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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, 2026

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, 2026 was: 13,363,391.

TVARDI THERAPEUTICS, INC.

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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, 2026	As of December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 22,275	$ 20,734
Short-term investments	—	10,077
Prepaid expenses and other current assets	855	727
Total current assets	23,130	31,538
Property and equipment, net	28	52
Intangible assets, net	275	322
Operating lease right-of-use assets	83	144
Other non-current assets	17	17
Total assets	$ 23,533	$ 32,073
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,076	$ 3,219
Accrued expenses	5,885	7,707
Operating lease liabilities, current portion	116	116
Total current liabilities	8,077	11,042
Operating lease liabilities, net of current portion	—	85
Total liabilities	8,077	11,127
Commitments and contingencies (Note 12)		
Stockholders' Equity:		
Common stock, $0.001 par value; 150,000,000 shares authorized as of September 30, 2026 and December 31, 2025; 13,345,956 shares and 9,381,344 shares issued and outstanding as of September 30, 2026 and December 31, 2025, respectively	13	9
Additional paid-in capital	145,278	131,379
Accumulated other comprehensive income	—	8
Accumulated deficit	(129,835)	(110,450)
Total stockholders' equity	15,456	20,946
Total liabilities and stockholders' equity	$ 23,533	$ 32,073

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

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 Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balances as of December 31, 2025	—	$ —	9,381,344	$ 9	$ 131,379	$ (110,450)	$ 8	$ 20,946
Stock-based compensation	—	—	—	—	370	—	—	370
Unrealized loss on short-term investments	—	—	—	—	—	—	(7)	(7)
Net loss	—	—	—	—	—	(6,804)	—	(6,804)
Balances as of March 31, 2026	—	$ —	9,381,344	$ 9	$ 131,749	$ (117,254)	$ 1	$ 14,505
Stock-based compensation	—	—	—	—	335	—	—	335
Unrealized loss on short-term investments	—	—	—	—	—	—	(1)	(1)
Net loss	—	—	—	—	—	(6,457)	—	(6,457)
Balances as of June 30, 2026	—	$ —	9,381,344	$ 9	$ 132,084	$ (123,711)	$ —	$ 8,382
Stock-based compensation	—	—	—	—	386	—	—	386
Issuance of common stock under at-the-market facility	—	—	3,964,612	4	13,340	—	—	13,344
Commissions and issuance costs in connection with at-the-market facility	—	—	—	—	(532)	—	—	(532)
Net loss	—	—	—	—	—	(6,124)	—	(6,124)
Balances as of September 30, 2026	—	$ —	13,345,956	$ 13	$ 145,278	$ (129,835)	$ —	$ 15,456
Balances as of December 31, 2024	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

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,	
	2026	2025
Cash flows from operating activities:		
Net loss	$ (19,385)	$ (10,939)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	71	71
Stock-based compensation expense	1,091	1,046
Change in fair value of Convertible Notes	—	(7,810)
Non-cash lease expense	61	53
Accretion of net discounts on short-term investments	(49)	(166)
Interest accrued on Convertible Notes	—	651
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(127)	(1,564)
Accounts payable and accrued expenses	(3,044)	919
Operating lease liabilities	(86)	(75)
Net cash used in operating activities	(21,468)	(17,814)
Cash flows from investing activities:		
Purchases of short-term investments	—	(31,486)
Maturities of short-term investments	10,118	16,402
Net cash provided by (used in) investing activities	10,118	(15,084)
Cash flows from financing activities:		
Proceeds from sale of common stock in connection with at-the-market facility	13,344	—
Commissions and offering costs paid in connection with at-the-market facility	(453)	—
Cash acquired in connection with the Merger	—	24,992
Payments for Merger transaction costs	—	(2,821)
Proceeds from exercise of stock options	—	531
Net cash provided by financing activities	12,891	22,702
Net increase (decrease) in cash and cash equivalents	1,541	(10,196)
Cash and cash equivalents - beginning of year	20,734	31,614
Cash and cash equivalents - end of period	$ 22,275	$ 21,418
Non-cash investing and financing activities		
Deferred offering costs included in accounts payable and accrued expenses	$ 79	$ —
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., together with its subsidiary (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 Signal Transducer and Activator of Transcription 3 (STAT3) to treat inflammatory and proliferative diseases with significant unmet need. Based upon its founders' 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 pipeline includes two oral, small molecule STAT3 inhibitors: TTI-101 and TTI-109. TTI-101 is the Company's first-generation direct STAT3 inhibitor, currently in Phase 1b/2 clinical development in hepatocellular carcinoma (HCC). TTI-109 is a phosphate prodrug of TTI-101 that is mechanistically identical to its parent molecule but is designed to enhance systemic drug delivery and improve tolerability. The Company submitted an Investigational New Drug (IND) application for TTI-109 in June 2025. In July 2026, the Company reported positive results from its Phase 1 clinical trial of TTI-109 in healthy volunteers evaluating safety, tolerability, pharmacokinetics and bioequivalence to TTI-101 and announced that it had selected ulcerative colitis (UC) as the initial disease indication for TTI-109.

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.

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 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, 2026, the Company had cash and cash equivalents of $22.3 million. Since inception, the Company has incurred net operating losses and negative cash flows from operations. During the three and nine months ended September 30, 2026, the Company incurred net losses of $6.1 million and $19.4 million, respectively, and used $21.5 million of cash in operating activities during the nine months ended September 30, 2026. As of September 30, 2026, the Company had an accumulated deficit of $129.8 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 Company evaluated whether there were conditions and events, considered in the aggregate, 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.

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, 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 include the accounts of the Company and its consolidated subsidiaries 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, 2026 and December 31, 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, 2026.

Upon the closing of the Merger, 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) were converted into shares of the Company's common stock, based on an exchange ratio calculated in accordance with the Merger Agreement (the Exchange Ratio). The Exchange Ratio was retroactively applied to all outstanding common shares, redeemable convertible preferred stock, and stock options of Legacy Tvardi throughout the condensed consolidated financial statements and notes to condensed consolidated financial statements. Refer to Note 3 to the consolidated financial statements included in the Company's Annual Report on Form 10-K for the year ended December

31, 2025, as filed with the Securities and Exchange Commission (SEC) on March 31, 2026, for additional information regarding the Merger.

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 to the consolidated financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 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 11, *Net Loss Per Share*), 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,
	2026	2025	2026	2025	2026	2025
	% of operating expenses		% of operating expenses		% of accounts payable	
Vendor A	44 %	35 %	39 %	39 %	66 %	84 %

For the three and nine months ended September 30, 2026 and 2025, no additional suppliers accounted for more than 10% of the Company's operating expenses or accounts payable. 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 $21.5 million and $20.0 million as of September 30, 2026 and December 31, 2025, respectively.

The Company recorded interest income on its cash equivalents of $0.2 million and $0.3 million for the three months ended September 30, 2026 and 2025, respectively, and $0.5 million and $0.6 million for the nine months ended September 30, 2026 and 2025 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) income, 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 during the nine months ended September 30, 2026, with no related interest income recorded in the third quarter of 2026 since the Company did not have any short-term investments during the period. 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. These amounts are classified as interest income in the condensed consolidated statements of operations and comprehensive loss.

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, are recorded in the condensed consolidated statement of operations and comprehensive loss accordingly, as needed. 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 the three and nine months ended September 30, 2026 and 2025.

Comprehensive Loss

Comprehensive 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 the three months ended September 30, 2026, comprehensive loss only includes net loss. For the nine months ended September 30, 2026, comprehensive loss includes net loss and a net unrealized loss on short-term investments. For the three and nine months ended September 30, 2025, comprehensive loss includes net loss and a net unrealized gain on short-term investments.

