activities. For example, patients may use social media channels to comment on their experience in an ongoing blinded clinical trial or to report an alleged adverse event. When such disclosures occur, there is a risk that clinical trial enrollment may be adversely impacted, that Tvardi may fail to monitor and comply with applicable adverse event reporting obligations or that Tvardi may not be able to defend its business or the public's legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what Tvardi may say about its product candidates. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about Tvardi on any social networking website. If any of these events were to occur or Tvardi otherwise fails to comply with applicable regulations, Tvardi could incur liability, face regulatory actions or incur other harm to its business.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

On September 29, 2025, Tvardi issued 1,899 shares of its common stock to a former employee for aggregate proceeds of $11,610.68 pursuant to the exercise of options with an exercise price of $6.1141 per share under Legacy Tvardi's 2018 Stock Incentive Program. The issuance of such shares was exempt from registration under Rule 701 promulgated under Section 3(b) of the Securities Act.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

During the three months ended September 30, 2025, none of our directors or officers (as defined in Rule 16a-1(f) under the Exchange Act) adopted or terminated any "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as those terms are defined in Item 408 of Regulation S-K.

Item 6. Exhibits.

		Incorporated by Reference			
Exhibit No.	**Description of Exhibit**	**Form**	**File No.**	**Exhibit No.**	**Date Filed**
2.1‡	Agreement and Plan of Merger and Reorganization, dated as of December 17, 2024, by and among Cara Therapeutics, Inc., CT Convergence Merger Sub, Inc. and Tvardi Therapeutics, Inc.	8-K	001-36279	2.1	December 18, 2024
3.1	Amended and Restated Certificate of Incorporation.	8-K	001-36279	3.1	February 7, 2014
3.2	Amended and Restated Bylaws.	10-Q	001-36279	3.2	November 14, 2024
3.3	Certificate of Amendment to Amended and Restated Certificate of Incorporation.	8-K	001-36279	3.1	June 7, 2024
3.4	Certificate of Amendment to Amended and Restated Certificate of Incorporation.	8-K	001-36279	3.1	December 30, 2024
3.5	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Cara Therapeutics, Inc., dated April 15, 2025 (Stock Split Amendment).	8-K	001-36279	3.1	April 15, 2025
3.6	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Cara Therapeutics, Inc., dated April 15, 2025 (Authorized Shares Amendment).	8-K	001-36279	3.2	April 15, 2025
3.7	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Cara Therapeutics, Inc., dated April 15, 2025 (Name Change Amendment).	8-K	001-36279	3.3	April 15, 2025
31.1†	Certification of Chief Executive Officer of Tvardi Therapeutics, Inc. pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934.				

31.2†	Certification of Chief Financial Officer of Tvardi Therapeutics, Inc. pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934.
32.1†*	Certifications of Chief Executive Officer and Chief Financial Officer of Tvardi Therapeutics, Inc. pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.CAL†	Inline XBRL Taxonomy Extension Calculation Linkbase.
101.INS†	Inline XBRL Instance Document.
101.LAB†	Inline XBRL Taxonomy Extension Label Linkbase.
101.PRE†	Inline XBRL Taxonomy Extension Presentation Linkbase.
101.SCH†	Inline XBRL Taxonomy Extension Schema Linkbase.
101.DEF†	Inline XBRL Taxonomy Extension Definition Linkbase Document.
104†	Cover page interactive data file (formatted as Inline XBRL and contained in Exhibit 101).

† Filed herewith.

* This certification is deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended.

‡ Schedules and exhibits have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The registrant undertakes to furnish supplemental copies of any of the omitted schedules upon request by the SEC.

SIGNATURES

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

TVARDI THERAPEUTICS, INC.

Date: November 13, 2025

By: /s/ IMRAN ALIBHAI
Name: Imran Alibhai
Title: Chief Executive Officer
(*Principal Executive Officer*)

Date: November 13, 2025

By: /s/ DAN CONN
Name: Dan Conn
Title: Chief Financial Officer
(*Principal Financial Officer*)

EXHIBIT 31.1

Certification of Chief Executive Officer Pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Imran Alibhai, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Tvardi Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 13, 2025

By: /s/ Imran Alibhai
IMRAN ALIBHAI
CHIEF EXECUTIVE OFFICER
(Principal Executive Officer)

EXHIBIT 31.2

Certification of Chief Financial Officer Pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Dan Conn, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Tvardi Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 13, 2025

By: /s/ Dan Conn
DAN CONN
CHIEF FINANCIAL OFFICER
(Principal Financial Officer)

EXHIBIT 32.1

CERTIFICATIONS OF
CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER
OF TVARDI THERAPEUTICS, INC.
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906 OF THE
SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Tvardi Therapeutics, Inc. (the "Company") for the quarter ended September 30, 2025, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Imran Alibhai, Chief Executive Officer of the Company, and Dan Conn, Chief Financial Officer of the Company, each hereby certifies, pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), that, to the best of his knowledge, based upon a review of the Report:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ IMRAN ALIBHAI
Name: Imran Alibhai
Title: Chief Executive Officer
(Principal Executive Officer)
Date: November 13, 2025

/s/ DAN CONN
Name: Dan Conn
Title: Chief Financial Officer
(Principal Financial Officer)
Date: November 13, 2025

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Tvardi Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.