Table of Contents

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

FORM 10-K

(Mark One)

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

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2025

OR

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

COMMISSION FILE NUMBER: 001-36279

TVARDI THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

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

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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, 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	☐
		Smaller Reporting Company	☒
Non-accelerated filer	☒	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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. Yes ☐ No ☒

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). Yes ☐ No ☒

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

The aggregate market value of the registrant's Common Stock (the only common equity of the registrant) held by non-affiliates, based on the closing sales price of the stock on the Nasdaq Stock Market for the last business day of the registrant's most recently completed second fiscal quarter, was $207,163,961. For purposes of this calculation, shares of common stock held by directors and officers and their affiliated entities at June 30, 2025 were excluded. Exclusion of shares held by any person should not be construed to indicate that the person possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the registrant, or that the person is controlled by or under common control with the registrant.

The number of shares outstanding of the registrant's Common Stock, par value $0.001 per share, as of March 26, 2026 was 9,381,344.

Documents Incorporated By Reference

Portions of the registrant's Proxy Statement for its 2026 Annual Meeting of Stockholders, to be filed with the Securities and Exchange Commission no later than 120 days after December 31, 2025, are incorporated by reference in Part III of this Annual Report on Form 10-K.

TVARDI THERAPEUTICS, INC.

2025 ANNUAL REPORT ON FORM 10-K

TABLE OF CONTENTS

EXPLANATORY NOTE

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 (the Closing Date), Cara changed its corporate name to Tvardi Therapeutics, Inc. and Legacy Tvardi's business continued as the business of Tvardi Therapeutics, Inc.

Pursuant to the Merger Agreement, on the Closing Date, (i) Cara effected a 1-for-3 reverse stock split of its common stock (the Reverse Stock Split), (ii) Cara increased its authorized shares of common stock to 150,000,000, (iii) Merger Sub was merged with and into Legacy Tvardi and Legacy Tvardi became a wholly owned subsidiary of Cara, and (iv) Cara changed its name to "Tvardi Therapeutics, Inc".

The consolidated financial statements included in this Annual Report on Form 10-K include historical information of Tvardi Therapeutics, Inc., including as of and for the years ended December 31, 2025 and 2024, unless otherwise indicated or as the context otherwise requires. In addition, except where otherwise indicated or the context otherwise requires, the information in this Annual Report on Form 10-K as of and for the periods prior to the effective time of the Merger gives effect to the Merger.

In this Annual Report on Form 10-K, unless the context otherwise dictates, the terms "we," "us," "Tvardi," the "Company," "our," and other similar terms refer to the business and operations of Legacy Tvardi prior to the Merger with Cara and to Tvardi Therapeutics, Inc. and its consolidated subsidiaries following the Closing Date.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements, within the meaning of the Private Securities Litigation Reform Act of 1995, that involve substantial risks and uncertainties. The forward-looking statements are contained principally in the sections of this Annual Report on Form 10-K titled "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business," but are also contained elsewhere in this Annual Report on Form 10-K. In some cases, you can identify forward-looking statements by the words "aim," "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "objective," "ongoing," "plan," "predict," "project," "potential," "seek," "should," "will," or "would," and or the negative of these terms, or other comparable terminology intended to identify statements about the future. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Annual Report on Form 10-K, we caution you that these statements are based on a combination of facts and factors currently known by us and our expectations of the future, about which we cannot be certain.

The forward-looking statements in this Annual Report on Form 10-K include, among other things, statements about:

- our ability to continue as a going concern;
- our ability to realize the anticipated benefits of the Merger;
- our ability to maintain compliance with Nasdaq listing requirements;
- the expectations surrounding the potential safety, efficacy, and regulatory and clinical progress of our product candidates, including TTI-101 and TTI-109, and anticipated milestones and timing therefor;
- our plans to develop and commercialize our product candidates or any potential future product candidates;
- the potential results of preclinical studies and clinical trials and future regulatory and development milestones for our product candidates or any potential future product candidates;
- the performance of third-party manufacturers, clinical research organizations (CROs), and other vendors;
- the size and growth of the potential markets for our product candidates;
- the rate and degree of market acceptance of any other future approved indications or products;
- our ability to obtain and maintain additional regulatory approval of our product candidates or any future product candidates, and the labeling under any approval we may obtain;
- our ability to maintain existing and establish additional collaborations for our product candidates or future product candidates;
- the continued service of our key scientific or management personnel;
- our ability to establish commercialization and marketing capabilities for any future approved products;
- regulatory developments in the United States and foreign countries;
- our ability to obtain and maintain coverage and adequate reimbursement from third-party payers and governments for any other future approved indications or products;
- our planned use of our cash and cash equivalents and the clinical milestones we expect to fund with such proceeds;
- the accuracy of our estimates regarding expenses, future revenues and capital requirements;

- our ability to obtain funding for our operations;
- our ability to obtain and maintain intellectual property protection for our product candidates or future product candidates and our ability to operate our business without infringing on the intellectual property rights of others;
- our ability to maintain proper and effective internal controls over financial reporting and to remediate and prevent material weaknesses in our internal controls;
- the success of competing drugs that are or may become available; and
- the potential effects of any global health crises, geopolitical tensions and macroeconomic conditions on our business, operations, and clinical development and regulatory timelines and plans.

You should refer to Part I Item 1A. “Risk Factors” of this Annual Report on Form 10-K for a discussion of material factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Annual Report on Form 10-K will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame or at all. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

You should read this Annual Report on Form 10-K and the documents that we reference in this Annual Report on Form 10-K and have filed as exhibits to this Annual Report on Form 10-K completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

RISK FACTORS SUMMARY

The following summarizes the principal factors that make an investment in us speculative or risky, all of which are more fully described below. This summary should be read in conjunction with the entire Risk Factors section included elsewhere in this Annual Report on Form 10-K and should not be relied upon as an exhaustive summary of the material risks facing our business. The occurrence of any of these risks could harm our business, financial condition, results of operations and/or growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this Annual Report on Form 10-K and those we may make from time to time. You should consider all the risk factors described in our public filings when evaluating our business.

- We have a limited operating history, which may make it difficult to evaluate our prospects and likelihood of success.
- We have not generated any revenue to date and may never become or remain profitable.
- Our financial condition raises substantial doubt as to our ability to continue as a going concern.
- We will require substantial additional capital to fund its operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and drug development programs, future commercialization efforts or other operations.
- Our business is highly dependent on the success of our product candidates, TTI-101, TTI-109 and any other product candidates that we advance into the clinic. All of our product candidates will require significant additional preclinical and clinical development before we may be able to seek regulatory approval for and launch a product commercially.
- Preclinical and clinical development involves a lengthy, complex and expensive process, with an uncertain outcome.
- Our ongoing and future clinical trials may reveal significant adverse events or unexpected drug-drug interactions not seen in preclinical studies and may result in a safety profile that could delay or prevent regulatory approval or market acceptance of any of our product candidates.
- Interim, blinded and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available or as additional analyses are conducted and as the data are subject to audit and verification procedures that could result in material changes in the final data.
- Positive results from early preclinical studies and clinical trials of our current or future product candidates are not necessarily predictive of the results of later preclinical studies and clinical trials of our current or future product candidates. If we cannot replicate the positive results from our preclinical studies or early clinical trials of our current or future product candidates in future clinical trials, we may be unable to successfully develop, obtain regulatory approval for and commercialize any current or future product candidates.
- Although we have received U.S. orphan drug designation for TTI-101 for IPF and HCC, we may be unable to obtain and maintain orphan drug designation for our other product candidates and, even if we obtain such designation, we may not be able to realize the benefits of such designation, including potential marketing exclusivity of our product candidates, if approved.
- Although we have received a Fast Track designation from the FDA for TTI-101 for HCC, we may not benefit from a faster development or regulatory review or approval process, and a Fast Track designation does not increase the likelihood that our product candidates will receive marketing approval.
- The regulatory approval process is highly uncertain, and we may be unable to obtain, or may be delayed in obtaining, U.S. or foreign regulatory approval and, as a result, unable to commercialize TTI-101, TTI-109 or any current or future product candidates. Even if we believe our current, or planned, clinical trials are successful, regulatory authorities may not agree that they provide adequate data on safety or efficacy.

- We do not currently own or in-license any composition of matter patent protection for the TTI-101 molecule. As such, we rely solely upon patents related to methods of use, manufacturing and pharmaceutical compositions.
- It is difficult and costly to protect our intellectual property and our proprietary technologies, and we may not be able to ensure their protection.
- We rely on third parties to conduct certain aspects of our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval of or commercialize any potential product candidates.
- Legacy Tvardi identified material weaknesses in its internal control over financial reporting. If we fail to remediate these material weaknesses, or if we experience additional material weaknesses in the future or otherwise fail to maintain effective internal control over financial reporting in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock.
- The market price of our common stock is expected to be volatile.
- We will incur costs and demands upon management as a result of complying with the laws, rules and regulations affecting public companies.
- An active trading market for our common stock may not develop and our stockholders may not be able to resell their shares of common stock for a profit, if at all.
- Future sales of shares by existing stockholders could cause our stock price to decline.
- If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline.

PART I

Item 1. *Business*.

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). TTI-109 is a phosphate prodrug of TTI-101 that is mechanistically identical to its parent molecule but is designed to enhance our ability to target STAT3. We have been developing TTI-109 for several years, based on our recognition that retaining the full STAT3 inhibition mechanism of TTI-101 while enhancing delivery would broaden the potential utility of our platform across inflammatory and proliferative indications. We filed an Investigational New Drug (IND) application for TTI-109 in June 2025 and, following FDA acceptance, initiated a Phase 1 trial in healthy volunteers evaluating safety, tolerability, pharmacokinetics, and bioequivalence to TTI-101. We expect to report topline data from this trial in the second quarter of 2026, after which we intend to announce the clinical indication in which we plan to advance TTI-109.

We are currently enrolling patients in the REVERT LIVER CANCER Phase 1b/2 clinical trial of TTI-101 in patients with HCC. We have extended the timing of the anticipated data readout from the first half of 2026 to the second half of 2026 in order to allow the data to mature. This timing adjustment is intended to enhance the depth of insights from the program, including longitudinal and translational assessments, characterization of durability and dose optimization (including the addition of up to 15 participants in the monotherapy arm to explore modified dosages) to better inform subsequent development and regulatory strategy. The program otherwise continues to progress on schedule, and we believe the data package will strengthen decision-making and future development of our pipeline assets.

In October 2025, we reported preliminary data from our REVERT IPF Phase 2 clinical trial of TTI-101 in idiopathic pulmonary fibrosis (IPF) and concluded that the study did not meet its goals. Subsequently, we conducted additional analyses of a subset of patients who received study drug for 12 weeks. Based on these analyses, which excluded certain patients due to dosing, pharmacokinetic, or clinical factors, treatment with TTI-101 demonstrated greater reductions in certain exploratory measures, including fibrosis and inflammatory markers, compared to placebo. These results are consistent with findings from multiple preclinical models of fibrotic disease and providing human clinical proof of concept for our STAT3 inhibition mechanism. We continue to evaluate these results to inform potential future development decisions.

Our approach is rooted in our expertise around STAT3's functional composition and its critical role in disease pathogenesis, as well as other essential biological functions. Our co-founder, David J. Tweardy, M.D., was one of the first to identify that STAT3, when activated by phosphorylation on tyrosine (Y) residue 705 (pY-STAT3), acts as a central node across multiple inflammatory, proliferative and immune pathways. Intrinsically (within proliferative cells), pY-STAT3 enhances cell proliferation and survival, while extrinsically (within the immune system), pY-STAT3 contributes to immune dysregulation. Collectively, persistent pY-STAT3 drives the development and progression of inflammatory and proliferative diseases characterized by dysregulated STAT3 signaling. By targeting pY-STAT3, our approach is designed to simultaneously modulate key pathways of the inflammatory and proliferative cascade, whereas previous approaches only targeted single pathways. Beyond its role in inflammation and proliferation, STAT3 also has an essential role in cellular respiration in the mitochondria. Dr. Tweardy made the critical discovery that blocking pY-STAT3 could inhibit STAT3's role as a transcription factor without affecting its role in the mitochondria. We have leveraged this discovery to design our product candidates to inhibit STAT3 activation which, we believe, will lead to disease modifying activity without impairing essential biological functions.

We believe our oral small molecule STAT3 inhibitors have the potential for broad applicability across a diverse range of inflammatory and proliferative diseases driven by immune dysregulation, aberrant cytokine signaling, pathologic cellular proliferation, and maladaptive tissue remodeling. Across multiple preclinical models involving hematopoetic, gastrointestinal, dermatologic, respiratory organ specific tissue pathology, inhibition of STAT3 signaling has been associated with reductions in inflammatory burden, proliferation and improvement in disease relevant histological, molecular, and clinical parameters. Importantly, clinical data

from the REVERT IPF trial, including observed reductions in IL-6 and improvements in fibrosis score, is consistent with preclinical observations, which we believe supports the translational validity of our platform.

Our Pipeline

Our current pipeline is depicted below:

The FDA has granted Orphan Drug Designation for TTI-101 in both IPF and HCC as well as Fast-Track Designation for TTI-101 in HCC.

Overview of Inflammatory and Proliferative Diseases and the Role of STAT3

Chronic inflammatory and proliferative diseases are characterized by persistent immune activation, aberrant cellular proliferation, and pathologic tissue remodeling, which together can lead to progressive organ dysfunction and, in severe cases, mortality. Although inflammatory and repair pathways are normally activated as part of a regulated response to tissue injury or infection, sustained or dysregulated signaling can result in maladaptive immune responses, uncontrolled cellular survival and expansion, and excessive deposition of extracellular matrix (ECM) components. These processes contribute to structural damage, impaired organ function, and disease progression across a broad range of conditions affecting hematopoetic, gastrointestinal, dermatologic, respiratory and other organ systems leaving many patients suffering from these disorders without adequate therapeutic options. Diseases driven by dysregulated STAT3 signaling can affect multiple tissues and cell types and are associated with significant morbidity and mortality.

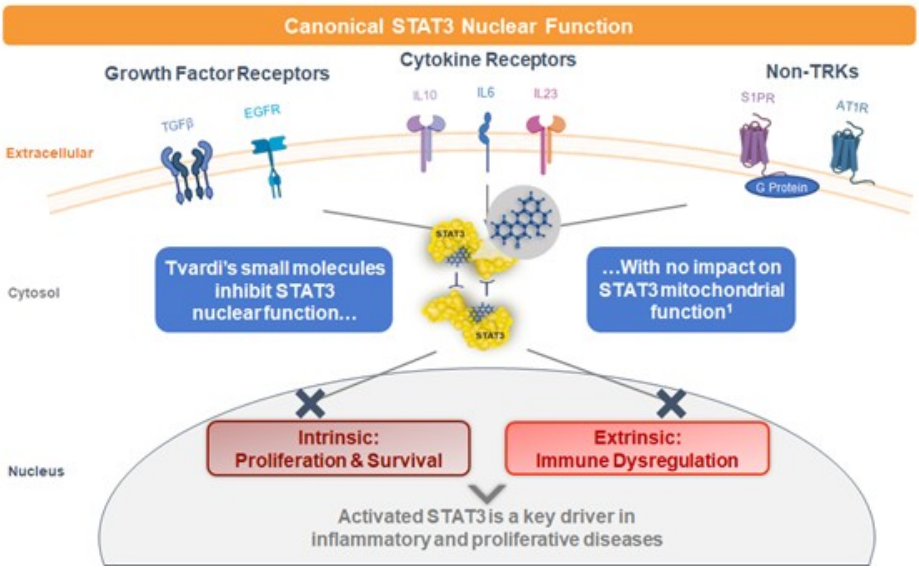
As a central downstream signaling node, activated STAT3 regulates gene expression programs that control cellular proliferation, survival, cytokine production, immune modulation, and tissue remodeling. Persistent activation of STAT3 is believed to be a central mediator to aberrant proliferation, chronic inflammation, and maladaptive remodeling observed in inflammatory and proliferative diseases driven by dysregulated STAT3 signaling.

STAT3's Canonical and Non-Canonical Functions

STAT3 can be activated by a variety of cytokines, growth factors and non-tyrosine receptor kinases (non-TRKs). Activation of STAT3 plays multiple roles in cells, including cell survival and proliferation in response to injury in the canonical pathway and cellular respiration within the mitochondria in the non-canonical pathway. The canonical pathway is the primary STAT3 pathway linking to inflammation and proliferation. In the canonical pathway, STAT3 becomes phosphorylated on tyrosine residue Y705, pY-STAT3, forms a dimer, translocates into the nucleus and activates the transcription of responsive genes. In the non-canonical pathway, STAT3 becomes phosphorylated on serine residue S724, pS-STAT3, and translocates into mitochondria, playing a key role in the essential biological function of cellular respiration.

In the canonical pathway, STAT3 activation can be triggered by an inflammatory reaction to injury and is sustained to repair the wound. Upon achieving homeostasis or recovery, feedback loops inactivate STAT3's response. Persistent STAT3 activation can lead to uncontrolled chronic inflammation and proliferation leading to a variety of chronic, debilitating diseases.

STAT3's Canonical Function Plays a Central Role in Inflammatory and Proliferative Diseases

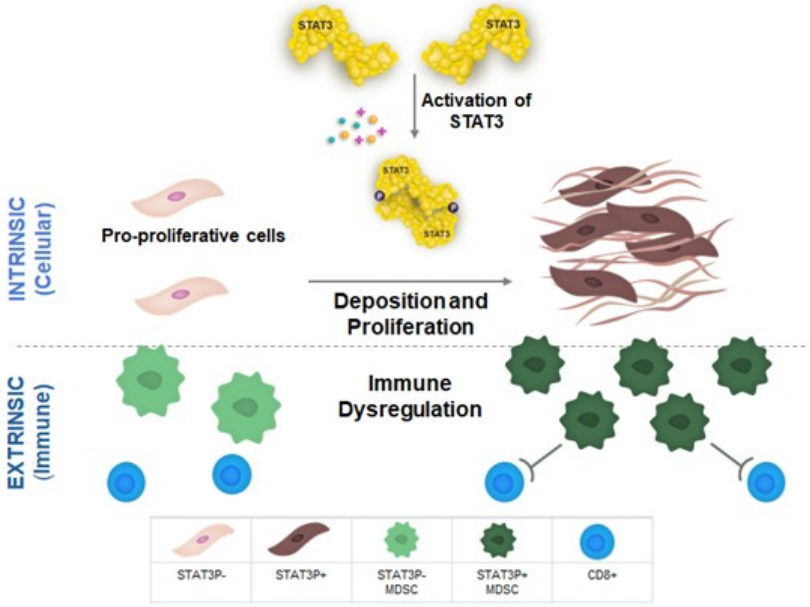


Source: Image adapted from "Therapeutically exploiting STAT3 activity in cancer — using tissue repair as a road map" by Jennifer Huynh, et al., and "Contribution of STAT3 to Inflammatory and Fibrotic Diseases and Prospects" by Moses M. Kasembeli, *et al.*

STAT3's Dual Mechanism of Action in Disease

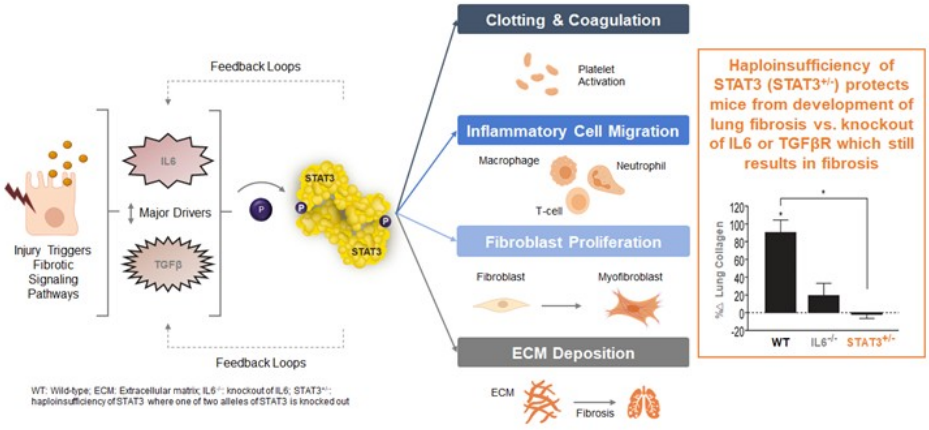
The canonical STAT3 pathway associated with inflammatory and proliferative diseases can be broadly defined by a dual mechanism of action: intrinsic activity (within proliferative cells) and extrinsic activity (within the immune system). Intrinsically (within proliferative cells), pY-STAT3 increases cell proliferation and survival, while extrinsically (within the immune system), pY-STAT3 contributes to immune dysregulation. Inhibition of pY-STAT3 simultaneously down-regulates both cascades — reducing inflammation and proliferation while restoring immune homeostasis. This dual mechanism differentiates STAT3 inhibition from therapies that target only single upstream pathways because STAT3 integrates multiple redundant signals.

The Dual Mechanism of Action of STAT3's Function in the Canonical Pathway



Critical and well-established signaling regulators of inflammation and proliferation, such as IL-6 and TGF-β, have been shown to induce pY-STAT3-dependent fibrotic conditions. pY-STAT3 is known to act both independently and in conjunction with other signaling networks that contribute to fibrosis. pY-STAT3 drives the development and progression of fibrosis through clotting and coagulation, inflammatory cell migration and fibroblast proliferation, ultimately leading to ECM deposition. STAT3's role as the central mediator in the pathogenesis of fibrosis has been validated in third-party preclinical haploinsufficiency models, where one of two alleles of STAT3 were knocked out. In these preclinical studies, haploinsufficient STAT3 mice did not develop lung fibrosis despite injury, whereas the knockout of IL-6 or TGF-β receptor (TGF-βR), still resulted in fibrosis. These preclinical studies suggest that targeting individual signaling pathways is insufficient to block the development of fibrosis, however inhibiting STAT3 activation can potentially prevent fibrosis.

STAT3 Activation is a Central Catalyst in Proliferation



Our Approach to Targeting STAT3

STAT3, like many transcription factors, has historically been deemed undruggable due largely to its intracellular location and the failure to identify residues within its Src-homology (SH) 2 domain critical for its activation. Though STAT3 has been a recognized and interrogated target for drug development, there is yet to be an FDA-approved STAT3-targeting therapeutic. Prior approaches to target the STAT3 signaling pathway have largely been indirect, focused on upstream signaling mechanisms, including cytokines and growth factors, such as IL-6 and TGF-β, their receptors, or receptor-intrinsic or receptor-associated tyrosine kinases. Due to the adaptive nature of most signaling cascades, indirect approaches have led to off target effects or acquired resistance. As a result, we believe that direct targeting of STAT3 is the more robust approach to impacting downstream mediators of inflammation and proliferation within the STAT3 signaling pathway. Previous attempts to directly inhibit STAT3 have often demonstrated lack of selectivity, poor pharmacokinetics (PK) and/or poor absorption. In addition, some molecules identified to date are not reversible competitive inhibitors of STAT3; rather, their binding to STAT3 leads to its instability and degradation, which reduces non-canonical STAT3 functions within the mitochondria, resulting in off-target impacts and toxicities such as persistent peripheral neuropathies or lactic acidosis. Other approaches to inhibit the translation of STAT3 have been hampered by safety concerns, such as high rates of thrombocytopenia (reduced platelet count) and transaminitis (elevated liver enzymes), poor pharmacodynamics (PD) and burdensome administration regimens requiring frequent intravenous infusions.

Our strategy for clinical development of therapies targeting inhibition of STAT3 activation is rooted in our deep understanding of STAT3 structure and function, and our critical role in disease pathogenesis. One of our co-founders, Dr. Tweardy, was among the first to discover pY-STAT3 in normal blood cells. He pioneered the scientific community's understanding of STAT3 biology in hematopoiesis and determined that targeting residues within the STAT3 SH2 domain that are critical to the first step in its activation, pY-STAT3, was the key to selectively inhibiting STAT3's role as a transcription factor without affecting its role in the mitochondria. We believe our approach to directly inhibiting STAT3 enables us to develop product candidates with the potential to provide meaningful therapeutic benefit to patients with inflammatory and proliferative diseases, if approved.

Preclinical Foundation: STAT3 Inhibition Across Inflammatory and Proliferative Disease Models

The preclinical biological rationale for STAT3 inhibition has been validated extensively across multiple disease models. These studies established the scientific foundation for clinical development of both TTI-101 and TTI-109.

Across animal models, TTI-101 demonstrated dose-dependent decreases in validated targets associated with intrinsic proliferation, as well as upregulation of markers associated with extrinsic immune modulation. The table below summarizes key preclinical observations across inflammatory and proliferative disease models:

Inflammatory and Proliferative Disease	Mouse Models	Observations of TTI-101 Administration
IPF	BLM-induced IPF	• Observed histologic reduction in lung fibrosis, quantified using Ashcroft score and Masson's trichrome from murine lung tissues, and increased BLM-induced decline in lung function, measured by percent or SO_2 • Significant reduction in IL-6 levels, the key pro-inflammatory cytokine that signals through STAT3 • Targeted multiple pathogenic steps as evidenced by decreased BLM-induced expression levels of validated biomarkers for deposition; increased BLM-reduced expression levels validated biomarkers for degradation as measured by transcripts from isolated RNA and relative real time polymerase reaction (RT-PCR) • Reduced levels of pY-STAT3 in lung tissue
Systemic Sclerosis (SSc)	GEM (Tsk-1) and BLM-induced skin fibrosis	• Significant fold-change reduction in IL-6 levels versus placebo • Marked reduction in dermal fibrosis as measured by histologic evaluation of skin tissue thickness • Consistent with BLM-IPF model findings, confirming cross-model replicability of STAT3-mediated fibrosis reversal
Inflammatory Bowel Disease	Chemically induced colitis (DSS and TNBS)	• Normalized colon length and improved clinical disease parameters, including reducing weight loss and disease activity index • Observed reduction in colonic inflammation and mucosal injury, as assessed by histological scoring of H&E-stained colon sections • Decreased expression of pro-inflammatory cytokines, colonic Th17+ cells and increased apoptosis among colonic CD4+ T cells, measured by RT-PCR and protein analyses
HCC	NASH-induced HCC	• Reduced elevated hepatic enzymes and microsteatosis, or abnormal liver fat accumulation, reduced hepatic fibrosis, measured by Masson's trichrome staining and reduced tumor growth by comparing the average tumor volume determined by MRI
	Humanized mice + patient derived HCC xenografts	• Reduced tumor size with monotherapy, as measured by tumor weight • Observed additive effect in reducing tumor size, as measured by tumor weight, with TTI-101 in combination with HCC standard of care therapies

BLM: bleomycin; GEM: genetically engineered mouse; DSS: dextran sulfate sodium; TNBS: trinitrobenzenesulfonic acid; NASH: nonalcoholic steatohepatitis

Across preclinical models, the consistent and replicable findings were: (1) reduction of STAT3-mediated inflammatory markers; (2) reduction of established fibrosis; and (3) restoration of immune homeostasis. These findings were consistent across model types, including genetic and chemically-induced models — providing validation of the biological rationale. One study, described in detail below, provided the most comprehensive mechanistic characterization of how STAT3 inhibition using our inhibitors simultaneously reduced the intrinsic proliferative/inflammatory cascade and upregulated markers associated with extrinsic immune modulation in a single, dose-controlled experiment.

Mechanistic Characterization: TTI-101 Simultaneously Modulates Intrinsic and Extrinsic Cascades

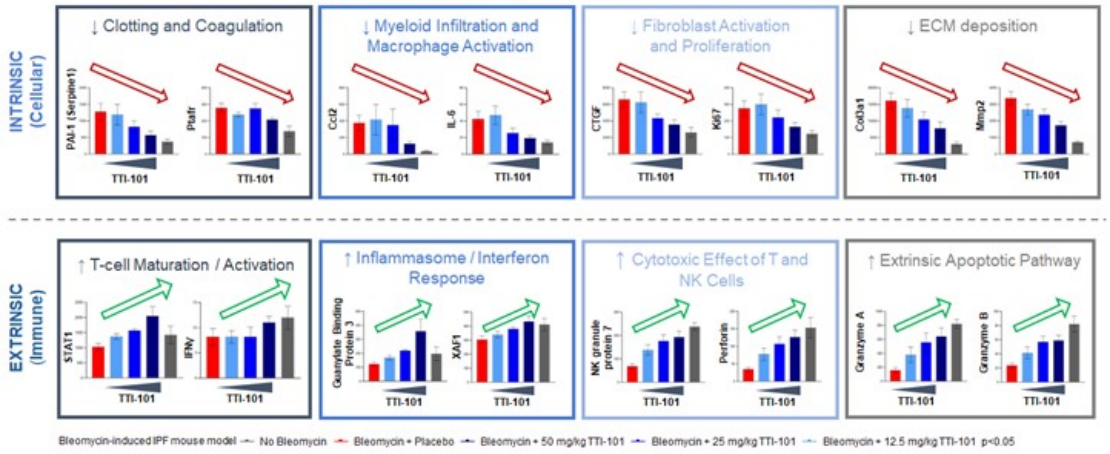
A central challenge in treating STAT3-driven inflammatory and proliferative diseases is that STAT3 operates through two parallel and reinforcing pathways: it drives cellular proliferation, ECM deposition, and tissue remodeling intrinsically within diseased cells, while simultaneously suppressing the immune response. A therapy that addresses only one pathway leaves the other intact. A

key objective of our preclinical program has been to demonstrate that direct STAT3 inhibition addresses both pathways simultaneously.

We conducted a dose-range-finding, PK and PD preclinical study using a well-characterized model of STAT3-driven proliferative and inflammatory tissue disease to characterize the impact of TTI-101 on both pathways of STAT3's canonical function. The study employed the bleomycin (BLM)-induced model, which generates robust, pY-STAT3-dependent proliferative and immunosuppressive pathology in a titratable, reproducible manner — making it well suited as a mechanistic platform for characterizing the dose-response behavior of our STAT3 inhibitor across both intrinsic and extrinsic biology. TTI-101 was administered therapeutically after pathology was already established, at human equivalent doses (HED) of 200, 400, and 800 mg/day (12.5, 25, and 50 mg/kg). Biomarkers characterizing mechanism of action, drug exposure, pY-STAT3 levels, and functional outcomes were evaluated across both canonical STAT3 pathways.

We observed dose-dependent decreases in validated biomarkers associated with myofibroblast proliferation and ECM deposition downstream of intrinsic STAT3 signaling, as measured in florescence units of gene expression by RT-PCR, BLM + placebo vs BLM + either 12.5, 25 or 50mg/kg TTI-101. Specifically, we demonstrated significant decreases in biomarkers associated with clotting and coagulation (PAI1 and Ptafr), myeloid infiltration and macrophage activation (Ccl2 and IL-6), fibroblast activation and proliferation (Ccl2 and IL-6) and ECM deposition (Ccl2 and IL-6) with increased doses of TTI-101 ($p<0.05$ for trend). In addition, we demonstrated dose-dependent increases in validated biomarkers associated with increased degradation downstream of extrinsic STAT3 signaling. Specifically, we demonstrated significant increases in biomarkers associated with T-cell activation (STAT1 and IFNγ), interferon responses (GBP3 and XAF1), cytotoxic T- and NK cells (NK GP7 and Perforin) and apoptosis-inducing factors (Granzyme A and B) with increased doses of TTI-101 ($p<0.05$ for trend).

TTI-101's Impact on Both Extrinsic and Intrinsic STAT3 Functions



These findings translated into a dose-dependent relationship between TTI-101 dose and observed effects:

- Pharmacokinetics — we observed TTI-101 concentration in mouse lungs accumulated in the lung four times as much as compared to its accumulation in the plasma as measured by LC/MS/MS (50mg/kg: 8868 vs 1672; 25mg/kg: 8927 vs 2348; 12.5mg/kg: 7407 vs 1995). Administration of TTI-101 in a non-disease mouse model did not accumulate in the lung.

- Pharmacodynamics — Dose-dependent decrease of pY-STAT3 observed: the higher the dose of TTI-101 administered, the lower the levels of activated STAT3.

- Biological activity — At the higher two doses of 25 mg/kg and 50 mg/kg, TTI-101 demonstrated statistically significant improvement in lung function as compared to treatment with placebo (50mg/kg: 91.3; 25mg/kg: 92.7; 12.5mg/kg: 87.9 versus 94.9) ($p<0.05$) or with BLM alone (86.1) ($p<0.05$) as measured by SO_2, where mice continued to experience loss of lung function.

The study established a coherent dose-response relationship from selective tissue accumulation, to pY-STAT3 suppression, to simultaneous intrinsic and extrinsic cascade modulation, to measurable functional improvement — which is the mechanistic core of our STAT3 inhibition platform. It demonstrated that direct STAT3 inhibition with our orally administered small molecule can address the biology that drives a broad class of inflammatory and proliferative diseases. As TTI-109 is designed to deliver the identical active moiety through an optimized prodrug design, this mechanistic foundation should apply equally to both molecules in our pipeline.

Preclinical-to-Clinical Translation: Proof of Mechanism

We believe a central strength of our platform is the alignment between preclinical findings and clinical observations to date, with effects of STAT3 inhibition observed in preclinical studies recapitulated in human data.

- Fibrosis reduction (REVERT IPF Phase 2): We observed, in a subgroup of pooled patients treated with TTI-101, approximately 9.4% baseline-weighted reduction in fibrosis score versus approximately 2.4% in the placebo arm — a 7 percentage point difference — consistent with the histologic fibrosis reversal observed across preclinical models.

- IL-6 reduction (REVERT IPF Phase 2): We observed, in a subgroup of pooled patients treated with TTI-101, a 4.5-fold greater decline in IL-6 slope compared to placebo — replicating IL-6 reductions observed in preclinical models. IL-6 is a key pro-inflammatory cytokine that signals through STAT3.

- pY-STAT3 target engagement (Oncology Phase 1): In the Phase 1 oncology trial, we observed 100% of patients with elevated baseline pY-STAT3 demonstrated a decrease in pY-STAT3 within approximately 6 weeks of TTI-101 therapy, with a median 55% decrease overall and 79% in patients with stable disease —replicating the STAT3 pathway suppression observed in preclinical models.

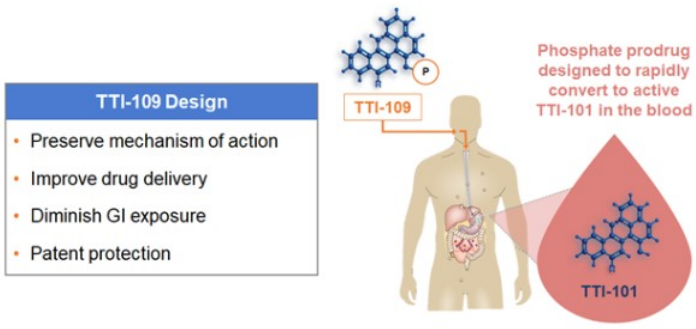
This preclinical-to-clinical translation represents a critical validation of the STAT3 inhibition platform, strengthening the foundation for advancing both TTI-109 into the next inflammatory/proliferative indication and TTI-101 in HCC.

TTI-109

Design Rationale and Development History

TTI-109 is an oral, small-molecule phosphate prodrug of TTI-101. TTI-109 itself does not directly inhibit STAT3; rather, it is designed to rapidly convert to TTI-101 in the bloodstream, delivering the mechanism of action of direct pY-STAT3 inhibition while minimizing gastrointestinal (GI) luminal exposure to the active moiety prior to systemic absorption. The development of TTI-109 has been a strategic priority for several years, grounded in our recognition that retaining the well-characterized mechanism of TTI-101 while improving the delivery profile and tolerability would strengthen our platform's potential across a wide range of inflammatory and proliferative diseases.

TTI 109: Prodrug of TTI 101 and Next Generation STAT3 Inhibitor



The key design goals for TTI-109, established at the outset of its development, are to:

- Preserve the mechanism of action of TTI-101 — direct, reversible, selective inhibition of pY-STAT3 nuclear function
- Improve drug delivery through a prodrug strategy by minimizing excipients to solubilize the drug
- Reduce GI luminal exposure to the active moiety, with the potential to improve GI tolerability relative to TTI-101
- Provide additional intellectual property protection for the Tvardi platform

TTI-109 is mechanistically identical to TTI-101. Once converted to TTI-101, it engages the same STAT3 inhibitory mechanism and is expected to deliver the same biological activity demonstrated preclinically and clinically with TTI-101.

IND-Enabling Studies and Preclinical Pharmacology

IND-enabling Good Laboratory Practice (GLP) toxicology studies conducted in rats and non-human primates demonstrated the following:

- No toxicology findings were observed with TTI-109, consistent with the preclinical safety profile of TTI-101
- Systemic exposures of TTI-101 derived from TTI-109 administration provided a large safety margin relative to anticipated clinical doses
- At equimolar doses, TTI-109 produced equivalent systemic exposures of the active moiety TTI-101
- Rapid conversion was observed; in the 28-day GLP non-human primate study, greater than 95% of TTI-109 converted to TTI-101 within two hours of administration

We believe these findings, which confirmed TTI-109's function as an efficient and reliable delivery vehicle for TTI-101, as well as its pharmacokinetic and safety profile, supported clinical development of TTI-109. An IND application was submitted to and accepted by the FDA in June 2025.

Ongoing Phase 1 Healthy Volunteer Trial

Following FDA acceptance of the IND, we initiated a three-part Phase 1 clinical trial of TTI-109 in healthy volunteers:

- Part 1 — Single Ascending Dose: evaluating pharmacokinetics, rapid conversion to TTI-101, and dose-dependent systemic exposure
- Part 2 — Bioequivalence Crossover: directly comparing TTI-109 versus TTI-101 to confirm equivalent exposures of the active moiety
- Part 3 — Multiple Ascending Dose: evaluating safety, tolerability, and pharmacokinetics with repeated dosing

The primary objectives of the trial include:

- Confirmation of rapid pharmacokinetic conversion of TTI-109 to TTI-101 in humans
- Demonstration of dose-dependent increases in systemic TTI-101 exposures derived from TTI-109
- Demonstration of bioequivalence between TTI-109 and TTI-101 for the active moiety
- Characterization of the safety and tolerability profile of TTI-109 relative to TTI-101

We expect to report topline data from this Phase 1 trial in the second quarter of 2026.

Next Indication Strategy

After reporting topline Phase 1 data, we plan to announce the indication in which we intend to advance TTI-109 into Phase 2 development. The indication will be of an inflammatory and/or proliferative nature. The selection will be informed by: (i) preclinical data demonstrating that STAT3 inhibition is associated with reversal of fibrosis, reduction of inflammation, and restoration of immune homeostasis across multiple disease models; (ii) clinical findings from the REVERT IPF Phase 2 trial and oncology Phase 1 program, which support translation of the STAT3 inhibition mechanism from preclinical models to human disease; (iii) the potential for TTI-109's improved tolerability and delivery profile to enable better patient outcomes; and (iv) regulatory and clinical development pathway considerations.

Because TTI-109 shares the same mechanism of action as TTI-101, we believe that the body of preclinical and clinical evidence supporting STAT3 inhibition — across fibrosis, inflammation, and oncology — is applicable to TTI-109. Clinical observations from the REVERT IPF trial including reductions in IL-6 and improvements in fibrosis score in adequately exposed patients, together with Phase 1 data demonstrating pY-STAT3 target engagement and evidence of clinical activity, provide a scientific rationale for futher development of TTI-109.

TTI-101 in Idiopathic Pulmonary Fibrosis: Clinical Program and Findings

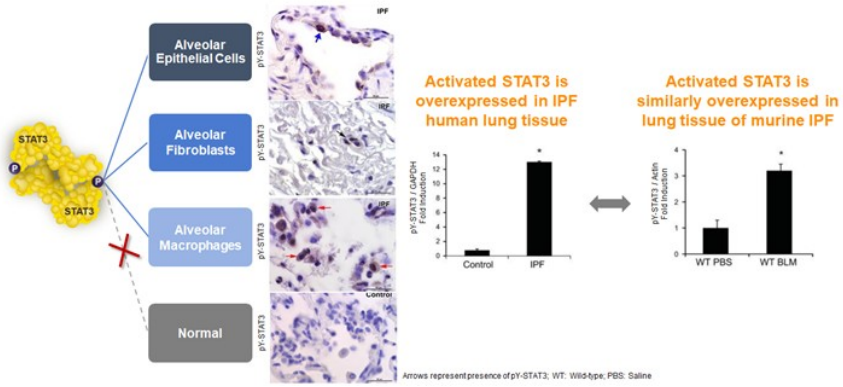
Disease Background

IPF is a rare, chronic, debilitating interstitial lung disease characterized by inflammation, progressive fibrosis, and lung damage of unknown cause. As IPF progresses, it leads to thickening and stiffening of lung tissue and, eventually, the inability of the lungs to transfer oxygen into the bloodstream. Patients experience a poor quality of life, constant shortness of breath, fatigue, and weakness. The five-year mortality rate ranges from 60% to 80%. IPF is also associated with comorbidities including pulmonary hypertension, obstructive sleep apnea, lung cancer, ischemic heart disease, and gastroesophageal reflux.