Recently Issued Accounting Pronouncements Not Yet Adopted

In December 2025, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2025-11, *Interim Reporting (Topic 270): Narrow Scope Improvements* (or ASU 2025-11). The amendments in ASU 2025-11 are intended to improve the clarity and navigability of the interim reporting guidance in Topic 270 by clarifying its applicability, the types of interim reporting subject to the guidance, and the form and content of interim financial statements. The update also provides a comprehensive list of required interim disclosures and introduces a disclosure principle requiring entities to disclose events occurring since the end of the most recent annual reporting period that have a material impact on the entity, without fundamentally changing or expanding existing disclosure requirements. This guidance is effective for interim reporting periods within annual reporting periods beginning after December 15, 2027 for public business entities, 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.

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. 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, 2026			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Cash equivalents:				
Money market funds	$ 21,525	$ —	$ —	$ 21,525
Total financial assets	$ 21,525	$ —	$ —	$ 21,525

	Fair Value Measurements as of December 31, 2025			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Cash equivalents:				
Money market funds	$ 20,011	$ —	$ —	$ 20,011
Short-term investments				
U.S. Treasury Notes	10,077	—	—	10,077
Total financial assets	$ 30,088	$ —	$ —	$ 30,088

The Company did not have any Level 3 assets or liabilities as of September 30, 2026 and December 31, 2025. There were no transfers between Levels during the periods presented.

The unrealized (losses) gains on the Company's short-term investments for the nine months ended September 30, 2026, and the three and nine months ended September 30, 2025, were not material. The Company did not have any short-term investments in the third quarter of 2026.

4. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following as of September 30, 2026 and December 31, 2025 (in thousands):

	As of September 30, 2026	As of December 31, 2025
Prepaid research and development expenses	$ 295	$ 303
Prepaid insurance	364	194
Other prepaid expenses	196	230
Total prepaid expenses and other current assets	$ 855	$ 727

5. Intangible Assets

Intangible assets consisted of the following as of September 30, 2026 and December 31, 2025 (in thousands):

	As of September 30, 2026	As of December 31, 2025
Licensed patent rights	$ 826	$ 826
Less: accumulated amortization	(551)	(504)
Total intangible assets, net	$ 275	$ 322

As of September 30, 2026, the expected remaining amortization expense is as follows (in thousands):

Year Ended December 31,	Amount
2026 (remaining three months)	$ 16
2027	63
2028	63
2029	63
2030	63
Thereafter	7
Total	$ 275

The Company recognized less than $0.1 million for amortization expense for each of the three and nine months ended September 30, 2026 and 2025. Amortization expense is included in research and development expense in the condensed consolidated statements of operations and comprehensive loss.

6. Accrued Expenses

Accrued expenses consisted of the following as of September 30, 2026 and December 31, 2025 (in thousands):

	As of September 30, 2026	As of December 31, 2025
Accrued research and development expenses	$ 3,730	$ 5,744
Accrued employee compensation and benefits	1,620	1,297
Accrued professional fees	408	345
Other accrued expenses	127	321
Total accrued expenses	$ 5,885	$ 7,707

7. 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, 2026, the remaining term of lease was 0.83 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,	
	2026	2025	2026	2025
Lease costs:				
Operating lease cost	$ 24	$ 24	$ 72	$ 72
Variable lease cost	22	21	65	61
Total lease costs	$ 46	$ 45	$ 137	$ 133

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2026	2025	2026	2025
Operating cash flows from operating leases	$ 51	$ 50	$ 152	$ 150

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,	
	2026	2025	2026	2025
Weighted-average discount rate	9.50 %	9.50 %	9.50 %	9.50 %
Weighted-average remaining lease term	0.83	1.83	0.83	1.83

As of September 30, 2026, the maturities of the Company's operating lease liabilities were as follows (in thousands):

Year Ended December 31,	Amount
2026 (remaining three months)	$ 33
2027	88
Total lease payments	121
Less: imputed interest	(5)
Present value of lease liabilities	116
Less: operating lease liabilities, current portion	$ 116
Operating lease liabilities, net of current portion	$ —

8. Stockholders' Equity (Deficit)

Preferred Stock

As of September 30, 2026, the Company had 5,000,000 shares of preferred stock authorized, $0.001 par value, pursuant to its amended and restated certificate of incorporation which was assumed in connection with the Merger Agreement in April 2025. No shares of preferred stock were issued or outstanding as of September 30, 2026 or December 31, 2025.

Common Stock

As of September 30, 2026 and December 31, 2025, 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 13,345,956 shares and 9,381,344 shares were issued and outstanding as of September 30, 2026 and December 31, 2025, respectively.

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 of Directors, if any. As of September 30, 2026 and December 31, 2025, no dividends were declared.

Redeemable Convertible Preferred Stock

Prior to the Merger Agreement in April 2025, Legacy Tvardi had issued Series A preferred stock and Series B preferred stock (the Preferred Stock) and classified the Preferred Stock as temporary equity since the shares had redemption features that were not entirely within the control of Legacy Tvardi. Upon the closing of the Merger in April 2025, Legacy Tvardi's Preferred Stock converted into 3,963,910 shares of the Company's common stock. As a result, there was no Preferred Stock remaining as of September 30, 2026 and December 31, 2025.

Shelf Registration and ATM Facility

On May 1, 2026, the Company filed a shelf registration statement on Form S-3 (the Registration Statement) which permits the offering, issuance and sale of common stock, preferred stock, debt securities and warrants having an aggregate offering price of up to $200.0 million in one or more offerings and in any combination of the foregoing. The Registration Statement contains two prospectuses, a base prospectus and an at-the-market offering prospectus (the Original Sales Agreement Prospectus) that covered the offering, issuance and sale of up to $12.5 million of common stock pursuant to a Capital on Demand Sales Agreement (the Sales Agreement), dated as of May 1, 2026 by and between

the Company and JonesTrading Institutional Services LLC acting as sales agent (the ATM Facility). The Registration Statement was declared effective by the SEC on May 12, 2026.

On July 17, 2026, the Company filed a new sales agreement prospectus supplement (New Sales Agreement Prospectus Supplement) included in the Registration Statement. The New Sales Agreement Prospectus Supplement authorizes the offering, issuance and sale of up to approximately $9.7 million of common stock, in addition to any amounts previously sold by the Company.

The Company is subject to General Instruction I.B.6 of Form S-3 which limits the amount that the Company may sell under the Registration Statement of which the New Sales Agreement Prospectus Supplement forms a part. During the three months ended September 30, 2026, the Company sold an aggregate of 3,110,769 shares of common stock for aggregate gross proceeds of approximately $11.0 million under the Original Sales Agreement Prospectus. No additional common stock will be sold under the Original Sales Agreement Prospectus following the date of the New Sales Agreement Prospectus Supplement.

Following the effectiveness of the New Sales Agreement Prospectus Supplement, the Company sold an additional aggregate of 853,843 shares of common stock for aggregate gross proceeds of approximately $2.3 million during the three months ended September 30, 2026.

Through the sales under both the Original Sales Agreement Prospectus and New Sales Agreement Prospectus Supplement, the Company recorded total commissions and offering expenses of $0.5 million during the three months ended September 30, 2026.

As of September 30, 2026, approximately $7.4 million remained available for future sales under the New Sales Agreement Prospectus Supplement.

9. 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 the Company'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 Equity Incentive Plan (the 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. On January 1, 2026, the aggregate number of shares of common stock that may be issued pursuant to the 2025 Plan increased from 935,554 to 1,465,233, as approved by the Board of Directors.

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 or 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, 2026, the Company had 649,650 shares remaining available for grant under the 2025 Plan.

2025 Employee Stock Purchase Plan

The Company's 2025 Employee Stock Purchase Plan (the 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, 2026. On January 1, 2026, the aggregate number of shares of common stock that may be issued pursuant to the 2025 ESPP automatically increased from 93,555 to 199,490.