Forced vital capacity (FVC), a measure of pulmonary function, is the established efficacy endpoint for IPF clinical trials. Approved anti-fibrotic therapies (nintedanib and pirfenidone) slow the rate of FVC decline but do not reverse established fibrosis or improve lung function, representing a critical unmet need.

pY-STAT3 levels are elevated in human lung tissue samples from patients with IPF, driving fibrosis through inflammatory cell migration, myofibroblast proliferation, and ECM deposition. STAT3 is activated across all three major compartments of IPF-affected lungs — alveolar epithelial cells, alveolar fibroblasts, and alveolar macrophages — and high STAT3 expression correlates with higher mortality.

STAT3 is Activated in Major Compartments of IPF-Affected Mouse and Human Lung Tissue



Images on the right hand side were derived from Pedroza, M., Le, T.T., Lewis, K., Karmouty-Quintana, H., To, S., George, A.T., Blackburn, M.R., Tweardy, D.J. and Agarwal, S.K. (2016), *STAT-3 contributes to pulmonary fibrosis through epithelial injury and fibroblast-myofibroblast differentiation*. The FASEB Journal, 30: 129 — 140. Western blot analysis of phospho-STAT-3 expression in human patients with mild and severe IPF. STAT-3 and GAPDH were used as controls (n ≥ 4). Phospho-

STAT-3 band intensity was quantified using ImageJ analysis. Values are presented as the percentages of Glyceraldehyde 3-phosphate dehydrogenase (GAPDH), ± sem ($n \geq 4$). *$P \leq 0.05$ control vs. IPF. Western blot analysis using an antibody against phospho-STAT-3 in whole-lung lysates. STAT-3 and α-actin were used as controls. Phospho-STAT-3 band intensity was quantified using ImageJ analysis. Values are presented as the percentages of α-actin ± sem ($n \geq 4$). *$P \leq 0.05$ PBS vs. bleomycin ("BLM").

Preclinical Studies Supporting TTI-101 in IPF

In the bleomycin (BLM)-induced IPF mouse model, TTI-101 administration resulted in:

- Statistically significant reductions in validated biomarkers of cell proliferation, most notably COL1A1 ($p \leq 0.05$), indicating decreased ECM deposition
- Histologic reduction in the amount of fibrotic tissue in the lungs ($p \leq 0.05$), as measured by Ashcroft scoring and Masson's trichrome staining
- Restoration of oxygen saturation (SO_2) toward near-normal levels, compared to continued decline in placebo-treated animals
- Statistically significant reduction in IL-6 levels, consistent with the central role of STAT3 in mediating IL-6 downstream signaling in fibrotic tissue

In the Tsk-1 systemic sclerosis model, TTI-101 produced consistent findings — significant IL-6 reduction and marked reversal of dermal fibrosis — confirming that the anti-fibrotic activity of STAT3 inhibition extended beyond pulmonary fibrosis to other fibrotic disorders. We believe the replicability of these findings across two independent, mechanistically distinct fibrosis models (one pharmacologically induced, one genetic) is a key indicator of the robustness of the STAT3 biology underlying our platform.

REVERT IPF Phase 2 Clinical Trial

The trial was a Phase 2, multicenter, randomized, double-blind, placebo-controlled clinical trial of TTI-101 to evaluate safety, tolerability and PK in patients suffering from IPF. In addition to safety and PK endpoints, we evaluated efficacy endpoints including pulmonary function tests (PFTs), providing measurements for FVC and imaging, including Quantitative Lung Fibrosis High Resolution CT (HRCT), among others. Additionally, we evaluated validated biomarkers. The clinical trial was conducted in 28 sites across the United States and enrolled patients with mild and moderate IPF who had been on a stable dose of nintedanib or were not on anti-fibrotic therapy.

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

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

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

As reported in October 2025, the study did not meet its goals. Preliminary analysis of exploratory efficacy showed no statistically significant differences between placebo and treatment arms. FVC change from baseline overlapped between treatment arms, with large variability within each cohort. Notably, the placebo-treated patients' FVC decline was lower than expected compared to historical controls.

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

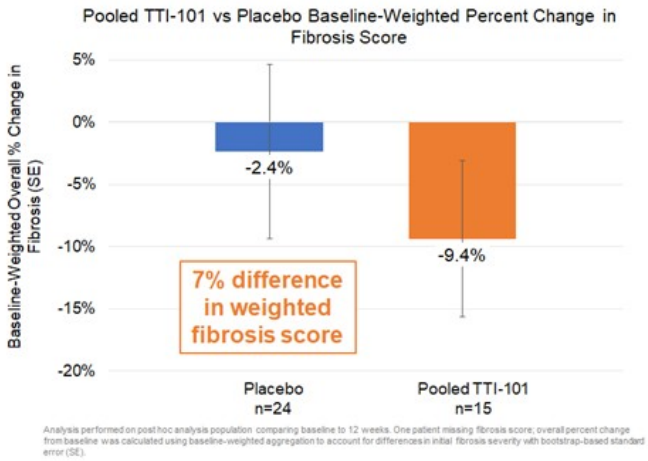
	Placebo	TTI-101 – 400mg	TTI-101 – 800mg
n	24	8	13
Mean in mL (SD^2)	-22.2 (126.0)	-61.1 (190.7)	-102.8 (238.3)

Subsequently, additional analysis was conducted to interrogate the impact of STAT3 inhibition using TTI-101 on fibrosis, inflammatory markers and pulmonary function. In order to do so, the additional analysis was limited to patients who were exposed to study drug for 12 weeks. Upon interrogation of pharmacokinetics and adverse events, one patient was removed because the patient was not exposed to TTI-101 for 12 weeks, one patient was removed from the analysis due to receiving less than 60% of the expected dosing, two patients were removed due to no measurable TTI-101 observed in the blood as well as no reported adverse events, and one additional patient was removed as an outlier for the 12-week analysis as their pulmonary function initially improved on treatment, but was subsequently severely impacted by acute bronchitis deemed unrelated to study drug. This resulted in a dataset of 40 patients analyzed: 16 pooled patients treated with TTI-101, and 24 patients treated with placebo.

Fibrosis Score

Fibrosis decline was greater in pooled patients treated with TTI-101 compared to placebo, -9.4% vs -2.4%, respectively, in baseline-weighted high resolution CT lung fibrosis score (centrally read, blinded and independently assessed).

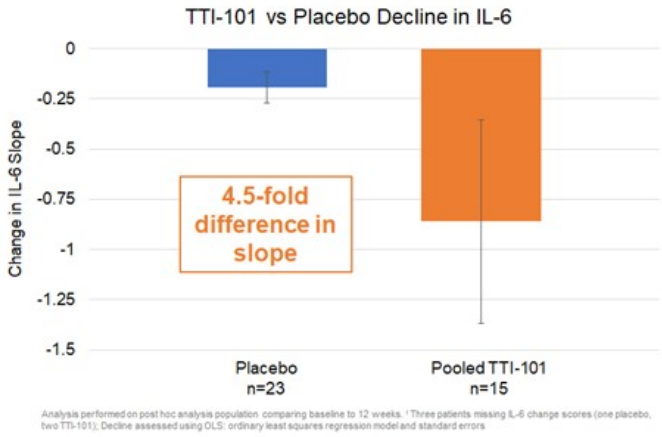
Pooled Patients Treated with TTI-101 Demonstrated Greater Decline in Fibrosis Score (Baseline to 12 Weeks) vs Placebo



IL-6

A greater IL-6 decline was observed among pooled patients treated with TTI-101 vs placebo. In addition, greater reduction in IL-6 was observed among patients with higher baseline IL-6 in the pooled patients treated with TTI-101. IL-6 is a key pro-inflammatory cytokine that signals through STAT3. Inhibition of STAT3 is expected to reduce downstream inflammatory signaling associated with disease.

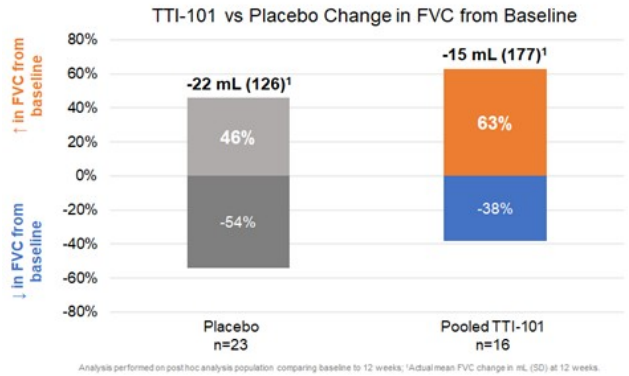
Pooled Patients Treated with TTI-101 Demonstrated Greater IL-6 Decline vs Placebo



Forced Vital Capacity (FVC)

63% of pooled patients treated with TTI-101 demonstrated an increase in FVC at 12 weeks, compared to 46% of the placebo group. Mean FVC change in pooled patients treated with TTI-101 was -15mL; less of a decline when compared to the REVERT IPF placebo (-22mL) and historical placebo groups from comparable IPF trials (such as the Phase 2 bexotegrast study's -110.7mL placebo FVC change at 12 weeks).

A Greater Proportion of Pooled Patients Treated with TTI-101 Demonstrated Increase in FVC vs Placebo



We believe these findings – specifically the 4.5-fold greater decline in IL-6 and the 7 percentage point greater reduction in fibrosis score — provide direct human clinical proof of concept for the STAT3 inhibition platform despite our conclusion that the study did not meet its goals, and the results recapitulate what was observed in multiple preclinical proliferative models, confirming the translation of the biology of STAT3 inhibition from animal models to human disease tissue when the drug is adequately delivered. These data inform our overall understanding of the platform and the potential of TTI-109, which is designed to improve the systemic delivery of the same active moiety.

TTI-101 in Hepatocellular Carcinoma (HCC)

Disease Background and Unmet Need

HCC is the third-leading cause of cancer-related mortality globally and in the United States. Furthermore, HCC incidence and mortality rates have been increasing for decades. According to the World Health Organization, mortality in the United States was approximately 31,000 in 2022. There remains a high unmet need in HCC given a two-year survival rate less than 50% and a five-year survival rate of only 10% in the U.S. The majority of patients diagnosed with HCC present with advanced disease and have an estimated survival time of six to 20 months following diagnosis.

More than 90% of HCC cases arise in the setting of hepatic injury and inflammation, which involve production of several cytokines, notably hepatocyte growth factor and IL-6, which activate STAT3 to drive further injury, inflammation, fibrosis and proliferation. In addition, pY-STAT3 is a major contributor to immune resistance in HCC through its actions that promote the development and function of several immunosuppressive cells found within the tumor microenvironment, including myeloid-derived suppressor cells (MDSC). MDSCs have been demonstrated to impair the anticancer activity of immune-checkpoint inhibitor (ICI), therapies, and therefore, we believe that a drug inhibiting STAT3 has the potential to improve responsiveness to ICI therapy.

We believe that HCC represents a large commercial opportunity. In 2024, an estimated 42,000 new cases of liver cancer were diagnosed in the United States. In 2022, the incidence was 850,000 cases worldwide, approximately a third of whom are treated with systemic therapies. The first-line standard of care treatment for HCC are ICI combination therapies and second-line treatments primarily consist of anti-angiogenic therapies. Currently there are no approved third-line treatments. None of the existing approved therapies for HCC target STAT3.

Despite the approval and use of ICIs, current standard of care therapies remain suboptimal for the treatment of HCC. In Roche's IMBrave150 clinical trial, the combination of atezolizumab, an anti-PD-L1 antibody, and bevacizumab, an anti-vascular endothelial growth factor (anti-VEGF), antibody, the current first-line standard of care, resulted in an ORR of 27% with a median duration of 18.1 months. Second-line therapies consist of anti-angiogenic therapies, such as tyrosine kinase inhibitors and anti-VEGF therapies, for patients who progress on first-line combination ICI therapy, with modest expected clinical benefit.

Approved treatments for advanced HCC can prolong survival in some patients, but most patients do not respond to treatment. Furthermore, as a result of the significant toxicities associated with atezolizumab + bevacizumab standard of care therapy, over 40% of patients experienced treatment interruptions in registrational studies. Similarly, second-line therapies have high rates of discontinuations due to associated severe adverse events. The limited efficacy across a broad patient population, coupled with the advanced stage of disease upon diagnosis, emphasizes the ongoing high medical need for more effective therapies in HCC.

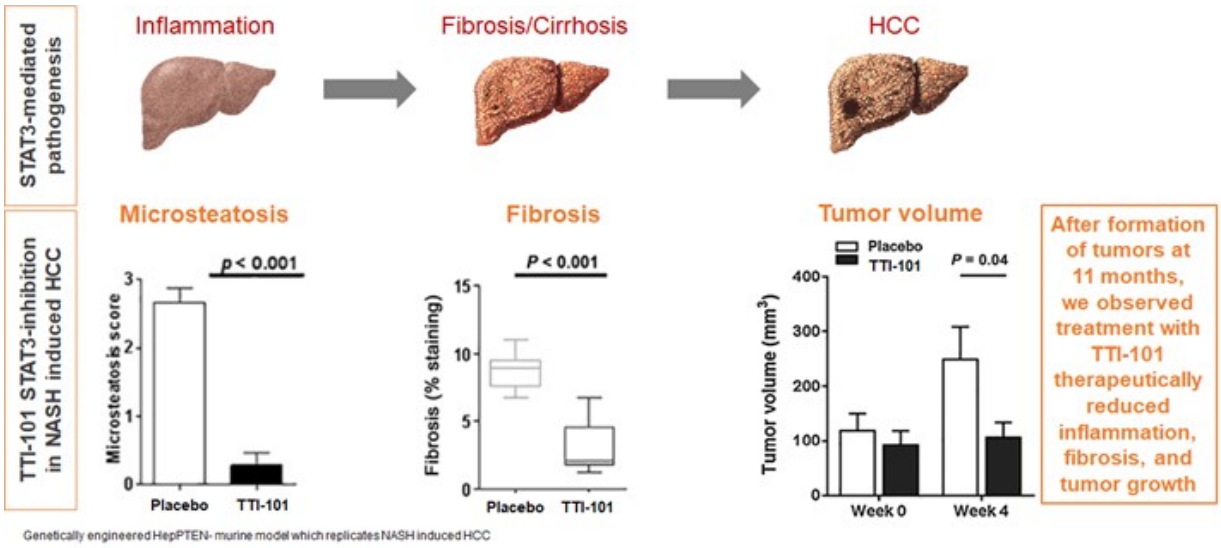
TTI-101 is designed to deliver therapeutic benefit as monotherapy and in combination with existing approved agents for the treatment of HCC. STAT3 has been shown to be activated in 89% to 100% of patients with HCC samples and correlate closely with tumor vascularity and aggressiveness, and its expression is significantly associated with poor overall survival. The pathogenesis of HCC is mediated by pY-STAT3 through intrinsically increasing tumor cells proliferation and extrinsically playing a major role in immune dysregulation. We believe TTI-101 is a novel therapeutic candidate that could offer a much-needed treatment option in HCC.

Preclinical Studies in HCC

Preclinical studies in genetically engineered mouse models replicating nonalcoholic steatohepatitis (NASH)-induced HCC demonstrated TTI-101's potential to reverse inflammation and fibrosis and inhibit tumor growth. In addition, as further described below, HCC models demonstrated the synergistic effect of double and triple combination therapy with inhibition of multiple pathways in HCC, ultimately leading to reduced tumor size, supporting further exploration of TTI-101 in combination with ICIs and anti-VEGF therapies.

Dr. Tweardy and his collaborators at the University of Texas MD Anderson Cancer Center, conducted a preclinical study where TTI-101 was tested in a NASH-induced HCC mouse model. The model replicated the human pathogenesis over an 11-month period, where the livers in mice over that time period developed inflammation and fibrosis and formed tumors. Thereafter, mice were administered TTI-101 or placebo once a day for four weeks. TTI-101 statistically significantly impacted critical STAT3-mediated steps of pathogenesis; specifically, TTI-101 demonstrated statistically significant changes in (1) microsteatosis score (abnormal liver fat accumulation) that was 89% lower in animals treated with TTI-101 versus placebo treated animals ($p<0.001$), (2) fibrosis, measured by histologic staining, that was 65% lower in animals treated with TTI-101 versus placebo treated animals ($p<0.001$) and (3) tumor growth, measured by comparing the average tumor volume determined by MRI, that was 57% lower in animals treated with TTI-101 versus placebo treated animals ($p=0.04$).

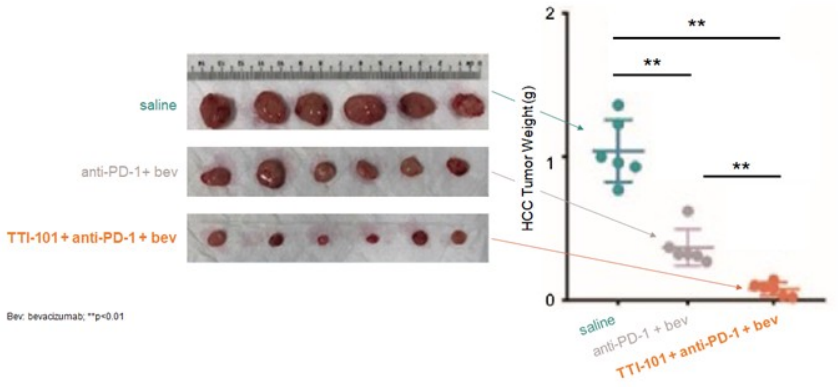
TTI-101 in NASH-induced HCC Mouse Model



An independent academic lab in Singapore conducted a preclinical study to evaluate the activity of TTI-101 where mice with humanized immune systems were implanted with human-derived HCC cells, an HCC-PDX model. HCC-PDX mice were randomized into different groups, including TTI-101 monotherapy and in combination therapy with a PD-1 inhibitor and/or anti-VEGF.

TTI-101 showed enhanced activity in combination with bevacizumab and/or an anti-PD-1, an ICI, therapy for HCC. In the HCC-PDX model, TTI-101 showed clinically meaningful benefit as monotherapy compared to placebo as measured by tumor weight ($p<0.01$), which was further enhanced when combined with either anti-PD-1 or bevacizumab. After four weeks of treatment, the triple combination of TTI-101 with anti-PD-1 and bevacizumab (n=6) demonstrated markedly larger reduction in tumor weight compared to treatment with saline (n=6), TTI-101 with bevacizumab (n=6), anti-PD-1 with bevacizumab (n=6) or TTI-101 with anti-PD-1 (n=6) ($p<0.01$). In addition, the results showed the anti-tumor effect of triple combination therapy was inhibited in the absence of human CD8+ or CD14+ immune cells confirming that these two immune cell types were critical in the triple combination. Taken together, the results showed that triple combination therapy using TTI-101, anti-PD-1 and bevacizumab significantly increased the anti- tumor response in vivo compared with monotherapy or dual therapy.

TTI-101 Response in Humanized Mouse Model Engrafted with HCC-PDX Tumor



Phase 1 Monotherapy Trial

We completed a Phase 1, multicenter, open-label, dose-escalation/dose-expansion clinical trial in the United States in patients with advanced solid tumors (n=64), enriched for patients with HCC (n=17) to determine the maximum tolerated dose (MTD), safety, PK, PD and clinical outcomes of TTI-101. TTI-101 was observed to be generally well tolerated. Over the conduct of the trial, multiple formulations were investigated per protocol, which decreased pill burden. The last formulation was observed to be better tolerated than the previous two and was therefore selected for further development. The results summarized below represent pooled data from all evaluated formulations. No dose limiting toxicities or fatal treatment-related adverse events (fatal TRAEs), were observed. The most common TRAE was diarrhea, mostly grade 1 or 2.

TTI-101 showed linear PK from dose level 1 - 3 plateauing at dose level 3 which was selected as the RP2D. The exposures of patients treated with TTI-101 at its trough exceeded the expected concentration required for 90% inhibition of STAT3-dependent growth, or the IC90. PD values were available from ten patients who agreed to pre- and on-treatment paired tumor biopsies. Eight of these patients had elevated pre-treatment pY-STAT3. Each of these patients demonstrated a decrease in their pY-STAT3 levels at the follow-up biopsy (approximately six weeks after initiating treatment), with a median decrease of 55% in pY-STAT3 levels. Among the three patients who demonstrated a clinical benefit, the median decrease was 79% in pY-STAT3 levels.

The biologic effect of TTI-101 monotherapy in patients with advanced diseases, who had previously been treated with a median of over three prior systemic therapies and evaluable for tumor response is outlined in the table below. Overall, 41 patients were evaluable for response, and we observed a disease control rate of 54%, as measured by RECIST v1.1, among all tumor types, including confirmed partial responses in HCC, ovarian and gastric tumor types. Among the 17 patients with HCC, we observed a disease control rate of 53%, as measured by RECIST v1.1.

	Patients with HCC (N=17) n (%)	All Patients with Advanced Solid Tumors (N=41) n (%)
Confirmed partial response[(1)]	3 (18)	5 (12)*
Stable disease[(2)]	6 (35)	17 (41)
Progressive disease[(3)]	8 (47)	19 (46)
Disease Control Rate[(4)]	53%	54%
Median Number of Therapies	2	3.5

Evaluable patients included patients with a follow-up on-study tumor assessment at least 42 days following cycle 1, day 1. *Two non-HCC patients demonstrated a confirmed partial response: one had ovarian cancer, the second had gastric cancer.

(1) Confirmed partial response (cPR), means at least a 30% decrease in the sum of diameters of target lesions, taking as reference the baseline sum diameters.

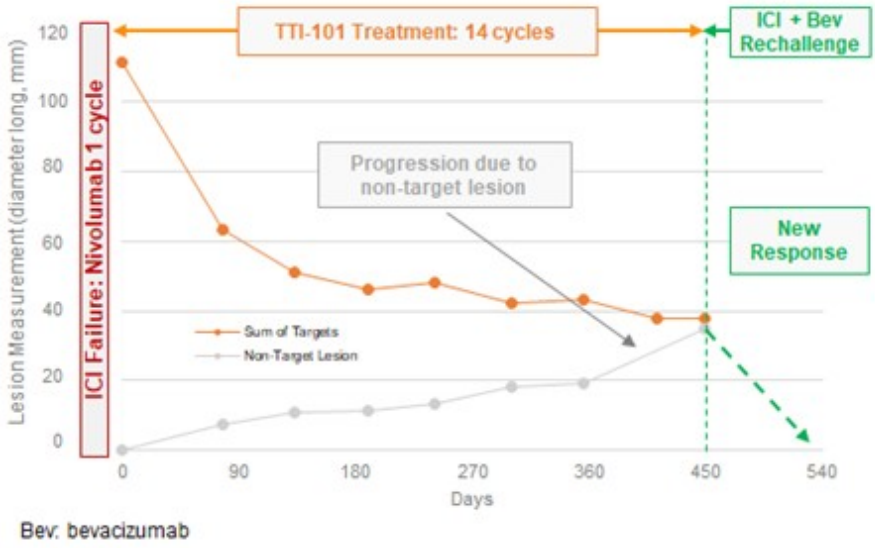
(2) Stable disease means neither sufficient shrinkage to qualify for PR nor sufficient increase to qualify for progressive disease, taking as reference the smallest sum diameters while on study.

(3) Progressive disease means at least a 20% increase in the sum of diameters of target lesions, taking as reference the smallest sum on study (this includes the baseline sum if that is the smallest on study). In addition to the relative increase of 20%, the sum must also demonstrate an absolute increase of at least 5 mm. Note that the appearance of one or more new lesions is also considered progression.

(4) The disease control rate was calculated as the proportion of participants with a complete response, cPR, or SD, as the best overall response, per RECIST v1.1.

All patients with HCC who demonstrated partial responses were refractory to prior immunotherapy and anti-angiogenic agents. In addition to observing biologic effect of TTI-101 monotherapy in advanced HCC tumors, we observed clinical proof of concept, in a single patient, supporting the potential of TTI-101 monotherapy to overcome ICI resistance. The patient previously failed treatment with lenvatinib, and subsequently nivolumab, before initiating treatment with TTI-101. Their best response was a 66% reduction in the sum of overall RECIST targets. They sustained the partial response for 14 months, after which time they demonstrated disease progression and discontinued treatment with TTI-101. They were subsequently treated with atezolizumab + bevacizumab within 30 days of discontinuation of TTI-101, and after two months of treatment demonstrated a new response, with decreases in target and nontarget lesions, suggesting a potential role for TTI-101 in resensitizing the tumor to ICI therapy. We believe resensitizing patients to ICI therapy has the potential to further improve survival and quality of life for patients with HCC.

Tumor Trajectories for Participant on TTI-101 Treatment Demonstrated Potential Resensitization to ICI Therapy



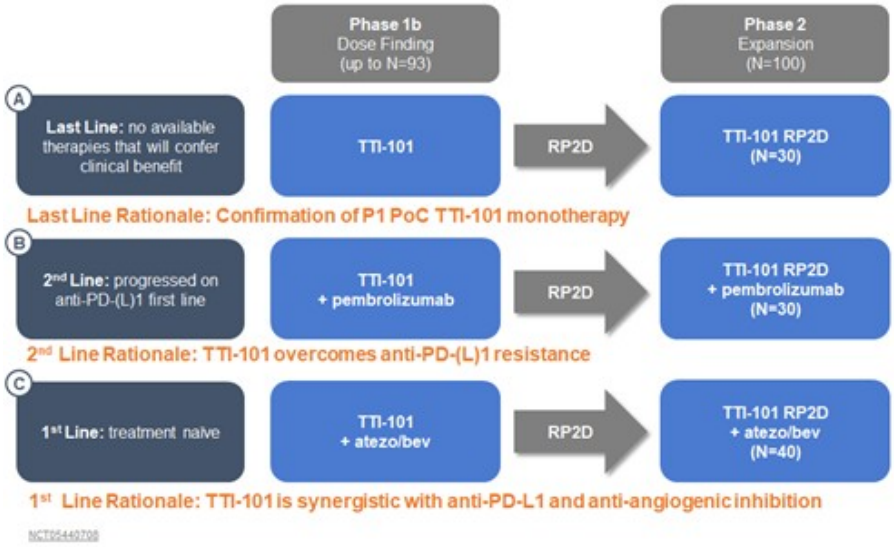
Based on our data from the Phase 1 clinical trial in advanced solid tumors along with the preclinical combination data, we initiated a Phase 1b/2 clinical trial designed to evaluate TTI-101 across multiple lines of therapy as monotherapy and combination therapy.

REVERT LIVER CANCER Phase 1b/2 Clinical Trial of TTI-101 as a Monotherapy and in Combination in Patients with HCC

The completed Phase 1 clinical trial was a first in human clinical trial with the primary objectives of evaluating safety and efficacy of TTI-101 as monotherapy in a variety of advanced, or metastatic cancers (including HCC). We have initiated a multicenter, open-label Phase 1b/2 clinical trial to further investigate the safety and efficacy of TTI-101 in patients with locally advanced or metastatic, and unresectable HCC, both as a monotherapy and in combination with standard of care therapy. Eligible patients are treated in one of three preselected treatment arms:

- Cohort A: TTI-101 as a single agent in participants who have recently demonstrated objective progression on up to three prior lines of systemic drug therapy.
- Cohort B: TTI-101 in combination with pembrolizumab in participants who have recently demonstrated objective progression following at least three months of first-line anti-PD-1 or anti-PD-L1 monotherapy or combination therapy.
- Cohort C: TTI-101 in combination with atezolizumab and bevacizumab in participants who are treatment-naïve.

REVERT LIVER CANCER Phase 1b/2 Clinical Trial Design



Overall, a total of up to 193 participants in all cohorts and phases of the clinical trial will be enrolled across 21 sites. For Phase 1b, a 3+3 dose-escalation design will be used. The primary objectives for the Phase 1b portion are to evaluate the safety and tolerability of TTI-101 as a single agent (Cohort A) and in combination with pembrolizumab (Cohort B) and in combination with atezolizumab + bevacizumab (Cohort C) and to determine the MTD and/or RP2D of TTI-101 as a single agent or in combination with pembrolizumab or atezolizumab + bevacizumab. The secondary objectives are to assess the preliminary efficacy of TTI-101 (ORR using RECIST) as a single agent or in combination with pembrolizumab therapy (Cohort B) and in combination with atezolizumab + bevacizumab therapy (Cohort C) in participants with locally advanced or metastatic, and unresectable HCC, to assess additional efficacy endpoints, to characterize the plasma PK of TTI-101 following oral administration and to determine the pharmacodynamics of TTI-101 following oral administration.

For Phase 2, a single-stage design will be used. The co-primary objectives for the Phase 2 portion are to evaluate the safety and tolerability of TTI-101 at the RP2D as a single agent (Cohort A) and in combination with pembrolizumab (Cohort B) and in combination with atezolizumab + bevacizumab (Cohort C) and to assess the preliminary efficacy of TTI-101 at the RP2D as a single agent (Cohort A) and in combination with pembrolizumab (Cohort B) and in combination with atezolizumab + bevacizumab (Cohort C). The secondary objectives are to assess additional efficacy endpoints, to characterize the plasma PK of TTI-101 following oral administration and to determine the PD of TTI-101 following oral administration.

The data from each of the cohorts will be used to inform future clinical development of TTI-101 in patients with locally advanced or metastatic, and unresectable HCC.

As of August 2024, we had completed enrollment in the Phase 1b portion of the clinical trial for Cohorts A and B, determined the RP2D and were enrolling patients in the Phase 2 portion of the clinical trial. As of May 2025, we completed enrollment in Cohort C of the Phase 1b portion of the clinical trial. In preliminary safety data, we observed similar incidence, grade and TEAEs in Cohort A treated with TTI-101 monotherapy as observed in the Phase 1 clinical trial, with diarrhea being the most commonly reported TEAE, mostly grade 1 or 2. Early safety data from the combination arms (TTI-101 + pembrolizumab (Cohort B) or TTI-101 + atezolizumab + bevacizumab (Cohort C)) of the Phase 1b portion of the clinical trial in HCC revealed a higher than expected incidence of pulmonary-related TEAEs, which are known side effects when treated with SoC. Based upon this information, and after consultations with thought leaders and investigators, the protocol was modified to explore lower dosages and intermittent schedules of TTI-101 in combination with pembrolizumab (Cohort B) or atezolizumab + bevacizumab (Cohort C).

Preliminary efficacy as of August 2024, is available for all three cohorts. In Cohort A, of 21 efficacy evaluable patients, 14 patients achieved a best response of SD. This disease control rate of 67% is comparable to the disease control rate (53%) observed in

the HCC cohort of the Phase 1 trial of TTI-101 monotherapy. In Cohort B, four of eight patients achieved SD. Lastly, in Cohort C, out of 12 enrolled patients, four achieved a cPR with an overall disease control rate of 93%.

As of February 2026, informed by our completed and ongoing clinical trials, the protocol was amended to explore modified dosages of TTI-101 in the monotherapy arm (Cohort A), adding up to 15 participants.

Based on our Phase 1 data and this clinical trial design, TTI-101 received Fast Track designation from the FDA. Fast Track designation may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that TTI-101 will receive marketing approval.

Our Strategy

Our goal is to leverage our expertise in STAT3 biology to discover and develop novel, oral, small molecule therapeutics for the treatment of patients suffering from inflammatory and proliferative diseases with significant unmet need. We aim to achieve this goal by executing on the following strategies.

- ***Become a leading STAT3 company to unlock its potential in inflammatory and proliferative diseases***. As a central mediator across critical inflammatory and proliferative signaling pathways, pY-STAT3 is key to the cellular processes that drive aberrant proliferation, survival, ECM, deposition and immune dysregulation. Based upon our founders' seminal work, we have made breakthrough discoveries that helped identify the structural basis and medicinal chemistry required to target the highly validated, yet historically undruggable, pY-STAT3. We leverage our deep understanding of STAT3 biology to design product candidates which specifically inhibit the activation of STAT3's nuclear functions without interfering with essential biological functions of STAT3. We believe our approach to directly inhibiting STAT3 enables us to develop product candidates with the potential to provide meaningful therapeutic benefit to patients with inflammatory and proliferative diseases, if approved.

- ***Advance TTI-109 in an inflammatory and/or proliferative indication.*** TTI-109, our phosphate prodrug of TTI-101, is designed to retain the full STAT3 inhibition mechanism of TTI-101 using a more efficient delivery vehicle with the potential to improve tolerability. Following Phase 1 healthy volunteer data expected in the second quarter of 2026, we plan to initiate Phase 2 development of TTI-109 in a disease indication supported by our extensive preclinical and clinical proof of concept data. Because TTI-109 shares the same mechanism of action as TTI-101, we believe that the body of preclinical and clinical evidence directly informs the potential of TTI-109.

- ***Progress TTI-101 through pivotal development for the treatment of an inflammatory and proliferative cancer driven by dysregulated STAT3 signaling, with initial development in HCC.*** STAT3 serves an integral role in HCC, with greater than 95% of patients having activated STAT3 in their tumors. Our Phase 1 data demonstrated an ORR exceeding current second-line standard of care, and preliminary Phase 1b/2 data as of August 2024 showed encouraging activity across all treatment lines. We plan to report topline data from the REVERT LIVER CANCER trial in the second half of 2026 and use those data to inform our pivotal development strategy.

- ***Expand our pipeline into additional indications where STAT3 activation plays a central role in disease pathogenesis.*** We intend to continue leveraging our deep expertise in STAT3 biology to develop product candidates for a broad range of inflammatory and proliferative diseases. We believe our preclinical data across multiple fibrotic, inflammatory, and oncologic models provide a rich foundation for indication expansion beyond our current clinical programs.

- ***Evaluate and pursue tailored strategies to maximize the impact of our product candidates and benefit to patients.*** We retain exclusive worldwide rights to all of our product candidates. We intend to independently develop our product candidates in indications and geographies with clear clinical and regulatory approval pathways where we can commercialize successfully on our own, if approved. We may also seek to establish strategic partnerships around certain product candidates in disease areas or geographies that are better served by the resources or specific expertise of other biopharmaceutical companies. To better serve patients with rare inflammatory and proliferative diseases, we continue to grow and strengthen our relationship with key constituents such as physicians, caregivers and patient advocacy groups.

Our Team

We were founded in 2017 by world-renowned physician-scientists David J. Tweardy, M.D., and Ron DePinho, M.D. Dr. Tweardy is recognized for his work elucidating STAT3's contribution to inflammation, fibrosis and oncogenesis. Discoveries by Dr. Tweardy and his lab included identification of the structural basis for the activation of STAT3, which led to the identification of TTI-101. Dr. DePinho is the Past President of The University of Texas MD Anderson Cancer Center and a member of the National Academy of Science and National Academy of Medicine. Dr. DePinho's groundbreaking research program has contributed to our understanding of cancer and aging disorders.

Our management team is comprised of experienced entrepreneurs, innovative scientists and dedicated physicians with a mission to develop a new class of breakthrough medicines for inflammatory and proliferative diseases characterized by dysregulated STAT3 signaling. Imran Alibhai, Ph.D., our Chief Executive Officer, brings approximately 20 years of experience in the biopharmaceutical industry as an executive, advisor and investor across public and private equities including inflammatory and proliferative diseases. Dr. Alibhai has held several executive positions at MPM Capital LLC, Alexandria Venture Investments, LLC, Peter J. Solomon Company and most recently as senior vice president and managing director at DNAtrix, Inc. John Kauh, M.D., our Chief Medical Officer, is a board-certified medical oncologist with proven leadership in early- and late-phase drug development of multiple oncology programs including surufatinib (Sulanda) at HUTCHMED (China) Limited and ramucirumab (Cyramza) for HCC at Eli Lilly and Company. Dan Conn, J.D., M.B.A., our Chief Financial Officer, has an extensive background in corporate law, finance and business management, having held multiple senior positions at Morgan Stanley, D.E. Shaw & Co., L.P., Brookfield Asset Management, Peter J. Solomon Company and most recently as chief executive officer and member of the board of directors at Christie's International Real Estate.

License Agreements

First License Agreement with Baylor College of Medicine

In July 2012, Stem Med Limited Partnership (StemMed) entered into the Baylor College of Medicine (BCM) First Agreement (referred to herein as the BCM First Agreement). StemMed assigned the BCM First Agreement to us in connection with the transfer of all or substantially all of the assets and businesses to which the BCM First Agreement relates in January 2018. Under the BCM First Agreement, we obtained an exclusive, worldwide, sublicensable license under BCM's rights to certain patents in oncology and certain non-oncology indications (BCM Patent Rights), together with certain cell lines, biological materials, compounds, know-how and technologies (collectively, the BCM Technology). Under the license, 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 the BCM Patent Rights or BCM Technology (referred to as BCM1 Licensed Products), in all fields of use.

Our license is subject to specified retained rights, consisting of: BCM's rights to grant a non-exclusive license under the BCM Patent Rights and BCM Technology to other academic or research institutions for non-commercial research purposes, and, if required by law, to grant a non-exclusive license to the United States government or to a foreign state pursuant to a treaty with the United States; BCM's rights to make or use the BCM Patent Rights and BCM Technology for non-commercial research, patient care and educational purposes; the rights of academic institutions, research institutions and certain BCM employees, if at academic or research institutions, to make or use the BCM Patent Rights and BCM Technology for non-commercial research purposes; and additional rights reserved by the government of the United States.

We are obligated to use reasonable efforts to introduce BCM1 Licensed Products to the commercial market as soon as practicable. We are obligated to achieve specified development milestones by specified timelines or to make payments to BCM if we do not achieve certain diligence milestones, and to produce, market and support the BCM1 Licensed Products with at least the same diligence we employ for comparable products and services. In consideration for the license rights, we paid BCM a license fee of $75,000. We paid an annual maintenance fee of $30,000 each year on the anniversary of the agreement until a specified anniversary before it increased to $50,000 each year on the anniversary of the agreement and are required to pay such annual maintenance fee until the introduction of a BCM1 Licensed Product. 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 the date of expiration of the last-to-expire of the BCM Patent Rights, or, if no BCM Patent Rights issued in such country, the tenth anniversary of the date of 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 obligated 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 the first BCM1 Licensed Product in a non-oncology indication to achieve such milestones. Furthermore, 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 obligated 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 terms of the BCM First Agreement, following a specified notice and cure period. Additionally, BCM may terminate the BCM First Agreement if we undergoes specified bankruptcy or insolvency events, following the expiration of a specified period. Upon expiration of the term of the BCM First Agreement in a given country, the license grant from BCM to us will be fully paid and perpetual in such country.

In April 2015, we entered into a first amendment with BCM to update the schedule of BCM Patent Rights and description of BCM Technology covered by the license and paid an additional $5,000 as consideration. In August 2019, we entered into a second amendment with BCM which amended our diligence and insurance obligations and further updated the schedule of BCM Patent Rights.

Second License Agreement with Baylor College of Medicine

In June 2015, StemMed entered into a license agreement with BCM (referred to herein as the BCM Second Agreement). StemMed assigned the BCM Second Agreement to us in connection with the transfer of all or substantially all of the assets and business to which the BCM Second Agreement relates in February 2018. 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 (Licensed Patent Rights). Under the license, we are permitted to make, to 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 (BCM2 Licensed Products) in all fields of use.

Our license is subject to specified retained rights, consisting of: BCM's rights to grant a non-exclusive license under the Licensed Patent Rights to other academic or research institutions for non-commercial research purposes, and, if required by law, to grant a non-exclusive license to the United States government or to a foreign state pursuant to a treaty with the United States; BCM's rights to grant a research license to a third party as required by the NIH; BCM's rights to make or use the Licensed Patent Rights for non-commercial research, patient care and educational purposes; the rights of academic institutions, research institutions and the inventors of the Licensed Patent Rights at BCM and NIH, to make or use the Licensed Patent Rights for non-commercial research purposes; and additional rights reserved by the government of the United States.

We are obligated to use reasonable efforts to introduce BCM2 Licensed Products to the commercial market as soon as practicable. We are obligated to achieve specified development milestones by specified timelines or to make payments to BCM if we do not achieve certain diligence milestones, and to produce, market and support the BCM2 Licensed Products with at least the same diligence we employ for comparable products and services.

In consideration for the license rights, we paid BCM a license execution fee of $5,000. We initially paid an annual maintenance fee of $30,000 each year on the anniversary of the agreement until a specified anniversary before it increased to $50,000 each year on the anniversary of the agreement. We are obligated to pay BCM royalties in the amount of a low-single-digit percent of net sales of BCM2 Licensed Products during the term, which expires, on a country-by-country basis, on the later of the date of expiration of the last to expire of the Licensed Patent Rights, or, if no Licensed Patent Rights issued in such country, the tenth anniversary of the date of first commercial sale of the BCM2 Licensed Product in such country. We currently expect the License Patent Rights to expire July 18, 2034. Upon the achievement of specified development and regulatory milestones, we are obligated 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 milestone. Furthermore, in connection with the initiation of the Phase 3 clinical trial, we would expect to incur approximately $300,000 in costs. Additionally, we are obligated 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.

We may terminate the BCM Second Agreement at our convenience following a specified notice period upon advance written notice to BCM. The BCM Second Agreement may also be terminated by BCM for our default or failure to perform any of terms of the BCM Second Agreement, following a specified notice and cure period. Additionally, BCM may terminate the BCM Second

Agreement if we undergo specified bankruptcy or insolvency events, following the expiration of a specified period. The NIH may terminate its license to BCM under specified limited circumstances, including our failure to fulfill certain obligations. Upon expiration of the term of the BCM Second Agreement in a given country, the license grant from BCM to us will be fully paid and perpetual in such country.

The BCM Second Agreement was amended in June 2019 to amend our diligence and insurance obligations. We entered into a second amendment 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.

Intellectual Property

Our success depends in large part upon our ability to obtain and maintain our technology and intellectual property. To protect our intellectual property rights, we primarily rely on patents, trade secret laws, confidentiality procedures and employee disclosure and invention assignment agreements. Our intellectual property is critical to our business, and we strive to protect it through a variety of approaches, including by obtaining and maintaining patent protection in various countries for our product candidates and other inventions that are important to our business.

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. The time required for development, testing and regulatory review of our product candidates limits the commercially useful lifespan of our patents.

The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. No consistent policy regarding the scope of patentable claims in the field of pharmaceuticals has emerged, for example, in the United States and in Europe. Changes in the patent laws and rules, either by legislation, judicial decisions or regulatory interpretation may diminish our ability to protect our inventions and enforce our intellectual property rights. These changes could affect the scope and value of our intellectual property.

Filing, prosecuting, enforcing and defending patents protecting our product candidates in all countries throughout the world would be prohibitively expensive. We cannot seek patent protection for our product candidates throughout the world. Furthermore, the intellectual property rights we obtain in some countries outside the United States can be less extensive than those obtained in the United States. The requirements for patentability may differ in certain countries, particularly in developing countries; thus, even in countries where we pursue patent protection, there can be no assurance that any patents will issue with claims that cover our product candidates.

Our ability to stop third parties from infringing any of our patented inventions, either directly or indirectly, will depend in part on our success in obtaining, defending and enforcing patent claims that cover our product candidates. We cannot be sure that any patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future. We cannot be sure that any of our existing patents or any patents that may be granted to us in the future will be found by a court to be enforceable. Protecting our competitive position around our product candidates may involve lawsuits to enforce our patents or other intellectual property, which is expensive and time-consuming, and may ultimately be unsuccessful. Furthermore, our issued patents and those that may issue in the future may be challenged, narrowed, circumvented or invalidated, which could limit our ability to stop competitors from marketing related product candidates or limit the length of the term of patent protection that we may have for our product candidates and future product candidates. We cannot be sure that any of our existing patents or any patents that may be granted to us in the future will be useful in protecting our commercialized product candidates. The rights granted under any issued patents may not provide us with complete protection or competitive advantages against competitors with similar but not identical technology or technologies that achieve similar outcomes but with different approaches. For these reasons, we may have competition for our product candidates.

Our issued patents and those that may issue in the future do not guarantee us the right to practice our product candidates. Third parties may have issued patents or be granted patents in the future that could block our ability to commercialize our product candidates.

We rely on trade secrets to protect certain aspects of our product candidates. If we are unable to protect the confidentiality of our trade secrets, our competitive position could be harmed. Furthermore, reliance on trade secrets does not prevent third parties from independently inventing those aspects of our product candidates. While we take commercially reasonable steps to ensure that our

employees do not use the trade secrets of third parties, third parties may file claims asserting that we or our employees have misappropriated their trade secret.

For this and other risks related to our inventions, please see the section titled "*Risk Factors — Risks Related to Our Intellectual Property.*"

Patent Portfolio

As of December 31, 2025, we have in-licensed four issued U.S. patents, one pending U.S. non-provisional patent application and 56 issued foreign patents, including patents issued in Australia, Canada, France, Italy, Germany, Spain and the United Kingdom, all in-licensed from BCM and all related to TTI-101. We co-own two issued U.S. patents, one pending U.S. non-provisional patent application, 21 issued foreign patents, including patents issued in Australia, China, Japan, France, Italy, Germany, Spain and the United Kingdom, and 8 pending foreign patent applications, including patent applications pending in Canada, China, Europe and Japan, all co-owned with BCM. We own four issued U.S. patents, five pending U.S. non-provisional patent applications, two pending U.S. provisional patent applications, two issued foreign patents including patents in China and Russia, 69 foreign patent applications, including patent applications pending in Australia, Canada, China, Europe and Japan, and three pending PCT applications.

The patent portfolios of our product candidates as of December 31, 2025, are summarized below.

TTI-101 is protected by twelve patent families.

Four patent families are in-licensed from BCM.

The first patent family in-licensed from BCM relates to methods of using TTI-101 to treat certain specific cancers and pulmonary fibrosis. The first patent family includes one issued U.S. patent expiring on November 13, 2030, and 11 issued foreign patents in Australia, Canada, Denmark, France, Germany, Italy, Netherlands, Norway, Spain, Switzerland and the United Kingdom, all expiring on June 3, 2029.

The second patent family in-licensed from BCM relates to methods of using TTI-101 to treat cachexia, muscle wasting and muscle weakness. This family includes two issued U.S. patents and 15 issued foreign patents in Australia, Canada, France, Germany, Italy, Spain, the United Kingdom and Hong Kong, all expiring on July 18, 2034.

The third patent family in-licensed from BCM relates to methods of using TTI-101 to treat fibrosis, excluding pulmonary fibrosis and myelofibrosis. This family includes one issued U.S. patent and 22 issued foreign patents in Australia, Canada, Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Netherlands, Norway, Poland, Portugal, Spain, Sweden, Switzerland, Turkey, the United Kingdom and Hong Kong, all expiring on July 18, 2034.

The fourth patent family in-licensed from BCM relates to methods of using TTI-101 to reduce the risk or severity of or prevent allergic reaction. This family includes one pending U.S. patent application and 8 issued foreign patents in Australia, Canada, France, Germany, Italy, Spain, United Kingdom and Hong Kong, all expiring on July 18, 2034.

We co-own one patent family with BCM. This family is directed to methods of using TTI-101 to treat insulin resistance. This patent family includes one pending U.S. patent application and five pending foreign patent applications in Canada, China, Europe, Hong Kong and Japan. If issued, the patent applications in this patent family are expected to expire on December 3, 2040.

In addition to the above, TTI-101 is protected by seven patent families owned by us.

The first patent family we own relates to self-emulsifying drug dispersion formulation of TTI-101 and includes three issued U.S. patents and one issued foreign patent in China, all expiring on January 22, 2041, and two pending foreign patent applications in Europe and Hong Kong.

The second patent family we own relates to spray-dried dispersion tablets of TTI-101 and includes one pending U.S. patent application and 17 pending patent applications in Argentina, Pakistan, Taiwan, Australia, Brazil, Canada, China, Eurasia, Europe, Hong Kong, India, Israel, Japan, Korea, Mexico, New Zealand and Singapore. If issued, patents in this family are expected to expire on March 1, 2043.

The third patent family we own relates to highly pure compositions of TTI-101 and includes one pending U.S. patent application and 17 pending foreign patent applications in Argentina, Pakistan, Taiwan, Australia, Brazil, Canada, China, Eurasia, Europe, Hong Kong, India, Israel, Japan, Korea, Mexico, New Zealand and Singapore. If issued, patents in this family are expected to expire on July 18, 2043.

The fourth patent family we own relates to methods of treating cancer using a combination of TTI-101 and an immune checkpoint inhibitor such as anti-PD-1 antibody and anti-PD-L1 antibody and includes one pending U.S. patent application, one granted Eurasian patent, and 10 pending foreign patent applications in Australia, Canada, China, Europe, Hong Kong, Japan, Korea, Mexico, New Zealand and Singapore. If issued, patents in this family are expected to expire on March 3, 2043.

The fifth patent family we own relates to methods of treating non-viral liver cancer with TTI-101 and includes one pending U.S. application and three pending foreign patent applications in Australia, Canada and Europe. If issued, patents in this family are expected to expire on December 11, 2043.

The sixth patent family we own relates to methods of treating cancer with certain doses of TTI-101 and includes one pending PCT application. If issued, patents in this family are expected to expire on September 5, 2044.

The seventh patent we own relates to methods of treating cancer with TTI-101 in certain patient populations and includes one pending PCT application. If issued, patents in this family are expected to expire on February 28, 2045.

TTI-109 is protected by four patent families owned by us.

The first patent family claims the TTI-109 compound and includes one issued U.S. patent expiring on June 9, 2043, one pending U.S. patent application, 20 pending foreign patent applications in Argentina, Pakistan, Taiwan, Australia, Brazil, Canada, China, Eurasia, Europe, Hong Kong, India, Indonesia, Israel, Japan, Korea, Mexico, Malaysia, New Zealand, Philippines, and Singapore. If issued, patents in this family are expected to expire on June 9, 2043.

The second patent family relates to methods of treating cancer with TTI-109 in certain patient populations and includes one pending PCT application. If issued, patents in this family are expected to expire on February 28, 2045.

The third patent family relates to solid forms of TTI-109 and includes one pending PCT application. If issued, patents in this family are expected to expire on December 19, 2044.

The fourth patent family relates to formulations of TTI-109 and includes one pending U.S. provisional application. If issued, patents in this family are expected to expire on May 29, 2046.

We cannot predict whether the patent applications we pursue or may license in the future will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide any protection from competitors. Even if its pending patent applications are granted as issued patents, those patents, as well as any patents we may license in the future from third parties now or in the future, may be challenged, circumvented or invalidated by third parties. Consequently, we may not obtain or maintain adequate patent protection for any of our programs and product candidates.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing of a non-provisional patent application. In the United States, the patent term of a patent may be extended by patent term adjustment, which compensates the patent owner for patent office delays. Additionally, in the United States, patents that cover an FDA-approved drug or biologic may also be eligible for patent term extension, which permits patent term restoration as compensation for the patent term lost during FDA regulatory review process. The Hatch-Waxman Act permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug or biologic is under regulatory review. Patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent applicable to an approved drug or biologic may be extended and only those claims covering the approved drug or biologic, a method for using it, or a method for manufacturing it may be extended. Similar provisions are available in European Member States and other foreign jurisdictions to extend the term of a patent that covers an approved drug or biologic. In the future, if our product candidates receive FDA approval, we expect to apply for patent term extensions where applicable on patents covering those products. We plan to seek patent term extensions to any of our issued patents in any jurisdiction where these are available, however there is no guarantee that the

applicable authorities, including the U.S. Patent and Trademark Office (USPTO) in the United States, will agree with our assessment of whether these extensions should be granted, and if granted, the length of these extensions.

Our intellectual property is critical to our business, and we strive to protect it through a variety of approaches, including by obtaining and maintaining patent protection in various countries for our product candidates and other inventions that are important to our business.

Trademarks

As of December 31, 2025, we own the trademark registrations for the company. Trademarks include "TVARDI," which is registered in Australia, China, European Union, Japan, Korea, the United Kingdom and the United States, and pending in Canada.

Trade Secrets and Proprietary Information

In addition to our reliance on patent protection for our inventions, we also rely on trade secrets, know-how, confidentiality agreements and continuing technological innovation to develop and maintain our competitive position. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees, advisors and consultants, these agreements may be breached, and we may not have adequate remedies for any breach. In addition, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. As a result, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual or entity during the course of the party's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions conceived of by the individual during the course of employment, and which relate to or are reasonably capable or being used in our current or planned business or research and development are our exclusive property. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our technology by third parties. However, such agreements and policies may be breached, and we may not have adequate remedies for such breaches. For more information regarding the risks related to our intellectual property, see the section titled "*Risk Factors — Risks Related to Our Intellectual Property*."

Competition

The biotechnology and biopharmaceutical industries are characterized by rapidly advancing technologies and understanding of disease etiology, intense development, strong competition and an emphasis on intellectual property. While we believe that our approach, strategy, scientific capabilities, know-how and experience, particularly in the field of STAT3 biology and product development provide us with competitive advantages, we face substantial competition from many different sources, including larger pharmaceutical companies with greater resources. Smaller specialty biotechnology and biopharmaceutical companies, academic research institutions and governmental agencies, as well as public and private institutions, are also potential sources of competitive products and technologies, including through collaborative arrangements with large and established biopharmaceutical companies. We also face competition in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and enrolling patients for clinical trials and acquiring technologies complementary to, or necessary for, our programs. We believe that the key competitive factors affecting the success of any of our product candidates will include efficacy, safety profile, convenience, method of administration, cost, level of promotional activity and intellectual property protection.

There are a number of large biopharmaceutical and biotechnology companies that are currently pursuing the development of products for the treatment of inflammatory and proliferative diseases. Companies that we are aware of that are actively developing STAT3 inhibitors preclinically and clinically to treat inflammatory and proliferative diseases include Moleculin Biotech, Purple Biotech and Scopus BioPharma.

Although our novel approach is differentiated from most other existing or investigational therapies across the disease areas where we are focusing our development, we will need to compete with currently approved therapies, and potentially those in currently in development if they are approved. We are aware of several marketed and investigational products in our leading disease areas, including but not limited to:

- *IPF*: There are currently three approved products for the treatment of IPF, including nerandomilast (JASCAYD, Boehringer Ingelheim Pharma GmbH & Co. KG), nintedanib (Ofev, Boehringer Ingelheim Pharma GmbH & Co. KG) and pirfenidone (Esbriet, marketed by Roche Holding AG), with generics marketed by Sandoz Group AG, Teva Pharmaceutical Industries Ltd. and others. Companies currently developing product candidates in IPF include, but are not limited to, AbbVie, Avalyn Pharma, Boehringer Ingelheim, Bristol Myers Squibb, Celea Therapeutics, Contineum Therapeutics, CSL Behring, Endeavor BioMedicines, Roche, Syndax Pharmaceuticals, United Therapeutics and Vicore Pharma.

- *HCC:* There are currently multiple available treatments for HCC, including sorafenib (Nexavar, marketed by Bayer HealthCare Pharmaceuticals), atezolizumab in combination with bevacizumab (Tecentriq and Avastin, respectively, marketed by Genentech), lenvatinib (Lenvima, marketed by Eisai R&D Management Co., Ltd.), durvalumab in combination with tremelimumab (Imfinzi and Imjudo, respectively, marketed by AstraZeneca), regorafenib (Stivarga, marketed by Bayer HealthCare Pharmaceuticals), ramucirumab (Cyramza, marketed by Eli Lilly and Company), cabozantinib (Cabometyx, marketed by Exelixis Inc.), pembrolizumab (Keytruda, marketed by Merck & Co., Inc.), and nivolumab in combination with ipilimumab (Opdivo and Yervoy, marketed by Bristol-Myers Squibb Company). Companies currently developing product candidates in HCC include, but are not limited to, AstraZeneca, BeOne Medicine, Bristol Myers Squibb, Elevar Therapeutics, Eli Lilly, Immune-Onc, and Iterion Therapeutics.

The availability of reimbursement from government and other third-party payors will also significantly affect the pricing and competitiveness of our product candidates, if approved for marketing. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we do, which could result in our competitors establishing a strong market position before we are able to enter the market.

Sales and Marketing

We currently have no sales, marketing or commercialization capabilities and have no experience as a company performing such activities. However, we intend to build the necessary capabilities and infrastructure over time following the advancement of our product candidates through clinical development. Clinical data, the size of the opportunity and the size of the commercial infrastructure required will influence our commercialization plans and decision making.

Commercialization

None of our product candidates have been approved for sale. If and when our product candidates receive marketing approval, we intend to commercialize them on our own, or jointly with a partner, in the United States and potentially in other geographies. We will continually evaluate the economics of commercializing our product candidates versus other strategic commercialization arrangements.

Manufacturing

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We have engaged, and expect to continue to rely on, well-established third-party Contract Development and Manufacturing Organizations (CDMOs), to supply our product candidates for use in our preclinical studies and clinical trials. Should any of these CDMOs become unavailable to us for any reason, we believe that there are a number of potential replacements, although we may incur some delay in identifying and qualifying such replacements.

Additionally, we intend to rely on third-party CDMOs for commercial manufacturing, if our product candidates receive marketing approval. As our lead product candidates advance through development, we expect to enter into longer-term commercial supply agreements to fulfill and secure our production needs. Additionally, to adequately meet our projected commercial manufacturing needs, our CDMOs will need to scale-up production, or we will need to secure additional suppliers. Processes for producing drug substances and drug product for commercial supply are currently being developed, with the goal of achieving reliable, reproducible and cost-effective production.

Government Regulation

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the clinical development, manufacture and marketing of pharmaceutical and diagnostic products. These agencies and other federal, state and local entities regulate research and development activities and the testing, manufacture, quality control, safety, effectiveness, labeling, storage, packaging, recordkeeping, tracking, approval, import, export, distribution, advertising and promotion of drug products.

U.S. Government Regulation of Drug Products

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act (FDCA), and its implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to a variety of administrative or judicial sanctions, such as the FDA's refusal to approve a pending new drug application (NDA), withdrawal of an approval, imposition of a clinical hold, issuance of untitled or warning letters, product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution, injunctions, debarment, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. FDA approval is required before a drug may be marketed in the United States and drug candidates are also subject to other federal, state and local statutes and regulations.

The process required by the FDA before drug candidates may be marketed in the United States generally involves the following:

- completion of extensive nonclinical laboratory and animal tests, which must be conducted in accordance with applicable regulations, including good laboratory practices and applicable requirements for the humane use of laboratory animals or other applicable regulations;
- submission to the FDA of an IND application, which must become effective before clinical trials may begin and must be updated annually;
- approval by an independent institutional review board (IRB) or ethics committee for each clinical site or centrally before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug candidate for its intended use, performed in accordance with Good Clinical Practices (GCPs) requirements to establish the safety and efficacy of the product candidate for each proposed indication;
- submission to the FDA of an NDA after completion of all pivotal clinical studies that include substantial evidence of safety and efficacy of the drug from analytical studies and from results of nonclinical testing and clinical trials and payment of user fees;
- determination by the FDA within 60 days of its receipt of an NDA to file the application for review;
- satisfactory completion of a pre-approval inspection of manufacturing facilities and selected clinical investigators for their compliance with current Good Manufacturing Practices (cGMPs) and GCPs;
- satisfactory completion of FDA audits of clinical trial sites to ensure compliance with GCPs and the integrity of the clinical data;
- satisfactory completion of an FDA advisory committee review, if applicable;
- FDA review and approval of an NDA to permit commercial marketing for particular indications for use in the United States; and
- compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy (REMS), and the potential requirement to conduct post-approval studies.

- The testing and approval process requires substantial time, effort and financial resources.

Preclinical Studies

Preclinical studies include laboratory evaluation of drug substance chemistry, pharmacology, toxicity and drug product formulation, as well as animal studies to assess potential safety and efficacy. Prior to commencing the first clinical trial with a drug candidate, a sponsor must submit the results of the preclinical tests and preclinical literature, together with manufacturing information, analytical data and any available clinical data or literature, among other required information, to the FDA as part of an IND. An IND is a request for authorization from the FDA to administer an investigational new drug or biological product to humans. Some preclinical studies may continue even after the IND is submitted. The central focus of an initial IND submission is on the general investigational plan and the protocol or protocols for clinical trials. The IND submission also includes results of animal and *in vitro* preclinical studies assessing the toxicology, PK, PD and pharmacology characteristics of the product, chemistry, manufacturing and controls (CMC) information, and any available human data or literature to support the use of the investigational product. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the conduct of the clinical trial and imposes a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA also may impose a partial clinical hold that would limit a clinical trial, for example, to certain doses or for a certain length of time or to a certain number of subjects. As a result, submission of an IND may not result in FDA authorization to commence a clinical trial.

Clinical Trials

Clinical trials involve the administration of the investigational new drug to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development, as well as amendments to previously submitted clinical trials. Further, an independent IRB for each institution participating in the clinical trial must review and approve the plan for any clinical trial, its informed consent form and other communications to clinical trial subjects before the clinical trial commences at that site. An IRB is charged with protecting the welfare and rights of clinical trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB must continue to oversee the clinical trial while it is being conducted, including any changes to the clinical trial plans. While the IND is active, and before approval, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report, among other information, must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected AEs, findings from other clinical trials suggesting a significant risk to humans exposed to the same or similar drugs, findings from animal or *in vitro* preclinical testing suggesting a significant risk to humans and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure.

Regulatory authorities, an IRB or the sponsor may suspend or discontinue a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk, the clinical trial is not being conducted in accordance with the FDA's or the IRB's requirements, or if the drug has been associated with unexpected serious harm to subjects. Some clinical trials also include a DSMB, which receives special access to unblinded data during the clinical trial and may advise the sponsor to halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy.

In general, for purposes of NDA approval, human clinical trials are typically conducted in three sequential phases that may overlap.

Phase 1. Clinical trials are initially conducted to test the drug candidate for safety, dosage tolerance, structure-activity relationships, mechanism of action, absorption, metabolism, distribution and excretion in healthy volunteers or subjects with the target disease or condition. Phase 1a trials are typically single ascending dose escalation of the investigational drug alone, while Phase 1b trials, or the Phase 1b portion of a combined phase trial (Phase 1b/2) may have multiple ascending doses to expand and identify optimal dosing, including in combination with other drugs. If possible, Phase 1 clinical trials may also be used to gain early evidence of product effectiveness.

Phase 2. Controlled clinical trials are conducted with groups of subjects with a specified disease or condition to provide enough data to evaluate the preliminary efficacy, optimal dosages and dosing schedule and expanded evidence of safety. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expansive Phase 3 clinical trials.

Phase 3. These clinical trials are generally undertaken in larger subject populations to provide statistically significant evidence of clinical efficacy and to further test for safety in an expanded subject population at multiple clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for product labeling. These clinical trials may be done at clinical trial sites outside the United States as long as the global sites are also representative of the U.S. population and the conduct of the clinical trial at global sites comports with FDA regulations and guidance, such as compliance with GCPs.

The FDA may require, or companies may pursue, additional clinical trials after a product is approved. These so-called Phase 4 post-marketing studies may be made a condition to be satisfied after approval. The results of Phase 4 post-marketing studies can confirm the effectiveness of a drug candidate and can provide important safety information.

Clinical trials must be conducted under the supervision of qualified investigators in accordance with GCP requirements, which include the requirements that all research subjects provide their informed consent in writing for their participation in any clinical trial, and the review and approval of the clinical trial by an IRB. Investigators must also provide information to the clinical trial sponsors to allow the sponsors to make specified financial disclosures to the FDA. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, the clinical trial procedures, the parameters to be used in monitoring safety and the efficacy criteria to be evaluated and a statistical analysis plan. Information about some clinical trials, including a description of the clinical trial and clinical trial results, must be submitted within specific time frames to the NIH for public dissemination on their *clinicaltrials.gov* website. Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and the IRB and more frequently if SAEs occur.

The manufacture of investigational drugs for the conduct of human clinical trials is subject to cGMP requirements. Investigational drugs and active pharmaceutical ingredients imported into the United States are also subject to regulation by the FDA relating to their labeling and distribution. Further, the export of investigational drug products outside of the United States is subject to regulatory requirements of the receiving country as well as U.S. export requirements under the FDCA.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug candidate as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

NDA Submission and Review by the FDA

Assuming successful completion of the required clinical and preclinical testing, among other items, the results of product development, including chemistry, manufacture and controls, nonclinical studies and clinical trials are submitted to the FDA, along with proposed labeling, as part of an NDA. The submission of an NDA requires payment of a substantial user fee to the FDA. Fee waivers or reductions are available in some circumstances.

In addition, under the Pediatric Research Equity Act, an NDA or supplement to an NDA for a new active ingredient, indication, dosage form, dosage regimen or route of administration must contain data that are adequate to assess the safety and efficacy of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective.

The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults or full or partial waivers from the pediatric data requirements.

The FDA may refer drugs to an advisory committee. An advisory committee is typically a panel that includes clinicians and other experts who review, evaluate and make a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

The FDA reviews applications to determine, among other things, whether a product is safe and effective for its intended use and whether the manufacturing controls are adequate to assure and preserve the product's identity, strength, quality and purity. Before approving an NDA, the FDA will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities, including contract manufacturers and subcontracts, are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical trial sites to assure compliance with GCPs.

Once the FDA receives an application, it has 60 days to review the NDA to determine if it is substantially complete to permit a substantive review, before it accepts the application for filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act (PDUFA), the FDA has set the review goal of 10 months from the 60-day filing date to complete its initial review of a standard NDA for a new molecular entity (NME), and make a decision on the application. For priority review applications, the FDA has set the review goal of reviewing NME NDAs within six months of the 60-day filing date. Such deadlines are referred to as the PDUFA date. The PDUFA date is only a goal, and the FDA does not always meet its PDUFA dates. The review process and the PDUFA date may also be extended if the FDA requests or the NDA sponsor otherwise provides additional information or clarification regarding the submission during the review period that amends the original application.

Once the FDA's review of the application is complete, the FDA will issue either a Complete Response Letter (CRL) or an approval letter. A CRL indicates that the review cycle of the application is complete, and the application is not ready for approval. A CRL generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA and may require additional clinical or preclinical testing, or other information or analyses in order for the FDA to reconsider the application in the future. Even with the submission of additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA may issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

The FDA may delay or refuse approval of an NDA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product, or impose other conditions, including distribution restrictions or other risk management mechanisms. For example, the FDA may require a REMS as a condition of approval or following approval to mitigate any identified or suspected serious risks and ensure safe use of the drug. The FDA may prevent or limit further marketing of a product, or impose additional post-marketing requirements, based on the results of post-marketing studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements, FDA notification and FDA review and approval. Further, should new safety information arise, additional testing, product labeling or FDA notification may be required.

If regulatory approval of a product is granted, such approval may entail limitations on the indicated uses for which such product may be marketed or may include contraindications, warnings or precautions in the product labeling, which has resulted in a boxed warning. A boxed warning is the strictest warning put in the labeling of prescription drugs or drug products by the FDA when there is reasonable evidence of an association of a serious hazard with the drug. The FDA also may not approve the inclusion of all labeling claims sought by an applicant. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing regulatory standards is not maintained or if problems occur after the product reaches the marketplace. In addition, the FDA may require Phase 4 post-marketing studies to monitor the effect of approved products and may limit further marketing of the product based on the results of these post-marketing studies.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat patients with a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States, or 200,000 or more than individuals in the United States for which there is no reasonable expectation that the cost of developing and making available in the United States a drug or biologic for this type of disease or condition will be recovered from sales in the United States for that drug or biologic. Orphan drug designation must be requested before submitting an NDA. After the FDA grants Orphan Drug Designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. The Orphan Drug Designation does not convey any advantage in, or shorten the duration of, the regulatory review or approval process.

If a product that has Orphan Drug Designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusive approval (or exclusivity), which means that the FDA may not approve any other applications, including a full NDA, to market the same drug for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or if the holder of the orphan drug exclusivity cannot assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of Orphan Drug Designation are tax credits for certain research and a waiver of the NDA application user fee.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of FDA-regulated products, including drugs, are required to register and disclose certain clinical trial information on the website *www.clinicaltrials.gov*. Information related to the product, patient population, phase of investigation, clinical trial sites and investigators and other aspects of a clinical trial are then made public as part of the registration. Sponsors are also obligated to disclose the results of their clinical trials after completion. Disclosure of the results of clinical trials can be delayed in certain circumstances for up to two years after the date of completion of the clinical trial. Competitors may use this publicly available information to gain knowledge regarding the progress of clinical development programs as well as clinical trial design.

U.S. Post-Approval Requirements

Any products manufactured or distributed pursuant to FDA approvals are subject to continuing regulation by the FDA, including periodic reporting, product sampling and distribution, advertising, promotion, drug shortage reporting, compliance with any post-approval requirements imposed as a conditional of approval such as Phase 4 clinical trials, REMS and surveillance, recordkeeping and reporting requirements, including adverse experiences.

After approval, most changes to the approved product, such as adding new indications or other labeling claims are subject to prior FDA review and approval. There also are continuing, annual program fee requirements for approved products, as well as new application fees for supplemental applications with clinical data. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies and to list their drug products and are subject to periodic announced and unannounced inspections by the FDA and these state agencies for compliance with cGMPs and other requirements, which impose procedural and documentation requirements.

Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented or FDA notification. FDA regulations also require investigation and correction of any deviations from cGMPs and specifications and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. Manufacturers and other parties involved in the drug supply chain for prescription drug products must also comply with product tracking and tracing requirements and for notifying the FDA of counterfeit, diverted, stolen and intentionally adulterated products or products that are otherwise unfit for distribution in the United States.

Later discovery of previously unknown problems with a product, including AEs of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in withdrawal of marketing approval, mandatory revisions to the approved labeling to add new safety information or other limitations, imposition of post-market studies or clinical trials to assess new safety risks or imposition of distribution or other restrictions under a REMS program, among other consequences.

The FDA closely regulates the marketing and promotion of drugs. A company can make only those claims relating to safety and efficacy that are consistent with the FDA approved labeling. Physicians, in their independent professional medical judgment, may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested and approved by the FDA. However, manufacturers and third parties acting on their behalf are prohibited from marketing or promoting drugs in a manner inconsistent with the approved labeling. The FDA and other agencies actively enforce the laws and regulations

prohibiting the promotion of off-label uses and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

Failure to comply with any of the FDA's requirements could result in significant adverse enforcement actions. These include a variety of administrative or judicial sanctions, such as refusal to approve pending applications, license suspension or revocation, withdrawal of an approval, imposition of a clinical hold or termination of clinical trials and/or post-approval clinical studies, refusal to approve pending applications or supplements to approved applications, warning letters, untitled letters, mandated modification of promotional materials or labeling, required issuance of corrective information, issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product, product recalls, product seizures or detentions, refusal to allow imports or exports, total or partial suspension of production or distribution, debarment, injunctions, fines, consent decrees, corporate integrity agreements, refusals of government contracts and new orders under existing contracts, exclusion from participation in federal and state healthcare programs, restitution, disgorgement or civil or criminal penalties, including fines and imprisonment. It is also possible that failure to comply with the FDA's requirements relating to the promotion of prescription drugs may lead to investigations alleging violations of federal and state healthcare fraud and abuse and other laws, as well as state consumer protection laws. Any of these sanctions could result in adverse publicity, among other adverse consequences.

U.S. Marketing Exclusivity

Market exclusivity provisions authorized under the FDCA can delay the submission or the approval of some marketing applications. The FDA provides periods of non-patent regulatory exclusivity, which provides the holder of an approved NDA limited protection from new competition in the marketplace for the innovation represented by its approved drug for a period of three or five years following the FDA's approval of the NDA. For example, five years of exclusivity are available to new chemical entities (NCEs). A drug is an NCE if the FDA has not previously approved any other new drug containing the same active moiety. An active moiety is the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt, including a salt with hydrogen or coordination bonds, or other noncovalent, or not involving the sharing of electron pairs between atoms, derivatives, such as a complex (i.e., formed by the chemical interaction of two compounds), chelate (i.e., a chemical compound), or clathrate (i.e., a polymer framework that traps molecules), of the molecule, responsible for the therapeutic activity of the drug substance. During the exclusivity period, the FDA may not accept for review or approve an Abbreviated New Drug Application (ANDA) or a 505(b)(2) NDA submitted by another company that contains the previously approved active moiety. An ANDA or 505(b)(2) application, however, may be submitted one year before NCE exclusivity expires if a Paragraph IV certification is filed.

The FDCA alternatively provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, for new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions of approval for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for drugs containing the active agent for the original indication or condition of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to any preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Pediatric exclusivity is another type of marketing exclusivity available in the United States. Pediatric exclusivity provides for an additional six months of marketing exclusivity attached to another period of patent or non-patent exclusivity if a sponsor conducts clinical trials in children in response to a written request from the FDA. The issuance of a written request does not require the sponsor to undertake the described clinical trials. In addition, orphan drug exclusivity, as described above, may offer a seven-year period of marketing exclusivity, except in some circumstances.

Regulation Outside the United States

In order to market any product outside of the United States, numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety, and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution would apply. Whether or not FDA approval is obtained for a product, the necessary approvals by the comparable foreign regulatory authorities must be obtained before clinical trials or marketing of the product can commence in foreign countries and jurisdictions. Although many of the issues discussed above with respect to the United States apply similarly in the context of the European Union, the approval process varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not

ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

Other Healthcare Laws and Compliance Requirements

Our business activities, including but not limited to, research, sales, promotion, distribution, medical education and other activities are subject to regulation by numerous regulatory and law enforcement authorities in the United States in addition to the FDA, including the Department of Justice, the U.S. Department of Health and Human Services (HHS), and its various divisions, including the Centers for Medicare & Medicaid Services and the Health Resources and Services Administration, the Department of Veterans Affairs, the Department of Defense and state and local governments. Our business activities must comply with numerous healthcare laws and regulations, including those described below.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, the referral of an individual for, or purchasing, leasing, ordering, or arranging for the purchase, lease or order of, any good, facility, item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other hand. The term remuneration has been interpreted broadly to include anything of value. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the federal Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Additionally, a person or entity no longer does not need to have actual knowledge of the federal Anti-Kickback Statute, or the specific intent to violate it, to have violated the statute.

The federal civil and criminal false claims laws, including the False Claims Act (FCA) prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to, or approval by, the U.S. federal government, including Medicare and Medicaid programs, or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or to avoid, decrease or conceal an obligation to pay money to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes “any request or demand” for money or property presented to the U.S. government. In addition, manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims. The FCA also permits a private individual acting as a “whistleblower” to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery. FCA liability is potentially significant in the healthcare industry because the statute provides for treble damages and mandatory penalties. Government enforcement agencies and private whistleblowers have investigated pharmaceutical companies for or asserted liability under the FCA for a variety of alleged promotional and marketing activities, such as providing free products to customers with the expectation that the customers would bill federal programs for the products; providing consulting fees and other benefits to physicians to induce them to prescribe products; engaging in promotion for “off-label” uses; and submitting inflated best price information to the Medicaid Rebate Program. Moreover, a violation of the federal Anti-Kickback Statute is grounds for the government or a whistleblower to assert that a claim for payment of items or services resulting from such violation constitutes a false or fraudulent claim for purposes of the FCA.

Health Insurance Portability and Accountability Act (HIPAA), created additional federal criminal statutes that prohibits, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of whether the payor is public or private, knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense and knowingly and willfully falsifying, concealing or covering up by any trick, scheme or device a material fact or making any materially false, fictitious or fraudulent statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Additionally, a person or entity does not need to have actual knowledge of the statute, or the specific intent to violate it, to have committed a violation.

The federal Open Payments program pursuant to the Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health

Insurance Program (with specified exceptions) to report annually information related to specified payments or other transfers of value provided to physicians, as defined by such law, certain other healthcare providers (such as physician assistants and nurse practitioners) and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually specified ownership and investment interests held by physicians and their immediate family members. Failure to submit timely, accurately and completely the required information for all payments, transfers of value and ownership or investment interests may result in civil monetary penalties.

In addition, we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), and its implementing regulations, impose requirements relating to the privacy, security and transmission of individually identifiable health information held by covered entities and their business associates and their covered subcontractors. Among other things, HITECH makes HIPAA's security standards directly applicable to business associates, defined as independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions.

Many states have also adopted laws similar to each of the above federal laws, which may be broader in scope and apply to items or services reimbursed by any third-party payor, including commercial insurers. Additionally, some state and local laws require certain regulatory licenses to manufacture or distribute pharmaceutical products commercially and/or the registration of pharmaceutical sales representatives in the jurisdiction. We may also be subject to state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, and/or state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information.

Ensuring that our internal operations and business arrangements with third parties comply with applicable healthcare laws and regulations will likely be costly. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations were found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, possible exclusion from government funded healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and curtailment of our operations, any of which could substantially disrupt our operations. If the physicians or other providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Coverage and Reimbursement

Our ability to commercialize any products successfully will also depend in part on the extent to which coverage and adequate reimbursement for the procedures utilizing our drug candidates, performed by health care providers, once approved, will be available from government health administration authorities, private health insurers and other organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, determine which procedures, and the products utilized in such procedures, they will cover and establish reimbursement levels. Assuming coverage is obtained for procedures utilizing a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. Patients who undergo procedures for the treatment of their conditions, and their treating physicians, generally rely on third-party payors to reimburse all or part of the costs associated with the procedures which utilize our products. Treating physicians are unlikely to use and order our products unless coverage is provided and the reimbursement is adequate to cover all or a significant portion of the cost of the procedures which utilize our products. Therefore, coverage and adequate reimbursement for procedures which utilize new products is critical to the acceptance of such new products. Coverage decisions may depend upon clinical and economic standards that disfavor new products when more established or lower cost therapeutic alternatives are already available or subsequently become available.

Government authorities and other third-party payors are developing increasingly sophisticated methods of cost containment, such as including price controls, restrictions on coverage and reimbursement and requirements for substitution of less expensive products

and procedures. For example, HHS imposes rebates on many Medicare Part B and Medicare Part D products to penalize price increases that outpace inflation on an annual basis. HHS has also been empowered to negotiate the price of certain single-source drugs that have been on the market for at least seven years covered under Medicare as part of the Medicare Drug Price Negotiation Program. Each year up to 20 products will be selected by HHS for the Medicare Drug Price Negotiation Program. Products subject to the Medicare Drug Price Negotiation Program are expected to experience a significant reduction in reimbursement from the Medicare program on a per unit basis. Government and other third-party payors are increasingly challenging the prices charged for health care products and procedures, examining the cost effectiveness of procedures, and the products used in such procedures, in addition to their safety and efficacy, and limiting or attempting to limit both coverage and the level of reimbursement. Further, no uniform policy requirement for coverage and reimbursement exists among third-party payors in the United States, which causes significant uncertainty related to the insurance coverage and reimbursement of newly approved products, and the procedures which may utilize such newly approved products. Therefore, coverage and reimbursement can differ significantly from payor to payor and health care provider to health care provider. As a result, the coverage determination process is often a time-consuming and costly process that requires the provision of scientific and clinical support for the use of new products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Further, coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we or our collaborators receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

There may also be significant delays in obtaining coverage and reimbursement for newly approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA. Moreover, eligibility for coverage and reimbursement does not imply that a product, or the procedures which utilize such product, will be paid for in all cases or at a rate which the health care providers who purchase those products will find cost effective. For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization. Additionally, there may be pricing pressures in connection with the sale of any of our drug candidates, once approved, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, and additional legislative changes.

Coverage and reimbursement may impact the demand for, the price of, or our ability to successfully commercialize, any drug candidate for which we obtain marketing approval.

Healthcare Reform

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. By way of example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the ACA), was signed into law, intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose taxes and fees on the healthcare industry and impose additional health policy reforms.

There have been executive, judicial and Congressional challenges to certain aspects of the ACA. Moreover, there have been a number of health reform initiatives that have impacted the ACA. For example, on July 4, 2025, the One Big Beautiful Bill Act (the OBBBA) was signed into law, which narrowed access to ACA marketplace exchange enrollment and declined to extend the ACA enhanced advanced premium tax credits that expired at the end of 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. The OBBBA also is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. Congress is considering proposed legislation intended to further reduce healthcare costs with alternatives to replace the expired ACA subsidies.

The current administration is pursuing policies to reduce regulations and expenditures across government agencies including at HHS, the FDA, CMS and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. For example, the current administration has announced agreements with several pharmaceutical companies that require the drug manufacturers to offer, through a direct to consumer platform, U.S. patients and Medicaid programs prescription drug Most-Favored Nation pricing equal to or lower than those paid in other developed nations, with additional mandates for direct-to-patient discounts and repatriation of foreign revenues. Other recent actions, for example, include (1) directing agencies to reduce agency workforce and cut programs; (2) directing

HHS and other agencies to lower prescription drug costs through a variety of initiatives, including by establishing Most-Favored-Nation pricing for pharmaceutical products and launching an online clearinghouse (TrumpRx) for patients to purchase certain products from manufacturers on a cash pay basis; (3) imposing tariffs on imported pharmaceutical products; and (4) as part of the Make America Healthy Again (MAHA) Commission's Strategy Report released in September 2025, working across government agencies to increase enforcement on direct-to-consumer pharmaceutical advertising. Additionally, the current administration recently called on Congress to enact "The Great Healthcare Plan," to codify and expand Most-Favored Nation pricing, lower government subsidies to private insurance companies, increase healthcare price transparency, expand pharmaceutical drugs available for over-the-counter purchase, and enact restrictions on pharmacy benefit manager (PBM) payment methodologies, among other things. These actions and policies may significantly reduce U.S. drug prices, potentially impacting manufacturers' global pricing strategies and profitability, while increasing their operational costs and compliance risks. In June 2024, the U.S. Supreme Court's Loper Bright decision greatly reduced judicial deference to regulatory agencies, which could increase successful legal challenges to federal regulations affecting our operations. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payors. The implementation of current and future cost containment measures or other healthcare reforms may adversely affect our operations and prevent us from being able to generate revenue, attain profitability or commercialize our drug candidates.

At the state level, individual states in the United States have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Some third-party payors also require pre-approval of coverage for new or innovative devices or therapies before they will reimburse healthcare providers that use such therapies.

Data Privacy and Security

In the ordinary course of our business, we process data including sensitive and personal data. Accordingly, we are, and may in the future become, subject to numerous data privacy and security obligations, including federal, state, local, and foreign laws, regulations, guidance, and industry standards related to data privacy, security, and protection. Such laws may include, without limitation, the Federal Trade Commission Act, the Telephone Consumer Protection Act of 1991, the Controlling the Assault of Non-Solicited Pornography And Marketing Act of 2003, and the California Consumer Privacy Act of 2018 (CCPA). Several states within the United States have enacted or proposed data privacy laws. Additionally, we are, or may become, subject to various U.S. federal and state consumer protection laws which require us to publish statements that accurately and fairly describe how we handle personal data and choices individuals may have about the way we handle their personal data.