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 the assumptions used in the Black-Scholes option-pricing model to determine the fair value of stock options granted. For options granted during the three and nine months ended September 30, 2026 and 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,	
	2026	2025	2026	2025
Per share fair value of common stock	n/a	$ 36.32	$ 3.79	$ 17.14
Expected volatility	n/a	67.72 %	67.6 - 70.5 %	67.72 - 68.86 %
Expected dividends	n/a	— %	— %	— %
Expected term (in years)	n/a	6.25	5.50 - 6.25	5.50 - 6.25
Risk-free rate	n/a	3.8 %	3.8 - 4.3 %	3.8 - 4.0 %

Stock Options

The Company granted 325,750 stock options during the nine months ended September 30, 2026, with no grant activity in the third quarter of 2026. The Company granted 2,000 stock options and 399,940 stock options during the three and nine months ended September 30, 2025, respectively.

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, 2026 was $2.51. 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. Forfeitures of stock options are recorded as incurred.

The following table summarizes option activity during the nine months ended September 30, 2026:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (In Years)	Intrinsic Value (In Thousands)
Outstanding as of January 1, 2026	1,212,246	$ 8.68	6.83	$ 1,086
Granted	325,750	3.79		
Forfeited	(670)	6.11		
Outstanding as of September 30, 2026	1,537,326	$ 7.64	6.76	$ 183
Options exercisable as of September 30, 2026	922,617	$ 6.90	5.26	$ 183
Vested and expected to vest as of September 30, 2026	1,537,326	$ 7.64	6.76	$ 183

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. There were no exercises of stock options during the three and nine months ended September 30, 2026. 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 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,	
	2026	2025	2026	2025
Research and development	$ 103	$ 79	$ 288	$ 255
General and administrative	283	260	803	791
Total stock-based compensation	$ 386	$ 339	$ 1,091	$ 1,046

As of September 30, 2026, there was $3.3 million of total unrecognized compensation cost related to unvested stock options, which is expected to be recognized over a weighted-average period of 2.53 years.

10. Income Taxes

For the three and nine months ended September 30, 2026 and 2025, 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, 2026, 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.

11. 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,	
	2026	2025	2026	2025
Numerator:				
Net loss for basic net loss per share attributable to common stockholders	$ (6,124)	$ (5,527)	$ (19,385)	$ (10,939)
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	$ (6,124)	$ (5,527)	$ (19,385)	$ (18,098)
Denominator:				
Weighted-average common shares outstanding, basic	12,653,836	9,377,079	10,484,162	6,757,955
Effect of potentially dilutive securities:				
Convertible Notes	—	—	—	486,830
Weighted-average common shares outstanding, diluted	12,653,836	9,377,079	10,484,162	7,244,785
Net loss per share attributable to common stockholders:				
Basic	$ (0.48)	$ (0.59)	$ (1.85)	$ (1.62)
Diluted	$ (0.48)	$ (0.59)	$ (1.85)	$ (2.50)

[1] In December 2024, Legacy Tvardi entered into a note purchase agreement to issue and sell convertible notes (the Convertible Notes). Under the fair value option, which the Company elected to account for its Convertible Notes, any change in fair value of the Convertible Notes was recorded to the Company's condensed consolidated statements of operations and comprehensive loss as a gain or loss from a fair value measurement. When calculating the diluted net loss per share for the prior year-to-date period, 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 was 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 statements of operations and comprehensive loss during the nine months ended September 30, 2025 was added back as an adjustment to the numerator.

Upon the closing of the Merger in April 2025, the Convertible Notes converted into 1,265,757 shares of the Company's common stock, $0.001 par value per share, in the aggregate. As a result, there were no Convertible Notes outstanding as of September 30, 2026 and December 31, 2025.

For the three and nine months ended September 30, 2026, and the three months ended September 30, 2025, the Company's potentially dilutive securities include its stock options to purchase common stock. All of the Company's potentially dilutive securities have been excluded from the computation of diluted net loss per share for the three and nine months ended September 30, 2026, as well as the three months ended September 30, 2025, as the effects 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 and nine months ended September 30, 2026, as well as the three months ended September 30, 2025, is the same. For the nine months ended September 30, 2025, the Company's potentially dilutive securities included its stock options to purchase common stock, Preferred Stock, and Convertible Notes. The Company's Convertible Notes had been included in the computation of diluted net loss per share for the nine months ended September 30, 2025 as the effect 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 calculation as the effect was determined to be anti-dilutive.

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,	
	2026	2025	2026	2025
Stock options to purchase common stock	1,537,326	1,108,758	1,537,326	1,108,758

12. 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, 2026, and December 31, 2025, the Company was not a party to any material legal proceedings or claims.

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 of Directors 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, 2026 and December 31, 2025.

Other Commitments

In addition to the Company's obligation to make potential royalty payments under the BCM First Agreement (as discussed and defined in Note 13, *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 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 a 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.

13. 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 BCM Second 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. In April 2026, the Company terminated the BCM Second Agreement in its entirety, effective immediately. The Company determined that this termination was not material because the Company has not been and will not be pursuing development in conditions like anaphylaxis.

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 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, 2026, the Company accrued $37,500 in annual maintenance fees under the BCM First Agreement. As of December 31, 2025, the full amount of $50,000 in annual maintenance fees had already been paid under the BCM First Agreement and thus no accrual was needed. No payments for maintenance or milestone fees were made during the three and nine months ended September 30, 2026. 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.

14. 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 Chief Executive Officer and Chief Financial Officer collectively serve as its Chief Operating Decision Maker (CODM) and manage the Company’s operations at a 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 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,	
	2026	2025	2026	2025
Direct research and development expenses by program:				
TTI-101:				
HCC	$ 2,430	$ 597	$ 4,248	$ 2,001
IPF	(307)	—	(170)	3,863
mBC	—	—	(5)	(268)
Preclinical, CMC, and other (unallocated) [1]	160	112	352	427
TTI-109	1,016	1,991	5,280	3,171
Unallocated research and development expense:				
Personnel costs	931	741	2,861	2,516
Consultant fees and other costs [2]	244	162	821	810
General and administrative expense:				
Personnel costs	955	1,012	2,820	2,659
Other general and administrative expenses [3]	899	1,323	3,801	3,982
Interest income	(204)	(411)	(623)	(1,063)
Other income, net	—	—	—	(7,159)
Net loss	$ (6,124)	$ (5,527)	$ (19,385)	$ (10,939)

(1) Preclinical, chemistry, manufacturing and control (CMC), and other (unallocated) costs include preclinical 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. The Company does not have intra-entity sales or transfers.

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

You should read the following discussion of our financial condition and results of operations in conjunction with our 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. Our 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.

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 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

We are a clinical-stage biopharmaceutical company focused on the development of novel, oral, small molecule therapies targeting Signal Transducer and Activator of Transcription 3 (STAT3) to treat inflammatory and proliferative diseases with significant unmet need. Based upon our founders' seminal work and deep understanding of the transcription factor STAT3, we have designed an innovative approach to directly inhibit STAT3, a highly validated, yet historically undruggable target. Leveraging this expertise, we are developing a pipeline of STAT3 inhibitors with a differentiated mechanism of action and convenient oral dosing.

Our pipeline includes two oral, small molecule STAT3 inhibitors: TTI-101 and TTI-109. TTI-101 is our first-generation direct STAT3 inhibitor, currently in Phase 1b/2 clinical development in hepatocellular carcinoma (HCC). We expect to report topline data of TTI-101 across the three cohorts of the REVERT LIVER CANCER Phase 1b/2 clinical trial in patients with HCC early in the first quarter of 2027 to allow for complete cohort evaluation. TTI-109 is a phosphate prodrug of TTI-101 that is mechanistically identical to its parent molecule but is designed to enhance systemic drug delivery and improve tolerability. We submitted an Investigational New Drug (IND) application for TTI-109 in June 2025 and, following U.S. Food and Drug Administration (FDA) acceptance, initiated a Phase 1 trial in healthy volunteers evaluating safety, tolerability, pharmacokinetics and bioequivalence to TTI-101.