Numerous U.S. states have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the CCPA applies to personal data of consumers, business representatives, and employees who are California residents, and requires covered businesses to provide specific disclosures in privacy notices and respond to requests of such individuals to exercise certain privacy rights. The CCPA provides for fines and allows private litigants affected by certain data breaches to recover significant statutory damages. See the section titled "Risk Factors — *General Risk Factors — We, and the third parties with whom we work, are or may become subject to stringent and evolving U.S. and foreign laws, regulations, and rules; contractual obligations; and policies, all related to data privacy or security. Our (or the third parties with whom we work) actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse business consequences*" for additional information about the data protection laws and regulations to which we are or may become subject and about the risks to our business associated with such laws and regulations.

Additional Regulation

In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservation and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern the use, handling and disposal of various biologic, chemical and radioactive substances used in,

and wastes generated by, operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. Equivalent laws have been adopted in other countries that impose similar obligations.

Foreign Corrupt Practices Act

The U.S. Foreign Corrupt Practices Act of 1977, as amended (FCPA), prohibits any U.S. individual or business, as well as its directors, officers, employees, agents, and representatives, from paying, offering or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, employees of state-owned or controlled entities or public international organizations, political party or candidate for political office for the purpose of influencing any act or decision of a foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the companies to maintain books and records that accurately and fairly reflect all transactions of the companies, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Employees and Human Capital Resources

As of December 31, 2025, we had 12 full-time employees, 8 of whom are involved in research and development activities. Eight of our employees hold Ph.D. or M.D. degrees. None of our employees are subject to a collective bargaining agreement. We consider our relationship with our employees to be good.

We recognize that our continued ability to attract, retain and motivate exceptional employees is vital to ensuring our long-term competitive advantage. Our employees are critical to our long-term success and are essential to helping us meet our goals. Among other things, we support and incentivize our employees in the following ways:

- Talent development, compensation and retention: Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. The principal purposes of our equity incentive plans are to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards.

- Health and safety: We support the health and safety of our employees by providing comprehensive insurance benefits, an employee assistance program, company-paid holidays, a personal time-off program and other additional benefits which are intended to assist employees to manage their well-being.

- Inclusion: We are committed to efforts to foster an inclusive work environment that supports our workforce.

Corporate Information

We were incorporated under the laws of the State of Delaware in July 2004 under the name “Cara Therapeutics, Inc.” Legacy Tvardi was incorporated under the laws of the State of Delaware in December 2017. On the Closing Date, Cara completed its previously announced merger with Legacy Tvardi, in accordance with the terms of the Merger Agreement, pursuant to which Merger Sub merged with and into Legacy Tvardi, with Legacy Tvardi surviving the Merger as a wholly owned subsidiary of Cara. Also on the Closing Date, Cara changed its name from “Cara Therapeutics, Inc.” to “Tvardi Therapeutics, Inc.”

Our principal executive offices are located at 3 Sugar Creek Ctr. Blvd., Suite 525, Sugar Land, Texas, and our telephone number is (713) 489-8654.

Our website address is *www.tvarditherapeutics.com*. Our website is included as an inactive textual references and the information contained on, or that can be accessed through, our website is not a part of this Annual Report on Form 10-K.

All brand names or trademarks appearing in this Annual Report on Form 10-K are the property of their respective holders. Use or display by us of other parties’ trademarks, trade dress, or products in this Annual Report on Form 10-K is not intended to, and does not, imply a relationship with, or endorsements or sponsorship of, us by the trademark or trade dress owners.

Website Access to Reports

We are subject to the informational requirements of the Exchange Act and file or furnish reports, including our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to reports filed pursuant to Sections 13(a) and 15(d) of the Exchange Act, proxy statements and other information with the SEC. We make copies of these reports and other information available free of charge through our website (under the heading "Financials & Filings - SEC Filings") as soon as reasonably practicable after we file or furnish them with the SEC. The SEC maintains a website that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC at *www.sec.gov*. We intend to announce material information to the public through filings with the SEC, the "Investors" page on our website, press releases, public conference calls, and public webcasts.

The information disclosed through the foregoing channels could be deemed to be material information. As such, we encourage investors, the media, and others to follow the channels listed above and to review the information disclosed through such channels. The information contained on or accessible through the websites referenced herein is not incorporated by reference into this Annual Report on Form 10-K, and the website addresses are provided only as inactive textual references. Any updates to the list of disclosure channels through which we will announce information will be posted on the Investors page on our website.

Item 1A. *Risk Factors*

An investment in our common stock involves a high degree of risk. In addition to the risks and uncertainties described under the section titled "Cautionary Note Regarding Forward-Looking Statements," you should carefully consider the risks and uncertainties described below, together with all of the other information contained in this Annual Report on Form 10-K, including our audited consolidated financial statements and related notes and in our other public filings, in evaluating our business. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline. 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.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant net losses since inception, and we expect to continue to incur significant net losses for the foreseeable future.

Development of biopharmaceutical product candidates is a highly speculative undertaking and involves a substantial degree of risk. We are still in the early stages of development of our product candidates and TTI-101 is only in a Phase 2 clinical trial for HCC. We have no products approved for commercial sale and have not generated any revenue to date. We have incurred significant net losses since our inception and have financed operations principally through equity and debt financing. We continue to incur significant research and development and other expenses related to our ongoing operations. Our net losses were $18.2 million and $29.4 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, we had an accumulated deficit of $110.5 million. We have devoted substantially all of our resources and efforts to research and development, and expect that it will be several years, if ever, before we have a commercialized product candidate and generate revenue from sales. Even if we receive marketing approval for and commercialize one or more of our product candidates, we expect that we will continue to incur substantial research and development and other expenses in order to further develop and, if approved, market additional potential product candidates.

We expect to continue to incur significant losses for the foreseeable future, and anticipate that our expenses will increase substantially if, and as, we:

- 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, any other product candidates and any future product candidates, if approved;
- increase the amount of research and development activities to identify and develop product candidates;
- 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.

We have a limited operating history, which may make it difficult to evaluate our prospects and likelihood of success.

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

We have not generated any revenue to date and may never become or remain profitable.

Our ability to become profitable depends upon our ability to generate revenue. To date, we have not generated any revenue. We do not expect to generate significant product revenue unless or until we successfully complete clinical development and obtain regulatory approval of, and then successfully commercialize, at least one of our product candidates. All of our product candidates will require additional preclinical studies or clinical development as well as regulatory review and approval,

substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before we can generate any revenue from product sales. We will face significant development risk as our product candidate advances through clinical development. Our ability to generate revenue depends on a number of factors, including, but not limited to:

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

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

Our financial condition raises substantial doubt as to our ability to continue as a going concern.

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, general and administrative costs. Our net losses 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. The

assessment of our ability to meet our future obligations is inherently judgmental, subjective and susceptible to change. Given the inherent uncertainties in the forecast, we considered both quantitative and qualitative factors that are known or reasonably knowable as of the date that these 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.

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

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

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

As of December 31, 2025, we had cash and cash equivalents and short-term investments of approximately $20.7 million and $10.1 million, respectively, and we will require additional capital in order to complete clinical development of any of our current programs. Our monthly spending levels will vary based on new and ongoing development and corporate activities. Because the length of time and activities associated with development of our product candidates is highly uncertain, we are unable to estimate the actual funds we will require for development, marketing and commercialization activities. Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the initiation, progress, timing, costs and results of preclinical studies and clinical trials for our 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 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.

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

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

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

- the timing and success or failure of clinical trials for our product candidates or competing product candidates;
- our ability to successfully recruit and retain subjects for clinical trials, and any delays caused by difficulties in such efforts;
- our ability to obtain marketing approval for our product candidates, and the timing and scope of any such approvals we may receive;
- the timing and cost of, and level of investment in, research and development activities relating to our product candidates, which may change from time to time;
- the cost of manufacturing our product candidates, which may vary depending on the difficulty of manufacturing, quantity of production and the terms of our agreements with manufacturers;
- our ability to attract, hire and retain qualified personnel;
- expenditures that we will or may incur to develop additional product candidates;

- the level of demand for our product candidates should they receive approval, which may vary significantly;
- the risk/benefit profile, cost and reimbursement policies with respect to our product candidates, if approved;
- existing and potential future therapeutics that compete with our product candidates;
- changes in the competitive landscape of our industry, including consolidation among competitors or partners;
- general market conditions or extraordinary external events, such as recessions or the effects of health epidemics;
- the changing and volatile U.S. and global economic and political environments; and
- future accounting pronouncements or changes in our accounting policies.

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

Risks Related to Research and Development and the Biopharmaceutical Industry

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

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

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

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

- negative or inconclusive results from 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 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 our clinical and preclinical data by the FDA and other comparable foreign regulatory authorities.

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

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

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

our future clinical trials will ultimately be successful or support further clinical development of TTI-101, TTI-109 or any of our other product candidates. Product candidates that appear promising in the early phases of development may fail to reach the market for several reasons, including:

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

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

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

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

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

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

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

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

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

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

- regulatory authorities may withdraw approvals of such product, seize the product or seek an injunction against its manufacture or distribution;
- we, or any future collaborators, may be required to recall the product, change the way such product is administered to patients or conduct additional clinical trials;

- additional restrictions may be imposed on the marketing of, or the manufacturing processes for, the particular product;
- regulatory authorities may require additional warnings on the label, such as a "black box" warning or a contraindication, or impose distribution or use restrictions;
- we, or any future collaborators, may be required to create a REMS, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers and/or other elements to assure safe use;
- we, or any future collaborators, may be subject to fines, injunctions or the imposition of civil or criminal penalties;
- we, or any future collaborators, could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

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

We may be subject to additional risks because we intend to evaluate our product candidates in combination with the standard of care for the indications that we are pursuing.

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

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

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

- regulators or institutional review boards (IRBs), or ethics committees may not authorize us and our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- the FDA or other comparable regulatory authorities may disagree with our clinical trial design, including with respect to dosing levels administered in our planned clinical trials, which may delay or prevent us from initiating our clinical trials with our originally intended trial design;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective CROs, which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- patient enrollment in our clinical trials may be slower than anticipated;

- the number of subjects required for clinical trials of any product candidates may be larger than we anticipate, or subjects may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;

- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the clinical trial, which may require that we add new clinical trial sites or investigators;

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

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

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

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

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

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

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

Interim, blinded and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available or as additional analyses are conducted and as the data are subject to audit and verification procedures that could result in material changes in the final data.

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

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

Positive results from our preclinical studies of current or future product candidates, and any positive results we may obtain from early clinical trials of our current or future product candidates, including the ongoing and future clinical trials of TTI-101, may not necessarily be predictive of the results from required later preclinical studies and clinical trials. Similarly, even if we are able to complete our planned preclinical studies or clinical trials of current or future product candidates according to our current development timeline, the positive results from such preclinical studies and/or clinical trials of current or future product candidates, including TTI-101 and TTI-109, may not be replicated in subsequent preclinical studies or clinical trials. In particular, while we have conducted certain preclinical studies of TTI-109 and Phase 1 clinical trials of TTI-101, we do not know whether either of these product candidates will perform in planned clinical trials as it has performed in these prior preclinical studies or early clinical trials. For example, we reported preliminary data from our Phase 2 clinical trial of TTI-101 in IPF in October 2025 and concluded that the study did not meet its goals. Although we subsequently conducted a post hoc exploratory analysis of TTI-101 in IPF which demonstrated greater reductions in certain exploratory measures, such analysis should be interpreted with caution and any results therefrom may not be reflective of future clinical success or our continued development of TTI-101 for IPF.

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

If we encounter difficulties enrolling patients in clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

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

- the patient eligibility and exclusion criteria defined in the protocol;
- the size of the patient population required for analysis of the clinical trial's primary endpoints and the process for identifying patients;
- the willingness or availability of patients to participate in our clinical trials;
- the proximity of patients to clinical trial sites;
- the design of the clinical trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating or other preclinical studies or clinical trials enrolling for similar diseases;

- the availability of competing commercially available therapies and other competing product candidates' clinical trials;
- our ability to obtain and maintain patient informed consents; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

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

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

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

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

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

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

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

- our inability to design such product candidates with the pharmacological properties that we desire or attractive PK; or

- potential product candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be medicines that will receive marketing approval and achieve market acceptance.

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

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

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

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

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

We may in the future choose to conduct one or more clinical trials outside the United States. The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice, (ii) the clinical trials were performed by clinical investigators of recognized competence and (iii) the data may be considered valid without the need for an on-site inspection by the FDA, or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign clinical trials would be subject to the applicable local laws of the foreign jurisdictions where the clinical trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from clinical trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional clinical trials, which could be costly and time-consuming, and which may result in current or future product candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction.

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

Regulatory authorities in some jurisdictions, including the United States and other major markets, may designate drugs intended to treat conditions or diseases affecting relatively small patient populations as orphan drugs. Under the Orphan Drug Act of 1983, the FDA may designate a product candidate as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as having a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the

drug will be recovered from sales in the United States. Although we have received U.S. orphan drug designation for TTI-101 for IPF and HCC, the designation of any of our product candidates as an orphan drug does not mean that any regulatory agency will accelerate regulatory review of, or ultimately approve, that product candidate, nor does it limit the ability of any regulatory agency to grant orphan drug designation to product candidates of other companies that treat the same indications as our product candidates.

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

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

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

If a drug product is intended for the treatment of a serious or life-threatening disease or condition and it demonstrates the potential to address unmet medical needs for such a disease or condition, the drug sponsor may apply for FDA Fast Track designation for a particular indication. We have received Fast Track designation for TTI-101 for the treatment of relapsed/refractory locally advanced, unresectable or metastatic HCC but may never receive Fast Track designation for our pipeline programs. Marketing applications submitted by sponsors of products in Fast Track development may qualify for priority review under the policies and procedures offered by the FDA, but the Fast Track designation does not assure any such qualification or ultimate marketing licensure by the FDA. Although we received Fast Track designation for TTI-101, we may not experience a faster development process, review or licensure compared to conventional FDA procedures or pathways, and receiving a Fast Track designation does not provide assurance of ultimate FDA licensure. In addition, the FDA may withdraw any Fast Track designation granted to us if it believes that the designation is no longer supported by data from our clinical development program. The FDA may also withdraw any Fast Track designation at any time.

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

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

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

- efficacy and potential advantages compared to alternative treatments;
- the ability to offer our products, if approved, for sale at competitive prices;

- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the recommendations with respect to our product candidates in guidelines published by various scientific organizations applicable to us and our product candidates;
- the strength of marketing and distribution support;
- the ability to obtain sufficient third-party coverage and adequate reimbursement; and
- the prevalence and severity of any side effects.

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

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than us.

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

There are a number of biopharmaceutical and biotechnology companies that are currently pursuing the development of products for the treatment of inflammatory and proliferative diseases. Companies that we are aware of that are targeting the treatment of various inflammatory and proliferative indications include companies with significantly more financial resources such as AbbVie Inc., AstraZeneca plc, Bristol Myers Squibb Co., Merck & Co., Inc. and Roche Holding AG. Companies that we are aware of that are targeting the treatment of the HCC indication include large companies such as AstraZeneca plc, Bristol Myers Squibb Co., Eli Lilly and Company and Merck & Co., Inc.

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

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

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

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

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

We face an inherent risk of product liability as a result of testing TTI-101, TTI-109 and any of our other product candidates in clinical trials and will face an even greater risk if we commercialize any products. For example, we may be sued if our product candidates cause, or are perceived to cause, injury or are found to be otherwise unsuitable during clinical trials, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourself against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

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

Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. We will need to obtain additional

insurance for clinical trials as TTI-101 and TTI-109 continue clinical development. However, we may be unable to obtain, or may obtain on unfavorable terms, clinical trial insurance in amounts adequate to cover any liabilities from any of our clinical trials. Our insurance policies may also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

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

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

TTI-101, TTI-109 and any other current or future product candidates we develop are subject to extensive governmental regulations relating to, among other things, research, testing, development, manufacturing, approval, recordkeeping, reporting, labeling, storage, packaging, advertising and promotion, pricing, post-approval monitoring, marketing and distribution of products. Rigorous preclinical studies and clinical trials and an extensive regulatory approval process are required to be completed successfully in the United States and in many foreign jurisdictions before a new product can be marketed. Satisfaction of these and other regulatory requirements is costly, time-consuming, uncertain and subject to unanticipated delays. It is possible that none of our product candidates will obtain the regulatory approvals necessary for us to begin selling them.

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

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

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

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

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

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

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

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

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

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

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines, warning or untitled letters or holds on clinical trials;
- refusal by the Medicines and Healthcare Products Regulatory Agency or the FDA to approve pending applications or supplements to approved applications filed by us or our strategic partners;
- suspension or revocation of product license approvals;
- product seizure or detention or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

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

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

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

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

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

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

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

A primary trend in the United States and European healthcare industries is toward cost containment, as legislative bodies, government authorities, third-party payors, and others have attempted to control costs by limiting coverage, pricing and the amount of reimbursement available for certain treatments. For example, HHS imposes rebates on many Medicare Part B and Medicare Part D products to penalize price increases that outpace inflation on an annual basis. HHS has also been empowered to negotiate the price of certain single-source drugs that have been on the market for at least seven years covered under Medicare as part of the Medicare Drug Price Negotiation Program. Each year up to 20 products will be selected by HHS for the Medicare Drug Price Negotiation Program. Products subject to the Medicare Drug Price Negotiation Program are expected to experience a significant reduction in reimbursement from the Medicare program on a per unit basis. Such third-party payors, including Medicare, may question the coverage of, and challenge or seek to lower the prices charged for medical products, and many third-party payors limit coverage and reimbursement for newly approved health care products. Moreover, reimbursement, if available, may vary according to the use of the product and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost products and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors or by future laws, regulations or guidance seeking to limit prescription drug prices. Further, coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. If we are unable to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved products that we develop, or if net prices are reduced by mandatory discounts or rebates, there could be a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and overall financial condition.

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

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

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

For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the ACA), was enacted in the United States, which substantially changed the way healthcare is financed by both governmental and private insurers. Since its enactment, there have been amendments and judicial, Congressional and executive branch challenges to certain aspects of the ACA. For example, on July 4, 2025, the OBBBA was signed into law, which narrowed access to ACA marketplace exchange enrollment and declined to extend the ACA enhanced advanced premium tax credits that expired at the end of 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. The OBBBA also is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program.

Congress is considering proposed legislation intended to further reduce healthcare costs with alternatives to replace the expired ACA subsidies.

The current administration is pursuing policies to reduce regulations and expenditures across government agencies including at HHS, the FDA, CMS and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. For example, the current administration has announced agreements with several pharmaceutical companies that require the drug manufacturers to offer, through a direct to consumer platform, U.S. patients and Medicaid programs prescription drug Most-Favored Nation pricing equal to or lower than those paid in other developed nations, with additional mandates for direct-to-patient discounts and repatriation of foreign revenues. Other recent actions, for example, include (1) directing agencies to reduce agency workforce and cut programs; (2) directing HHS and other agencies to lower prescription drug costs through a variety of initiatives, including by establishing Most-Favored-Nation pricing for pharmaceutical products and launching an online clearinghouse (TrumpRx) for patients to purchase certain products from manufacturers on a cash pay basis; (3) imposing tariffs on imported pharmaceutical products; and (4) as part of the MAHA Commission's Strategy Report released in September 2025, working across government agencies to increase enforcement on direct-to-consumer pharmaceutical advertising. Additionally, the current administration recently called on Congress to enact "The Great Healthcare Plan," to codify and expand Most-Favored Nation pricing, lower government subsidies to private insurance companies, increase healthcare price transparency, expand pharmaceutical drugs available for over-the-counter purchase, and enact restrictions on pharmacy benefit manager (PBM) payment methodologies, among other things. These actions and policies may significantly reduce U.S. drug prices, potentially impacting manufacturers' global pricing strategies and profitability, while increasing their operational costs and compliance risks. In June 2024, the U.S. Supreme Court's Loper Bright decision greatly reduced judicial deference to regulatory agencies, which could increase successful legal challenges to federal regulations affecting our operations. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program. The implementation of current and future cost containment measures or other healthcare reforms may adversely affect our operations and prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates.

Our ability to develop and market new drug products may be impacted if litigation challenging the FDA's approval of another company's drug continues. In April 2023, the U.S. District Court for the Northern District of Texas invalidated the approval by the FDA of mifepristone, a drug product, which was originally approved in 2000, and whose distribution is governed by various measures adopted under a REMS. The Court of Appeals for the Fifth Circuit declined to order the removal of mifepristone from the market but did hold that plaintiffs were likely to prevail in their claim that changes allowing for expanded access of mifepristone, which the FDA authorized in 2016 and 2021, were arbitrary and capricious. In June 2024, the Supreme Court reversed and remanded that decision after unanimously finding that the plaintiffs did not have standing to bring this legal action against the FDA. Depending on the outcome of this litigation, if it continues, our ability to develop TTI-101, TTI-109 or future product candidates we may develop may be at risk and could be delayed, undermined or subject to protracted litigation. Finally, we could be adversely affected by several significant administrative law cases decided by the U.S. Supreme Court. Additionally, in *Corner Post, Inc. v. Board of Governors of the Federal Reserve System*, the court held that actions to challenge a federal regulation under the APA can be initiated within six years of the date of injury to the plaintiff, rather than the date the rule is finalized. The decision appears to give prospective plaintiffs a personal statute of limitations to challenge longstanding agency regulations. These decisions could introduce additional uncertainty into the regulatory process and may result in additional legal challenges to actions taken by federal regulatory agencies, including the FDA and the Centers for Medicare & Medicaid Services that we rely on. In addition to potential changes to regulations as a result of legal challenges, these decisions may result in increased regulatory uncertainty and delays and other impacts, any of which could adversely impact our business and operations.

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

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

Our future arrangements with healthcare providers, healthcare organizations, third-party payors and customers will expose us to broadly applicable anti-bribery, fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research, market, sell and distribute our products, if approved. Restrictions under applicable federal and state anti-bribery and healthcare laws and regulations, include the following:

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

- the federal criminal and civil false claims laws, including the federal False Claims Act, which can be enforced through civil whistleblower or qui tam actions against individuals or entities, and the Federal Civil Monetary Penalties Laws, which prohibit, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. Moreover, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act;

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

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

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

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

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

- certain state and local laws that require pharmaceutical companies to obtain certain regulatory licenses to manufacture or distribute their products commercially and/or register their pharmaceutical sales representatives in the jurisdiction. Further, certain states require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to clinicians and other healthcare providers or marketing expenditures and drug pricing information.

If we or our collaborators, manufacturers or service providers fail to comply with applicable federal, state or foreign laws or regulations, we could be subject to enforcement actions, which could affect our ability to develop, market and sell our product candidates successfully and could harm our reputation and lead to reduced acceptance of our products, if approved by the market.

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

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

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

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

Our future growth may depend, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties that could materially adversely affect our business.

We are not permitted to market or promote any of our current or future product candidates before we receive regulatory approval from the applicable regulatory authority in that foreign market, and we may never receive such regulatory approval for any of our current or future product candidates. To obtain separate regulatory approval in many other countries, we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of our current or future product candidates, and we cannot predict success in these jurisdictions. If we obtain approval of our current or future product candidates and ultimately commercialize our current or future product candidates in foreign markets, we would be subject to additional risks and uncertainties, including:

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

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

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

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

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

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

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

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

Among other matters, U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations, which are collectively referred to as Trade Laws, prohibit companies and their employees, agents, contract research organizations, legal counsel, accountants, consultants, contractors and other partners from authorizing, promising, offering, providing, soliciting or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We also expect our non-U.S. activities to increase in time. We plan to engage third parties for clinical trials and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals and we can be held liable for the corrupt or other illegal activities of our personnel, agents or partners, even if we do not explicitly authorize or have prior knowledge of such activities.

We are also subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations and various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls. Compliance with applicable regulatory requirements regarding the export of

our products may create delays in the introduction of our products in international markets or, in some cases, prevent the export of our products to some countries altogether. Furthermore, U.S. export control laws and economic sanctions prohibit the provision of certain products and services to countries, governments and persons targeted by U.S. sanctions.

Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

Risks Related to Our Intellectual Property

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

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

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

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

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

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

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

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

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

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

Pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Assuming the other requirements for patentability are met, currently, the first to file a patent application is generally entitled to the patent. However, prior to March 16, 2013, in the United States, the first to invent was entitled to the patent. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or our licensor were the first to make the inventions claimed in our own or in-licensed patents and patent applications, or that we or our licensor were the first to file for patent protection of such inventions. If third parties have filed prior patent applications on inventions claimed in our patent portfolio that were filed on or before March 15, 2013, an interference proceeding in the United States can be initiated by such third parties to determine who was the first to invent any of the subject matter covered by our patent portfolio. If third parties have filed such prior applications after March 15, 2013, a derivation proceeding in the United States can be initiated by such third parties to determine whether our invention was derived from theirs.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

all relevant information has been identified. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our own patent portfolio.

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

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

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

- we may not be able to generate sufficient data to support full patent applications that protect the entire breadth of developments in one or more of our programs;
- it is possible that one or more of the patent applications in our patent portfolio will not become an issued patent or, if issued, that the patent(s) claims will have sufficient scope to protect our technology, provide us with commercially viable patent protection or provide us with any competitive advantages;
- if the pending applications in our patent portfolio issue as patents, they may be challenged by third parties as invalid or unenforceable under United States or foreign laws;
- we may not successfully commercialize our product candidates, if approved, before the relevant patents in our patent portfolio expire;
- we may not be the first to make the inventions covered by our patent portfolio;
- we may not develop additional proprietary technologies or inventions on our product candidates that are separately patentable; or
- it is possible that there are unpublished patent applications maintained in secrecy that may later issue with claims related to our product candidates or products or technology similar to ours.

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

Our intellectual property licensed from third parties may be subject to retained rights.

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

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

Patent terms may be inadequate to protect our competitive position on our products for an adequate amount of time.

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

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

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

In the United States, U.S. Patent No. 8,779,001, which protects the use of TTI-101 for inhibiting STAT3, is set to expire on November 13, 2030. We may potentially apply PTE to U.S. Patent No. 8,779,001, extending the patent term of the patent by up to five years. If approved, Orphan Drug Exclusivity would also provide a separate seven years of regulatory exclusivity for TTI-101 from the date of approval.

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

In the context of the European Union, the Court of Justice of the European Union has recently restricted grant of supplementary protection certificate (SPC), for new medical uses of existing products, thus narrowing the availability of patent term extension for second medical uses. Therefore, any development of our product candidates with respect to second medical uses may be adversely affected in the European Union. In addition, within the European Union, regulatory protections afforded to medicinal products such as data exclusivity, marketing protection, market exclusivity for orphan indications and pediatric extensions are currently under review and may likely be curtailed in future years. On April 26, 2023, the European Commission adopted a proposal for a new Regulation set to replace Regulation (EC) No 726/2004 and a new Directive replacing Directive 2001/83 on the Community Code relating to medicinal products for human use. If made into law, this proposal will revise and replace the existing general pharmaceutical legislation and will affect the existing period of regulatory protection afforded to medicinal products in the European Union and Northern Ireland. If we are unable to obtain patent term extension or the term of any such extension is less than we request, or if data exclusivity or other regulatory protections are reduced, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations and prospects could be materially harmed.

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

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

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

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

Further, a new court system recently became operational in the European Union. The Unified Patent Court (UPC), began accepting patent cases on June 1, 2023. The UPC is a common patent court with jurisdiction over patent infringement and revocation proceedings effective for multiple member states of the European Union. The broad geographic reach of the UPC could enable third parties to seek revocation of any of our European patents in a single proceeding at the UPC rather than through multiple proceedings in each of the individual European Union member states in which the European patent is validated. Under the UPC, a successful revocation proceeding for a European Patent under the UPC would result in loss of patent protection in those European Union countries. Accordingly, a single proceeding under the UPC could result in the partial or complete loss of patent protection in numerous European Union countries. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize our technology and product candidates and, resultantly, on our business, financial condition, prospects and results of operations. Moreover, the controlling laws and regulations of the UPC will develop over time and we cannot predict what the outcomes of cases tried before the UPC will be. The case law of the UPC may adversely affect our ability to enforce or defend the validity of our European patents. Patent owners have the option to opt-out their European Patents from the jurisdiction of the UPC, defaulting to pre-UPC enforcement mechanisms. We have decided to opt out certain European patents and patent applications from the UPC. However, if certain formalities and requirements are not met, our European patents and patent applications could be subject to the jurisdiction of the UPC. We cannot be certain that our European patents and patent applications will avoid falling under the jurisdiction of the UPC, if we decide to opt out of the UPC.

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

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

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

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

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

In addition, geopolitical actions in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any current or future licensors and the maintenance, enforcement or defense of our issued patents or those of any current or future licensors. For example, the United States and foreign government actions related to Russia's conflict in Ukraine may limit or prevent filing, prosecution and maintenance of patent applications in Russia. Government actions may also prevent maintenance of issued patents in Russia. These actions could result in abandonment or lapse of our patents or patent applications, resulting in partial or complete loss of patent rights in Russia. If such an event were to occur, it could have a material adverse effect on our business. In addition, a decree was adopted by the Russian government in March 2022, allowing Russian companies and individuals to exploit inventions owned by patentees from the United States without consent or compensation. Consequently, we would not be able to prevent third parties from practicing its inventions in Russia or from selling or importing products made using its inventions in and into Russia. Accordingly, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

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

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

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

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

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

Litigation is inherently expensive, and the outcome is often uncertain. Any litigation likely would substantially increase our operating losses and reduce our resources available for development activities. Further, we may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. As a result, we may conclude that even if a competitor is infringing any of our patents, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of us or our stockholders. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution.

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

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

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

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

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

We cannot guarantee the completeness or thoroughness of any of our patent searches or analyses including, but not limited to, the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, nor can we be certain that we have identified each and every patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of any of our product candidates in any jurisdiction. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that any of our product candidates may be accused of infringing. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Accordingly, third parties may assert infringement claims against us based on

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

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

Others may challenge inventorship or claim an ownership interest in our intellectual property which could expose us to litigation and have a significant adverse effect on our prospects.

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

While we typically require employees, consultants and contractors who may develop intellectual property on our behalf to execute agreements assigning such intellectual property to us, we may be unsuccessful in obtaining execution of assignment agreements with each party who in fact develops intellectual property that we regard as our own. Moreover, even when we obtain agreements assigning intellectual property to us, the assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached. In either case, we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Furthermore, individuals executing agreements with us may have preexisting or competing obligations to a third party, such as an academic institution, and thus an agreement with us may be ineffective in perfecting ownership of inventions developed by that

individual. If we are unsuccessful in obtaining assignment agreements from an employee, consultant or contractor who develops intellectual property on our behalf, the employee, consultant or contractor may later claim ownership of the invention. Any disagreement over ownership of intellectual property could result in us losing ownership, or exclusive ownership, of the contested intellectual property, paying monetary damages and/or being enjoined from clinical testing, manufacturing and marketing of the affected product candidate(s). Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our senior management and scientific personnel.

We may be subject to claims by third parties asserting that our employees or we have misappropriated our intellectual property or claiming ownership of what we regard as our own intellectual property.

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

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

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

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

Trade secrets or confidential know-how can be difficult to maintain as confidential. To protect this type of information against disclosure or appropriation by competitors, our policy is to require our employees, consultants, contractors and advisors to enter into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with us prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. However, current or former employees, consultants, contractors and advisers may unintentionally or willfully disclose our confidential information to competitors, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. The need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have an adverse effect on our business and results of operations. Enforcing a claim that a third party obtained illegally and is using trade secrets or confidential know-how is expensive, time consuming and unpredictable. The enforceability of confidentiality agreements may vary from jurisdiction to jurisdiction.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party

collaborators. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

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

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

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

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

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

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

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

- the priority of invention of patented technology.

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

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

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

Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We rely on both registration and common law protection for our trademarks. As a means to enforce our trademark rights and prevent infringement, we may be required to file trademark claims against third parties or initiate trademark opposition proceedings. This can be expensive and time-consuming, particularly for a company of our size. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. During trademark registration proceedings, we may receive rejections. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. Moreover, any name we propose to use for our products in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA objects to any of our proposed product names, we may be required to expend significant additional resources in an effort to identify a usable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively, and our business may be adversely affected.

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

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

- others may be able to make products that are competitive to our product candidates or any of our product candidates but that are not covered by the claims of our patent portfolio;

- others may independently develop similar or alternative technologies or otherwise circumvent any of our technologies without infringing our patent portfolio;

- we or any of our collaborators might not have been the first to invent the inventions covered by our patent portfolio;

- we or any of our collaborators might not have been the first to file patent applications covering certain of the patents or patent applications that we or they own or have obtained a license, or will own or will have obtained a license;
- it is possible that our own and in-licensed pending patent applications or those that we may file in the future will not lead to issued patents;
- others may have access to the same intellectual property rights licensed to us on a non-exclusive basis in the future;
- issued patents that we own or in-licensed may not provide us with any competitive advantage, or may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights, or in countries where research and development safe harbor laws exist, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- ownership of our patent portfolio may be challenged by third parties;
- the patents of third parties or pending or future applications of third parties, if issued, may have an adverse effect on our business;
- patent enforcement is expensive and time-consuming and difficult to predict; thus, we may not be able to enforce any of our patents against a competitor; and
- we may choose not to file a patent application for certain inventions, instead choosing to rely on trade secret protection, and a third party may subsequently file a patent covering such intellectual property.

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

Risks Related to Our Reliance on Third Parties

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- an inability to initiate or continue clinical trials of product candidates under development;
- delay in submitting regulatory applications, or receiving regulatory approvals, for product candidates;
- loss of the cooperation of an existing or future collaborator;
- subjecting third-party manufacturing facilities or our manufacturing facilities to additional inspections by regulatory authorities;
- requirements to cease distribution or to recall batches of our product candidates; and

- in the event of approval to market and commercialize a product candidate, an inability to meet commercial demands for our products.

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

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

A part of our strategy is to selectively evaluate partnerships in indications and geographies where we believe partners can add significant commercial and/or development capabilities. Further, we have limited capabilities for product development and do not yet have any capability for commercialization. Accordingly, we may in the future enter into collaborations with other companies to provide us with important technologies and funding for our programs and technology.

Any future collaborations we enter into may pose a number of risks, including the following:

- collaborators may have significant discretion in determining the efforts and resources that they will apply;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs or license arrangements based on clinical trial results, changes in the collaborators' strategic focus or available funding or external factors, such as a strategic transaction that may divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products and product candidates if the collaborators believe that the competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- collaborators may fail to comply with applicable regulatory requirements regarding the development, manufacture, distribution or marketing of a product candidate or product;
- collaborators with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product or products;
- collaborators may not provide us with timely and accurate information regarding development progress and activity under any future license agreement, which could adversely impact our ability to report progress to our investors and otherwise plan development of our product candidates;

- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or terminations of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;

- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;

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

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

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

If collaborations we enter into do not result in the successful discovery, development and commercialization of product candidates or if a future collaborator terminates its agreement with us, we may not receive any research funding or milestone or royalty payments under such collaboration. All of the risks relating to product development, regulatory approval and commercialization described in this Annual Report on Form 10-K also apply to the activities of our therapeutic collaborators.

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

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

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

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

- the imposition of new laws and regulations, including those relating to labor conditions, quality, and safety standards, imports, duties, taxes and other charges on imports, as well as trade restrictions and restrictions on currency exchange or the transfer of funds, particularly new or increased tariffs imposed on imports from countries where our suppliers operate;

- greater challenges and increased costs with enforcing and periodically auditing or reviewing our suppliers' and manufacturers' compliance with cGMPs or status acceptable to the FDA, EMA or comparable foreign regulatory authorities;

- reduced protection for intellectual property rights, including trademark protection, in some countries;

- disruptions in operations due to global, regional or local public health crises or other emergencies or natural disasters;

- disruptions or delays in shipments; and

- changes in local economic conditions in countries where our manufacturers or suppliers are located.

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

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

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

Risks Related to Managing Our Business and Operations

We may encounter difficulties in managing our growth, which could adversely affect our operations.

As of December 31, 2025, we had 12 full-time employees. As our clinical development and commercialization plans and strategies develop, we will need to expand our managerial, clinical, regulatory, sales, marketing, financial, development, manufacturing and legal capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various strategic collaborators, suppliers and other third parties. Our future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, retaining and motivating additional employees;

- managing our development and commercialization efforts effectively, including the clinical and FDA review process for TTI-101, TTI-109 and any other product candidates, while complying with our contractual obligations to contractors and other third parties; and

- improving our operational, financial and management controls, reporting systems and procedures.

Our ability to continue to develop and, if approved, commercialize our product candidates will depend, in part, on our ability to effectively manage our future growth. Our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

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

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

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

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

If we lose key management personnel, or if we fail to recruit additional highly skilled personnel, our ability to develop current product candidates or identify and develop new product candidates will be impaired, could result in loss of markets or market share and could make us less competitive.

Our ability to compete in the highly competitive biotechnology and biopharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, scientific and medical personnel, including key members of our senior management and executive team. Although we have employment agreements with our key employees, these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. The loss of the services of any of our executive officers, other key employees and other scientific and medical advisors, and our inability to find suitable replacements could result in delays in product development and harm our business. Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all.

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

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

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

We or the third parties upon whom we depend may be adversely affected by natural disasters, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

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

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

Risks Related to Ownership of Our Common Stock

The market price of our common stock is expected to be volatile.

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

- our ability to obtain regulatory approvals for our product candidates, and delays or failures to obtain such approvals (such as our announcement regarding our Phase 2 trial of TTI-101 in IPF in October 2025);

- failure of any of our product candidates, if approved, to achieve commercial success;
- failure by us to maintain our existing third-party license and supply agreements;
- failure by us or our licensors to prosecute, maintain, or enforce our intellectual property rights;
- changes in laws or regulations applicable to our product candidates;
- any inability to obtain adequate supply of our product candidates or the inability to do so at acceptable prices;
- adverse regulatory authority decisions;
- introduction of new products, services or technologies by our competitors;
- failure to meet or exceed financial and development projections we may provide to the public;
- failure to meet or exceed the financial and development projections of the investment community;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by us or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- additions or departures of key personnel;
- significant lawsuits, including patent or stockholder litigation;
- if securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our business and stock;
- changes in the market valuations of similar companies;
- general market or macroeconomic conditions;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- failure to maintain compliance with the listing requirements of The Nasdaq Capital Market;
- announcements by commercial partners or competitors of new commercial products, clinical progress or the lack thereof, significant contracts, commercial relationships or capital commitments;
- adverse publicity generally, including with respect to other products and potential products in such markets;
- the introduction of technological innovations or new therapies that compete with potential products of ours;
- changes in the structure of health care payment systems; and
- period-to-period fluctuations in our financial results.

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

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

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

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

We have, and expect to continue to, incur significant legal, accounting and other expenses that we did not incur as a private company, including costs associated with public company reporting requirements.

We have, and expect to continue to, also incur costs associated with corporate governance requirements, including requirements under the laws, rules and regulations of the SEC as well as the Nasdaq rules. These laws, rules and regulations are expected to increase our legal and financial compliance costs and to make some activities more time consuming and costly. For example, our management team includes our executive officers prior to the Merger, some of whom have not previously managed and operated a public company. These executive officers and other personnel need to devote substantial time to gaining expertise regarding operations as a public company and compliance with applicable laws and regulations. These laws, rules and regulations also may make it difficult and expensive for us to obtain directors' and officers' liability insurance. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on the board of directors or as executive officers of us, which may adversely affect investor confidence in us and could cause our business or stock price to suffer.

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

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

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

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

that, if and only if the Court of Chancery of the State of Delaware dismisses any such action for lack of subject matter jurisdiction, such action may be brought in another state or federal court sitting in the State of Delaware.

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

We do not anticipate paying any cash dividends in the foreseeable future.

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

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

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

Future sales of shares by existing stockholders could cause our stock price to decline.

If existing stockholders of us sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after legal restrictions on resale lapse, the trading price of our common stock could decline. We are not able to predict the effect that sales may have on the prevailing market price of our common stock.

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

The trading market for our common stock is influenced by the research and reports that equity research analysts publish about us and our business. Equity research analysts may elect not to provide research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. In the event we do have equity research analyst coverage, we will not have any control over the analysts, or the content and opinions included in their reports. The price

of our common stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of us or fails to publish reports on us regularly, demand for our common stock could decrease, which in turn could cause our stock price or trading volume to decline.

If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.

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

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

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

If we fail to attract and retain management and other key personnel, we may be unable to continue to successfully develop or commercialize our product candidates or otherwise implement our business plan.

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

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

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

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

New tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business, prospects, financial condition and operating results. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, the legislation commonly referred to as OBBBA, enacted in 2025, the Coronavirus Aid, Relief, and Economic Security Act enacted in 2020, and the Tax Cuts and Jobs Act enacted in 2017, and the Inflation Reduction Act enacted many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to such legislation may affect us, and certain aspects of such legislation could be repealed or modified in future legislation. Such tax law changes could have a material adverse impact on us. In addition, it is uncertain if and to what extent various states will conform to newly enacted federal tax legislation. While it is too early to assess the overall impact of these changes, as these and other tax laws and related regulations are revised, enacted, and implemented, our financial condition, results of operations, and cash flows could be materially adversely impacted.

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

As of December 31, 2025, we had a U.S. federal net operating loss (NOL) carryforward and state NOL carryforwards of $383.6 million and $419.2 million, respectively. Under current law, U.S. federal NOL carryforwards generated in taxable periods beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such NOL carryforwards is limited to 80% of taxable income. The availability and utilization of state NOL carryforwards depend on each state's degree of conformity to federal law, which varies by jurisdiction. In addition, under Sections 382 and 383 of the Code, federal NOL carryforwards and other tax attributes may become subject to an annual limitation in the event of certain cumulative changes in ownership. An "ownership change" pursuant to Section 382 of the Code generally occurs if one or more stockholders or groups of stockholders who own at least 5% of a company's stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. Our ability to utilize our NOL carryforwards and other tax attributes to offset future taxable income or tax liabilities may be limited as a result of ownership changes, including changes in connection with the Merger or other transactions. Similar rules may apply under state tax laws. If we earn taxable income, such limitations could result in increased future income tax liability to us, and our future cash flows could be adversely affected.

We are subject to the SEC requirements applicable to reporting shell company business combinations. As a result, we are subject to more stringent reporting requirements, offering limitations and resale restrictions.

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

- we were required file a Current Report on Form 8-K to report the Form 10 type information (the Super 8-K) after the closing of the Merger reflecting our status as an entity that is not a shell company;
- we will not be eligible to use a Form S-3 until 12 full calendar months after the closing of the Merger on April 15, 2025 (the Closing Date);
- we had to wait at least 60 calendar days after the filing of the Super 8-K to file a Form S-8 for any equity plans or awards, such as the 2025 Equity Plan and the 2025 Employee Stock Purchase Plan;
- we will be an "ineligible issuer" for three years following the Closing Date, which will prevent us from (i) incorporating by reference in our Form S-1 filings, (ii) using a free writing prospectus or (iii) taking advantage of the well-known seasoned issuer (WKSI) status despite our public float;

- investors who (i) were affiliates of Legacy Tvardi at the time the Merger was submitted for the vote or consent of Legacy Tvardi's stockholders, (ii) received our securities in the Merger and (iii) publicly offer or sell such securities will be deemed to be engaged in a distribution of such securities, and therefore would be underwriters with respect to resales of those securities; and

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

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

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

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

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

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

General Risk Factors

Legacy Tvardi identified material weaknesses in its internal control over financial reporting. If we fail to remediate these material weaknesses, or if we experience additional material weaknesses in the future or otherwise fail to maintain effective internal control over financial reporting in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

As of December 31, 2025, we had limited accounting personnel and other resources to address our 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.

These material weaknesses could result in a misstatement of substantially all of our accounts or disclosures that would result in a material misstatement of our future annual or interim financial statements that would not be prevented or detected. These material weaknesses must be remediated by us.

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.

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

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

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

Our issuance of additional capital stock in connection with financings, acquisitions, investments, our stock incentive plans or otherwise will dilute all other stockholders.

We expect to issue additional capital stock in the future that will result in dilution to all other stockholders. We expect to grant equity awards to employees, directors, and consultants under our stock incentive plans. As part of our business strategy, we may acquire or make investments in complementary companies, products or technologies and issue equity securities to pay for any such acquisition or investment. Any such issuances of additional capital stock may cause stockholders to experience significant dilution of their ownership interests and the per share value of our common stock to decline.

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

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

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

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

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

We and the third parties with whom we work, are or may become subject to stringent and evolving U.S. and foreign laws, regulations, and rules; contractual obligations; and policies, all related to data privacy or security. Our (or the third parties with whom we work) actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse business consequences.

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process or processing) certain sensitive information, including personal information, proprietary data, confidential business data, trade secrets, personnel data, intellectual property, data we collect about clinical trial participants in connection with clinical trials, and other sensitive third-party data (collectively, sensitive data). The global data protection landscape is rapidly evolving and we are or may become subject to numerous data privacy and security obligations, such as various state, federal and foreign laws, regulations, guidance, industry standards; external and internal privacy and security policies; contractual requirements; and other obligations governing the collection use, disclosure, retention, security or other processing of personal information or otherwise relating to data privacy or security, including as relates to information that we may collect in connection with clinical trials in the United States and in other jurisdictions.

Various federal, state, local and foreign legislative and regulatory bodies, as well as self-regulatory organizations, may expand current laws, rules or regulations, enact new laws, rules or regulations or issue revised rules or guidance regarding data privacy and security. Implementation standards and enforcement practices may vary. This evolution may create uncertainty in our business, affect our ability to operate in certain jurisdictions or to collect, store, transfer, use, share and otherwise process personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. The cost of compliance with these obligations is high and is likely to increase in the future. Any actual or perceived failure by us or the third parties with whom we work to comply with relevant obligations governing the processing of

sensitive data (including personal information) could result in, among other things, negative publicity, government investigations and enforcement actions (including the imposition of fines, penalties, audits, and similar); claims by third parties (including class-action claims and mass arbitration demands); additional reporting requirements and/or oversight; bans or restrictions on processing personal information; orders to destroy or not use personal information; imprisonment of company officials; and damage to our reputation, any of which could have a material adverse effect on our business, results of operations, and financial condition.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act) and other similar laws (e.g., wiretapping laws). For example, HIPAA, as amended by HITECH, imposes among other things, certain requirements relating to the privacy, security, transmission, and breach of individually identifiable health information. We may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA. Depending on the facts and circumstances, we could be subject to significant penalties if we violate HIPAA.

Numerous states have also adopted privacy and security laws and regulations, which govern the privacy, processing and protection of health-related and other personal information and impose certain obligations on covered businesses. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us. For example, the California Consumer Privacy Act (CCPA) applies to the personal information of consumers, business representatives, and employees who are California residents, and increases the privacy and security obligations of covered businesses under the CCPA that handle personal information subject to the CCPA, including among other things, requiring such businesses to provide specific disclosures in privacy notices and respond to requests of California residents to exercise certain privacy rights, including the right to opt out of certain disclosures of their information. The CCPA provides for civil penalties as well as a private right of action with statutory damages for certain data breaches, thereby potentially increasing the likelihood of, and risks associated with, data breach litigation. Although the CCPA and other comprehensive U.S. state privacy laws exempt some data processed as part of clinical trials, these developments may impact our processing of personal information and increase compliance costs for us and the third parties with whom we work. Other jurisdictions have also enacted comprehensive privacy laws, and similar laws are being considered in other various governmental levels, and we expect more legislative bodies to pass similar laws in the future. Outside the United States, an increasing number of laws, regulations, and industry standards govern data privacy and security. For example, the European Union's General Data Protection Regulation (EU GDPR), the United Kingdom's GDPR (UK GDPR) (collectively, GDPR), and India's Information Technology Act and supplementary rules, and India's new privacy legislation, the Digital Personal Data Protection Act (DPDP) impose strict requirements for processing personal data.

Our employees and personnel use generative artificial intelligence (AI) and/or automated decision-making technologies to perform their work, and the disclosure and use of personal data in AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws and regulations regulating AI and/or automated decision-making technologies. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and lawsuits. If we were unable to use AI and/or automated decision-making technologies, it could make our business less efficient and result in competitive disadvantages.

Any liability from our actual or perceived failure to comply with the requirements of our data privacy or security obligations could adversely affect our financial condition. In addition to government activity, privacy advocacy groups and technology and other industries are considering various new, additional or different self-regulatory standards that may place additional burdens on us or the third parties with whom we work. In addition to data privacy and security laws, we are also bound by other contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. Further, we post certain of our privacy policies which describe our practices concerning our collection, use, disclosure and other processing of the personal information. Although we endeavor to comply with our public statements and documentation, we may at times fail to do so or be perceived to have failed to do so. Regulators are increasingly scrutinizing these statements, and if these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, misleading, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

We cannot be certain that our CROs, CMOs or other third-parties with access to our or our suppliers', manufacturers', clinical trial participants' and employees' sensitive information in relation to which we are responsible will not breach contractual obligations imposed by us, or that they will not experience data security incidents, which could have a corresponding effect on our business, including putting us in breach of our obligations under applicable obligations and/or which could in turn adversely affect our business, financial condition, results of operations and prospects. We cannot be certain that our contractual measures and our own privacy and security-related safeguards will protect us from the risks associated with the third-party processing of such information. Any of the foregoing could adversely affect our business, financial condition, results of operations and prospects.

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

Obligations related to data privacy and security (and consumers' data privacy expectations) are quickly changing, becoming increasingly stringent, and creating uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Complying with these numerous, complex and often changing obligations is expensive and difficult, and any actual or perceived failure to comply with any data privacy or security obligations, whether by us, one of our CROs, CMOs, partners or another third party with whom we work, could adversely affect our business, financial condition, results of operations and prospects, including but not limited to: investigation costs; material fines and penalties; compensatory, special, punitive and statutory damages; litigation; consent orders regarding our privacy and security practices; requirements that we provide notices, credit monitoring services and/or credit restoration services or other relevant services to impacted individuals; adverse actions against our licenses to do business; reputational damage; and injunctive relief. In addition, new regulation or legislative actions regarding data privacy and security (together with applicable industry standards) may increase our costs of doing business. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for significant statutory damages, depending on the volume of data and the number of violations.

In this regard, we expect that there will continue to be new proposed laws, regulations and industry standards relating to privacy and data protection in the United States, the EEA and other jurisdictions. For example, the U.S. Department of Justice issued a rule entitled the Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons, which places additional restriction on certain data transactions involving countries of concern (e.g., China, Russia, Iran) and covered individuals (i.e., individuals and entities located in or controlled by individuals or entities located in those jurisdictions) that impacts certain business activities such as vendor engagements, sale or sharing of data, employment of certain individuals, and investor agreements. Violations of the rule could lead to significant civil and criminal fines and penalties. The rule applies regardless of whether data is anonymized, key-coded, pseudonymized, de-identified or encrypted, which presents particular challenges for companies like us that operates in the clinical trial space and impacts our ability to transfer data in connection with certain transactions.

Any actual or perceived failure by us or third parties with whom we work to comply with any federal, state or foreign laws, rules, or regulations; industry self-regulatory principles; industry standards or codes of conduct; regulatory guidance; orders to which we may be subject or other legal obligations relating to data privacy, data protection, security or consumer protection could adversely affect our reputation, brand and business. We may also be contractually required to indemnify and hold harmless third parties from the costs or consequences of non-compliance with any laws, rules and regulations or other legal obligations relating to privacy or any inadvertent or unauthorized use or disclosure of data that we store or handle as part of operating our business. Any of these events could adversely affect our reputation, business, or financial condition, including but not limited to: interruptions or stoppages in our business operations (including clinical trials); inability to process personal information or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time

and resources to comply or defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

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

Our information systems and those of our current and any future collaborators, contractors, consultants, and other third parties with whom we work (i.e., our supply chain) are vulnerable to a variety of evolving threats, including but not limited to social-engineering attacks (including through deepfakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks, credential stuffing attacks, credential harvesting, ransomware attacks, supply-chain attacks, software bugs, software or hardware failures, personnel error or malfeasance, loss of data or other information technology assets, adware, earthquakes, fires, floods, attacks enhanced or facilitated by AI, malicious code (such as computer viruses and worms), unauthorized access, natural disasters, terrorism, war, telecommunication failures, electrical failures, and other similar threats. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors. Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties with whom we work may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt relevant systems and operations. In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, ability to provide our products or services, loss of sensitive data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

We have in the past and will in the future expend resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. Certain data privacy and security obligations have required us to implement and maintain specific security measures or industry-standard or reasonable security measures to protect our information technology systems and sensitive information.

We exercise little or no direct control over how the third parties with whom we work operate their information systems, which increases our vulnerability to problems with their systems. If we or third parties with whom we work have in the past or were in the future to experience any material system failure, accident, or security breach, it could result in a disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions, as well as reputational harm and adverse legal and regulatory consequences. For example, the loss of clinical trial data from future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position could be harmed, and the further development and commercialization of our product candidates could be delayed. While we may be entitled to damages if the third parties with whom we work fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or that of the third parties with whom we work have not been compromised.

We and the third parties with whom we work are also subject to cybersecurity risks caused by misappropriation, misuse, leakage, falsification or intentional or accidental release, exposure or loss of information maintained in the information systems and networks of us and the third parties with whom we work, including personal information of our employees and clinical trial subjects, and our confidential data. In addition, outside parties may attempt to penetrate our systems or those of the third parties with whom we work or fraudulently induce our personnel or the personnel of the third parties with whom we work to disclose sensitive information in order to gain access to our data and/or systems (or those of the third parties with whom we work).

Remote work has increased risks to our information technology systems and data, as our personnel utilize network connections, computers and devices outside our premises or network, including working at home, while in transit and in public locations. Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity

risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

If a material breach of, or accidental or intentional loss of data from, our information technology systems or those of the third parties with whom we work occurs, the market perception of the effectiveness of our security measures could be harmed and our reputation and credibility could be damaged, and we could be subject to material adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive information (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; diversion of management attention; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant material consequences may negatively impact our ability to grow and operate our business. Applicable data privacy and security obligations may require us, or we may voluntarily choose, to notify relevant stakeholders, including affected individuals, customers, regulators, and investors, of security incidents, or to take other actions, such as providing credit monitoring and identity theft protection services. Such disclosures and related actions can be costly, and the disclosure or the failure to comply with such applicable requirements could lead to adverse consequences.

We take steps designed to detect, mitigate, and remediate vulnerabilities in our information systems (such as our hardware and/or software, including that of third parties with whom we work). We have not and may not in the future, however, detect and remediate all such vulnerabilities including on a timely basis. Further, we have and may in the future experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident.

Although we develop and maintain systems and controls designed to prevent these events from occurring and we have a process to identify and mitigate threats, the development and maintenance of these systems, controls and processes is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become increasingly sophisticated. It may be difficult and/or costly to detect, investigate, mitigate, contain, and remediate a security incident. Our efforts to do so may not be successful. Actions taken by us or the third parties with whom we work to detect, investigate, mitigate, contain, and remediate a security incident could result in outages, data losses, and disruptions of our business. Threat actors may also gain access to other networks and systems after a compromise of our networks and systems. For example, threat actors may use an initial compromise of one part of our environment to gain access to other parts of our environment, or leverage a compromise of our networks or systems to gain access to the networks or systems of third parties with whom we work, such as through phishing or supply chain attacks.

Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated entirely. As we outsource more of our information systems to vendors, and rely more on cloud-based information systems, the related security risks will increase, and we will need to expend additional resources to protect our technology and information systems.

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

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

attempts in the past and expect such attempts will continue in the future. A security incident or other interruption could disrupt our ability (and that of third parties with whom we work) to operate our business.

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

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

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. Portions of our future clinical trials may be conducted outside of the United States and unfavorable economic conditions resulting in the weakening of the U.S. dollar would make those clinical trials costlier to operate. Furthermore, the most recent global financial crisis caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn, due to factors including the effects of health epidemics and pandemics, geopolitical events and related global escalation of geopolitical tensions, and inflationary pressures could result in a variety of risks to our business, including a reduced ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy or international trade disputes could also strain our suppliers, some of which are located outside of the United States, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

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

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

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

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

Although we assess our banking and customer relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect us, the financial institutions with whom we have credit agreements or arrangements directly, or the financial services industry or economy in general. These factors could include,

among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could involve financial institutions or financial services industry companies with which we have financial or business relationships, but could also include factors involving financial markets or the financial services industry generally.

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

- delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets;
- delayed or lost access to working capital sources and/or delays, inability or reductions in our ability to enter into new credit facilities or other working capital resources;
- potential or actual breach of contractual obligations that require us to maintain letters of credit or other credit support arrangements;
- potential or actual breach of financial covenants in any credit agreements or credit arrangements; or
- potential or actual cross-defaults in other credit agreements, credit arrangements or operating or financing agreements.

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

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

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

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

Social media is increasingly being used to communicate about our clinical development programs and the diseases our therapeutics are being developed to treat, and we intend to utilize appropriate social media in connection with our commercialization efforts following approval of our product candidates, if any. Social media practices in the biopharmaceutical industry continue to evolve and regulations and regulatory guidance relating to such use are evolving and not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business, resulting in potential regulatory actions against us, along with the potential for litigation related to off-label marketing or other prohibited activities. For example, patients may use social media channels to comment on their experience in an ongoing blinded clinical trial or to report an alleged adverse event. When such disclosures occur, there is a risk that clinical trial enrollment may be adversely impacted, that we may fail to monitor and comply with applicable adverse event reporting obligations or that we may not be able to defend our business or the public's legitimate interests in the face of the political and market pressures generated by

social media due to restrictions on what we may say about our product candidates. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions or incur other harm to our business.

Item 1B. ***Unresolved Staff Comments.***

None.

Item 1C. ***Cybersecurity.***

Risk Management and Strategy

We implement and maintain various information security processes designed to identify, assess and manage material risks from cybersecurity threats to our critical computer networks, third party hosted services, communications systems, hardware and software, products and our critical data (including intellectual property and confidential information that is proprietary, strategic or competitive in nature, and clinical trial data) (collectively, Information Systems and Data).

Our Vice President of Finance and other relevant personnel help identify, assess and manage our cybersecurity threats and risks. To monitor and evaluate our threat environment, we use various methods, including reliance upon our service providers, designed to accomplish this task including, for example: manual tools, automated tools, analyzing reports of threats and threat actors, conducting scans of the threat environment, evaluating our and our industry's risk profile, evaluating threats reported to us, conducting audits, conducting third-party threat assessments, and using external intelligence feeds.

Depending on the relevant information systems environment, we implement and maintain technical and organizational measures, processes, standards and policies, including reliance upon our service providers, designed to manage and mitigate material risks from cybersecurity threats to our Information Systems and Data, including, for example: incident detection and response measures, disaster recovery/business continuity measures, risk assessments, encryption of certain data, network security controls, data segregation, access controls, physical security, asset management (such as tracking and disposal of our information systems), systems monitoring, and cybersecurity insurance.

Our assessment and management of material risks from cybersecurity threats are integrated into our overall risk management processes. For example, our Vice President of Finance works with executive management and our service providers to prioritize our risk management processes and mitigate cybersecurity threats that are more likely to lead to a material impact on our business. Our Vice President of Finance and executive management also evaluate material risks from cybersecurity threats against our overall business objectives and report, as appropriate, to the Audit Committee.

We use third-party service providers to assist us in our efforts to identify, assess, and manage material risks from cybersecurity threats. These service providers may provide services related to: cybersecurity practices, cybersecurity software (such as through managed cybersecurity providers), dark web monitoring, and professional services (including legal counsel).

We use third-party service providers to perform a variety of functions throughout our business, such as application providers, hosting companies, contract research organizations, and contract manufacturing organizations. We manage cybersecurity risks associated with our use of these providers. Depending on the nature of the services provided, the sensitivity of the Information Systems and Data at issue, and the identity of the provider, our vendor management process may involve different levels of assessment (such as by reviewing certain vendors' cybersecurity controls) designed to help identify, mitigate and manage cybersecurity risks associated with a particular provider.

For a description of the risks from cybersecurity threats that may materially affect us and how they may do so, see our risk factors under Part 1. Item 1A. Risk Factors in this Annual Report on Form 10-K, including the subsection titled "*If our information technology systems or those third parties with whom we work, or its data, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences.*"

Governance

Our Board of Directors exercises oversight of our risk management process. The Board of Directors does not have a standing risk management committee, but rather administers this oversight function directly through the Board of Directors as a whole, as well as through various standing committees of the Board of Directors that address risks inherent in their respective areas of oversight. As part of its risk mitigation responsibilities, the Audit Committee is responsible for reviewing and discussing with management, as appropriate, material risks related to data privacy, technology, and information security, including our process for assessing, identifying, and managing such risks, as well as internal controls and disclosure controls and procedures relating to cybersecurity risk and mitigation of such risks.

Our cybersecurity risk assessment and management processes are implemented and maintained by our Vice President of Finance, who has experience developing and deploying network and data security policy and technology, as well as mitigating cybersecurity risks.

The Vice President of Finance, Chief Executive Officer (CEO), and Chief Financial Officer (CFO) are responsible for hiring appropriate personnel, helping to integrate cybersecurity risk considerations into our overall risk management strategy, and communicating key cybersecurity priorities to relevant personnel. The Vice President of Finance, CEO, and CFO are also responsible for helping prepare for cybersecurity incidents, approving cybersecurity processes, and reviewing security assessments and other security-related reports.

Our cybersecurity incident response and vulnerability management measures are designed to escalate certain cybersecurity incidents and threats to management members, including the Vice President of Finance, CEO, and CFO, depending on the circumstances. The Vice President of Finance, CEO, and CFO, together with our service providers, would work jointly to mitigate and remediate cybersecurity incidents of which they are notified, and, as appropriate, report such incidents to the Audit Committee.

The CFO is responsible for sending reports to the Audit Committee regarding significant cybersecurity threats and risks. The Audit Committee has access to information, as appropriate, related to cybersecurity threats, risk and mitigation efforts.

Item 2. *Properties*.

Our corporate headquarters is located in Sugar Land, Texas, where we lease approximately 5,900 square feet of space. Our lease expires in August 2027 and these facilities are used by our single operating segment. We believe our facilities are adequate and suitable for our current needs and that should it be needed, suitable additional or alternative space will be available to accommodate our operations. See Note 8 of Notes to Consolidated Financial Statements, *Leases*, in this Annual Report on Form 10-K.

Item 3. *Legal Proceedings*.

Merger Proceedings

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

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

Other 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 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.

From time to time, we may become subject to legal proceedings and claims arising in the ordinary course of its business. We are not currently a party 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 4. ***Mine Safety Disclosures.***

Not applicable.

PART II

Item 5. ***Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.***

Market Information and Holders for Common Stock

Our common stock is traded on The Nasdaq Capital Market under the symbol "TVRD". Prior to the consummation of the Merger, Cara's common stock was historically quoted on The Nasdaq Capital Market under the symbol "CARA".

Stockholders

As of March 26, 2026, there were 9,381,344 shares of common stock issued and outstanding held of record by 127 holders. The number of holders does not include a substantially greater number of "street name" holders or beneficial holders whose shares of our common stock are held of record by banks, brokers and other financial institutions.

Dividend Policy

We have never declared or paid any cash dividends on shares of our common stock. We anticipate that we will retain all of our future earnings to advance the preclinical studies and clinical trials for our product candidates, and do not anticipate paying any cash dividends on shares of our common stock in the foreseeable future. Investors should not purchase our common stock with the expectation of receiving cash dividends.

Any future determination to declare cash dividends on shares of our common stock will be made at the discretion of our Board of Directors, subject to applicable law and contractual restrictions and will depend on our financial condition, results of operations, capital requirements, general business conditions and other factors that the Board of Directors may deem relevant.

Recent Sales of Unregistered Securities

None.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

Not applicable.

Use of Proceeds

Not applicable.

Item 6. ***[Reserved]***

Item 7. ***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 audited consolidated financial statements and the related notes included elsewhere in this Annual Report on Form 10-K. 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 Annual Report on Form 10-K. You should read "Cautionary Note Regarding Forward-Looking Statements" and Item 1A. Risk Factors of this Annual Report on Form 10-K for a discussion of material factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

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 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). 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 IND application for TTI-109 in June 2025. After FDA acceptance of the IND, we have initiated a Phase 1 trial of TTI-109 in healthy volunteers to evaluate safety, tolerability, and pharmacokinetics, as well as bioequivalence to TTI-101. We expect to report topline data from this trial in the second quarter of 2026, following which we intend to announce the clinical indication in which we plan to advance TTI-109. Subsequently, in the second half of 2026, we expect to report topline data of TTI-101 across the three cohorts of the REVERT LIVER CANCER Phase 1b/2 clinical trial.

In October 2025, we reported preliminary data from our Phase 2 clinical trial of TTI-101 in IPF and concluded that the study did not meet its goals. Subsequently, we conducted additional analyses of a subset of patients who received study drug for 12 weeks. Based on these analyses, which excluded certain patients due to dosing, pharmacokinetic, or clinical factors, treatment with TTI-101 demonstrated greater reductions in certain exploratory measures, including fibrosis and inflammatory markers, compared to placebo – directly recapitulating findings from multiple preclinical models of fibrotic disease and providing human clinical proof of concept for the STAT3 inhibition mechanism. We continue to evaluate these results to inform potential future development decisions.

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 Notes (as defined below) in December 2024 and $83.4 million from the issuance and sale of its preferred stock and historical convertible debt, which was converted into preferred stock, in 2018 and 2021.

As of December 31, 2025, we had $20.7 million in cash and cash equivalents and $10.1 million in short-term investments. As further discussed below, in April 2025, we completed our Merger with Cara, through which we acquired approximately $23.9 million in net assets. We have incurred net losses since inception. As of and for the year ended December 31, 2025, we had an accumulated deficit of $110.5 million and a net loss of $18.2 million. As of and for the year ended December 31, 2024, we had an accumulated

deficit of $92.2 million and a net loss of $29.4 million. 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 considered both quantitative and qualitative factors that are known or reasonably knowable as of the date that these 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 of result of global business, political and macroeconomic events and conditions, including increasing financial market volatility and uncertainty, inflation, interest rate fluctuations, uncertainty with respect to the federal budget and debt ceiling, as well as the potential for future potential government shutdowns related thereto, potential instability in the global banking system, cybersecurity events, the impact of war or military conflict, including regional conflicts around the world, and public health pandemics. 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 Annual Report on Form 10-K.

Reverse Merger

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

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

- the outstanding shares of Legacy Tvardi's common stock (including the shares of common stock issuable upon conversion of all shares of preferred stock prior to the Merger), $0.001 par value per share (Legacy Tvardi common stock), were converted into 6,539,404 shares of our common stock, $0.001 par value per share in the aggregate, based on an exchange ratio calculated in accordance with the Merger Agreement (the Exchange Ratio);
- we acquired approximately $23.9 million in net assets in accordance with the Merger Agreement;
- Legacy Tvardi's outstanding Convertible Notes converted into 1,265,757 shares of our common stock in the aggregate, pursuant to the terms of the Convertible Notes; and
- all outstanding and unexercised options to purchase shares of Legacy Tvardi common stock were assumed by us and converted into options to purchase shares of our common stock based on the Exchange Ratio.

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

The Merger was accounted for as a reverse recapitalization in accordance with accounting principles generally accepted in the United States (U.S. GAAP). Legacy Tvardi was deemed to be the accounting acquirer for financial reporting purposes. Refer to Note 3, *Merger Agreement*, in the Notes to Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K.

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

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

As of the Effective Time, there were 935,554 and 93,555 shares of our common stock available for grant under the 2025 Plan and 2025 ESPP, respectively. As of December 31, 2025, there were 445,721 shares of our common stock remaining available for grant under the 2025 Plan. As of December 31, 2025, no offering periods under the 2025 ESPP had been initiated. On January 1, 2026, the aggregate number of shares of common stock that may be issued pursuant to the 2025 Plan increased to 1,465,233, as approved by the Board of Directors.

Convertible Notes

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

Upon the closing of the Merger, pursuant to the terms of the Convertible Notes, the outstanding principal balance of the Convertible Notes and all unpaid accrued interest automatically converted into 1,265,757 shares of our common stock in the aggregate. Utilizing the fair value option to account for the Convertible Notes, we recorded a gain of $12.8 million during the second quarter of 2025 and a net gain of $7.8 million for the year ended December 31, 2025 in our consolidated statements of operations and comprehensive loss as a result of the net changes in fair value over the 2025 period. There was no change in fair value recorded during the second half of 2025 as the Convertible Notes were fully converted during the second quarter of 2025.

License Agreements

In July 2012 and June 2015, StemMed entered into 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 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, sublicense licenses under certain of BCM's patents and patent applications and additionally in the case of the BCM First Agreement, certain BCM technology. Under these licenses, we are permitted to make, have made, use, market, sell, offer to sell, lease and import the BCM1 Licensed Products and BCM2 Licensed Products in all fields of use. The licenses, patents and patent applications and technologies applicable to the BCM First Agreement and BCM Second Agreement are further discussed below.

First License Agreement with Baylor College of Medicine (BCM)

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 its 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 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 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, the full amount of $50,000 in annual maintenance fees had already been paid as of December 31, 2025 and 2024, and thus no accrual was needed at each respective date. We also incurred $125,000 in milestones payments in relation to the initiation of a Phase 2 clinical trial during the year ended December 31, 2024. No royalty fees have been incurred to date. All related license costs are expensed as incurred within research and development on the 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.

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 are also required to pay BCM royalties in the amount of a low-single-digit percent of net sales of BCM2 Licensed Products during the term, which expires, on a country-by-country basis, on the later (i) of the date of expiration of the last to expire of the Licensed Patent Rights, or, (ii) if no Licensed Patent Rights issued in such country, the tenth anniversary of the first commercial sale of the BCM2 Licensed Product in such country. We currently expect the Licensed Patent Rights to expire July 18, 2034. Upon the achievement of additional specified development and regulatory milestones, we are required to pay BCM one-time milestone payments of up to $1,225,000 in the aggregate for the first BCM2 Licensed Product to achieve such milestones. Further, in connection with the initiation of the Phase 3 clinical trial, we would expect to incur approximately $300,000 in 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 Licensed Patent Rights.

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

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 years ended December 31, 2025 and 2024. No royalty fees have been incurred to date.

Components of Operating Results

The following discussion sets forth certain components of our Consolidated Statements of Operations and Comprehensive Loss as well as factors that impact those items or could impact those items in the future.

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 since inception, as well as 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 since inception, as well as our operating 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 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 includes salaries, benefits, stock-based compensation expense and travel expenses, for personnel engaged in research and development functions;
- facilities, amortization and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance and other supplies; and
- costs related to compliance with quality and regulatory requirements.

Pursuant to U.S. GAAP and 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 consolidated financial statements as prepaid or accrued research and development expenses.

The majority of our clinical spending during the years ended December 31, 2025 and 2024 was on TTI-101, for which certain direct research and development costs are tracked by clinical trial. We also incurred costs for TTI-109 related to CMC and clinical operations for the year ended December 31, 2025. Costs incurred for TTI-109 for the year ended December 31, 2024 were related to CMC and preclinical costs.

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 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 includes 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 SEC requirements, director and officer insurance premiums and investor relations costs associated with being a public company.

Interest Income

Interest income for the year ended December 31, 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 net discount of our short-term investments. Interest income for the year ended December 31, 2024 consisted of interest earned on our cash and cash equivalents.

Other Income (Expense), Net

Other income (expense), net consists 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 and any associated debt issuance costs incurred. See “Convertible Notes” above for further discussion of our Convertible Notes.

Income Taxes

We provide for income taxes using the asset and liability method. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and tax reporting bases of assets and liabilities and are measured using enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. Realization of deferred tax assets is dependent upon future earnings, the timing and amount of which are uncertain. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

For the years ended December 31, 2025 and 2024, there was no current or deferred income tax expense or benefit due to our current year loss and prior year loss and full valuation allowance in each respective year. As of December 31, 2025, 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.

On July 4, 2025, the OBBBA was signed into law. The OBBBA introduced multiple U.S. federal income tax changes such as favorable changes to the deductibility of domestic research and development expenses, bonus depreciation of certain property additions, and limitations on interest expense deductions. We have considered the impact of these provisions on our consolidated financial statements for the year ended December 31, 2025, however, the changes in tax law did not result in a change in our tax provision. Because we maintain a full valuation allowance and have no current income tax expense or cash tax payments, the enactment of OBBBA in 2025 did not have a material impact on our financial position, results of operations, liquidity or cash flows for the year ended December 31, 2025.

During the year ended December 31, 2025, we adopted Accounting Standards Update 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures.* The adoption did not impact our financial position, results of operations, or cash flows, but resulted in expanded income tax disclosures, primarily related to the disaggregation of effective tax rate reconciliation items and

income taxes paid, as presented in the notes to the consolidated financial statements. Refer to Note 11, *Income Taxes*, in the Notes to Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K.

Results of Operations

Comparison of the Years ended December 31, 2025 and 2024

The following table sets forth our results of operations for the years ended December 31, 2025 and 2024 (in thousands, except percentages):

	Year Ended December 31,		Change	
	2025	2024	Amount	Percent
Operating expenses:				
Research and development	$ 18,011	$ 23,650	$ (5,639)	(23.8)%
General and administrative	8,737	4,457	4,280	96.0 %
Total operating expenses	26,748	28,107	(1,359)	(4.8)%
Loss from operations	(26,748)	(28,107)	1,359	(4.8)%
Interest income	1,375	747	628	84.1 %
Other income (expense), net	7,159	(2,037)	9,196	n/a
Net loss	$ (18,214)	$ (29,397)	$ 11,183	(38.0)%

Research and Development Expenses

Research and development expenses for the years ended December 31, 2025 and 2024 were comprised of the following (in thousands, except percentages):

	Year Ended December 31,		Change	
	2025	2024	Amount	Percent
Direct research and development expenses by program:				
TTI-101:				
HCC	$ 3,183	$ 8,583	$ (5,400)	(62.9)%
IPF	4,683	6,703	(2,020)	(30.1)%
mBC	(262)	2,182	(2,444)	(112.0)%
Preclinical, CMC, and other (unallocated)	688	969	(281)	(29.0)%
TTI-109	5,371	1,193	4,178	350.2 %
Unallocated research and development expense:				
Personnel costs (including stock-based compensation)	3,329	2,988	341	11.4 %
Consultant fees and other costs	1,019	1,032	(13)	(1.3)%
Total research and development expenses	$ 18,011	$ 23,650	$ (5,639)	(23.8)%

Research and development expenses were $18.0 million for the year ended December 31, 2025, compared to $23.7 million for the year ended December 31, 2024. The decrease of $5.6 million was primarily driven by costs associated with our product candidate TTI-101, including decreases of $5.4 million, $2.4 million and $2.0 million related to our HCC, metastatic breast cancer (mBC) and IPF trials, respectively. The decrease in costs related to our HCC trial was attributable to the changes in patient enrollments and estimated study costs. The decrease in costs related to our mBC trial was due to the discontinuation of the trial in January 2024 and a related true-up recorded during the second quarter of 2025 due to the negotiation of wind-down costs. The decrease in costs related to our IPF trial was due to reduced patient enrollment as the study progressed and changes in estimated clinical trial costs resulting from clinical trial change orders.

The increase of $4.2 million related to our product candidate TTI-109 was primarily driven by the healthy volunteer study, which began in the third quarter of 2025, as well as related CMC costs related to clinical supply and preclinical studies.

The increase in personnel costs of $0.3 million was primarily related to increases in compensation across the research and development functions as well as an increase in stock-based compensation expense related to new option grants in 2025.

General and Administrative Expenses

General and administrative expenses for the years ended December 31, 2025 and 2024 were comprised of the following (in thousands, except percentages):

	Year Ended December 31,		Change	
	2025	2024	Amount	Percent
Personnel costs	$ 3,505	$ 2,085	$ 1,420	68.1 %
Professional fees	3,875	1,863	2,012	108.0 %
Insurance costs	494	59	435	737.3 %
Rent and other costs	863	450	413	91.8 %
Total general and administrative expenses	$ 8,737	$ 4,457	$ 4,280	96.0 %

General and administrative expenses were $8.7 million for the year ended December 31, 2025, compared to $4.5 million for the year ended December 31, 2024. The increase of approximately $4.3 million was primarily driven by increases in professional fees of $2.0 million, attributable to increased legal, accounting and audit fees incurred as a result of the Merger and subsequent filings as a public company. The remaining increase was attributable to increases in personnel costs, insurance costs, and rent and other costs.

Interest Income

Interest income was $1.4 million for the year ended December 31, 2025, compared to $0.7 million for the year ended December 31, 2024. The $1.4 million of interest income for the year ended December 31, 2025 includes $0.7 million of interest earned on our cash and cash equivalents and $0.7 million of interest from our short-term investments, as well as the accretion of the net discount on our short-term investments. The $0.7 million of interest income for the year ended December 31, 2024 was driven by interest income earned on our cash and cash equivalents.

Other Income (Expense), Net

Other income of $7.2 million for the year ended December 31, 2025 was primarily attributable to the $12.8 million remeasurement gain on our Convertible Notes recorded during the second quarter of 2025, partially offset by a $4.9 million remeasurement loss recorded during the first quarter of 2025, as well as a total of $0.7 million in interest accrued on the Convertible Notes during those respective periods. Other expense of $2.0 million for the year ended December 31, 2024 was primarily attributable to a $1.8 million remeasurement loss on our Convertible Notes and $0.1 million of debt issuance costs incurred.

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, and (iii) as discussed above in "—Recent Developments," our Merger with Cara in April 2025. 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 December 31, 2025, we had $20.7 million in cash and cash equivalents and $10.1 million in short-term investments. In April 2025, we acquired approximately $23.9 million of net assets in connection with the closing of the Merger.

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, general and administrative costs. We have incurred significant operating losses since our inception, and as of December 31, 2025, had an accumulated deficit of $110.5 million. Management has

determined that its present capital resources as of December 31, 2025 will not be sufficient to fund its planned operations for at least one year from the issuance date of the consolidated financial statements, included elsewhere in this Annual Report on Form 10-K, which raises substantial doubt as to our ability to continue as a going concern. In April 2025, as further discussed above, Legacy Tvardi completed its Merger with Cara, through which we acquired approximately $23.9 million in net assets. Subsequent to the completion of the Merger, we plan to seek additional funding through equity offerings or debt financings, credit or loan facilities, and strategic alliances and licensing arrangements. However, there can be no assurance that such funding will be available to 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 this Annual Report on Form 10-K for additional risks associated with our substantial capital requirements.

Cash Flows

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

	Year Ended December 31,	
	2025	2024
Net cash used in operating activities	$ (23,499)	$ (18,305)
Net cash used in investing activities	(10,084)	—
Net cash provided by financing activities	22,703	27,000
Net (decrease) increase in cash and cash equivalents	$ (10,880)	$ 8,695

Operating Activities

Net cash used in operating activities was $23.5 million for the year ended December 31, 2025, reflecting a net loss of $18.2 million and non-cash changes of $5.8 million, partially offset by changes in operating assets and liabilities of $0.5 million. The changes of $5.8 million in non-cash expenses were primarily driven by $7.8 million related to the net change in fair value of our Convertible Notes, partially offset by $1.4 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 $0.5 million were primarily driven by a $0.9 million increase in accounts payable and accrued expenses, driven by the timing of invoices and payments, partially offset by a $0.3 million increase in prepaid expenses and other current assets, attributable to payments for pre-clinical activities and prepaid insurance.

Net cash used in operating activities was $18.3 million for the year ended December 31, 2024, reflecting a net loss of $29.4 million, net of changes in operating assets and liabilities of $8.6 million, and non-cash changes of $2.5 million. The net changes in operating assets and liabilities of $8.6 million was primarily driven by a $3.2 million decrease in prepaid expenses and other current assets, attributable to the timing of patient enrollments, and a $5.6 million increase in accounts payable and accrued expenses, driven by the timing of invoices and payments. The changes of $2.5 million in non-cash expenses were primarily driven by $1.8 million related to the change in fair value of our Convertible Notes, $0.2 million in interest accrued on its Convertible Notes, $0.3 million in stock-based compensation, and $0.1 million in depreciation and amortization.

Investing Activities

Net cash used in investing activities was $10.1 million for the year ended December 31, 2025, attributable to purchases of short-term investments of $31.5 million, partially offset by maturities of short-term investments of $21.4 million.

There was no net cash provided by or used in investing activities for the year ended December 31, 2024.

Financing Activities

The net cash provided by financing activities for the year ended December 31, 2025 was primarily due to approximately $25.0 million of cash acquired in connection with the Merger and proceeds of $0.5 million from the exercise of stock options, partially offset by payments of $2.8 million related to Merger transaction costs.

The net cash provided by financing activities for the year ended December 31, 2024 was primarily due to the proceeds from our Convertible Notes, partially offset by payments of deferred offering 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 December 31, 2025, we had future operating lease liabilities of $0.2 million, of which $0.1 million is included within operating lease liabilities, current portion on our consolidated balance sheet.

License Agreements

As discussed above, we have license agreements with BCM for exclusive use of patent rights of TTI-101. The license agreements contain terms for annual maintenance fees, milestone payments and net revenue royalties. Annual maintenance fees range from $30,000 to $50,000 per year, per license. Potential milestone payments are up to $1,225,000 in the aggregate per license. Milestones include new drug filings, clinical trial stages, and NDA approval by the FDA. We are obligated to pay BCM royalties in the amount of a low-single-digit percent of net sales of BCM1 Licensed Products or BCM2 Licensed Products during the term, which expire, on a country-by-country basis, on the later of (i) the date of expiration of BCM Patent Rights or Licensed Patent Rights, whichever is the last to expire, or, (ii) if no BCM Patent Rights or Licensed Patent Rights are issued in such country, the tenth anniversary the first commercial sale of the BCM1 Licensed Products or BCM2 Licensed Products in such country. License fees are expensed as incurred within research and development within our consolidated statements of operations and comprehensive loss. Under the BCM First Agreement, the full amount of $50,000 in annual maintenance fees had already been paid as of December 31, 2025 and 2024, and thus no accrual was needed in either respective year. We also incurred $125,000 in milestones payments in relation to the initiation of a Phase 2 clinical trial during the year ended December 31, 2024. 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 vary and are based on the timing of the cancellation or termination and the specific terms of the agreement. These obligations and commitments are not presented separately.

In addition to our obligation to make potential royalty payments under the BCM First Agreement and BCM Second 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 Royalty Bearing Product is no longer covered by a Covered Patent (as defined below) in such country, or (ii) 15 years after the first commercial sale of Royalty Bearing Product in such country. The timing of when 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 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 audited consolidated financial statements are prepared in accordance with U.S. GAAP. The preparation of the audited 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 audited 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.