In July 2026, we announced Phase 1 results for TTI-109, our next-generation STAT3 inhibitor. TTI-109 is a phosphate prodrug of TTI-101 designed to improve delivery and tolerability while preserving the parent compound's mechanism of action. The study confirmed rapid prodrug conversion, dose-proportional pharmacokinetics with exposures above the STAT3 IC_{50} and, in an exploratory pharmacodynamic analysis, reductions of up to 60% in STAT3-driven immune cell populations across Th17, Tfh and B cell subsets.

Key findings included:

- Confirmed prodrug conversion and exposure equivalence: Validating its prodrug design, TTI-109 rapidly converted to TTI-101 within two hours and produced nearly identical plasma levels at molar-equivalent doses.
- Sustained target-level exposure: 21-day repeat dosing showed stable, dose-proportional pharmacokinetics, with TTI-101 concentrations above the STAT3 IC_{50}.
- Evidence of target engagement: Pharmacodynamic data showed reductions of up to 60% across disease-relevant STAT3-driven immune cell populations including Th17 cells, Tfh and B cell subsets.

- Improved tolerability vs. TTI-101: Compared with placebo, diarrhea events with TTI-109 were similar in duration, transient and resolved without treatment interruption. Compared with TTI-101 at near-equivalent doses, diarrhea events with TTI-109 were substantially shorter in duration (0.46 vs. 3.35 days).

We have identified dermatologic and gastrointestinal therapeutic areas with shared STAT3-driven disease biology, specifically the convergence of cytokines, growth factors and Th17 and B cell immune pathways at the STAT3 node. TTI-109 is designed to address both the cellular and humoral components of inflammation and proliferation with a single oral agent. Recent programs in related STAT3-driven indications have validated the underlying biology, but each acts on a single upstream target, while TTI-109 targets STAT3, the downstream node where these pathways converge.

STAT3 sits at the center of the core disease processes in dermatologic and gastrointestinal diseases, including inflammation, proliferation and cellular and humoral dysregulation. Our STAT3 inhibitors have demonstrated biologic activity in these pathways in both preclinical models and in the clinic. In preclinical disease models, our STAT3 inhibitors reduced inflammatory cascades, fibrosis and modulated immune activity. Similarly, in humans, TTI-101 reduced activated STAT3 levels, inflammatory cascades and fibrosis. The TTI-109 healthy volunteer study extended this translational profile, with reductions in STAT3-driven immune cell populations.

Later in July 2026, we announced that we had selected UC as the initial disease indication for TTI-109. Our decision follows our successful Phase 1 healthy volunteer study, in which TTI-109 successfully modulated multiple STAT3-driven immune cell populations, including Th17, Tfh and B cells. These same cell types are known to expand with UC disease severity and infiltrate the inflamed colon.

Further analysis of immune cell populations across the active dose range elucidated:

- Broad suppression of pathogenic Th17-associated immune populations, including up to 76% reduction in subsets associated with mucosal destruction and treatment-refractory UC

- The Tfh immune populations that drive mucosal B cell responses were reduced up to 43% in Tfh subsets associated with disease UC activity

- Suppression extended to B cell (humoral) immunity, including up to 71% decline in subsets associated with colonic inflammation

STAT3 sits at the center of the three interconnected processes that drive UC: immune dysregulation, chronic inflammation and the tissue remodeling that leads to fibrosis, positioning it as a single, convergent therapeutic target for a disease with multiple underlying drivers. These findings are further supported by published clinical studies linking reductions in activated STAT3 with higher rates of clinical remission across multiple UC therapeutic classes.

UC is a large and underserved market. More than 1.25 million patients are diagnosed with UC in the United States, representing an addressable market of approximately $3 billion in the U.S. and $9 billion globally. Currently approved therapies, including anti-TNF, anti-integrin, anti-IL-12/23, S1P and JAK inhibitors, achieve placebo-adjusted clinical remission rates below 30%, and most are administered parenterally. Additionally, JAK inhibitors carry a black box warning for major adverse cardiovascular events, mortality, thrombosis, serious infections and malignancy.

By contrast, TTI-109, an oral small molecule, is designed to inhibit STAT3 directly, addressing the inflammation, immune dysregulation and proliferation that single-pathway therapies leave unresolved. Across more than 400 subjects dosed to date with our STAT3 inhibitors demonstrated a differentiated safety profile from JAK inhibitors. TTI-109 is administered orally without a loading dose, and in preclinical models of UC, the active moiety, TTI-101, achieved more than eight-fold greater drug concentration in target tissue relative to plasma.

Our ability to initiate these programs is subject to clearance of an IND application and the availability of additional funding.

Since commencing operations in 2017, we have devoted substantially all of our efforts and financial resources to developing our product candidates, organizing and staffing our company, business planning, raising capital, establishing our intellectual property portfolio and performing research and development of our product candidates, signaling and

biology, medicinal chemistry and clinical insights to discover and develop novel therapies for the treatment of inflammatory and proliferative diseases driven by dysregulated STAT3 signaling. Through the date of this filing, we have historically financed our operations principally through the issuance and sale of our preferred stock and convertible debt. We received $28.3 million from the sale and issuance of our convertible promissory notes (Convertible Notes) in December 2024, which were converted into common stock in April 2025, and $83.4 million from the issuance and sale of our preferred stock and historical convertible debt, which was converted into preferred stock, in 2018 and 2021. We acquired approximately $23.9 million of net assets in connection with our Merger with Cara in April 2025. We received gross proceeds of approximately $13.3 million in connection with sales of common stock in at the market transactions under our Original Sales Agreement Prospectus and New Sales Agreement Prospectus Supplement. Additional information regarding the Merger is included in Note 1, *Nature of the Business and Basis of Presentation*, of the Notes to Condensed Consolidated Financial Statements included elsewhere in this Quarterly Report. Additional information regarding the recent issuance of common stock under our at-the-market sales agreement is included in Note 8, *Stockholders' Equity (Deficit)*, of the Notes to Condensed Consolidated Financial Statements included elsewhere in this Quarterly Report and in the subsection titled "— *Liquidity and Capital Resources*" below.

As of September 30, 2026, we had $22.3 million in cash and cash equivalents. We have incurred net losses since inception. As of September 30, 2026 and December 31, 2025, our accumulated deficit was $129.8 million and $110.5 million, respectively. For the three and nine months ended September 30, 2026, we reported net losses of $6.1 million and $19.4 million, respectively. For the three and nine months ended September 30, 2025, we reported net losses of $5.5 million and $10.9 million, respectively. Our net loss may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical development activities and other research and development activities. We expect to continue to incur significant operating losses for the foreseeable future and may never become profitable. Losses are expected to continue as we continue to invest in research and development activities. We evaluated whether there were conditions and events, considered in the aggregate, 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 our ability to continue as a going concern. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our capital resources sooner than we expect. See the subsection titled "— *Liquidity and Capital Resources*" below for further discussion.