While our significant accounting policies are described in more detail in Note 2 to the audited consolidated financial statements for the years ended December 31, 2025 and 2024, both as included elsewhere within this Annual Report on Form 10-K, management believes that the following accounting policies are critical to understanding our historical and future performance, as the policies relate to the more significant areas involving management's judgments and estimates used in the preparation of the audited consolidated financial statements.

Prepaid and Accrued Research and Development Expenses

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

Examples of estimated accrued research and development expenses include:

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

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

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

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

Convertible Notes

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

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

As of December 31, 2024, prior to the Merger with Cara in April 2025, Legacy Tvardi assessed the probability of (i) an automatic conversion of the Convertible Notes into equity securities upon a Qualified or non-Qualified Financing, (ii) an automatic conversion of the Convertible Notes into shares of Legacy Tvardi common stock upon an IPO, (iii) an automatic conversion of the Convertible Notes into the combined company's common stock upon a reverse merger, and (iv) an event of default, dissolution, or liquidation, weighted with 20%, 10%, 60%, and 10%, respectively. Immediately prior to the Merger closing in April 2025, the probability of these events were weighted as 2.5%, 0%, 95%, and 2.5%, respectively.

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

Since we elected the fair value option for the Convertible Notes, at the time of conversion, the fair value was measured as the quoted market price of our common shares into which the Convertible Notes were exchanged. The fair value was determined to be the closing market trading price on April 16, 2025, the first day of trading for our common stock after the reverse merger with Cara.

Under the fair value option, any change in fair value was recorded to our consolidated statements of operations and comprehensive loss as a gain or loss from a fair value measurement. At the time of conversion, the fair value of the Convertible Notes was $23.1 million, calculated as 1,265,757 shares of common stock at the closing market trading price on April 16, 2025. The $12.8 million change in fair value when comparing the $23.1 million at the time of conversion to the $35.9 million recorded value of the Convertible Notes immediately prior to the conversion date was recorded to our consolidated statements of operations and comprehensive loss within other income (expense), net for the second quarter of 2025. Net fair value changes of $7.8 million were recorded to our consolidated statement of operations and comprehensive loss as a remeasurement gain within other income (expense), net for the year ended December 31, 2025. Net fair value changes of $1.8 million were recorded to our consolidated statement of operations and comprehensive loss as a remeasurement loss within other income (expense), net for the year ended December 31, 2024.

As discussed above, upon the closing of the Merger, the Convertible Notes converted into 1,265,757 shares of our common stock in the aggregate. As a result, there were no Convertible Notes as of December 31, 2025.

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

Stock-Based Compensation Expense

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

These assumptions are estimated as follows:

- *Fair Value* — Because our common stock was not yet publicly traded prior to the Merger, we had to estimate the fair value of our common stock. Our board of directors considered numerous objective and subjective factors to determine the fair value of our common stock at each meeting in which awards were approved. Subsequent to the Merger, our common stock is publicly traded.
- *Expected Volatility* — Because we did not have any trading history for our common stock prior to the Merger, the expected volatility was estimated using averages of the historical volatility of our peer group of companies for a period equal to the expected term of the stock options granted. Our peer group of publicly traded companies was chosen based on their similar size, stage in the life cycle or area of specialty. Subsequent to the Merger, we intend to continue to consistently apply this process using the same or a similar peer group of public companies, until a sufficient amount of historical information regarding the volatility of our own common stock price becomes available.
- *Expected Term* — Derived from the life of the options granted under the option plan and is based on the simplified method which is essentially the weighted average of the vesting period and contractual term.

- *Risk-Free Interest Rate* — The risk-free interest rate is based on the implied yield currently available on U.S. Treasury zero-coupon issues with a term that is equal to the options' expected term at the grant date.
- *Dividend Yield* — We had not declared or paid dividends, and we do not anticipate declaring dividends. As such, the dividend yield has been estimated to be zero.

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

Fair Value of Stock-Based Awards

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

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

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

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

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

Following the Merger and the establishment of a public trading market for our common stock, it is no longer necessary for our board of directors to estimate the fair value of our common stock in connection with our accounting for stock options and other such awards we may grant, as the fair value of our common stock will be determined based on the quoted market price of our common stock.

Recently Issued and Adopted Accounting Pronouncements

We do not expect that 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 Consolidated Financial Statements*, Summary of Significant Accounting Policies*, in this Annual Report on Form 10-K, for a full description of accounting pronouncements recently adopted, and issued but not yet adopted, if applicable.

Item 7A. ***Quantitative and Qualitative Disclosures About Market Risk.***

Interest Rate Risk

As of December 31, 2025, we had $20.7 million in cash and cash equivalents and $10.1 million in short-term investments. Our cash, cash equivalents and short-term investments are primarily maintained in accounts with multiple financial institutions in the United States. We may maintain cash and cash equivalent balances in excess of Federal Deposit Insurance Corporation limits. We do not believe that we are subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships, particularly because our investments are in short-term marketable securities. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. Due to the short-term duration and low risk profile of our cash equivalents and short-term investments, we believe an immediate 10% change in interest rates would not have a material effect on their fair market value. We have the ability to hold our investments until maturity, and therefore, would not expect our operating results or cash flows to be affected to any significant degree by the effect of a change in market interest rates on our investment portfolio.

Effects of Inflation

Inflation generally affects us by increasing the cost of labor and research and development contract costs. We do not believe inflation has had a material effect on our results of operations during the periods presented in our audited consolidated financial statements included elsewhere within in this Annual Report on Form 10-K.

Foreign Currency Exchange Risk

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

Item 8. Financial Statements and Supplementary Data.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

OF

TVARDI THERAPEUTICS, INC.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the shareholders and the Board of Directors of Tvardi Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Tvardi Therapeutics, Inc. and subsidiaries (the "Company") as of December 31, 2025 and 2024, the related consolidated statements of operations and comprehensive loss, redeemable convertible preferred stock and stockholders' equity (deficit) and cash flows, for each of the two years in the period ended December 31, 2025, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2025, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations and does not have sufficient cash on hand or available liquidity to fund operations, which raises substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current-period audit of the financial statements that was communicated or required to be communicated to the audit committee and that (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Prepaid and Accrued Research and Development Expenses – Refer to Notes 2, 5 and 7 to the financial statements

Critical Audit Matter Description

The Company recognizes research and development expenses and records accruals for estimated costs of research and development activities conducted by third-party contract research organizations (CROs) service providers. The majority of the Company's service providers invoice in arrears for services performed, on a pre-determined schedule, or when contractual milestones are met; however, some require advanced payments. The Company records advance payments to service providers as prepaid expenses and other current assets, which are expensed as the contracted services are performed. The Company accrues for these costs based on factors such as the time period over which services will be performed, the enrollment of patients, and the level of effort to be expended in each period in accordance with its agreements with its third-party service providers for such services.

Given the significant judgments made by the Company in estimating the progress or stage of completion of the services, auditing the Company's prepaid and accrued research and development expenses related to CROs was especially challenging. Specifically, because the amount of prepaid and accrued research and development expenses is dependent on the Company's receipt of timely and accurate reporting from third-party service providers, the Company's estimates of work completed as of the balance sheet date, and the Company's estimates of the period over which this work will be performed, auditing prepaid and accrued research and development expenses related to CROs required a high degree of auditor judgment and an increased extent of effort.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to testing the prepaid and accrued research and development expenses included the following, among others:

- We tested the design and implementation of relevant controls over the Company's review of prepaid and accrued research and development expenses related to CROs.
- We evaluated the Company's accounting policy for prepaid and accrued research and development liabilities, including the estimation approach for the expenses, for reasonableness.
- We evaluated the Company's judgments, including but not limited to, patient enrollment, using the evidence obtained to determine the prepaid and accrued research and development liabilities.
- We confirmed the monthly patient enrollment directly with the CROs.
- For a sample of agreements and contracts, we agreed inputs utilized in the estimate of prepaid and accrued research and development liabilities to the underlying contract, corresponding invoices incurred during the period and evidence of payment to test the Company's disbursements made to third-party service providers.
- We compared invoices received by the Company subsequent to December 31, 2025, to the accrued research and development expenses related to CROs recognized by the Company.

/s/ Deloitte & Touche LLP

Houston, Texas
March 31, 2026

We have served as the Company's auditor since 2022.

TVARDI THERAPEUTICS, INC.

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

	As of December 31,	
	2025	2024
Assets		
Current assets:		
Cash and cash equivalents	$ 20,734	$ 31,614
Short-term investments	10,077	—
Prepaid expenses and other current assets	727	72
Total current assets	31,538	31,686
Property and equipment, net	52	84
Intangible assets, net	322	385
Operating lease right-of-use assets	144	216
Deferred offering costs	—	2,811
Other non-current assets	17	17
Total assets	$ 32,073	$ 35,199
Liabilities, Redeemable Convertible Preferred Stock, and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 3,219	2,186
Accrued expenses	7,707	8,078
Operating lease liabilities, current portion	116	103
Total current liabilities	11,042	10,367
Operating lease liabilities, net of current portion	85	201
Convertible Notes	—	30,259
Total liabilities	11,127	40,827
Commitments and contingencies (Note 13)		
Redeemable convertible preferred stock (Series A, B), $0.001 par value; 0 shares and 29,723,540 shares authorized as of December 31, 2025 and 2024, respectively; 0 shares and 3,963,910 shares issued and outstanding as of December 31, 2025 and 2024, respectively; aggregate liquidation preference of $0 and $85,902 as of December 31, 2025 and 2024, respectively	—	85,503
Stockholders' Equity (Deficit):		
Common stock, $0.001 par value; 150,000,000 shares and 58,251,629 shares authorized as of December 31, 2025 and 2024, respectively; 9,381,344, and 2,574,767 shares issued and outstanding as of December 31, 2025 and 2024, respectively	9	2
Additional paid-in capital	131,379	1,103
Accumulated other comprehensive income	8	—
Accumulated deficit	(110,450)	(92,236)
Total stockholders' equity (deficit)	20,946	(91,131)
Total liabilities, redeemable convertible preferred stock, and stockholders' equity (deficit)	$ 32,073	$ 35,199

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

TVARDI THERAPEUTICS, INC.

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

	For the Year Ended December 31,	
	2025	2024
Operating expenses:		
Research and development	$ 18,011	$ 23,650
General and administrative	8,737	4,457
Total operating expenses	26,748	28,107
Loss from operations	(26,748)	(28,107)
Interest income	1,375	747
Other income (expense), net	7,159	(2,037)
Net loss	$ (18,214)	$ (29,397)
Net loss per share attributable to common stockholders:		
Basic	$ (2.46)	$ (11.42)
Diluted	$ (3.26)	$ (11.42)
Weighted-average common shares outstanding:		
Basic	7,419,060	2,574,233
Diluted	7,783,182	2,574,233
Comprehensive loss:		
Net loss	$ (18,214)	$ (29,397)
Unrealized gain on short-term investments	8	—
Comprehensive loss	$ (18,206)	$ (29,397)

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

TVARDI THERAPEUTICS, INC.

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

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balances as of December 31, 2023	29,555,538	$ 85,503	19,134,164	$ 19	$ 762	$ (62,839)	$ —	$ (62,058)
Retroactive application of reverse recapitalization	(25,591,628)	—	(16,567,945)	(17)	17	—	—	—
Adjusted balance, beginning of period	3,963,910	85,503	2,566,219	2	779	(62,839)	—	(62,058)
Exercise of stock options	—	—	8,548	—	5	—	—	5
Stock-based compensation	—	—	—	—	319	—	—	319
Net loss	—	—	—	—	—	(29,397)	—	(29,397)
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	—	—	26,529	—	532	—	—	532
Stock-based compensation	—	—	—	—	1,399	—	—	1,399
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 gain on short-term investments	—	—	—	—	—	—	8	8
Net loss	—	—	—	—	—	(18,214)	—	(18,214)
Balances as of December 31, 2025	—	$ —	9,381,344	$ 9	$ 131,379	$ (110,450)	$ 8	$ 20,946

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

TVARDI THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS
(Amounts in thousands)

	For the Year Ended December 31,	
	2025	2024
Cash flows from operating activities:		
Net loss	$ (18,214)	$ (29,397)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	95	95
Stock-based compensation expense	1,399	319
Change in fair value of Convertible Notes	(7,810)	1,807
Non-cash lease expense	72	76
Accretion of net discounts on short-term investments	(200)	—
Interest accrued on Convertible Notes	651	154
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(308)	3,167
Accounts payable and accrued expenses	919	5,567
Operating lease liabilities	(103)	(93)
Net cash used in operating activities	(23,499)	(18,305)
Cash flows from investing activities:		
Purchases of short-term investments	(31,486)	—
Maturities of short-term investments	21,402	—
Net cash used in investing activities	(10,084)	—
Cash flows from financing activities:		
Cash acquired in connection with the Merger	24,992	—
Payments for Merger transaction costs	(2,821)	(1,303)
Proceeds from Convertible Notes	—	28,298
Proceeds from exercise of stock options	532	5
Net cash provided by financing activities	22,703	27,000
Net (decrease) increase in cash and cash equivalents	(10,880)	8,695
Cash and cash equivalents - beginning of year	31,614	22,919
Cash and cash equivalents - end of year	$ 20,734	$ 31,614
Non-cash investing and financing activities		
Merger transaction costs included in accounts payable and accrued expenses	$ —	$ 1,508
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 consolidated financial statements.

TVARDI THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of the Business and Basis of Presentation

Tvardi Therapeutics, Inc. and subsidiaries (Tvardi or the Company) is a Delaware corporation headquartered in Houston, Texas. The Company is a clinical-stage biopharmaceutical company focused on the development of novel, oral, small molecule therapies targeting STAT3 to treat 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. After U.S. Food and Drug Administration (FDA) acceptance of the IND, the Company has initiated a Phase 1 trial of TTI-109 in healthy volunteers to evaluate safety, tolerability, and pharmacokinetics, as well as bioequivalence to TTI-101. In October 2025, the Company reported preliminary data from its Phase 2 clinical trial of TTI-101 in idiopathic pulmonary fibrosis (IPF) and concluded that the study did not meet its goals. The Company is continuing to evaluate the results from the trial to inform potential future development decisions.

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 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 consolidated financial statements to "Tvardi" and "the Company" refer to the business and operations of Legacy Tvardi prior to the Merger and to Tvardi Therapeutics, Inc. and its consolidated subsidiaries following the Merger. See Note 3, *Merger Agreement*, for additional information on the Merger.

Risks and Uncertainties

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

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

Liquidity and Going Concern

The accompanying 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 December 31, 2025, the Company had cash and cash equivalents and short-term investments of $20.7 million and $10.1 million, respectively, which included approximately $23.9 million in net assets acquired from the consummation of the Merger Agreement (as further discussed in Note 3, *Merger Agreement*) in April 2025. Since inception, the Company has incurred net operating losses and negative cash flows from operations. During the year ended December 31, 2025, the Company incurred a net loss of $18.2 million and used $23.5 million of cash in operating activities. As of December 31, 2025, the Company had an accumulated deficit of $110.5 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 considered both quantitative and qualitative factors that are known or reasonably knowable as of the date that these 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 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 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 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 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 consolidated financial statements reflect all adjustments (consisting of normal recurring adjustments) necessary to present fairly the financial position of the Company as of December 31, 2025 and 2024, and results of operations and cash flows for all periods presented.

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, Convertible Notes and stock options of Legacy Tvardi throughout the consolidated financial statements and notes to consolidated financial statements. See Note 3, *Merger Agreement*, for additional information on the Merger.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of consolidated 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 consolidated financial statements include, but are not limited to, prepaid and accrued research and development expenses, including those related to contract research organizations (CROs), contract development manufacturing organizations (CDMOs), and other third-party vendors, and the valuation of the Company's common stock prior to the Merger, stock-based awards, and the fair value of Convertible Notes (as defined in Note 4, *Fair Value Measurements*), which converted to common stock upon close of the Merger. Changes in estimates are recorded in the period in which they become known.

Concentration of Credit Risk and of Significant Suppliers

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

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

	For the Year Ended December 31,		As of December 31,	
	2025	2024	2025	2024
	% of operating expenses		% of accounts payable	
Vendor A	36 %	62 %	84 %	43 %

For the years ended December 31, 2025 and 2024, 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 supplier.

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 $20.0 million and $31.3 million as of December 31, 2025 and 2024, respectively.

The Company recorded interest income on its cash equivalents of $0.7 million for each of the years ended December 31, 2025 and 2024 on its 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 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 are included within the non-operating section of the consolidated statements of operations and comprehensive loss, as needed. The Company recorded interest income on short-term investments, inclusive of accretion of its net discounts on its short-term investments, of $0.7 million for the year ended December 31, 2025, which is classified as interest income in the consolidated statements of operations and comprehensive loss. There were no short-term investments for the year ended December 31, 2024.

At each balance sheet date, the Company assesses available-for-sale debt securities in an unrealized loss position to determine whether the unrealized loss or any potential credit losses should be recognized within the non-operating section of the 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 consolidated statements 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 for the years ended December 31, 2025 and 2024.

Deferred Offering Costs

The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated. After consummation of the equity financing, these costs are recorded as a reduction of the proceeds from the offering, either as a reduction of the carrying value of the preferred stock or in stockholders' equity (deficit) as a reduction of additional paid-in-capital generated as a result of the offering. Should any planned equity financing be abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the consolidated statements of operations and comprehensive loss.

The Company recorded deferred offering costs of $2.8 million as of December 31, 2024. With the addition of the Company's deferred costs incurred in 2025 prior to the Merger closing, a total of $4.1 million in deferred offering costs were reclassified as a reduction of additional paid-in-capital upon the close of the Merger.

Fair Value Measurements

Certain assets and liabilities of the Company are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs.

Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

Level 1 — Quoted prices in active markets for identical assets or liabilities.

Level 2 — Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.

Level 3 — Unobservable inputs that are supported by little or no market activity that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The Company's cash equivalents are carried at fair value in Level 1, determined according to the fair value hierarchy described above (refer to Note 4, *Fair Value Measurements)*. The carrying values of the Company's prepaid expenses and other current assets, accounts payable and accrued expenses approximate their fair values due to the short-term nature of these instruments. The Company's Convertible Notes were carried at fair value prior to their conversion in April 2025, determined according to level 3 inputs in the fair value hierarchy described above. Refer to Note 4, *Fair Value Measurements* for further information around the fair value of the Convertible Notes.

Property and Equipment

The Company records property and equipment at cost less accumulated depreciation and amortization. Depreciation and amortization expense is recognized using the straight-line method over the estimated useful life of each asset, as follows:

	Estimated Useful Life
Computer equipment	3 years
Office equipment	5 years
Leasehold improvements	Shorter of remaining lease term or estimated useful life

Estimated useful lives are periodically assessed to determine if changes are appropriate. Leasehold improvements are amortized using the straight-line method over the lesser of the lease term or its estimated useful life. Lease terms are based upon the initial lease agreement and do not consider potential renewals or extensions until such time that the renewals or extensions are contracted. Expenditures for maintenance and repairs that do not improve or extend the life of the respective assets are expensed as incurred. When assets are retired or otherwise disposed of, the cost of these assets and related accumulated depreciation or amortization are eliminated from the consolidated balance sheets and any resulting gains or losses are included in the consolidated statements of operations and comprehensive loss in the period of disposal.

Depreciation and amortization expense related to property and equipment was less than $0.1 million for each of the years ended December 31, 2025 and 2024.

Intangible Assets

Intangible assets consist of licenses for exclusive use of patent rights owned by a third party, which are amortized using the straight-line method over the estimated periods of benefit, generally the remaining life of the underlying licensed patents.

The Company reviews intangible assets for impairment whenever conditions exist that indicate the carrying value may not be recoverable, such as an economic downturn in the market or a change in the assessment of future operations. No impairment was recorded for the years ended December 31, 2025 and 2024.

Refer to Note 14, *License Agreements*, for further detail on the Company's licenses.

Impairment of Long-lived Assets

The Company evaluates its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset group for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset group to its carrying value. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset group are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset group over its fair value. For the years ended December 31, 2025 and 2024, the Company did not record any impairment losses on long-lived assets.

Operating Leases

The Company determines whether an arrangement is or contains a lease, as defined by Accounting Standards Update, or ASU, 2016-02, *Leases* (Topic 842) (or ASC 842), at contract inception by evaluating whether the arrangement conveys the right to use an identified asset and whether the Company obtains substantially all of the economic benefits from and has the ability to direct the use of the asset. If an arrangement is determined to be or contain a lease, the lease is assessed for classification as either an operating or finance lease at the lease commencement date, defined as the date on which the leased asset is made available for use by the Company, based on the economic characteristics of the lease.

ASC 842 includes certain practical expedients that can be elected for new leases that are executed after the adoption of the new requirements. The Company elected the practical expedient to not separate lease and non-lease components. The Company also

elected to apply the short-term lease recognition exemption which eliminates the requirement to present on the consolidated balance sheets leases with a term of 12 months or less. These two practical expedients were elected for all classes of underlying assets.

At the lease commencement date, the Company recognizes a lease liability and a right-of-use (ROU) asset representing its right to use the underlying asset over the lease term. The initial measurement of the lease liability is calculated as the present value of the future lease payments in the contract and the ROU asset is measured as the lease liability plus initial direct costs and prepaid lease payments, less lease incentives granted by the lessor. The subsequent measurement of a lease is dependent on whether the lease is classified as an operating lease or a finance lease. Operating lease cost is recognized on a straight-line basis over the lease term in the consolidated statements of operations and comprehensive loss.

The Company's lease requires other payments such as costs related to taxes, insurance, maintenance, and other expenses. These costs are generally variable in nature and based on the actual costs incurred and required by the lease. As the Company has elected to not separate lease and non-lease components for all classes of underlying assets, all variable costs associated with the lease are expensed in the period incurred and presented and disclosed as variable lease costs. The Company's lease agreement does not contain any material residual value guarantees or material restrictive financial covenants.

ASC 842 requires that a lessee use the rate implicit in the lease when measuring the lease liability and ROU asset. If the rate implicit in the lease is not readily determinable, the Company is permitted to use its incremental borrowing rate, which is defined as the rate of interest that the Company would have to pay to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment. Since the rate implicit in the lease is not readily determinable, the Company uses its incremental borrowing rate when measuring its leases. The incremental borrowing rate is calculated by considering the Company's credit standing, the lease term and other quantitative and qualitative factors.

Most leases include options to renew and, or, terminate the lease, which can impact the lease term. The exercise of these options is at the Company's discretion. Periods covered by an option to extend a lease are not included in the lease term as the Company is not reasonably certain it will exercise this option. Additionally, periods covered by an option to terminate the lease are included in the lease term as it is reasonably certain that the Company will not exercise this option.

Redeemable Convertible Preferred Stock

Legacy Tvardi previously issued Series A preferred stock and Series B preferred stock in 2018 and 2021, respectively (collectively, the Preferred Stock). As of December 31, 2024, Legacy Tvardi had authorized the issuance of 29,723,540 shares of Preferred Stock, par value of $0.001 per share, of which 9,499,999 were designated Series A preferred stock and 20,223,541 were designated Series B preferred stock. As of December 31, 2024, Legacy Tvardi had 3,963,910 shares of Preferred Stock outstanding, with an aggregate carrying value of $85,503 and an aggregate liquidation preference of $85,902. The outstanding shares of Preferred Stock as of December 31, 2024 reflect the retroactive application of the Exchange Ratio as discussed in Note 3, *Merger Agreement.*

Prior to the Merger, the holders of Preferred Stock had certain liquidation rights in the event of a liquidation event or a deemed liquidation event that, in certain situations, were not solely within the control of Legacy Tvardi and called for the redemption of the then outstanding Preferred Stock. Accordingly, as of December 31, 2024, the Preferred Stock was classified as temporary equity on the accompanying consolidated balance sheet. As the Preferred Stock was converted to common stock in accordance with the Merger Agreement in April 2025, there was no Preferred Stock remaining as of December 31, 2025. See Note 3, *Merger Agreement*, for further information.

Refer to Note 9, *Stockholders' Equity (Deficit)*, for further information regarding the authorized preferred stock, pursuant to Cara's amended and restated certificate of incorporation, which was assumed by the Company in connection with the Merger Agreement in April 2025.

Convertible Notes

At issuance in December 2024, Legacy Tvardi performed an analysis of all terms and features of the Convertible Notes (as defined in Note 4, *Fair Value Measurements*) and elected the fair value option to account for the Convertible Notes to simplify the accounting for the identified embedded derivatives. The Convertible Notes were remeasured at fair value at each balance sheet date until conversion under the Merger Agreement in April 2025. Changes to the fair value of the Convertible Notes were recorded in other income (expense), net in the Company's consolidated statements of operations and comprehensive loss for the years ended December 31, 2025 and 2024. The Company also elected the option of combining interest expense and the change in fair value as a single line item within the Company's consolidated statements of operations and comprehensive loss. Refer to Note 4, *Fair Value Measurements*, for further detail regarding the valuation and conversion of the Convertible Notes.

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker (CODM) in deciding how to allocate resources and in assessing performance. The Company's CODM, its Chief Executive Officer and Chief Financial Officer, view the Company's operations as a single operating segment, which is the business of discovering and developing novel orally bioavailable, small molecule therapies across a broad range of diseases driven by STAT3 with high unmet need.

All of the Company's long-lived assets are held in the United States.

Refer to Note 16, *Segment Reporting*, for additional disclosures related to segment information.

Research and Development Expenses

Research and development expenses are expensed as incurred. Research and development expenses include wages, associated employee benefits, and stock-based compensation expense of employees engaged in research, amortization of licensed intangible assets, external costs of third-party vendors that conduct research and development and manufacturing activities on behalf of the Company, and other operational costs related to the Company's research and development activities.

Prepaid and Accrued Research and Development Expenses

The Company recognizes research and development expense and records accruals for estimated costs of research and development activities conducted by third-party service providers, which include CROs that conduct research, preclinical studies and clinical trials on the Company's behalf, including in connection with the Company's research and development arrangement, and CDMOs that manufacture the Company's product candidate for use in preclinical studies and clinical trials. The majority of the Company's service providers invoice in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some require advanced payments. The Company makes estimates of its accrued expenses and includes these costs in accrued liabilities in the consolidated balance sheets and within research and development expense in the consolidated statements of operations and comprehensive loss based on facts and circumstances known to the Company at that time. The prepayments and accruals underlying these types of costs are a significant component of the Company's research and development expenses.

The Company accrues for these costs based on factors such as estimates of the amount of work completed through discussions with internal personnel and external service providers as to the progress or stage of completion of the services and in accordance with agreements established with its third-party service providers for such services. The Company makes significant judgments and estimates in determining the accrued research and development liabilities balance at each reporting period. As actual costs become known, the Company adjusts its accrued estimates. To date, there have been no material adjustments to the Company's estimates of accrued research and development expenses. The Company records advance payments to service providers as prepaid expenses and other current assets, which are expensed as the contracted services are performed. If the actual timing of the performance of services varies from the estimate, or the Company receives any change orders from its third-party providers, then the Company adjusts the amount of the accrued expense or the prepaid expense accordingly.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and benefits, including stock-based compensation expense, for employees and consultants in operating and finance functions and directors, as applicable; professional fees for legal, accounting, auditing, tax and consulting services; travel expenses; and facility-related expenses, which include expenses for rent and maintenance of facilities and other operating costs. The Company expenses all general and administrative expenses as incurred.

Patent Costs

All patent-related costs incurred in connection with filing and prosecuting patent applications are expensed as incurred due to the uncertainty about the recoverability of the expenditure. Amounts incurred are classified as general and administrative expenses in the Company's consolidated statements of operations and comprehensive loss.

Stock-based Compensation

The Company measures all stock-based awards granted to employees, officers, directors, consultants, and advisors based on the fair value on the date of the grant, and recognizes the resulting fair value over the requisite service period. The Company uses the Black-Scholes option-pricing model to estimate the fair value of stock options granted. The Company has elected to recognize stock-based compensation expense for service-based stock options with graded vesting on a straight-line basis over the requisite service period, which is generally the vesting period. The Company accounts for forfeitures as they occur. The Company classifies stock-based compensation expense in its consolidated statements of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

The Company measures stock-based compensation costs for employees and non-employees at the grant date based on the estimated fair value of the award, which is reviewed periodically, and recognizes compensation expense on a straight-line basis over the vesting period which approximates the requisite service period. Compensation expense is recognized with an offsetting credit to additional paid-in capital.

Net Loss Per Share

Prior to the close of the Merger, as further described in Note 3, *Merger Agreement*, the Company calculated net loss per share using the two-class method required for participating securities. The Company's redeemable convertible preferred stock was considered participating as the holders were entitled to receive dividends in preference and priority to the holders of common stock. The two-class method determines net loss per share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income available to common stockholders for the period to be allocated between common and participating securities based upon their respective rights to receive dividends as if all income for the period has been distributed. There was no allocation required under the two-class method during periods of loss prior to the Merger since the participating securities did not have a contractual obligation to share in the losses of the Company. Upon close of the Merger in April 2025, the Company's redeemable convertible preferred stock converted into shares of the Company's common stock, and as such, there were no remaining participating securities as of December 31, 2025.

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

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

As such, although the Company had a net loss for the year ended December 31, 2025, diluted earnings per share was computed by dividing net loss attributable to common stockholders, as adjusted by removing the $7.8 million net gain on the fair value

remeasurement of its Convertible Notes and adding back the $0.7 million of interest expense, by the weighted-average number of shares of common stock outstanding, adjusted to give effect to potentially dilutive elements.

Income Taxes

The Company provides for income taxes using the asset and liability method. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and tax reporting bases of assets and liabilities and are measured using enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. Realization of deferred tax assets is dependent upon future earnings, the timing and amount of which are uncertain. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

The Company utilizes a two-step approach to recognize and measure uncertain tax positions. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained upon tax authority examination, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount that is more than 50% likely of being realized upon ultimate settlement.

Comprehensive Income (Loss)

Comprehensive income (loss) is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from nonowner sources, including unrealized gains and losses on short-term investments held as available-for-sale. For the year ended December 31, 2025, comprehensive loss includes net loss and a net unrealized gain on short-term investments. There was no difference between net loss and comprehensive loss for the year ended December 31, 2024.

Recently Adopted Accounting Pronouncements

In December 2023, the Financial Accounting Standards Board (FASB) issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* (or ASU 2023-09), which focuses on the rate reconciliation and income taxes paid. ASU 2023-09 requires a public business entity (PBE) to disclose, on an annual basis, a tabular rate reconciliation using both percentages and currency amounts, broken out into specified categories with certain reconciling items further broken out by nature and jurisdiction to the extent those items exceed a specified threshold. In addition, all entities are required to disclose income taxes paid, net of refunds received disaggregated by federal, state/local, and foreign and by jurisdiction if the amount is at least 5% of total income tax payments, net of refunds received. For PBEs, the new standard is effective for annual periods beginning after December 15, 2024, with early adoption permitted. For entities other than PBEs, the requirements will be effective for annual periods beginning after December 15, 2025. An entity may apply the amendments in this ASU prospectively by providing the revised disclosures for the period ending December 31, 2025 and continuing to provide the pre-ASU disclosures for the prior periods, or may apply the amendments retrospectively by providing the revised disclosures for all periods presented. As of December 31, 2025, the Company adopted this new ASU retrospectively and it only impacts the Company's income tax disclosures with no impact to its operations, cash flows, or financial position.

Recently Issued Accounting Pronouncements Not Yet Adopted

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 statements 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 consolidated financial statements and disclosures.

3. Merger Agreement

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

Upon the closing of the Merger:

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

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

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

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

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

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

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

The Company incurred total capitalizable transaction costs of $4.1 million, all of which was paid in cash as of December 31, 2025. Of the $4.1 million in transaction costs paid in cash as of December 31, 2025, $1.3 million was paid during fiscal 2024. The total amount of $4.1 million was recorded as a reduction to additional paid-in capital in the consolidated statements of redeemable convertible preferred stock and stockholders' equity (deficit) for the year ended December 31, 2025.

4. Fair Value Measurements

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

	Fair Value Measurements as of 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

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

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

The unrealized gain on the Company's short-term investments for the year ended December 31, 2025 was not material.

Convertible Notes

In December 2024, Legacy Tvardi entered into a note purchase agreement to issue and sell convertible notes (the Convertible Notes) in an aggregate principal amount of $28.3 million. The Convertible Notes accrued interest at 8% per annum and had a maturity date of December 31, 2026 (the Maturity Date). As further discussed in Note 3, *Merger Agreement*, the Company completed its Merger with Cara in April 2025. Upon the closing of the Merger, the Convertible Notes converted into 1,265,757 shares of the Company's common stock, $0.001 par value per share, in the aggregate.

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

conversion of the Convertible Notes and the expected timing of such events. As of December 31, 2024, prior to the closing of the Merger, the events that would trigger the conversion of the Convertible Notes and their respective probabilities were as follows: (i) an automatic conversion of the Convertible Notes into equity securities upon a Qualified or non-Qualified Financing, (ii) an automatic conversion of the Convertible Notes into shares of Legacy Tvardi's common stock upon an IPO, (iii) an automatic conversion of the Convertible Notes into the combined company's common stock upon a reverse merger, and (iv) an event of default, dissolution, or liquidation, weighted with 20%, 10%, 60%, and 10%, respectively. Immediately prior to the Merger closing in April 2025, the probability of these events were weighted as 2.5%, 0%, 95%, and 2.5%, respectively.

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

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

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

Under the fair value option, any change in fair value was recorded to the Company's consolidated statements of operations and comprehensive loss as a gain or loss from a fair value measurement. At the time of conversion, the fair value of the Convertible Notes was $23.1 million, calculated as 1,265,757 shares of common stock at the closing market trading price on April 16, 2025. The $12.8 million change in fair value when comparing the $23.1 million at the time of conversion to the $35.9 million recorded value of the Convertible Notes immediately prior to the conversion date was recorded to the Company's consolidated statements of operations and comprehensive loss as a gain within other income, net during the second quarter of 2025. For the year ended December 31, 2025, the net change in fair value recorded to the Company's consolidated statements of operations and comprehensive loss within other income (expense), net was $7.8 million.

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

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

The change in the fair value of the Convertible Notes from its issuance of $28.3 million to the fair value of $30.1 million as of December 31, 2024 was $1.8 million, which was recorded within other income (expense), net on the Company's consolidated statement of operations and comprehensive loss for the year ended December 31, 2024. There was approximately $0.1 million of debt issuance costs incurred in connection with the Convertible Notes that was also recognized within other income (expense), net in the Company's consolidated statement of operations and comprehensive loss during the year ended December 31, 2024.

5. Prepaid Expenses and Other Current Assets

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

	As of December 31,	
	2025	2024
Prepaid research and development expenses	$ 303	$ 18
Prepaid insurance	194	—
Other prepaid expenses	230	54
Total prepaid expenses and other current assets	$ 727	$ 72

6. Intangible Assets

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

	As of December 31,	
	2025	2024
Licensed patent rights	$ 826	$ 826
Less: accumulated amortization	(504)	(441)
Total intangible assets, net	$ 322	$ 385

As of December 31, 2025, the expected remaining amortization expense is as follows (in thousands):

Year Ended December 31,	Amount
2026	$ 63
2027	63
2028	63
2029	63
2030	63
Thereafter	7
Total	$ 322

The Company recognized less than $0.1 million for amortization expense for each of the years ended December 31, 2025 and 2024. Amortization expense is included in research and development expense in the consolidated statements of operations and comprehensive loss.

7. Accrued Expenses

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

	As of December 31,	
	2025	2024
Accrued research and development expenses	$ 5,744	$ 5,172
Accrued employee compensation and benefits	1,297	1,142
Accrued professional fees	345	1,756
Other accrued expenses	321	8
Total accrued expenses	$ 7,707	$ 8,078

8. Leases

The Company has one operating lease pertaining to 5,969 square feet of corporate office space in Sugar Land, Texas pursuant to a lease agreement that commenced April 1, 2022. As of December 31, 2025, the remaining term of lease was 1.58 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 consolidated statements of operations and comprehensive loss were as follows (in thousands):

	For the Year Ended December 31,	
	2025	2024
Lease costs:		
Operating lease cost	$ 96	$ 96
Variable lease cost	83	80
Total lease costs	$ 179	$ 176

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

	For the Year Ended December 31,	
	2025	2024
Operating cash flows from operating leases	$ 200	$ 197

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

	For the Year Ended December 31,	
	2025	2024
Weighted-average discount rate	9.50 %	9.50 %
Weighted-average remaining lease term	1.58	2.58

As of December 31, 2025, the maturities of the Company's operating lease liabilities were as follows (in thousands):

Year Ended December 31,	Amount
2026	$ 129
2027	88
Total lease payments	217
Less: imputed interest	(16)
Present value of lease liabilities	201
Less: operating lease liabilities, current portion	$ 116
Operating lease liabilities, net of current portion	$ 85

9. Stockholders' Equity (Deficit)

Preferred Stock

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

Common Stock

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

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

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

As of December 31, 2025 and as a result of the Merger, the Company's amended and restated certificate of incorporation authorized the issuance of 150,000,000 shares of $0.001 par value common stock, of which 9,381,344 shares were issued and outstanding.

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are entitled to receive dividends, as may be declared by the Board of Directors, if any. As of December 31, 2025, no dividends were declared.

10. Stock-based Compensation and Other Employee Matters

2018 Equity Incentive Plan

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

2025 Equity Incentive Plan

The Company's 2025 Plan became effective at the closing of the Merger. As of the effective time of the Merger, there were 935,554 shares of the Company's common stock available for grant under the 2025 Plan. In addition, the number of shares initially reserved and available for issuance under the 2025 Plan may be increased at the discretion of the Company's Board of Directors (and without any further action by the Company's stockholders) on January 1 of each year for a period of five years, commencing on January 1, 2026 and ending on January 1, 2030, in an amount not to exceed 5% of the total number of shares of the Fully Diluted Common Stock (as defined in the 2025 Plan) determined on December 31 of the preceding year, if the Company's Board of Directors acts prior to January 1 of a given year to provide that the increase for such year will occur and to determine the applicable number of additional shares of the Company's common stock. In the absence of action by the Company's Board of Directors, no such increase will automatically occur. 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 of unused common stock underlying any Awards that are forfeited, canceled or reacquired by the Company prior to vesting will again be available for the grant of Awards under the 2025 Plan. Shares underlying any Awards that are forfeited, canceled, or reacquired by the Company prior to vesting, satisfied without the issuance of stock or otherwise terminated and shares that are withheld upon exercise of an option of settlement of an award to cover the exercise price or tax withholding shall be added back to the shares available for issuance under the 2025 Plan. As of December 31, 2025, the Company had 445,721 shares remaining available for grant under the 2025 Plan.

2025 Employee Stock Purchase Plan

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

2025 Severance and Change in Control Plan

On December 16, 2025, the Company's Board of Directors approved the Company's Severance and Change in Control Plan (the Severance Plan), which provides severance benefits and equity vesting acceleration to certain eligible employees, including the Company's named executive officers, upon a qualifying termination of employment (Covered Termination) occurring either in connection with, or outside of, a Change in Control (as defined in the Severance Plan) of the Company. Participation is conditioned on execution of a participation agreement and a general waiver and release of claims.

If a Covered Termination occurs during a Change in Control protection period (beginning three months prior to and ending 12 months following the closing of a Change in Control), the Severance Plan provides for full acceleration of any then-outstanding, unvested time-vesting equity awards held by the applicable participant, subject to the terms and conditions of the Severance Plan.

If a Covered Termination occurs outside the Change in Control protection period, the Severance Plan provides for partial acceleration of outstanding, unvested time-vesting equity awards for certain executive officers to the extent such awards were scheduled to vest during a specified period following termination.

In addition, in connection with a Change in Control, if the acquiror does not assume, continue, or substitute an eligible employee's outstanding unvested equity awards, and the eligible employee remains employed immediately prior to the Change in Control, the Severance Plan provides for full acceleration of such awards effective immediately prior to, and subject to the consummation of, the Change in Control (with performance-vesting awards generally accelerating at 100% of target, unless otherwise specified in the applicable award documentation). Equity awards remain subject to the terms of the applicable equity plans and award agreements.

Fair Value Inputs

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

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

	For the Year Ended December 31,	
	2025	2024
Per share fair value of common stock	$ 14.44	$ 4.62
Expected volatility	67.72 - 70.82 %	73.79 %
Expected dividends	— %	— %
Expected term (in years)	5.50 - 6.25	5.94
Risk-free rate	3.7 - 4.0 %	3.9 %

Stock Options

The Company granted 505,440 stock options during the year ended December 31, 2025. The Company granted 3,352 stock options during the year ended December 31, 2024.

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 year ended December 31, 2025 was $9.45. The weighted-average grant date fair value

per share of options granted to one employee during the year ended December 31, 2024 was $4.62. Forfeitures of stock options are recorded as incurred.

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

The following table summarizes option activity during the year ended December 31, 2025:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (In Years)	Intrinsic Value (In Thousands)
Outstanding as of January 1, 2025	729,010	$ 3.21	6.06	$ 2,914
Granted [1]	505,440	14.44		
Exercised [2]	(26,529)	20.07		
Forfeited/expired [3]	(109,162)	319.57		
Options assumed from Cara upon Merger closing	113,487	319.80		
Outstanding as of December 31, 2025	1,212,246	$ 8.68	6.83	$ 1,086
Options exercisable as of December 31, 2025	701,913	$ 4.95	5.04	$ 1,075
Vested and expected to vest as of December 31, 2025	1,212,246	$ 8.68	6.83	$ 1,086

(1) Includes one-time retention options of 105,500 granted in December 2025 for certain of the Company's employees to support retention and continued execution of key clinical and operational objectives. The retention options were granted pursuant to the Company's standard exercise and vesting terms.
(2) Includes 21,665 of exercises of assumed Cara options after the Merger closed.
(3) Includes 83,293 of assumed Cara options that expired after the Merger closed.

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying stock options and the estimated fair value of the Company's common stock for those stock options that had exercise prices lower than the estimated fair value of the Company's common stock. The aggregate intrinsic value of stock options exercised during the year ended December 31, 2025 was $0.2 million. The aggregate intrinsic value of stock options exercised during the year ended December 31, 2024 was less than $0.1 million.

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

	For the Year Ended December 31,	
	2025	2024
Research and development	$ 340	$ 169
General and administrative	1,059	150
Total stock-based compensation	$ 1,399	$ 319

As of December 31, 2025, there was $3.8 million of total unrecognized compensation cost related to unvested stock options, which is expected to be recognized over a weighted-average period of 2.91 years.

11. Income Taxes

During the years ended December 31, 2025 and 2024, the Company did not record a provision for income taxes because it has incurred net operating losses (NOLs) entirely in the United States since inception and maintains a full valuation allowance against its deferred tax assets. The Company's entire pre-tax loss for the years ended December 31, 2025 and 2024 were from U.S. operations and resulted in no tax expense or benefit.

A reconciliation of the Company's total tax using the statutory income tax rate to the Company's total tax using their effective income tax rate is as follows (in thousands):

	For the Year Ended December 31,			
	2025		2024	
	Amount	%	Amount	%
Pre-tax loss	$ (18,214)		$ (29,397)	
U.S. federal statutory tax rate	(3,824)	21.0 %	(6,173)	21.0 %
Tax credits:				
Research and development tax credits	(2,597)	14.3 %	—	— %
Orphan drug tax credit	(6,010)	33.0 %	—	— %
Change in valuation allowance	11,372	(62.5)%	5,735	(19.5)%
Nontaxable or nondeductible items:				
Debt extinguishment	(380)	2.1 %	—	— %
Change in fair value of debt	1,038	(5.7)%	—	— %
Transaction costs	344	(1.9)%	—	— %
Stock-based compensation	(82)	0.5 %	25	(0.1)%
Disallowed interest expense	137	(0.8)%	412	(1.4)%
Other	2	— %	1	— %
Total income tax	$ —	— %	$ —	— %

State and local income taxes, net of the federal income tax benefit, do not have any impact on the Company's effective tax rate since the Company is in a cumulative loss position over the past three years, and as a result, the Company offsets any deferred state tax with a valuation allowance.

The Company's significant components of deferred tax assets are as follows (in thousands):

	As of December 31,	
	2025	2024
Capitalized research and development expense	$ 35,076	$ 8,652
Net operating loss carryforwards	103,459	9,903
Tax credits	9,023	417
Other	994	180
Total deferred tax assets before valuation allowance	148,552	19,152
Valuation allowance	(148,552)	(19,152)
Total deferred tax assets after valuation allowance	—	—
Net deferred tax assets (liabilities)	$ —	$ —

As of December 31, 2025 and 2024, the Company had a federal NOL carryforward of $383.6 million and $47.2 million, respectively. Of the federal NOL carryforward, $0.4 million begin to expire in 2037 and $383.2 million have an unlimited carryforward period.

As of December 31, 2025, the Company has state NOL carryforwards of $419.2 million. Of the state NOL carryforwards, $368.3 million begin to expire in 2027 and $50.9 million have an unlimited carryforward period. The Company had no state NOL carryforwards as of December 31, 2024.

As of December 31, 2025 and 2024, the Company had $9.0 million $0.4 million, respectively, of U.S. federal research and development tax credits that begin to expire 2039.

The future realization of the tax benefits from existing temporary differences and tax attributes ultimately depends on the existence of sufficient taxable income. The Company assesses the realizability of its deferred tax assets at each balance sheet date. In assessing the realization of its deferred tax assets, the Company considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The Company considers the projected future taxable income, expected reversal of existing deferred tax liabilities, and tax planning strategies in making this assessment. After consideration of all available evidence, both

positive and negative, the Company determined that it is not more likely than not that its net deferred tax assets will be realized in the foreseeable future. As a result, the Company increased its federal and state valuation allowance by $106.5 million and $22.9 million, respectively, as of December 31, 2025.

The future realization of the Company's NOL carryforwards and other tax attributes may also be limited by the change in ownership rules under the U.S. Internal Revenue Code Section 382. Under Section 382, if a corporation undergoes an ownership change (as defined), the corporation's ability to utilize its NOL carryforwards and other tax attributes to offset income may be limited. The Company has calculated/analyzed whether an ownership change has occurred on April 15, 2025, in relation to the Merger with Cara, and has determined that an ownership change more likely than not has occurred. Next, the Company calculated a high level annual limit based on the ownership change, which as a result puts a very restrictive limit on the legacy Cara tax attributes. The Company concluded its likely that substantially none of the legacy Cara federal or state research and development credits or pre-2018 federal NOL carryforwards will be able to be utilized moving forward, and therefore, the related deferred tax assets have been written off entirely and are not included in the consolidated financial statements.

The Company files income tax returns in the U.S. federal and multiple state jurisdictions. Therefore, the Company is subject to tax examination by various U.S. taxing authorities. The Company is not currently under examination, and is not aware of any issues under review that could result in significant payments, accruals or material deviation from its tax positions. As of December 31, 2025, tax years from 2022 to present remain open to examination by the Company's relevant taxing jurisdictions. To the extent the Company has tax attribute carryforwards, the tax years in which the attribute was generated may still be adjusted upon examination by the Internal Revenue Service and state tax authorities to the extent utilized in a future period.

The calculation and assessment of the Company's income tax exposures generally involve the uncertainties in the application of complex tax laws and regulations for U.S. federal and state jurisdictions. A tax benefit from an uncertain tax position may be recognized when it is more likely than not that the position will be sustained upon examination, including resolutions of any related appeals or litigation, on the basis of the technical merits. As of December 31, 2025, the Company has not recorded any liabilities or interest and penalties related to uncertain tax positions in its consolidated financial statements. The Company recognizes accrued interest and penalties, if any, related to uncertain tax positions in tax expense in its consolidated financial statements.

The Company has not paid income taxes at the federal or state level as it has incurred losses since inception.

On July 4, 2025, the One Big Beautiful Bill Act (OBBBA) was signed into law. The OBBBA introduced multiple U.S. federal income tax changes such as favorable changes to the deductibility of domestic research and development expenses, bonus depreciation of certain property additions, and limitations on interest expense deductions. The Company has considered the impact of these provisions on its consolidated financial statements for the year ended December 31, 2025, however, the changes in tax law did not result in a change in the Company's tax provision. Because the Company maintains a full valuation allowance and has no current income tax expense or cash tax payments, the enactment of OBBBA did not have a material impact on its financial position, results of operations, or cash flows for the year ended December 31, 2025.

12. Net Loss Per Share

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

	For the Year Ended December 31,	
	2025	2024
Numerator:		
Net loss for basic net loss per share attributable to common stockholders	$ (18,214)	$ (29,397)
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	$ (25,373)	$ (29,397)
Denominator:		
Weighted-average common shares outstanding, basic	7,419,060	2,574,233
Effect of potentially dilutive securities:		
Convertible Notes	364,122	—
Weighted-average common shares outstanding, diluted	7,783,182	2,574,233
Net loss per share attributable to common stockholders:		
Basic	$ (2.46)	$ (11.42)
Diluted	$ (3.26)	$ (11.42)

(1) As the Company recorded its Convertible Notes at fair value, when calculating the diluted net loss per share for the year ended December 31, 2025, the respective fair value remeasurement net gain of $7.8 million recognized in the consolidated statement of operations and comprehensive loss during the year ended December 31, 2025 should be reversed and treated as an adjustment to the numerator. In addition, the $0.7 million of interest expense from the Convertible Notes recognized in the consolidated statement of operations and comprehensive loss during the year ended December 31, 2025 should be added back as an adjustment to the numerator.

The Company's potentially dilutive securities include its stock options to purchase common stock, Preferred Stock, and Convertible Notes. For the year ended December 31, 2025, the Company's Convertible Notes have been included in the computation of diluted net loss per share as the effect for the period was determined to be dilutive while its stock options to purchase common stock and Preferred Stock were excluded from the diluted net loss per share computation as the effect was determined to be anti-dilutive. All of the Company's potentially dilutive securities have been excluded from the computation of diluted net loss per share for the year ended December 31, 2024, as the effect would be anti-dilutive. Therefore, the weighted-average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders for the year ended December 31, 2024 is the same.

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

	For the Year Ended December 31,	
	2025	2024
Preferred stock (as converted to common stock)	—	3,963,910
Stock options to purchase common stock	1,212,246	729,010

13. Commitment 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 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 December 31, 2025 and 2024, the Company was not a party to any material legal proceedings or claims other than those described below.

Merger Proceedings

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

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

Contracts

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

Guarantees and Indemnifications

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with all members of the Board 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 consolidated financial statements as of December 31, 2025 and 2024.

Other Commitments

In addition to the Company's obligation to make potential royalty payments under the BCM First Agreement and BCM Second Agreement (both as discussed and defined in Note 14, *License Agreements*), the Company is also obligated to pay royalties to each of its founders in an amount equal to 1% each on the worldwide net sales of TTI-101 and any derivative formulations, or any Royalty

Bearing Products. These royalty obligations last, on a country-by-country basis, for the later of (i) the date on which the sale of any Royalty Bearing Products are no longer covered by a Covered Patent (as defined below) in such country, or (ii) 15 years after the first commercial sale of royalty bearing product in such country. The timing of when these royalty payments will actually be made is uncertain as the payments are contingent upon future activities, including the successful development, regulatory approval and commercialization of any Royalty Bearing Products. A Covered Patent means, subject to certain customary exceptions, an issued patent that is owned by the Company or an affiliate, or for which all rights to develop and commercialize pharmaceutical products for the treatment of any human disorder, are exclusively licensed to the Company or an affiliate by the owner of such patent, with the Company's right or its affiliate's right to grant sublicenses.

14. License Agreements

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

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

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

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

a. Annual maintenance fees, ranging from $30,000 to $50,000 per year, per license.
b. Milestone payments, up to a low seven-digit figure in the aggregate.
c. Royalty fees, set at 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 December 31, 2025 and 2024, the full amount of $50,000 in annual maintenance fees had already been paid in each year and thus no accrual was needed. The Company also incurred $125,000 in milestone payments during the year ended December 31, 2024 in relation to the initiation of a Phase 2 clinical trial. No royalty fees have been incurred to date. All related license costs are expensed as incurred within research and development on the consolidated statements of operations and comprehensive loss.

15. Retirement Savings Plan

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

16. Segment Reporting

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

The Company's CODM, its Chief Executive Officer and Chief Financial Officer, manages the Company's operations at a company-wide level for the purposes 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 consolidated statements of operations and comprehensive loss (in thousands):

	For the Year Ended December 31,	
	2025	2024
Direct research and development expenses by program:		
TTI-101:		
HCC	$ 3,183	$ 8,583
IPF	4,683	6,703
mBC	(262)	2,182
Preclinical, CMC, and other (unallocated) [1]	688	969
TTI-109	5,371	1,193
Unallocated research and development expense:		
Personnel costs	3,329	2,988
Consultant fees and other costs [2]	1,019	1,032
General and administrative expense:		
Personnel costs	3,505	2,085
Other general and administrative expenses [3]	5,232	2,372
Interest income	(1,375)	(747)
Other (income) expense, net	(7,159)	2,037
Net loss	$ (18,214)	$ (29,397)

(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 includes 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 consolidated balance sheets. The Company does not have intra-entity sales or transfers.

17. Related-party Transactions

During the years ended December 31, 2025 and 2024, the Company did not have any transactions with related parties. The Company evaluates transactions with counterparties who may be considered related parties, including owners, members of management or affiliates and then discloses the nature and amounts of those transactions in the notes to its consolidated financial statements.

Item 9. ***Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.***

None.

Item 9A. ***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 December 31, 2025. 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 December 31, 2025, 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.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our internal control over financial reporting is a process designed 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. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management utilized the criteria established in the Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) to conduct an assessment of the effectiveness of our internal control over financial reporting as of December 31, 2025. Based on the assessment, management has concluded that, as of December 31, 2025, our internal control over financial reporting was not effective as a result of the material weaknesses as described below.

Changes in Internal Control Over Financial Reporting

There was no change in our internal control over financial reporting that occurred during the quarter ended December 31, 2025 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 in 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

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 misstatement in the consolidated financial statements.

Item 9B. ***Other Information.***

There are no disclosures required by this Item 9B, including those relating to “Rule 10b5-1 trading arrangements” and “non-Rule 10b5-1 trading arrangements,” as those terms are defined in Item 408 of Regulation S-K.

Item 9C. ***Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.***

Not applicable.

PART III

Item 10. ***Directors, Executive Officers and Corporate Governance.***

Executive Officers and Directors

The information required by this item will be set forth under the captions “Executive Officers”, “Election of Directors”, “Delinquent Section 16(a) Reports” and “Board of Directors and Corporate Governance” in our Definitive Proxy Statement with respect to our 2026 Annual Meeting of Stockholders (our Proxy Statement) and is incorporated herein by reference.

Code of Business Conduct and Ethics

We have adopted the Tvardi Therapeutics, Inc. Code of Business Conduct and Ethics (the Code of Conduct) that applies to all officers, directors and employees, including our principal executive officer, principal financial officer and principal accounting officer or controller. The Code of Conduct is available on our website at https://www.tvarditherapeutics.com. Information contained on or accessible through our website is not a part of this Annual Report on Form 10-K, and the inclusion of our website address in this

Annual Report on Form 10-K is an inactive textual reference only. Our Board of Directors and audit committee of our Board of Directors are responsible for overseeing the Code of Conduct and must approve any waivers of the Code of Conduct for employees, executive officers and directors. We intend to promptly disclose on our website to the extent required by SEC rules (i) the nature of any amendment to the Code of Conduct that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions and (ii) the nature of any waiver, including an implicit waiver, from a provision of the Code of Conduct that is granted to one of these specified individuals, the name of such person who is granted the waiver and the date of the waiver.

Insider Trading Policy

The information required by this item will be set forth in the Proxy Statement under the caption "Insider Trading Policy and Policy Prohibiting Hedging or Pledging of Securities" and is incorporated herein by reference. A copy of our Amended and Restated Insider Trading Policy is filed as Exhibit 19.1 to this Annual Report.

Item 11. *Executive Compensation*.

The information required by this item will be set forth under the captions "Executive Compensation" and "Director Compensation" in our Proxy Statement and is incorporated herein by reference.

Item 12. *Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.*

The information required by this item will be set forth under the captions "Security Ownership of Certain Beneficial Owners and Management" and "Securities Authorized for Issuance under Equity Compensation Plans" in our Proxy Statement and is incorporated herein by reference.

Item 13. *Certain Relationships and Related Transactions and Director Independence.*

The information required by this item will be set forth under the captions "Transactions with Related Persons" and "Board of Directors and Corporate Governance" in our Proxy Statement and is incorporated herein by reference.

Item 14. *Principal Accountant Fees and Services.*

The information required by this item will be set forth under the caption "Independent Registered Public Accounting Firm's Fees" in our Proxy Statement and is incorporated herein by reference.

PART IV

Item 15. *Exhibits and Financial Statement Schedules.*

(a) We have filed the following documents as part of this Annual Report on Form 10-K:

(1) Consolidated Financial Statements of Tvardi Therapeutics, Inc.

The following consolidated financial statements of Tvardi Therapeutics, Inc., together with the report of Deloitte & Touche LLP, independent registered public accounting firm, required to be filed pursuant to Part II, Item 8 of this Annual Report on Form 10-K are included on the following pages:

(2) Financial Statement Schedules

All financial statement schedules are omitted because the information called for is not required or is shown either in the consolidated financial statements or in the notes thereto.

(3) List of 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
2.2^	Asset Purchase Agreement, dated December 17, 2024, by and among Cara Therapeutics, Inc., Cara Royalty Sub, LLC and Vifor Fresenius Medical Care Renal Pharma, Ltd.	8-K	001-36279	10.4	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
4.1†	Description of Securities				
10.1#	Form of Indemnification Agreement between the Company and each of its directors and executive officers.	8-K	001-36279	10.1	April 15, 2025
10.2	Registration Rights Agreement by and between the Company and the parties thereto, dated April 15, 2025.	8-K	001-36279	10.2	April 15, 2025
10.3^	Exclusive License Agreement by and between the StemMed, Ltd. (f/k/a Stem Med Limited Partnership) and Baylor College of Medicine, dated July 16, 2012, as amended April 26, 2015, subject to Notice of Assignment from Stem Med Limited Partnership to Tvardi Therapeutics, Inc. dated January 14, 2018, and as further amended August 13, 2019.	S-4	333-283900	10.32	December 18, 2024
10.4^	Exclusive License Agreement by and between the StemMed, Ltd. and Baylor College of Medicine, dated June 19, 2015, subject to Notice of Assignment from Stem Med Limited Partnership to Tvardi Therapeutics, Inc. dated February 22, 2018, and as amended on June 18, 2019 and April 6, 2023.	S-4	333-283900	10.33	December 18, 2024
10.5#	Offer Letter by and between Imran Alibhai, Ph.D. and Tvardi Therapeutics, Inc.	S-4	333-283900	10.27	December 18, 2024
10.6#	Offer Letter by and between Dan Conn and Tvardi Therapeutics, Inc.	S-4	333-283900	10.28	December 18, 2024

10.7#	Offer Letter by and between John Kauh, M.D. and Tvardi Therapeutics, Inc.	S-4	333-283900	10.29	December 18, 2024
10.8#	Tvardi Therapeutics, Inc. 2018 Stock Incentive Plan, as amended.	S-4	333-283900	10.24	December 18, 2024
10.9#	Form of Stock Option Grant Notice, Stock Option Agreement and Notice of Exercise under the Tvardi Therapeutics, Inc. 2018 Stock Incentive Plan.	S-4	333-283900	10.25	December 18, 2024
10.10#	Form of Restricted Stock Agreement under Tvardi Therapeutics, Inc. 2018 Stock Incentive Plan.	S-4	333-283900	10.26	December 18, 2024
10.11#	Tvardi Therapeutics, Inc. 2025 Equity Incentive Plan.	8-K	001-36279	10.14	April 15, 2025
10.12#	Forms of Option Grant Notices, Option Agreements and Notices of Exercise under Tvardi Therapeutics, Inc. 2025 Equity Incentive Plan.	8-K	001-36279	10.15	April 15, 2025
10.13#	Form of Restricted Stock Unit Grant Notice and Award Agreement under Tvardi Therapeutics, Inc. 2025 Equity Incentive Plan.	8-K	001-36279	10.16	April 15, 2025
10.14#	Tvardi Therapeutics, Inc. 2025 Employee Stock Purchase Plan.	8-K	001-36279	10.17	April 15, 2025
10.15^	Founder Restricted Stock Agreement, by and between Tvardi Therapeutics, Inc. and David Tweardy, dated January 25, 2018, as amended September 1, 2019.	S-4	333-283900	10.39	January 27, 2025
10.16^	Founder Restricted Stock Agreement, by and between Tvardi Therapeutics, Inc. and Ronald DePinho, dated January 25, 2018, as amended September 1, 2019.	S-4	333-283900	10.40	January 27, 2025
10.17#	Cara 2014 Equity Incentive Plan.	S-1/A	333-192230	10.3	January 17, 2014
10.18#	Form of Stock Option Agreement under Cara 2014 Equity Incentive Plan.	S-1/A	333-192230	10.3.1	January 17, 2014
10.19#	Form of Restricted Stock Unit Award under Cara 2014 Equity Incentive Plan.	S-1/A	333-192230	10.3.2	January 17, 2014
10.20#	Cara 2019 Inducement Plan.	8-K	001-36279	10.1	November 20, 2019
10.21#	Form of Stock Option Grant Notice under Cara 2019 Inducement Plan.	8-K	001-36279	10.2	November 20, 2019
10.22#	Form of Restricted Stock Unit Notice under Cara 2019 Inducement Plan.	8-K	001-36279	10.3	November 20, 2019

10.23#†	Tvardi Therapeutics, Inc. Amended and Restated Non-Employee Director Compensation Policy.				
10.24#†	Tvardi Therapeutics, Inc. Severance and Change in Control Plan.				
19.1†	Tvardi Therapeutics, Inc. Amended and Restated Insider Trading Policy				
21.1	List of Subsidiaries.	S-1	333-288965	21.1	May 30, 2025
23.1†	Consent of Deloitte & Touche LLP, Independent Registered Public Accounting Firm.				
24.1†	Power of Attorney (included on signature page).				
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.				
97.1†	Tvardi Therapeutics, Inc. Incentive Compensation Recoupment Policy				
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).

# Indicates a management contract or any compensatory plan, contract or arrangement.

^ Certain portions of this exhibit (indicated by asterisks) have been omitted because they are not material and are the type of information that the Company treats as private and confidential.

‡ 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.

† 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.

Item 16. ***Form 10-K Summary***.

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized on this 31st day of March 2026.

TVARDI THERAPEUTICS, INC.

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

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Imran Alibhai and Dan Conn, and each of them, as his or her true and lawful attorneys-in-fact and agents, with full power of substitution for him or her, and in his or her name in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the U.S. Securities and Exchange Commission, granting unto said attorneys-in-fact, proxy and agents, and each ot them, full power and authority to do and perform each and every act and thing requisite and necessary to be done therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, and either of them, his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Imran Alibhai Imran Alibhai	Chief Executive Officer and Director (*Principal Executive Officer)*	March 31, 2026
/s/ Dan Conn Dan Conn	Chief Financial Officer *(Principal Financial Officer)*	March 31, 2026
/s/ Stephen O'Brien Stephen O'Brien	Vice President, Finance and Corporate Controller *(Principal Accounting Officer)*	March 31, 2026
/s/ Sujal Shah Sujal Shah	Chairman of the Board of Directors	March 31, 2026
/s/ Wallace Hall Wallace Hall	Director	March 31, 2026
/s/ Michael S. Wyzga Michael S. Wyzga	Director	March 31, 2026
/s/ Cynthia Smith Cynthia Smith	Director	March 31, 2026
/s/ Susan Shiff Susan Shiff	Director	March 31, 2026

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

As of December 31, 2025, Tvardi Therapeutics, Inc. had one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended, or the Exchange Act: our common stock, par value $0.001 per share. References herein to the terms "we," "us" and "our" refer to Tvardi Therapeutics, Inc.

The following description of our capital stock is a summary and does not purport to be complete. It is subject to, and qualified in its entirety by reference to, the applicable provisions of our amended and restated certificate of incorporation and our amended and restated bylaws, which are filed as exhibits to our Annual Report on Form 10-K, of which this Exhibit 4.1 is a part, and are incorporated by reference herein. We encourage you to read our amended and restated certificate of incorporation, our amended and restated bylaws and the applicable provisions of the Delaware General Corporation Law, or the DGCL, for more information.

General

Under our amended and restated certificate of incorporation as amended to date, we are authorized to issue up to 150,000,000 shares of common stock, par value $0.001 per share, and up to 5,000,000 shares of preferred stock, par value $0.001 per share. The shares of common stock currently outstanding are fully paid and nonassessable. No shares of preferred stock are currently outstanding.

Additional shares of authorized common stock may be issued, as authorized by our board of directors, or the Board, from time to time, without stockholder approval, except as may be required by applicable stock exchange requirements. The rights of the holders of our common stock are subject to, and may be adversely affected by, the rights of holders of shares of any preferred stock that we may designate and issue in the future.

Our common stock is listed on the Nasdaq Capital Market under the symbol "TVRD."

No Preemptive, Redemption or Conversion Rights

The common stock is not redeemable, is not subject to sinking fund provisions, does not have any conversion rights and is not subject to call. Holders of shares of common stock have no preemptive rights.

Voting Rights

Each outstanding share of common stock entitles the holder thereof to one vote on each matter properly submitted to a vote. Holders of shares of common stock do not have cumulative voting rights in the election of directors.

Dividend Rights

Subject to preferences that may be applicable to any outstanding shares of preferred stock, the holders of our common stock are entitled to receive ratably such dividends as may be declared by the Board out of legally available funds.

Liquidation Rights

Upon our liquidation, dissolution or winding up, holders of our common stock are entitled to share ratably in all assets remaining after payment of liabilities and the liquidation preferences of any outstanding shares of preferred stock.

Board of Directors

Our Board is divided into three classes. The number of directors authorized to serve on the Board at any time will be fixed exclusively by a resolution adopted by a majority of the Board.

Antitakeover Effects of Provisions of Charter Documents and Delaware Law

Charter Documents. Our amended and restated certificate of incorporation and bylaws include a number of provisions that may have the effect of deterring hostile takeovers or delaying or preventing changes in control or management of our company. First, the Board is classified into three classes of directors. Under Delaware law, directors of a corporation with a classified board may be removed only for cause unless the corporation's certificate of incorporation provides otherwise. Our amended and restated certificate of incorporation provides that any director may be removed with cause by the affirmative vote of the holders of at least 66 2/3% of the voting power of all then-outstanding shares of our capital stock entitled to vote generally at an election of directors. Our amended and restated certificate of incorporation does not include a provision for cumulative voting for directors. Under cumulative voting, a minority stockholder holding a sufficient percentage of a class of shares may be able to ensure the election of one or more directors. In addition, our amended and restated certificate of incorporation provides that all stockholder action must be effected at a duly called meeting of stockholders and not by a consent in writing. Pursuant to our amended and restated bylaws, a special meeting of the stockholders may be called only by the Chairperson of the Board, the Chief Executive Officer, or the Board. Finally, our amended and restated bylaws establish procedures, including advance notice procedures, with regard to the nomination of candidates for election as directors and stockholder proposals. These and other provisions of our amended and restated certificate of incorporation and bylaws and Delaware law could discourage potential acquisition proposals and could delay or prevent a change in control or management of our company.

Delaware Takeover Statute. We are subject to Section 203 of the DGCL, which regulates acquisitions of some Delaware corporations. Section 203 generally prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years following the date of the transaction in which the person became an interested stockholder, subject to certain exceptions.

Choice of Forum. Our amended and restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the

State of Delaware shall be the sole and exclusive forum for (A) any derivative action or proceeding brought on our behalf (B) any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee to us or our stockholders; (C) any action asserting a claim against us arising pursuant to any provision of the DGCL, our certificate of incorporation or our bylaws; or (D) any action asserting a claim against us governed by the internal affairs doctrine.

TVARDI THERAPEUTICS, INC.
AMENDED AND RESTATED NON-EMPLOYEE DIRECTOR COMPENSATION POLICY
ADOPTED APRIL 17, 2025

Equity Compensation:

- Initial option grant upon joining the board: 12,000 shares (provided that for 2025, directors will only receive the initial grant and will not receive the annual grant at the 2025 Annual Meeting of Stockholders)
- Annual option grant on the date of each annual meeting of stockholders (for directors continuing as directors following the annual meeting): 6,000 shares

The initial option grant will vest over three years in 12 equal quarterly installments, from the date of appointment, subject to the director's continued service as a director through each such vesting date.

Each annual option grant will vest on the earlier of (1) the one year anniversary of the date of grant and (2) immediately prior to the next annual meeting of stockholders following the date of grant, in each case, subject to the director's continued service as a director through such date.

Cash Compensation:

- Annual board retainer fee - $40,000
- Chairperson or Lead Independent Director (if any) fee - $30,000
- Audit Committee
  - Chairperson fee (including member fee) - $15,000
  - Member fee - $7,500
- Compensation Committee
  - Chairperson fee (including member fee) - $12,000
  - Member fee - $6,000
- Nominating and Corporate Governance Committee
  - Chairperson fee (including member fee) - $10,000
  - Member fee - $5,000

These retainers are payable in arrears in four equal quarterly installments on the last day of each quarter, provided that the amount of such payment will be prorated for any portion of such quarter that the director is not serving on the board of directors or applicable committee.

Reimbursement of Expenses:

The Company will reimburse non-employee directors for reasonable travel and out-of-pocket expenses incurred in connection with attending board of director and committee meetings.

Tvardi Therapeutics, Inc.

Severance and Change in Control Plan

Effective Date: December 16, 2025

Section 1. Introduction.

The Tvardi Therapeutics, Inc. Severance and Change in Control Plan (the "*Plan*") is hereby established by the Board effective upon the Effective Date written above. The purpose of the Plan is to provide for severance and/or Change in Control (as defined below) benefits to eligible employees of the Company under circumstances described in the Plan. This Plan document also is the Summary Plan Description for the Plan.

For purposes of the Plan, the following terms are defined as follows:

(a) "*Affiliate*" means any corporation (other than the Company) in an "unbroken chain of corporations" beginning with the Company, if each of the corporations other than the last corporation in the unbroken chain owns stock possessing 50% or more of the total combined voting power of all classes of stock in one of the other corporations in such chain.

(b) "*Base Salary*" means base pay (excluding incentive pay, premium pay, commissions, overtime, bonuses and other forms of variable compensation) as in effect prior to any reduction that would give rise to an employee's right to a resignation for good reason (if applicable).

(c) "*Board*" means the Board of Directors of the Company.

(d) "*Cause*" means, with respect to a particular employee, the term "Cause" as defined in the Equity Plan, except as otherwise provided in an individual Participation Agreement. The determination of whether a termination is for Cause shall be made by the Plan Administrator in its sole and exclusive judgment and discretion.

(e) "*Change in Control*" has the meaning ascribed to the term in the Equity Plan; provided, however, to the extent necessary to avoid adverse personal income tax consequences to the employee in connection with the Plan, such event also constitutes a change in the ownership or effective control of the Company, or in the ownership of a substantial portion of the Company's assets, as provided in Section 409A(a)(2)(A)(v) of the Code and Treasury Regulations Section 1.409A-3(i)(5) (without regard to any alternative definition thereunder).

(f) "*Change in Control Period*" means the period commencing three months prior to, and ending 12 months following, the Closing of a Change in Control, except as otherwise provided in an individual Participation Agreement.

(g) "*Closing*" means the initial closing date of the Change in Control as set forth in the definitive agreement executed in connection with the Change in Control. In the case of a series of transactions constituting a Change in Control, "Closing" means the first closing that satisfies the threshold of the definition for a Change in Control.

(h) "*Code*" means the Internal Revenue Code of 1986, as amended, including any applicable regulations and guidance thereunder.

(i) "*Committee*" means the Board or the Compensation Committee of the Board.

(j) "*Company*" means Tvardi Therapeutics, Inc. or, following a Change in Control, the surviving entity resulting from such event.

(k) "*Confidentiality Agreement*" means the Company's standard form of Invention and Non-Disclosure Agreement and Non-Competition and Non-Solicitation Agreement (if applicable), or any similar or successor document.

(l) "*Covered Termination*" means, with respect to an employee and except as otherwise provided in an individual Participation Agreement, a termination of employment that is due to a termination by the Company without Cause (and other than as a result of the employee's death or Disability) and results in such employee's Separation from Service.

(m) "*Disability*" means any physical or mental condition which renders an employee incapable of performing the work for which such employee was employed by the Company or similar work offered by the Company. The Disability of an employee shall be established if (i) the employee satisfies the requirements for benefits under the Company's long-term disability plan or (ii) if no long-term disability plan, the employee satisfies the requirements for Social Security disability benefits.

(n) "*Eligible Employee*" means an employee of the Company that meets the requirements to be eligible to receive Plan benefits as set forth in Section 2.

(o) "*Equity Plan*" means the Tvardi Therapeutics, Inc. 2025 Equity Incentive Plan, as amended from time to time, or any successor plan thereto.

(p) "*Participation Agreement*" means an agreement between an employee and the Company in substantially the form of Appendix A attached hereto, and which may include

such other terms as the Committee deems necessary or advisable in the administration of the Plan.

(q) "*Plan Administrator*" means the Committee prior to the Closing and the Representative upon and following the Closing, as applicable.

(r) "*Representative*" means one or more members of the Committee or other persons or entities designated by the Committee prior to or in connection with a Change in Control that will have authority to administer and interpret the Plan upon and following the Closing as provided in Section 9(a).

(s) "*Section 409A*" means Section 409A of the Code and the treasury regulations and other guidance thereunder and any state law of similar effect.

(t) "*Separation from Service*" means a "separation from service" within the meaning of Treasury Regulations Section 1.409A-1(h), without regard to any alternative definition thereunder.

Section 2. Eligibility for Benefits.

(a) Eligible Employee. An employee of the Company is eligible to participate in the Plan if: (i) the Plan Administrator has designated such employee as eligible to participate in the Plan by providing such employee a Participation Agreement; (ii) such employee has signed and returned such Participation Agreement to the Company within the time period required therein; and (iii) such employee meets the other Plan eligibility requirements set forth in this Section 2 and in the Participation Agreement. The determination of whether an employee is an Eligible Employee shall be made by the Plan Administrator, in its sole discretion, and such determination shall be binding and conclusive on all persons.

(b) Release Requirement. Except as otherwise provided in an individual Participation Agreement, in order to be eligible to receive benefits under the Plan, the employee also must execute a general waiver and release, in such a form as provided by the Company (the "*Release*"), within the applicable time period set forth therein, and such Release must become effective in accordance with its terms, which must occur in no event more than 60 days following the date of the applicable Covered Termination.

(c) Plan Benefits Provided In Lieu of Any Previous Benefits. Except as otherwise provided in an individual Participation Agreement, the Plan shall supersede any change in control or severance benefit plan, policy or practice previously maintained by the Company with respect to an Eligible Employee and any change in control or severance benefits in any individually negotiated employment offer letter, contract or other agreement between the

Company and an Eligible Employee. Notwithstanding the foregoing, the Eligible Employee's outstanding equity awards shall remain subject to the terms of the Equity Plan or other applicable equity plan under which such awards were granted (including the award documentation governing such awards) that may apply upon a Change in Control and/or termination of such employee's service and no provision of the Plan shall be construed as to limit the actions that may be taken, or to violate the terms, thereunder.

(d) Exceptions to Severance Benefit Entitlement. An employee who otherwise is an Eligible Employee will not receive benefits under the Plan in the following circumstances, as determined by the Plan Administrator in its sole discretion:

(1) The employee's employment is terminated by the Company for any reason (including due to the employee's death or Disability) or the employee voluntarily terminates employment with the Company in any manner, and in either case, such termination does not constitute a Covered Termination. Voluntary terminations include, but are not limited to, resignation, retirement, job abandonment or failure to return from a leave of absence on the scheduled date.

(2) The employee voluntarily terminates employment with the Company in order to accept employment with another entity that is wholly or partly owned (directly or indirectly) by the Company or an Affiliate.

(3) The employee is offered an identical or substantially equivalent or comparable position with the Company or an Affiliate. For purposes of the foregoing, a "substantially equivalent or comparable position" is one that provides the employee substantially the same level of responsibility and compensation and would not give rise to the employee's right to a resignation for good reason (if applicable).

(4) The employee is offered immediate reemployment by a successor to the Company or an Affiliate or by a purchaser of the Company's assets, as the case may be, following a Change in Control and the terms of such reemployment would not give rise to the employee's right to a resignation for good reason (if applicable). For purposes of the foregoing, "immediate reemployment" means that the employee's employment with the successor to the Company or an Affiliate or the purchaser of its assets, as the case may be, results in uninterrupted employment such that the employee does not incur a lapse in pay or benefits as a result of the change in ownership of the Company or the sale of its assets. For the avoidance of doubt, an employee who becomes immediately reemployed as described in this Section 2(d)(4) by a successor to the Company or an Affiliate or by a purchaser of the Company's assets, as the case may be, following a Change in Control shall continue to be an Eligible Employee following the date of such reemployment.

(5) The employee is rehired by the Company or an Affiliate and recommences employment prior to the date severance benefits under the Plan are scheduled to commence.

(e) Termination of Severance Benefits. In addition to any other potential reduction or termination of severance benefits set forth in the Plan, an Eligible Employee's right to receive severance benefits under the Plan shall terminate immediately if, at any time prior to or during the period for which the Eligible Employee is receiving severance benefits under the Plan, the Eligible Employee:

(1) willfully breaches any material statutory, common law, or contractual obligation to the Company or an Affiliate (including, without limitation, the contractual obligations set forth in the Confidentiality Agreement and any other confidentiality, non-disclosure and developments agreement, non-competition, non-solicitation, or similar type agreement between the Eligible Employee and the Company, as applicable);

(2) fails to enter into the terms of the Confidentiality Agreement; or

(3) without the prior written approval of the Plan Administrator, engages in a Prohibited Action (as defined below). In addition, if benefits under the Plan have already been paid to the Eligible Employee and the Eligible Employee subsequently engages in a Prohibited Action during the Prohibited Period (as defined below) (or it is determined that the Eligible Employee engaged in a Prohibited Action prior to receipt of such benefits), any benefits previously paid to the Eligible Employee shall be subject to recoupment by the Company on such terms and conditions as shall be determined by the Plan Administrator, in its sole discretion. The "*Prohibited Period*" shall commence on the date of the Eligible Employee's Covered Termination and continue for the number of months corresponding to the Severance Period set forth in such Eligible Employee's Participation Agreement. A "*Prohibited Action*" shall occur if the Eligible Employee breaches a material provision of the Confidentiality Agreement and/or any obligations of confidentiality, non-solicitation, non-disparagement, no conflicts or non-competition set forth in the Eligible Employee's employment agreement, offer letter, any other written agreement between the Eligible Employee and the Company, or under applicable law.

Other Requirements. Upon termination of an Eligible Employee's employment for any reason, as a condition to receiving benefits under the Plan, such Eligible Employee must resign from all positions and terminate any relationships as an employee, advisor, officer or director with the Company and any of its Affiliates, each effective on the date of the Covered Termination, unless otherwise requested by the Plan Administrator.

Section 3. Amount of Benefits.

(a) Benefits in Participation Agreement. Benefits under the Plan shall be provided to an Eligible Employee as set forth in the Participation Agreement.

(b) Additional Benefits. Notwithstanding the foregoing, the Committee may, in its sole discretion, provide benefits to individuals who are not Eligible Employees ("*Non-Eligible Employees*") chosen by the Plan Administrator, in its sole discretion, and the provision of any such benefits to a Non-Eligible Employee shall in no way obligate the Company to provide such benefits to any other individual, even if similarly situated. If benefits under the Plan are provided to a Non-Eligible Employee, references in the Plan to "Eligible Employee" (and similar references) shall be deemed to refer to such Non-Eligible Employee.

(c) Certain Reductions. In addition to Section 2(e) above, the Company, in its sole discretion, shall have the authority to reduce an Eligible Employee's severance benefits, in whole or in part, by any other severance benefits, pay and benefits provided during a period following written notice of a business closing or mass layoff, pay and benefits in lieu of such notice, or other similar benefits payable to the Eligible Employee by the Company or an Affiliate that become payable in connection with the Eligible Employee's termination of employment pursuant to (i) any applicable legal requirement, including, without limitation, the Worker Adjustment and Retraining Notification Act or any other similar state law, or (ii) any Company policy or practice providing for the Eligible Employee to remain on the payroll for a limited period of time after being given notice of the termination of the Eligible Employee's employment. Any such reductions that the Company determines to make pursuant to this Section 3(c) shall be made such that any severance benefit under the Plan shall be reduced solely by any similar type of benefit under such legal requirement, agreement, policy or practice (i.e., any cash severance benefits under the Plan shall be reduced solely by any cash payments or severance benefits under such legal requirement, agreement, policy or practice). The Company's decision to apply such reductions to the severance benefits of one Eligible Employee and the amount of such reductions shall in no way obligate the Company to apply the same reductions in the same amounts to the severance benefits of any other Eligible Employee. In the Company's sole discretion, such reductions may be applied on a retroactive basis, with severance benefits previously paid being re-characterized as payments pursuant to the Company's statutory obligation.

(d) Parachute Payments. If any payment or benefit an Eligible Employee will or may receive from the Company or otherwise (a "*Payment*") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "*Excise Tax*"), then any such Payment shall be equal to the Reduced Amount. The "*Reduced Amount*" shall be either (x) the largest

portion of the Payment that would result in no portion of the Payment (after reduction) being subject to the Excise Tax or (y) the largest portion, up to and including the total, of the Payment, whichever amount (i.e., the amount determined by clause (x) or by clause (y)), after taking into account all applicable federal, state and local employment taxes, income taxes, and the Excise Tax (all computed at the highest applicable marginal rate), results in the Eligible Employee's receipt, on an after-tax basis, of the greater economic benefit notwithstanding that all or some portion of the Payment may be subject to the Excise Tax. If a reduction in a Payment is required pursuant to the preceding sentence and the Reduced Amount is determined pursuant to clause (x) of the preceding sentence, the reduction shall occur in the manner (the "*Reduction Method*") that results in the greatest economic benefit for the Eligible Employee. If more than one method of reduction will result in the same economic benefit, the items so reduced will be reduced pro rata (the "*Pro Rata Reduction Method*").