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

We expect that our expense and capital requirements will increase substantially in connection with our ongoing activities and for the foreseeable future, particularly if we, among other things:

- advance TTI-101, TTI-109 and our other product candidates through clinical development and, if successful, later-stage clinical trials;
- discover and develop additional product candidates;
- advance our preclinical development programs into clinical development;
- experience delays or interruptions to preclinical studies, clinical trials, receipt of services from our third-party service providers on whom we rely, or our supply chain;
- seek and maintain regulatory approvals for any product candidates that successfully complete clinical trials;
- commercialize TTI-101, TTI-109, our other product candidates and any future product candidates, if approved;
- hire additional clinical development, quality control, scientific and management personnel;
- expand our operational, financial and management systems and increase personnel, including personnel to support our clinical development and manufacturing efforts and operations as a public company;
- establish a sales, marketing, medical affairs and distribution infrastructure to commercialize any products for which we may obtain marketing approval and intend to commercialize on our own or jointly with third parties;

- maintain, expand and protect our intellectual property portfolio;
- invest in or in-license other technologies or product candidates;
- continue to build out our organization to engage in such activities; and
- incur additional legal, accounting, investor relations and other general and administrative expenses associated with operating as a public company.

Given our stage of development, to date we have not had any products approved for sale and have not generated any revenue. We do not expect to generate any revenues from product sales unless and until we successfully complete development and obtain regulatory approval for one or more of our product candidates, which may not be for several years, if ever. If we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. As a result, until such time, if ever, that we can generate substantial product revenue, we expect to finance our cash needs through equity offerings, debt financings or other capital sources, including collaborations, licenses or similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed or on favorable terms, if at all. If we do raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants or other restrictions limiting our 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 our financial condition and on our ability to pursue our business plans and strategies, including our research and development activities. If we are unable to raise capital, we will need to delay, reduce or terminate planned activities, including our ongoing and planned clinical trials, to reduce costs.

Additionally, we are 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 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. Our 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, our business has not been materially impacted by these global economic and geopolitical conditions, it is impossible to predict the extent to which our operations will be impacted in the short and long term, or the ways in which such instability could impact our 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.

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 us in connection with the transfer of all or substantially all of the assets and businesses to which the 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, we obtained exclusive, worldwide, sublicensable 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, we are 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 such patents and patent applications or technologies (respectively, the BCM1 Licensed Products and BCM2 Licensed Products) in all fields of use. In April 2026, we terminated the BCM Second Agreement in its entirety, effective immediately.

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, we 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 we refer to as the BCM Patent Rights, together with certain cell lines, biological materials, compounds, know-how and technologies, which we collectively refer 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 us, we became responsible for the payment of annual maintenance fees on the anniversary of the agreement, which range from $30,000 to $50,000. We are 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. We currently expect the BCM Patent Rights to expire April 18, 2039. Upon the initiation of the Phase 2 clinical trials for two BCM1 Licensed Products, we paid BCM development milestone payments of $250,000 in the aggregate. Upon the achievement of additional specified development and regulatory milestones, we are 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, we would expect to incur approximately $400,000 of oncology-related costs and approximately $300,000 of non-oncology-related costs. We are additionally required to pay BCM a tiered low double-digit percentage of sublicensing revenue obtained in connection with any sublicense granted by us under the BCM Patent Rights or BCM Technology.

We may terminate the BCM First Agreement at our convenience following a specified notice period upon advance written notice to BCM. The BCM First Agreement may also be terminated by BCM for our default or failure to perform any of the terms of the BCM First Agreement, following a specified notice and cure period. Additionally, BCM may terminate the BCM First Agreement if we undergo 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 us 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 BCM Technology covered by the license for immaterial consideration. The BCM First Agreement was further amended in August 2019 to amend our diligence and insurance obligations as well as to further update the schedule of BCM Patent Rights.

Under the BCM First Agreement, we accrued $37,500 in annual maintenance fees as of September 30, 2026. As of December 31, 2025, the full amount of $50,000 in annual maintenance fees had already been paid under the BCM First Agreement and thus no accrual was needed. No payments for maintenance or milestone fees were made during the three and nine months ended September 30, 2026. 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, we 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 we refer 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.

In April 2026, we terminated the BCM Second Agreement in its entirety, effective immediately. 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 us, we became responsible for the payment of maintenance fees on the anniversary of the agreement, which range from $30,000 to $50,000. We were 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. Upon the achievement of additional specified development and regulatory milestones, we were 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. We were additionally required to pay BCM a tiered low double-digit percentage of sublicensing revenue obtained in connection with any sublicense granted by us under the Licensed Patent Rights.

The BCM Second Agreement was amended in June 2019 to amend our diligence and insurance obligations. We entered into a second amendment in April 2023 to further amend our 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, 2026 and 2025. No royalty fees have been incurred to date.

Components of Operating Results

Revenue

We have not generated any revenue since our inception and we do not expect to generate any revenue from the sale of products in the near future, if at all. If our development efforts for TTI-101, TTI-109 or additional product candidates that we may develop in the future are successful and result in marketing approval, or if we enter into collaboration or license agreements with third parties, we may generate revenue in the future from a combination of product sales or payments from such collaboration or license agreements.

Operating Expenses

Our operating expenses have consisted primarily of research and development expenses and general and administrative costs.

Research and Development Expenses

Our 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 our 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 include 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 our internal policies, including our clinical trial accrual policy, we expense 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 us by our 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 our condensed consolidated financial statements as prepaid or accrued research and development expenses.

During the three months ended September 30, 2026, the majority of our clinical spending was on TTI-101, primarily for the HCC trial. The majority of our clinical spending during the nine months ended September 30, 2026 was on TTI-109, which included costs related to the second arm of the healthy volunteer study, chemistry, manufacturing and control (CMC) costs related to clinical supply, and preclinical studies. Costs for TTI-101 were also incurred for the HCC trial during the nine months ended September 30, 2026. The majority of our clinical spending during the three and nine months ended September 30, 2025 was on TTI-101, for which certain direct research and development costs were tracked by clinical trial. Costs incurred for TTI-109 during the three and nine months ended September 30, 2025 were related to CMC costs as well as clinical operations.

We expect our research and development expenses to increase substantially for the foreseeable future as we continue to invest in the development of TTI-101 and TTI-109, support our ongoing preclinical programs and discover any new product candidates, as well as increase our 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 our clinical activities, which are managed by our CROs, and Contract Development and Manufacturing Organizations (CDMOs), to manufacture materials for our product candidates and future commercial products, are much more costly as compared to early-stage preclinical development. We cannot determine with certainty the timing of initiation, the duration or the completion costs of current or future preclinical studies and clinical trials of our 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. We anticipate that we 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 our ongoing assessments as to each therapeutic candidate's commercial potential. We will need substantial additional capital in the future to support these efforts. In addition, we 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 our development plans and capital requirements.

At this time, we 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 our product candidates. We are also unable to predict when, if ever, material net cash inflows will commence from sales or licensing of our product candidates. This is due to the numerous risks and uncertainties associated with drug development, including:

- negative or inconclusive results from our preclinical studies or clinical trials or the clinical trials of others for product candidates similar to ours, 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 our clinical trials or by individuals using drugs or therapeutics similar to our product candidates;
- poor efficacy of our 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 our 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 our 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 our 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 our 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 our 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 us to conduct clinical trials beyond those that we anticipate would be required for the completion of clinical development of a product candidate or potential future product candidate, or if we experience significant delays in our clinical trials due to slower than expected patient enrollment or other reasons, we would be required to expend significant additional financial resources and time on the completion of clinical development. We may never obtain regulatory approval for any of our product candidates, and, even if we do, drug commercialization takes several years and millions of dollars in development costs.

General and Administrative Expenses

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

We expect our G&A expenses to increase over the next several years as we continue our research and development activities, prepare for potential commercialization of our current and future product candidates, as well as expand our operations and continue 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 Securities and Exchange Commission (SEC) requirements, director and officer insurance premiums and investor relations costs associated with being a public company.

Interest Income

Interest income for the three months ended September 30, 2026 consisted of interest earned on our cash and cash equivalents. Interest income for the nine months ended September 30, 2026 and the three and nine months ended September 30, 2025 consisted of interest earned on our cash and cash equivalents as well as interest earned on short-term investments and the accretion of the discount of our short-term investments.

Other Income, Net

Other income, net consisted of the net changes in fair value of our Convertible Notes, for which we elected the fair value option, as well as interest accrued on the Convertible Notes. The Convertible Notes converted into our common stock upon the closing of the Merger in April 2025. As a result, there were no Convertible Notes outstanding during the three and nine months ended September 30, 2026. See Note 11, *Net Loss Per Share*, included in the Notes to Condensed Consolidated Financial Statements, included elsewhere within this Quarterly Report for further discussion of our Convertible Notes.

Income Taxes

For the three and nine months ended September 30, 2026 and 2025, there was no current or deferred income tax expense or benefit due to our current year losses and full valuation allowance. As of September 30, 2026, we evaluated all available evidence and concluded that a valuation allowance was still required against our net deferred tax assets because it is more likely than not they will not be realized in the foreseeable future. As a result, our effective tax rate for each of the periods presented differs from the U.S. federal statutory rate primarily due to recurring operating losses and the full valuation allowance against deferred tax assets.

Results of Operations

Comparison of the Three and Nine Months Ended September 30, 2026 and 2025

The following table sets forth our results of operations for the three and nine months ended September 30, 2026 and 2025 (in thousands, except percentages):

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2026	2025	Amount	Percent	2026	2025	Amount	Percent
Operating expenses:								
Research and development	$ 4,474	$ 3,603	$ 871	24.2 %	$ 13,387	$ 12,520	$ 867	6.9 %
General and administrative	1,854	2,335	(481)	(20.6)%	6,621	6,641	(20)	(0.3)%
Total operating expenses	6,328	5,938	390	6.6 %	20,008	19,161	847	4.4 %
Loss from operations	(6,328)	(5,938)	(390)	6.6 %	(20,008)	(19,161)	(847)	4.4 %
Interest income	204	411	(207)	(50.4)%	623	1,063	(440)	(41.4)%
Other income, net	—	—	—	n/a	—	7,159	(7,159)	(100.0)%
Net loss	$ (6,124)	$ (5,527)	$ (597)	10.8 %	$ (19,385)	$ (10,939)	$ (8,446)	77.2 %

Research and Development Expenses

Research and development expenses for the three and nine months ended September 30, 2026 and 2025 were comprised of the following (in thousands, except percentages):

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2026	2025	Amount	Percent	2026	2025	Amount	Percent
Direct research and development expenses by program:								
TTI-101:								
HCC	$ 2,430	$ 597	$ 1,833	307.0 %	$ 4,248	$ 2,001	$ 2,247	112.3 %
IPF	(307)	—	(307)	n/a	(170)	3,863	(4,033)	(104.4)%
mBC	—	—	—	— %	(5)	(268)	263	(98.1)%
Pre-clinical, CMC, and other (unallocated)	160	112	48	42.9 %	352	427	(75)	(17.6)%
TTI-109	1,016	1,991	(975)	(49.0)%	5,280	3,171	2,109	66.5 %
Unallocated research and development expense:								
Personnel costs (including stock-based compensation)	931	741	190	25.6 %	2,861	2,516	345	13.7 %
Consultant fees and other costs	244	162	82	50.6 %	821	810	11	1.4 %
Total research and development expenses	$ 4,474	$ 3,603	$ 871	24.2 %	$ 13,387	$ 12,520	$ 867	6.9 %

Research and development expenses were $4.5 million for the three months ended September 30, 2026, compared to $3.6 million for the three months ended September 30, 2025. The increase of $0.9 million was primarily driven by a net increase in costs associated with our product candidate TTI-101, which included an increase of $1.8 million related to our HCC trial, partially offset by a decrease of $1.0 million in costs related to our product candidate TTI-109, which included costs associated with the second arm of the healthy volunteer study, CMC costs related to clinical supply, and preclinical studies. The increase in costs related to our HCC trial was primarily related to changes in total trial costs resulting from trial scope changes. The decrease in costs related to our product candidate TTI-109 in the three months ended September 30, 2026 was primarily related to higher costs incurred in the third quarter of 2025 when the healthy volunteer study was initiated.

Research and development expenses were $13.4 million for the nine months ended September 30, 2026, compared to $12.5 million for the nine months ended September 30, 2025. The increase of $0.9 million was primarily driven by an increase of $2.1 million in costs related to our product candidate TTI-109, which included costs associated with the second arm of the healthy volunteer study, CMC costs related to clinical supply, and preclinical studies, partially offset by a net decrease in costs associated with our product candidate TTI-101. The net decrease in costs related to our product candidate TTI-101 was primarily related to a decrease of $4.0 million in costs related to our IPF trial, partially offset by an increase of $2.2 million in costs related to our HCC trial. We incurred $3.9 million in costs related to our IPF trial during the nine months ended September 30, 2025 as we were still enrolling patients in this trial. Costs decreased substantially during the nine months ended September 30, 2026 given all patients had been enrolled prior to the current period and a true-up of total expected study costs occurred in the third quarter of 2026. The increase in costs related to our HCC trial was primarily due to changes in total trial costs resulting from trial scope changes.

The increase in personnel costs of $0.3 million for the year-to-date period was primarily related to an increase in stock-based compensation expense related to additional stock options granted in the fourth quarter of 2025 and in 2026.

General and Administrative Expenses

G&A expenses for the three and nine months ended September 30, 2026 and 2025 were comprised of the following (in thousands, except percentages):

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2026	2025	Amount	Percent	2026	2025	Amount	Percent
Personnel costs	$ 955	$ 1,012	$ (57)	(5.6)%	$ 2,820	$ 2,659	$ 161	6.1 %
Professional fees	478	1,001	(523)	(52.2)%	2,724	3,131	(407)	(13.0)%
Insurance costs	173	177	(4)	(2.3)%	513	342	171	50.0 %
Other costs	248	145	103	71.0 %	564	509	55	10.8 %
Total general and administrative expenses	$ 1,854	$ 2,335	$ (481)	(20.6)%	$ 6,621	$ 6,641	$ (20)	(0.3)%

G&A expenses were $1.9 million for the three months ended September 30, 2026, compared to $2.3 million for the three months ended September 30, 2025. The decrease of approximately $0.5 million was primarily driven by a decrease in professional fees. The decrease in professional fees was primarily attributable to higher accounting and legal fees during the three months ended September 30, 2025 due to the Merger in April 2025 and ongoing support following the Merger.

G&A expenses were $6.6 million for the nine months ended September 30, 2026, which was relatively consistent with the nine months ended September 30, 2025. The minimal decrease was primarily driven by a decrease in professional fees, partially offset by increases in personnel costs of $0.2 million and insurance costs of $0.2 million. The decrease in professional fees was primarily due to higher accounting, consulting and legal fees during the nine months ended September 30, 2025 due to the Merger in April 2025 and ongoing support following the Merger, partially offset by an increase in investor relations fees. The increase in personnel costs was primarily attributable to increases in stock-based compensation related to additional stock options granted in the fourth quarter of 2025 and in 2026 and additional headcount. The increase in insurance costs was primarily attributable to higher director and officer insurance premiums.

Interest Income

Interest income was $0.2 million for the three months ended September 30, 2026, compared to $0.4 million for the three months ended September 30, 2025. The $0.2 million of interest income for the three months ended September 30, 2026 includes interest earned on our cash and cash equivalents. The $0.4 million of interest income for the three months ended September 30, 2025 included $0.3 million of interest earned on our cash and cash equivalents and $0.1 million of interest from our short-term investments, as well as the accretion of the discount on our short-term investments.

Interest income was $0.6 million for the nine months ended September 30, 2026, compared to $1.1 million for the nine months ended September 30, 2025. The $0.6 million of interest income for the nine months ended September 30, 2026 includes $0.5 million of interest earned on our cash and cash equivalents and $0.1 million of interest from our short-term investments, as well as the accretion of the discount on our short-term investments. The $1.1 million of interest income for the nine months ended September 30, 2025 included $0.6 million of interest earned on our cash and cash equivalents and $0.5 million of interest from our short-term investments, as well as the accretion of the discount on our short-term investments.

Other Income, Net

For the three and nine months ended September 30, 2026, there was no other income, net recorded within the condensed consolidated statements of operations and comprehensive loss, as our Convertible Notes were fully converted during the second quarter of 2025, and there was no remeasurement gain or loss recorded for the three and nine months ended September 30, 2026.

For the three months ended September 30, 2025, there was no other income, net recorded within the condensed consolidated statements of operations and comprehensive loss, as our 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. For the nine months ended September 30, 2025, other income, net of $7.2 million was primarily attributable to the $12.8 million remeasurement gain on our Convertible Notes recorded during the three months ended June 30, 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 Note 11, *Net Loss Per Share*, included in the Notes to Condensed Consolidated Financial Statements, included elsewhere within this Quarterly Report for further discussion of our Convertible Notes.

Liquidity and Capital Resources

Sources of Liquidity

Since inception, we have not generated any revenue from product sales or any other sources and have incurred significant operating losses. We have not yet commercialized any products and do not expect to generate revenue from sales of any product candidates for several years, if ever. To date, we have financed our operations primarily through the (i) issuance and sale of our 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, (iii) our Merger with Cara in which we acquired approximately $23.9 million of net assets in April 2025 and (iv) sales under our ATM Facility described below. To date, we have devoted substantially all of our efforts and financial resources to developing our product candidates, organizing and staffing our company, business planning, raising capital, establishing our intellectual property portfolio and performing research and development of our product candidates, signaling and biology, medicinal chemistry and clinical insights to discover and develop novel therapies for the treatment of inflammatory and proliferative diseases driven by dysregulated STAT3 signaling. As of September 30, 2026, we had $22.3 million in cash and cash equivalents.

On May 1, 2026, we filed a shelf registration statement on Form S-3 (the Registration Statement) which permits the offering, issuance and sale of common stock, preferred stock, debt securities and warrants having an aggregate offering price of up to $200.0 million in one or more offerings and in any combination of the foregoing. The Registration Statement contains two prospectuses, a base prospectus and an at-the-market offering prospectus (the Original Sales Agreement Prospectus) that covered the offering, issuance and sale of up to $12.5 million of common stock pursuant to a Capital on Demand Sales Agreement (the Sales Agreement), dated as of May 1, 2026 by and between us and JonesTrading Institutional Services LLC acting as sales agent (the ATM Facility). The Registration Statement was declared effective by the SEC on May 12, 2026.

On July 17, 2026, we filed a new sales agreement prospectus supplement (New Sales Agreement Prospectus Supplement) included in the Registration Statement. The New Sales Agreement Prospectus Supplement authorizes the offering, issuance and sale of up to approximately $9.7 million of common stock, in addition to any amounts previously sold by us.

We are subject to General Instruction I.B.6 of Form S-3 which limits the amounts that we may sell under the Registration Statement of which the New Sales Agreement Prospectus Supplement forms a part. During the three months ended September 30, 2026, we sold an aggregate of 3,110,769 shares of common stock for aggregate gross proceeds of approximately $11.0 million under the Original Sales Agreement Prospectus. No additional common stock will be sold under the Original Sales Agreement Prospectus following the date of the New Sales Agreement Prospectus Supplement.

Following the effectiveness of the New Sales Agreement Prospectus Supplement, we sold an additional aggregate of 853,843 shares of common stock for aggregate gross proceeds of approximately $2.3 million during the three months ended September 30, 2026.

Through the sales under both the Original Sales Agreement Prospectus and New Sales Agreement Prospectus Supplement, we recorded total commissions and offering expenses of $0.5 million during the three months ended September 30, 2026.

As of September 30, 2026, approximately $7.4 million remained available for future sales under the New Sales Agreement Prospectus Supplement.

Funding Requirements

Our primary uses of cash are to fund our operations, which consist primarily of research and development costs related to the development of our product candidates, and, to a lesser extent, G&A costs. We have incurred significant operating losses since our inception, and as of September 30, 2026, had an accumulated deficit of $129.8 million. Management has determined that its present capital resources as of September 30, 2026 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 our ability to continue as a going concern. We plan to seek additional funding through equity offerings, including through our ATM Facility, or debt financings, credit or loan facilities, strategic alliances and licensing arrangements. However, there can be no assurance that such funding will be available to us, will be obtained on terms favorable to us, or will provide us with sufficient funds to meet our objectives.

We anticipate that we will continue to incur significant and potentially increasing expenses for the foreseeable future as we continue to advance our product candidates, expand our corporate infrastructure, including the costs associated with being a public company following the Merger, further our research and development initiatives for our product candidates and incur costs associated with the potential commercialization of our product candidates, if approved. We are 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 our business. We anticipate that we will need substantial additional funding in connection with our continuing operations. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. If we raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants or other restrictions limiting our 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 our financial condition and on our ability to pursue our business plans and strategies. If we are unable to raise capital, we 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, we are unable to estimate the exact amount of our operating capital requirements.

Our 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 our potential future product candidates;
- the clinical development plans we establish for our product candidates;
- the timelines of our 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 our product candidates at clinical and, if approved, commercial scales;
- the number and characteristics of product candidates that we develop;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA and other comparable foreign regulatory authorities;
- whether we are 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 our patent claims and other intellectual property rights, including patent infringement actions brought by third parties against us or our 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 we may receive regulatory approval in regions where we choose to commercialize our products on our own.

A change in the outcome of any of these or other variables with respect to the development of any of our 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 our Annual Report on Form 10-K for the year ended December 31, 2025, as filed with the SEC on March 31, 2026, for additional risks associated with our substantial capital requirements.

Cash Flows

The following table summarizes our cash flows for the periods indicated (in thousands):

	Nine Months Ended September 30,	
	2026	2025
Net cash used in operating activities	$ (21,468)	$ (17,814)
Net cash provided by (used in) investing activities	10,118	(15,084)
Net cash provided by financing activities	12,891	22,702
Net increase (decrease) in cash and cash equivalents	$ 1,541	$ (10,196)

Operating Activities

Net cash used in operating activities was $21.5 million for the nine months ended September 30, 2026, reflecting a net loss of $19.4 million and net changes in operating assets and liabilities of $3.3 million, partially offset by non-cash adjustments of $1.2 million. The net changes in operating assets and liabilities were primarily driven by a $3.0 million decrease in accounts payable and accrued expenses, driven by the timing of invoices and payments, and a $0.1 million increase in prepaid expenses and other current assets, attributable to timing of payments for pre-clinical activities and prepaid insurance. The non-cash adjustments were primarily driven by $1.1 million related to stock-based compensation expense.

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 adjustments of $6.2 million, and changes in operating assets and liabilities of $0.7 million. The non-cash adjustments of $6.2 million were primarily driven by $7.8 million related to the net change in fair value of our Convertible Notes, partially offset by $1.0 million related to stock-based compensation expense and $0.7 million in interest accrued on our 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.

Investing Activities

Net cash provided by investing activities was $10.1 million for the nine months ended September 30, 2026, attributable to maturities of short-term investments of $10.1 million.

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.

Financing Activities

Net cash provided by financing activities was $12.9 million for the nine months ended September 30, 2026, attributable to proceeds of $13.3 million from the sales of our common stock in connection with our ATM Facility, partially offset by commissions and offering expenses of $0.5 million paid in connection with our ATM Facility.

Net cash provided by financing activities was $22.7 million for the nine months ended September 30, 2025, attributable 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.

Contractual Obligations and Commitments

Lease Obligations

We lease space under one operating lease agreement for corporate office space in Sugar Land, Texas, which expires in August 2027. As of September 30, 2026, we had future operating lease liabilities of $0.1 million, of which $0.1 million is included within operating lease liabilities, current portion on our condensed consolidated balance sheet.

License Agreements

As discussed above, we were parties to two license agreements with BCM for exclusive use of patent rights of TTI-101. The BCM Second Agreement was terminated in its entirety in April 2026, and no additional payments remain due or accrued for under such agreement. The BCM First Agreement contains terms for annual maintenance fees, milestone payments and net revenue royalties. Annual maintenance fees range from $30,000 to $50,000 per year. Potential milestone payments are up to $2.2 million in the aggregate for the BCM First Agreement. Milestones include new drug filings, clinical trial stages, and NDA approval by the FDA. We are obligated to pay BCM royalties in the amount of a low single-digit percent of net sales of BCM1 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, (ii) if no BCM Patent Rights are issued in such country, the tenth anniversary of the first commercial sale of the BCM1 Licensed Products in such country. License fees are expensed as incurred within research and development within our condensed consolidated statements of operations and comprehensive loss. Under the BCM First Agreement, we accrued $37,500 in annual maintenance fees as of September 30, 2026. As of December 31, 2025, the full amount of $50,000 in annual maintenance fees had already been paid under the BCM First Agreement and thus no accrual was needed. No payments for maintenance or milestone fees were made during the three and nine months ended September 30, 2026. No royalty fees have been incurred to date.

Other Capital Requirements and Additional Royalty Obligations

We enter 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 our 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 varies and is 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 our obligation to make potential royalty payments under the BCM First Agreement discussed above, pursuant to our founder restricted stock purchase agreements with each of our founders, David J. Tweardy, M.D. and Ron DePinho, M.D., we are 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 a 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

a Royalty Bearing Product in such country. The timing of when our 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 a 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 us or an affiliate by the owner of such patent, with our right or our affiliate's right to grant sublicenses.

Critical Accounting Estimates

Our 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 our unaudited condensed consolidated financial statements. We base our 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. Our actual results may differ from these estimates.

Our significant accounting policies are described in more detail in Note 2 to the consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2025, as filed with the SEC on March 31, 2026.

Recently Issued and Adopted Accounting Pronouncements

We are currently evaluating whether any recently issued accounting pronouncements will have a material effect on our financial position, results of operations or cash flows. Refer to Note 2 of Notes to Condensed Consolidated Financial Statements, *Summary of Significant Accounting Policies*, in this Quarterly Report, for a full description of accounting pronouncements recently adopted, and issued but not yet adopted, if applicable.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

There have been no material changes to our quantitative and qualitative disclosures about market risk from those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2025, as filed with the SEC on March 31, 2026. Accordingly, the information required by this Item is incorporated herein by reference to Item 7A, "Quantitative and Qualitative Disclosures About Market Risk," of our Form 10-K.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain "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 us in the reports that we file or submit 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 our management, including our 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, our management, with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2026. See below "*Material Weaknesses in Internal Control Over Financial Reporting*".

Based on our evaluation, our principal executive officer and principal financial officer have concluded that, as of September 30, 2026, our disclosure controls and procedures were not effective at a reasonable assurance level as a result of material weaknesses that existed in our internal control over financial reporting as described below.

Changes in Internal Control Over Financial Reporting

Other than the ongoing efforts to remediate the material weaknesses as described below, there were no changes in our internal control over financial reporting that occurred during the quarter ended September 30, 2026 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Limitations on Controls and Procedures

Management, including our 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

In connection with the preparation of our consolidated financial statements for the year ended December 31, 2025, material weaknesses were identified in the design and operating effectiveness of our 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.

We did not design or maintain an effective control environment and lacked a sufficient number of professionals to consistently establish appropriate authorities and responsibilities in pursuit of our financial reporting objectives. The lack of sufficient number of finance and accounting professionals contributed to the inadequate design and inability to maintain effective controls over the segregation of duties.

We have further identified material weaknesses in our internal control over financial reporting which relate to: (a) the lack of a formalized risk assessment process; (b) inadequate review of financial statements and disclosures; (c) inadequate review of the prepaid and accrued research and development expenses related to the CRO; and (d) the lack of formal monitoring activities related to the evaluation of internal controls.

Status of Remediation of Material Weaknesses

While we believe that our efforts to date have enhanced our internal control over financial reporting, full remediation of the material weaknesses will require continued focus and commitment. To remediate the material weaknesses, we have begun a formal risk assessment process to identify control gaps and design new procedures and controls to remediate the identified material weaknesses. We are also establishing a monitoring program to evaluate the presence and functioning of internal controls. We have added additional experienced accounting and financial reporting personnel and resources and are 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 we have taken to date, and are continuing to design and implement, may not be sufficient to remediate the material weaknesses we identified or avoid potential future material weaknesses. If the steps we take do not correct these material weaknesses in a timely manner, we will be unable to conclude that we maintain effective internal control over financial reporting. Accordingly, there could continue to be a reasonable possibility that a material misstatement of our consolidated financial statements would not be prevented or detected on a timely basis.

During the fiscal year 2026, 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 consolidated financial statements.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings

On March 6, 2026, Shaheen Wirk, Palkon Holdings, LLC, and Palkon TT Holdings, LLC filed a complaint in the Supreme Court of the State of New York, County of New York, alleging that we breached the Registration Rights Agreement, dated April 15, 2025, by and among us and the investors party thereto (the Registration Rights Agreement) by failing to timely cause a resale registration statement to be declared effective. Such right to an effective resale registration statement had been waived by a majority of the holders of the registrable securities, as defined in the Registration Rights Agreement. On October 7, 2026, the Court granted our motion to dismiss the complaint. On November 6, 2026, plaintiffs filed motion to reargue.

We are, and from time to time may be, subject to legal proceedings and claims arising in the ordinary course of our business. We are not currently a party to, or aware of, any proceedings that we believe will have, individually or in the aggregate, a material adverse effect on our business, financial condition or results of operations. The results of any future legal proceedings or claims cannot be predicted with certainty, and regardless of the outcome, litigation can have an adverse impact on us because of defense and litigation costs, diversion of management resources, and other factors.

Item 1A. Risk Factors

Our business is subject to risks and events that, if they occur, could adversely affect our financial condition and results of operations and growth prospects. In such an event, the market price of our common stock could decline. In addition to 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," you should carefully consider the factors described in Part I, Item 1A. "Risk Factors" of our Annual Report on Form 10-K filed with the SEC on March 31, 2026. We may disclose changes to risk factors or disclose additional risk factors from time to time in our future filings with the SEC. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations and the market price of our common stock.

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

None.

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, 2026, 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

Exhibit No.	Description of Exhibit	Incorporated by Reference			
		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	Certificate of Amendment to Amended and Restated Certificate of Incorporation dated June 7, 2024 (First Authorized Shares Amendment).	8-K	001-36279	3.1	June 7, 2024
3.3	Certificate of Amendment to Amended and Restated Certificate of Incorporation dated December 30, 2024 (First Stock Split Amendment).	8-K	001-36279	3.1	December 30, 2024
3.4	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Cara Therapeutics, Inc., dated April 15, 2025 (Second Stock Split Amendment).	8-K	001-36279	3.1	April 15, 2025
3.5	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Cara Therapeutics, Inc., dated April 15, 2025 (Second Authorized Shares Amendment).	8-K	001-36279	3.2	April 15, 2025
3.6	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
3.7	Amended and Restated Bylaws.	10-Q	001-36279	3.2	November 14, 2024
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, 2026

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

Date: November 13, 2026

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, 2026

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, 2026

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, 2026, 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, 2026

/s/ DAN CONN
Name: Dan Conn
Title: Chief Financial Officer
(Principal Financial Officer)
Date: November 13, 2026

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.