Notwithstanding any provisions in this Section 3(d) to the contrary, if the Reduction Method or the Pro Rata Reduction Method would result in any portion of the Payment being subject to taxes pursuant to Section 409A that would not otherwise be subject to taxes pursuant to Section 409A, then the Reduction Method and/or the Pro Rata Reduction Method, as the case may be, shall be modified so as to avoid the imposition of taxes pursuant to Section 409A as follows: (A) as a first priority, the modification shall preserve to the greatest extent possible, the greatest economic benefit for the Eligible Employee as determined on an after-tax basis; (B) as a second priority, Payments that are contingent on future events (e.g., being terminated without Cause), shall be reduced (or eliminated) before Payments that are not contingent on future events; and (C) as a third priority, Payments that are "deferred compensation" within the meaning of Section 409A shall be reduced (or eliminated) before Payments that are not deferred compensation within the meaning of Section 409A.

The Company shall appoint a nationally recognized accounting or law firm to make the determinations required by this Section 3(d). The Company shall bear all expenses with respect to the determinations by such accounting or law firm required to be made hereunder. If the Eligible Employee receives a Payment for which the Reduced Amount was determined pursuant to clause (x) above and the Internal Revenue Service determines thereafter that some portion of the Payment is subject to the Excise Tax, the Eligible Employee agrees to promptly return to the Company a sufficient amount of the Payment (after reduction pursuant to clause (x) above) so that no portion of the remaining Payment is subject to the Excise Tax. For the avoidance of doubt, if the Reduced Amount was determined pursuant to clause (y) above, the Eligible Employee shall have no obligation to return any portion of the Payment pursuant to the preceding sentence.

Notwithstanding the foregoing, if at the time that a Payment would constitute a parachute payment within the meaning of Section 280G of the Code, the Company is a corporation no stock

in which is readily tradable on an established securities market (or otherwise) within the meaning of Code Section 280G(b)(5)(A)(ii)(I), then, provided the Eligible Employee chooses to timely and conditionally waive the right to all or any portion of the Payments that would be subject to the Excise Tax, the Company shall use its best efforts to timely seek a shareholder vote in accordance with Code Section 280G(b)(5)(B).

Section 4. Return of Company Property.

An Eligible Employee will not be entitled to any severance benefit under the Plan unless and until the Eligible Employee returns all Company Property. For this purpose, "*Company Property*" means all paper and electronic Company documents (and all copies thereof) and other Company property which the Eligible Employee had in his or her possession or control at any time, including, but not limited to, Company files, notes, drawings, records, plans, forecasts, reports, studies, analyses, proposals, agreements, financial information, research and development information, sales and marketing information, operational and personnel information, password, login and account information for any Company device or database or any Company accounts with third parties, specifications, code, software, databases, computer-recorded information, tangible property and equipment (including, but not limited to, computers, facsimile machines, mobile telephones and servers), credit cards, entry cards, identification badges and keys, and any materials of any kind which contain or embody any proprietary or confidential information of the Company (and all reproductions thereof in whole or in part). As a condition to receiving benefits under the Plan, an Eligible Employee must not make or retain copies, reproductions or summaries of any such Company documents, materials or property. However, an Eligible Employee is not required to return his or her personal copies of documents evidencing the Eligible Employee's hire, termination, compensation, benefits and stock options and any other documentation received as a shareholder of the Company.

Section 5. Time of Payment and Form of Benefits.

The Company reserves the right in the Participation Agreement to specify whether payments under the Plan will be paid in a single sum, in installments, or in any other form and to determine the timing of such payments. All such payments under the Plan will be subject to applicable withholding for federal, state, foreign, provincial and local taxes. It is intended that all of the benefits and other payments payable under the Plan satisfy, to the greatest extent possible, an exemption from the application of Section 409A, and the Plan will be construed to the greatest extent possible as consistent with those provisions, and to the extent not so exempt, the Plan (and any definitions hereunder) will be construed in a manner that complies with Section 409A, and any ambiguities herein shall be interpreted accordingly. Specifically, the severance benefits under the Plan are intended to satisfy the exemptions from application of Section 409A provided

under Treasury Regulations Sections 1.409A-1(b)(4), 1.409A-1(b)(5) and 1.409A-1(b)(9), and each installment of severance benefits, if any, is a separate "payment" for purposes of Treasury Regulations Section 1.409A-2(b)(2)(i). However, if such exemptions are not available and the Eligible Employee is, upon Separation from Service, a "specified employee" for purposes of Section 409A, then, solely to the extent necessary to avoid adverse personal tax consequences under Section 409A, the timing of the severance benefits payments shall be delayed until the earlier of: (i) six months and one day after the Eligible Employee's Separation from Service; or (ii) the Eligible Employee's death. Severance benefits shall not commence until the Eligible Employee has a Separation from Service. If severance benefits are not covered by one or more exemptions from the application of Section 409A and the Release could become effective in the calendar year following the calendar year in which the Separation from Service occurs, the Release will not be deemed effective, for purposes of payment of severance benefits, any earlier than the first day of the second calendar year. Except to the minimum extent that payments must be delayed because the Eligible Employee is a "specified employee" or until the effectiveness of the Release, all severance amounts will be paid as soon as practicable in accordance with the Plan and the Company's normal payroll practices.

Section 6. Transfer and Assignment.

The rights and obligations of an Eligible Employee under the Plan may not be transferred or assigned without the prior written consent of the Company. The Plan shall be binding upon any entity or person who is a successor by merger, acquisition, consolidation or otherwise to the business formerly carried on by the Company without regard to whether or not such entity or person actively assumes the obligations hereunder and without regard to whether or not a Change in Control occurs.

Section 7. Mitigation.

Except as otherwise specifically provided in the Plan, an Eligible Employee will not be required to mitigate damages or the amount of any payment provided under the Plan by seeking other employment or otherwise, nor will the amount of any payment provided for under the Plan be reduced by any compensation earned by an Eligible Employee as a result of employment by another employer or any retirement benefits received by such Eligible Employee after the date of the Eligible Employee's termination of employment with the Company.

Section 8. Clawback; Recovery.

All payments and severance benefits provided under the Plan will be subject to recoupment in accordance with any clawback policy that the Company is required to adopt pursuant to the listing standards of any national securities exchange or association on which the Company's

securities are listed or as is otherwise required by the Dodd-Frank Wall Street Reform and Consumer Protection Act or other applicable law. In addition, the Plan Administrator may impose such other clawback, recovery or recoupment provisions as the Plan Administrator determines necessary or appropriate, including but not limited to a reacquisition right in respect of previously acquired shares of the Company's common stock or other cash or property upon the occurrence of a termination of employment for Cause. No recovery of compensation under such a clawback policy will be an event giving rise to a right to resign for good reason, constructive termination or any similar term under any plan of or agreement with the Company.

Section 9. Right to Interpret and Administer Plan; Amendment and Termination.

(a) Interpretation and Administration. Prior to the Closing, the Committee shall be the Plan Administrator and shall have the exclusive discretion and authority to establish rules, forms, and procedures for the administration of the Plan and to construe and interpret the Plan and to decide any and all questions of fact, interpretation, definition, computation or administration arising in connection with the operation of the Plan, including, but not limited to, the eligibility to participate in the Plan and the amount of benefits paid under the Plan. The rules, interpretations, computations and other actions of the Committee shall be binding and conclusive on all persons. Upon and after the Closing, the Plan will be interpreted and administered in good faith by the Representative who shall be the Plan Administrator during such period. All actions taken by the Representative in interpreting the terms of the Plan and administering the Plan upon and after the Closing will be final and binding on all Eligible Employees. Any references in the Plan to the "Committee" or "Plan Administrator" with respect to periods following the Closing shall mean the Representative.

(b) Amendment. The Plan Administrator reserves the right to amend the Plan at any time; *provided, however*, that any amendment of the Plan will not be effective as to a particular employee who is or may be adversely impacted by such amendment or termination and has an effective Participation Agreement without the written consent of such employee.

(c) Termination. The Plan shall have an initial term of three years from the Effective Date and shall automatically renew for successive three-year terms thereafter unless (i) the Plan Administrator determines to terminate the Plan and (ii) written notice of such termination of the Plan is given to all participants at least three months in advance of the applicable renewal date. Notwithstanding the foregoing, in the event a Change in Control occurs during the term of the Plan, the Plan shall not terminate until the Change in Control Period has expired and any benefits payable have been paid. The Plan will automatically terminate following the satisfaction of all of the Company's obligations under the Plan.

Section 10. No Implied Employment Contract.

The Plan shall not be deemed (i) to give any employee or other person any right to be retained in the employ of the Company or (ii) to interfere with the right of the Company to discharge any employee or other person at any time, with or without cause, which right is hereby reserved. The Plan does not modify the at-will employment status of any Eligible Employee.

Section 11. Legal Construction.

The Plan is intended to be governed by and shall be construed in accordance with the Employee Retirement Income Security Act of 1974 ("*ERISA*") and, to the extent not preempted by ERISA, the laws of the State of Texas.

Section 12. Claims, Inquiries and Appeals.

(a) Applications for Benefits and Inquiries. Any application for benefits, inquiries about the Plan or inquiries about present or future rights under the Plan must be submitted to the Plan Administrator in writing by an applicant (or his or her authorized representative). The Plan Administrator is:

Tvardi Therapeutics, Inc.

Compensation Committee of the Board of Directors or Representative

Attention to: Corporate Secretary

3 Sugar Creek Ctr. Blvd.

Suite 525

Sugar Land, Texas 77478

(b) Denial of Claims. In the event that any application for benefits is denied in whole or in part, the Plan Administrator must provide the applicant with written or electronic notice of the denial of the application, and of the applicant's right to review the denial. Any electronic notice will comply with the regulations of the U.S. Department of Labor. The notice of denial will be set forth in a manner designed to be understood by the applicant and will include the following:

(1) the specific reason or reasons for the denial;

(2) references to the specific Plan provisions upon which the denial is based;

(3) a description of any additional information or material that the Plan Administrator needs to complete the review and an explanation of why such information or material is necessary; and

(4) an explanation of the Plan's review procedures and the time limits applicable to such procedures, including a statement of the applicant's right to bring a civil action under Section 502(a) of ERISA following a denial on review of the claim, as described in Section 12(d) below.

This notice of denial will be given to the applicant within 90 days after the Plan Administrator receives the application, unless special circumstances require an extension of time, in which case, the Plan Administrator has up to an additional 90 days for processing the application. If an extension of time for processing is required, written notice of the extension will be furnished to the applicant before the end of the initial 90-day period.

This notice of extension will describe the special circumstances necessitating the additional time and the date by which the Plan Administrator is to render its decision on the application.

(c) Request for a Review. Any person (or that person's authorized representative) for whom an application for benefits is denied, in whole or in part, may appeal the denial by submitting a request for a review to the Plan Administrator within 60 days after the application is denied. A request for a review shall be in writing and shall be addressed to:

Tvardi Therapeutics, Inc.

Compensation Committee of the Board of Directors or Representative

Attention to: Corporate Secretary

3 Sugar Creek Ctr. Blvd.

Suite 525

Sugar Land, Texas 77478

A request for review must set forth all of the grounds on which it is based, all facts in support of the request and any other matters that the applicant feels are pertinent. The applicant (or his or her representative) shall have the opportunity to submit (or the Plan Administrator may require the applicant to submit) written comments, documents, records, and other information relating to his or her claim. The applicant (or his or her representative) shall be provided, upon request and free of charge, reasonable access to, and copies of, all documents, records and other

information relevant to his or her claim. The review shall take into account all comments, documents, records and other information submitted by the applicant (or his or her representative) relating to the claim, without regard to whether such information was submitted or considered in the initial benefit determination.

(d) Decision on Review. The Plan Administrator will act on each request for review within 60 days after receipt of the request, unless special circumstances require an extension of time (not to exceed an additional 60 days), for processing the request for a review. If an extension for review is required, written notice of the extension will be furnished to the applicant within the initial 60-day period. This notice of extension will describe the special circumstances necessitating the additional time and the date by which the Plan Administrator is to render its decision on the review. The Plan Administrator will give prompt, written or electronic notice of its decision to the applicant. Any electronic notice will comply with the regulations of the U.S. Department of Labor. In the event that the Plan Administrator confirms the denial of the application for benefits in whole or in part, the notice will set forth, in a manner calculated to be understood by the applicant, the following:

(1) the specific reason or reasons for the denial;

(2) references to the specific Plan provisions upon which the denial is based;

(3) a statement that the applicant is entitled to receive, upon request and free of charge, reasonable access to, and copies of, all documents, records and other information relevant to his or her claim; and

(4) a statement of the applicant's right to bring a civil action under Section 502(a) of ERISA.

(e) Rules and Procedures. The Plan Administrator will establish rules and procedures, consistent with the Plan and with ERISA, as necessary and appropriate in carrying out its responsibilities in reviewing benefit claims. The Plan Administrator may require an applicant who wishes to submit additional information in connection with an appeal from the denial of benefits to do so at the applicant's own expense.

(f) Exhaustion of Remedies. No legal action for benefits under the Plan may be brought until the applicant (i) has submitted a written application for benefits in accordance with the procedures described by Section 12(a) above, (ii) has been notified by the Plan Administrator that the application is denied, (iii) has filed a written request for a review of the application in accordance with the appeal procedure described in Section 12(c) above, and (iv) has

been notified that the Plan Administrator has denied the appeal. Notwithstanding the foregoing, if the Plan Administrator does not respond to an Eligible Employee's claim or appeal within the relevant time limits specified in this Section 12, the Eligible Employee may bring legal action for benefits under the Plan pursuant to Section 502(a) of ERISA. Any legal action filed pursuant to ERISA Section 502(a) must be filed within one year of the date of the Plan Administrator's denial of the Eligible Employee's claim on appeal, and in the U.S. District Court for the Southern District of Texas.

Section 13. Basis of Payments to and from Plan.

The Plan shall be unfunded, and all cash payments under the Plan shall be paid only from the general assets of the Company.

Section 14. Other Plan Information.

(a) Employer and Plan Identification Numbers. The Employer Identification Number assigned to the Company (which is the "Plan Sponsor" as that term is used in ERISA) by the Internal Revenue Service is 75-3175693. The Plan Number assigned to the Plan by the Plan Sponsor pursuant to the instructions of the Internal Revenue Service is 510.

(b) Ending Date for Plan's Fiscal Year. The date of the end of the fiscal year for the purpose of maintaining the Plan's records is December 31.

(c) Agent for the Service of Legal Process. The agent for the service of legal process with respect to the Plan is:

Tvardi Therapeutics, Inc.

Attention to: Corporate Secretary

3 Sugar Creek Ctr. Blvd.

Suite 525

Sugar Land, Texas 77478

In addition, service of legal process may be made upon the Plan Administrator.

(d) Plan Sponsor. The "Plan Sponsor" is:

Tvardi Therapeutics, Inc.

3 Sugar Creek Ctr. Blvd.

Suite 525

Sugar Land, Texas 77478

(713) 489-8654

(e) Plan Administrator. The Plan Administrator is the Committee prior to the Closing and the Representative upon and following the Closing. The Plan Administrator's contact information is:

Tvardi Therapeutics, Inc.

Compensation Committee of the Board of Directors or Representative

3 Sugar Creek Ctr. Blvd.

Suite 525

Sugar Land, Texas 77478

The Plan Administrator is the named fiduciary charged with the responsibility for administering the Plan.

Section 15. Statement of ERISA Rights.

Participants in the Plan (which is a welfare benefit plan sponsored by Tvardi Therapeutics, Inc.) are entitled to certain rights and protections under ERISA. If you are an Eligible Employee, you are considered a participant in the Plan and, under ERISA, you are entitled to:

(a) Receive Information About Your Plan and Benefits.

(1) Examine, without charge, at the Plan Administrator's office and at other specified locations, such as worksites, all documents governing the Plan and a copy of the latest annual report (Form 5500 Series), if applicable, filed by the Plan with the U.S. Department of Labor and available at the Public Disclosure Room of the Employee Benefits Security Administration.

(2) Obtain, upon written request to the Plan Administrator, copies of documents governing the operation of the Plan and copies of the latest annual report (Form 5500

Series), if applicable, and an updated (as necessary) Summary Plan Description. The Administrator may make a reasonable charge for the copies.

(3) Receive a summary of the Plan's annual financial report, if applicable. The Plan Administrator is required by law to furnish each Eligible Employee with a copy of this summary annual report.

(b) Prudent Actions by Plan Fiduciaries. In addition to creating rights for Eligible Employees, ERISA imposes duties upon the people who are responsible for the operation of the employee benefit plan. The people who operate the Plan, called "fiduciaries" of the Plan, have a duty to do so prudently and in the interest of you and other Eligible Employees and beneficiaries. No one, including your employer, your union or any other person, may fire you or otherwise discriminate against you in any way to prevent you from obtaining a Plan benefit or exercising your rights under ERISA.

(c) Enforce Your Rights. If your claim for a Plan benefit is denied or ignored, in whole or in part, you have a right to know why this was done, to obtain copies of documents relating to the decision without charge, and to appeal any denial, all within certain time schedules.

Under ERISA, there are steps you can take to enforce the above rights. For instance, if you request a copy of Plan documents or the latest annual report from the Plan, if applicable, and do not receive them within 30 days, you may file suit in a federal court. In such a case, the court may require the Plan Administrator to provide the materials and pay you up to $110 a day until you receive the materials, unless the materials were not sent because of reasons beyond the control of the Plan Administrator.

If you have a claim for benefits which is denied or ignored, in whole or in part, you may file suit in a state or federal court.

In the event of any dispute, claim, or legal action arising out of or relating to a claim for benefits under the Plan, the prevailing party will be entitled to recover from the non-prevailing party all reasonable attorneys' fees, court costs, and other expenses incurred in connection with the dispute, claim, or legal action, including any appeal thereof, in addition to any other relief to which the prevailing party may be entitled. For these purposes, "prevailing party" means the party that substantially obtains or defeats the relief sought, whether by settlement, judgment, or otherwise.

If you are discriminated against for asserting your rights, you may seek assistance from the U.S. Department of Labor, or you may file suit in a federal court. The court will decide who should

pay court costs and legal fees. If you are successful, the court may order the person you have sued to pay these costs and fees. If you lose, the court may order you to pay these costs and fees, for example, if it finds your claim is frivolous.

Assistance with Your Questions. If you have any questions about the Plan, you should contact the Plan Administrator. If you have any questions about this statement or about your rights under ERISA, or if you need assistance in obtaining documents from the Plan Administrator, you should contact the nearest office of the Employee Benefits Security Administration, U.S. Department of Labor, listed in your telephone directory or the Division of Technical Assistance and Inquiries, Employee Benefits Security Administration, U.S. Department of Labor, 200 Constitution Avenue N.W., Washington, D.C. 20210. You may also obtain certain publications about your rights and responsibilities under ERISA by calling the publications hotline of the Employee Benefits Security Administration.

Tvardi Therapeutics, Inc.

Amended and Restated Insider Trading Policy

(As Amended April 17, 2025)

INTRODUCTION

During the course of your relationship with Tvardi Therapeutics, Inc. ("***Tvardi***"), you may receive material information that is not yet publicly available ("***material nonpublic information***") about Tvardi or other publicly traded companies. Material nonpublic information may give you, or someone you pass that information on to, a leg up over others when deciding whether to buy, sell or otherwise transact in Tvardi's securities or the securities of another publicly traded company that Tvardi has business relationships with. This policy sets forth guidelines with respect to transactions in Tvardi securities and in the securities of other applicable publicly traded companies, in each case by our employees, directors and consultants who may become aware of material non-public information ("***designated consultants***") and the other persons or entities subject to this policy as described below.

STATEMENT OF POLICY

It is the policy of Tvardi that an employee, director or designated consultant of Tvardi (or any other person or entity subject to this policy) who is aware of material nonpublic information relating to Tvardi **may not**, directly or indirectly:

1. engage in any transactions in Tvardi's securities, except as otherwise specified under the heading "Exceptions to this Policy" below;
2. recommend the purchase or sale of any of Tvardi's securities;
3. disclose material nonpublic information to persons within Tvardi whose jobs do not require them to have that information, or outside of Tvardi to other persons, such as family, friends, business associates and investors, unless the disclosure is made in accordance with Tvardi's policies regarding the protection or authorized external disclosure of information regarding Tvardi; or
4. assist anyone engaged in the above activities.

The prohibition against insider trading is absolute. It applies ***even if*** the decision to trade is not based on such material nonpublic information. It also applies to transactions that may be necessary or justifiable for independent reasons (such as the need to raise money for an emergency expenditure) and also to very small transactions. All that matters is whether you are aware of any material nonpublic information relating to Tvardi at the time of the transaction.

The U.S. federal securities laws do not recognize any mitigating circumstances to insider trading. In addition, even the appearance of an improper transaction must be avoided to preserve Tvardi's reputation for adhering to the highest standards of conduct. In some circumstances, you may need to forgo a planned transaction even if you planned it before becoming aware of the material nonpublic information. So, even if you believe you may suffer an economic loss or sacrifice an anticipated profit by waiting to trade, you must wait.

It is also important to note that the laws prohibiting insider trading are not limited to trading by the insider alone; advising others to trade on the basis of material nonpublic information is illegal and squarely prohibited by this policy. Liability in such cases can extend both to the "tippee"—the person to whom the insider disclosed material nonpublic information—and to the "tipper," the insider himself or herself. In such cases, you can be held liable for your own transactions, as well as the transactions by a tippee and even the transactions of a tippee's tippee. For these and other reasons, it is the policy of Tvardi that no employee, director or designated consultant of Tvardi (or any other person or entity subject to this policy) may either (a) recommend to another person or entity that they buy, hold or sell Tvardi's securities **at any time** or (b) disclose material nonpublic information to persons within Tvardi whose jobs do not require them to have that information, or outside of Tvardi to other persons (unless the disclosure is made in accordance with Tvardi's policies regarding the protection or authorized external disclosure of information regarding Tvardi).

In addition, it is the policy of Tvardi that no person subject to this policy who, in the course of his or her relationship with Tvardi, learns of any confidential information that is material to another publicly traded company with which Tvardi does business, including but not limited to a partner, collaborator, or supplier of Tvardi, may trade in that other company's securities until the information becomes public or is no longer material to that other company.

There are no exceptions to this policy, except as specifically noted above or below.

TRANSACTIONS SUBJECT TO THIS POLICY

This policy applies to all transactions in securities issued by Tvardi, as well as derivative securities that are not issued by Tvardi, such as exchange-traded put or call options or swaps relating to Tvardi's securities. Accordingly, for purposes of this policy, the terms "***trade***," "***trading***" and "***transactions***" include not only purchases and sales of Tvardi's common stock in the public market but also any other purchases, sales, transfers, gifts or other acquisitions and dispositions of common or preferred equity, options, warrants and other securities (including

debt securities) and other arrangements or transactions that affect economic exposure to changes in the prices of these securities.

PERSONS SUBJECT TO THIS POLICY

This policy applies to you and all other employees, directors and designated consultants of Tvardi and its subsidiaries. This policy also applies to members of your family who reside with you, any other persons with whom you share a household, any family members who do not live in your household but whose transactions in Tvardi's securities are directed by you or are subject to your influence or control and any other individuals or entities whose transactions in securities you influence, direct or control (including, e.g., a venture or other investment fund, if you influence, direct or control transactions by the fund). The foregoing persons who are deemed subject to this policy are referred to in this policy as "***Related Persons***." You are responsible for making sure that your Related Persons comply with this policy.

MATERIAL NONPUBLIC INFORMATION

Material information

It is not always easy to figure out whether you are aware of material nonpublic information. But there is one important factor to determine whether nonpublic information you know about a public company is material: whether the information could be expected to affect the market price of that company's securities or to be considered important by investors who are considering trading that company's securities. If the information makes you want to trade, it would probably have the same effect on others. Keep in mind that both positive and negative information can be material.

There is no bright-line standard for assessing materiality; rather, materiality is based on an assessment of all of the facts and circumstances, and is often evaluated by relevant enforcement authorities with the benefit of hindsight. Depending on the specific details, the following items may be considered material nonpublic information until publicly disclosed within the meaning of this policy. There may be other types of information that would qualify as material information as well; use this list merely as a non-exhaustive guide:

- clinical or pre-clinical data relating to products or product candidates;
- timelines for pre-clinical studies or clinical trials;
- regulatory developments, including product approvals or non-approvals, or halts of clinical trials;
- gain or loss of a significant licensing, partnering or collaboration agreement;

- acquisitions or dispositions of products or product candidates, assets, divisions or companies, or other strategic transactions;
- management or control changes;
- possible tender offers or proxy fights;
- financial results or forecasts;
- financial restatements;
- security incidents, including breach or unauthorized access of our property or assets, including facilities or information technology infrastructure;
- actual or threatened major litigation, Securities and Exchange Commission (the "***SEC***") or other investigations, or a major development in or the resolution of any such litigation or investigation;
- impending bankruptcy;
- significant changes or developments in suppliers;
- a disruption to or a delay in manufacturing of our products or product candidates;
- events regarding Tvardi securities (e.g., defaults on senior securities, calls of securities for redemption, repurchase plans, stock splits, public or private equity/debt offerings, declaration of stock splits or changes in our dividend policies or amounts);
- communications with government agencies; and
- notice of issuance or denial of patents, the acquisition of other material intellectual property rights or other significant intellectual property developments.

When information is considered public

The prohibition on trading when you have material nonpublic information lifts once that information becomes publicly disseminated. But for information to be considered publicly disseminated, it must be widely disseminated through a press release, a filing with the SEC, or other widely disseminated announcement. Once information is publicly disseminated, it is still necessary to afford the investing public with sufficient time to absorb the information. Generally speaking, information will be considered publicly disseminated for purposes of this policy only after two full trading days have elapsed since the information was publicly disclosed. For example, if we announce material nonpublic information before trading begins on Wednesday, then you may execute a transaction in our securities on Friday; if we announce material nonpublic information after trading ends on Wednesday, then you may execute a transaction in our securities on Monday. Depending on the particular circumstances, Tvardi may determine that a longer or shorter waiting period should apply to the release of specific material nonpublic information.

QUARTERLY TRADING BLACKOUT PERIODS

Because our workplace culture tends to be open, odds are that the vast majority of our employees, directors and designated consultants will possess material nonpublic information at

certain points during the year. To minimize even the appearance of insider trading among our employees, directors and designated consultants we have established "quarterly trading blackout periods" during which Tvardi employees, directors, designated consultants and their Related Persons—regardless of whether they are aware of material nonpublic information or not—may not conduct any trades in Tvardi securities. That means that, except as described in this policy, all Tvardi employees, directors, designated consultants and their Related Persons will be able to trade in Tvardi securities only during limited open trading window periods. Of course, even during an open trading window period, you may not (unless an exception applies) conduct any trades in Tvardi securities if you are otherwise in possession of material nonpublic information.

For purposes of this policy, each "***quarterly trading blackout period***" will generally begin at the end of the day that is the last day of each fiscal quarter and end after two full trading days have elapsed since the public dissemination of Tvardi's financial results for that quarter. Please note that the quarterly trading blackout period may commence early or may be extended if, in the judgment of the Chief Executive Officer or Chief Financial Officer, there exists undisclosed information that would make trades by Tvardi employees, directors and designated consultants inappropriate. It is important to note that the fact that the quarterly trading blackout period has commenced early or has been extended should be considered material nonpublic information that should not be communicated to any other person.

A Tvardi employee, director or designated consultant who believes that special circumstances require him or her to trade during a quarterly trading blackout period should consult the Chief Financial Officer. Permission to trade during a quarterly trading blackout period will be granted only where the circumstances are extenuating, the Chief Financial Officer concludes that the person is not in fact aware of any material nonpublic information relating to Tvardi or its securities, and there appears to be no significant risk that the trade may subsequently be questioned.

EVENT-SPECIFIC TRADING BLACKOUT PERIODS

From time to time, an event may occur that is material to Tvardi and is known by only a few directors, officers and/or employees. So long as the event remains material and nonpublic, the persons designated by the Chief Financial Officer may not trade in Tvardi's securities. In that situation, Tvardi will notify the designated individuals that neither they nor their Related Persons may trade in Tvardi's securities. The existence of a trading blackout should also be considered material nonpublic information and should not be communicated to any other person. Even if you have not been designated as a person who should not trade due to a trading blackout, you

should not trade while aware of material nonpublic information. Exceptions will not be granted during a trading blackout.

EXCEPTIONS TO THIS POLICY

This policy does not apply in the case of the following transactions, except as specifically noted:

1. ***Option Exercises***. This policy does not apply to the exercise of options granted under Tvardi's equity compensation plans for cash or, where permitted under the option, by a net exercise transaction with Tvardi. This policy does, however, apply to any sale of stock as part of a broker-assisted cashless exercise or any other market sale, whether or not for the purpose of generating the cash needed to pay the exercise price or pay taxes.

2. ***Tax Withholding Transactions***. This policy does not apply to the surrender of shares directly to Tvardi to satisfy tax withholding obligations as a result of the issuance of shares upon vesting or exercise of restricted stock units, options or other equity awards granted under Tvardi's equity compensation plans. Of course, any market sale of the stock received upon exercise or vesting of any such equity awards remains subject to all provisions of this policy whether or not for the purpose of generating the cash needed to pay the exercise price or pay taxes.

3. ***ESPP***. This policy does not apply to the purchase of stock by employees under Tvardi's Employee Stock Purchase Plan ("***ESPP***") on periodic designated dates in accordance with the ESPP. This policy does, however, apply to any sale of stock acquired pursuant to the ESPP.

4. ***10b5-1 Automatic Trading Programs***. Under Rule 10b5-1 of the Securities Exchange Act of 1934, as amended ("***Exchange Act***"), and as permitted by Tvardi, employees, directors and consultants may establish a trading plan under which a broker is instructed to buy and sell Tvardi securities based on pre-determined criteria (a "***Trading Plan***"). So long as a Trading Plan is properly established, purchases and sales of Tvardi securities pursuant to that Trading Plan are not subject to this policy. To be properly established, an employee's, director's or consultant's Trading Plan must be established in compliance with the requirements of Rule 10b5-1 of the Exchange Act and Tvardi's Rule 10b5-1 Trading Plan Guidelines at a time when Tvardi was not in a trading blackout period and they were not otherwise aware of any material nonpublic information relating to Tvardi or the securities subject to the Trading Plan. Moreover, all Trading Plans, including any amendment, modification or termination thereof, must be reviewed and pre-approved, in writing, by the Chief Financial Officer or an individual designated by the Chief Financial Officer of Tvardi.

SPECIAL AND PROHIBITED TRANSACTIONS

1. ***Inherently Speculative Transactions.*** No Tvardi employee, director or designated consultant may engage in short sales, transactions in put options, call options or other derivative securities on an exchange or in any other organized market, or in any other inherently speculative transactions with respect to Tvardi's stock.

2. ***Hedging Transactions.*** Hedging or monetization transactions can be accomplished through a number of possible mechanisms, including through the use of financial instruments such as prepaid variable forwards, equity swaps, collars and exchange funds. Tvardi employees, directors and consultants are prohibited from engaging in any such transactions.

3. ***Margin Accounts and Pledged Securities***. Securities held in a margin account as collateral for a margin loan may be sold by the broker without the customer's consent if the customer fails to meet a margin call. Similarly, securities pledged (or hypothecated) as collateral for a loan may be sold in foreclosure if the borrower defaults on the loan. Because a margin sale or foreclosure sale may occur at a time when the pledgor is aware of material nonpublic information or otherwise is not permitted to trade in Tvardi's securities, Tvardi employee, director and designated consultants are prohibited from holding Tvardi's securities in a margin account or otherwise pledging Tvardi's securities as collateral for a loan.

4. ***Standing and Limit Orders***. Standing and limit orders (except standing and limit orders under approved Trading Plans, as discussed above) create heightened risks for insider trading violations similar to the use of margin accounts. There is no control over the timing of purchases or sales that result from standing instructions to a broker, and as a result the broker could execute a transaction when a Tvardi employee, director or designated consultant is in possession of material nonpublic information. Tvardi therefore discourages placing standing or limit orders on Tvardi's securities. If a person subject to this policy determines that they must use a standing order or limit order (other than under an approved Trading Plan as discussed above), the order should be limited to short duration and the person using such standing order or limit order is required to cancel such instructions immediately in the event restrictions are imposed on their ability to trade pursuant to the "Event-Specific Blackout Periods" provisions above.

PRE-CLEARANCE AND ADVANCE NOTICE OF TRANSACTIONS

In addition to the requirements above, officers, directors and employees may not engage in any transaction in Tvardi's securities without first obtaining pre-clearance from Tvardi's Chief Financial Officer or his or her designee at least two business days in advance of the proposed transaction. The Chief Financial Officer or his or her designee will then determine whether the transaction may proceed. Pre-cleared transactions not completed within two business days will require new pre-clearance. Tvardi may choose to shorten this period.

Directors and officers must also give advance notice of their plans to exercise an outstanding stock option to the Chief Financial Officer. Once any transaction takes place, the officer, director or applicable member of management must immediately notify the Chief Financial Officer and his or her designee so that Tvardi may assist in any Section 16 reporting obligations.

SHORT-SWING TRADING, CONTROL STOCK AND SECTION 16 REPORTS

Officers and directors subject to the reporting obligations under Section 16 of the Exchange Act should take care to avoid short-swing transactions (within the meaning of Section 16(b) of the Exchange Act) and the restrictions on sales by control persons (Rule 144 under the Securities Act of 1933, as amended), and should file all appropriate Section 16(a) reports (Forms 3, 4 and 5), which are described in Tvardi's Section 16 Compliance Program, and any notices of sale required by Rule 144.

POLICY'S DURATION

This policy continues to apply to your transactions in Tvardi's securities and the securities of other applicable public companies as more specifically set forth in this policy, even after your relationship with Tvardi has ended. If you are aware of material nonpublic information when your relationship with Tvardi ends, you may not trade Tvardi's securities or the securities of other applicable publicly traded companies until the material nonpublic information has been publicly disseminated or is no longer material. Further, if you leave Tvardi during a trading blackout period, then you may not trade Tvardi's securities or the securities of other applicable companies until the trading blackout period has ended.

INDIVIDUAL RESPONSIBILITY

Persons subject to this policy have ethical and legal obligations to maintain the confidentiality of information about Tvardi and to not engage in transactions in Tvardi's securities or the securities of other applicable public companies while aware of material nonpublic information, as more specifically set forth in this policy. Each individual is responsible for making sure that he or she complies with this policy, and that any family member, household member or other person or entity whose transactions are subject to this policy, as discussed under the heading "Persons Subject to this Policy" above, also comply with this policy. In all cases, the responsibility for determining whether an individual is aware of material nonpublic information rests with that individual, and any action on the part of Tvardi or any employee or director of Tvardi pursuant to this policy (or otherwise) does not in any way constitute legal advice or insulate an individual from liability under applicable securities laws. You could be subject to

severe legal penalties and disciplinary action by Tvardi for any conduct prohibited by this policy or applicable securities laws. See "Penalties" below.

PENALTIES

Anyone who engages in insider trading or otherwise violates this policy may be subject to both civil liability and criminal penalties. Violators also risk disciplinary action by Tvardi, including termination of employment. Anyone who has questions about this policy should contact their own attorney or Tvardi's Chief Financial Officer, at legal@tvardi.com. Please also see Frequently Asked Questions, which are attached as **Exhibit A**.

AMENDMENTS

Tvardi is committed to continuously reviewing and updating its policies and procedures. Tvardi therefore reserves the right to amend, alter or terminate this policy at any time and for any reason. A current copy of the Tvardi's policies regarding insider trading may be obtained by contacting legal@tvardi.com.

EXHIBIT A

INSIDER TRADING POLICY

FREQUENTLY ASKED QUESTIONS

1. ***What is insider trading?***

A: Generally speaking, insider trading is the buying or selling of stocks, bonds, futures or other securities by someone who possesses or is otherwise aware of material nonpublic information about the securities or the issuer of the securities. Insider trading also includes trading in derivatives (such as put or call options) where the price is linked to the underlying price of a company's stock. It does not matter whether the decision to buy or sell was influenced by the material nonpublic information, how many shares you buy or sell, or whether it has an effect on the stock price. Bottom line: If, during the course of your relationship with Tvardi, you become aware of material nonpublic information about Tvardi and you trade in Tvardi's securities, you have broken the law and violated our insider trading policy. In addition, our insider trading policy provides that if in the course of your relationship with Tvardi, you learn of any confidential information that is material to another publicly traded company with whom Tvardi does business, including but not limited to a partner, collaborator or supplier of Tvardi, you may not trade in that other company's securities until the information becomes public or is no longer material to that other company.

2. ***Why is insider trading illegal?***

A: If company insiders are able to use their confidential knowledge to their financial advantage, other investors would not have confidence in the fairness and integrity of the market. This ensures that there is an even playing field by requiring those who are aware of material nonpublic information to refrain from trading.

3. ***What is material nonpublic information?***

A: Information is material if it would influence a reasonable investor to buy or sell a stock, bond future or other security. This could mean many things: financial results, clinical or regulatory results, potential acquisitions or major contracts to name just a few. Information is nonpublic if it has not yet been publicly disseminated within the meaning of our insider trading policy.

4. ***Who can be guilty of insider trading?***

A: Anyone who buys or sells a security while aware of material nonpublic information, or provides material nonpublic information that someone else uses to buy or sell a security, may be guilty of insider trading. This applies to all individuals, including officers, directors and others who don't even work at Tvardi. Regardless of who you are, if you know something material about the value of a security that not everyone knows and you trade (or convince someone else to trade) in that security, you may be found guilty of insider trading.

5. ***Does Tvardi have an insider trading policy?***

A: Yes, the insider trading policy is available to read on our website.

6. ***What if I work in a foreign office?***

A: The same rules apply to U.S. and foreign employees and consultants. The Securities and Exchange Commission (the U.S. government agency in charge of investor protection) and the Financial Industry Regulatory Authority (a private regulator that oversees U.S. securities exchanges) routinely investigate trading in a company's securities conducted by individuals and firms based abroad. In addition, as a Tvardi director, employee or consultant, our policies apply to you no matter where you work.

7. ***What if I don't buy or sell anything, but I tell someone else material nonpublic information and they buy or sell?***

A: That is called "tipping." You are the "tipper" and the other person is called the "tippee." If the tippee buys or sells based on that material nonpublic information, both you and the "tippee" could be found guilty of insider trading. In fact, if you tell family members who tell others and those people then trade on the information, those family members and the "tippee" might be found guilty of insider trading too. To prevent this, you may not discuss material nonpublic information about Tvardi with anyone outside Tvardi, including spouses, family members, friends or business associates (unless the disclosure is made in accordance with Tvardi's policies regarding the protection or authorized external disclosure of information regarding Tvardi). This includes anonymous discussions on the internet about Tvardi or companies with which Tvardi does business.

8. ***What if I don't tell them the information itself; I just tell them whether they should buy or sell?***

A: That is still tipping, and you can still be responsible for insider trading. You may never recommend to another person that they buy, hold or sell Tvardi's common stock or any derivative security related to Tvardi's common stock, since that could be a form of tipping.

9. ***What are the sanctions if I trade on material nonpublic information or tip off someone else?***

A: In addition to disciplinary action by Tvardi—which may include termination of employment—you may be liable for civil sanctions for trading on material nonpublic information. The sanctions may include return of any profit made or loss avoided as well as penalties of up to three times any profit made or any loss avoided. Persons found liable for tipping material nonpublic information, even if they did not trade themselves, may be liable for the amount of any profit gained or loss avoided by everyone in the chain of tippees as well as a penalty of up to three times that amount. In addition, anyone convicted of criminal insider trading could face prison and additional fines.

10. ***What is "loss avoided"?***

A: If you sell common stock or a related derivative security before negative news is publicly announced, and as a result of the announcement the stock price declines, you have avoided the loss caused by the negative news.

11. ***Am I restricted from trading securities of any companies other than Tvardi, for example a partner, competitor or supplier of Tvardi?***

A: Yes, you may be restricted from doing so due to your awareness of material nonpublic information. U.S. insider trading laws generally restrict everyone aware of material nonpublic information about a company from trading in that company's securities, regardless of whether the person is directly connected with that company, except in limited circumstances. You should be particularly conscious of this restriction if, through your position at Tvardi, you sometimes obtain sensitive, material information about other companies and their business dealings with Tvardi. Please also refer to Question 1 above and our insider trading policy with respect to restrictions on trading in the securities of other public companies.

12. ***So if I do not trade Tvardi securities when I have material nonpublic information, and I don't "tip" other people, I am in the clear, right?***

A: Not necessarily. Even if you do not violate U.S. law, you may still violate our policies. For example, employees and consultants may violate our policies by breaching their confidentiality obligations or by recommending Tvardi as an investment, even if these actions do not violate securities laws. Our policies are stricter than the law requires so that we and our employees and consultants can avoid even the appearance of wrongdoing. Therefore, please review the entire policy carefully.

13. ***So when can I buy or sell my Tvardi securities?***

A: If you are aware of material nonpublic information, you may not buy or sell our common stock until two full trading days have elapsed since the information was publicly disclosed. At that point, the information is considered publicly disseminated for purposes of our insider trading policy. For example, if we announce material nonpublic information before trading begins on Wednesday, then you may execute a transaction in our securities on Friday; if we announce material nonpublic information after trading ends on Wednesday, then you may execute a transaction in our securities on Monday. **Even if you are not aware of any material nonpublic information, you may not trade our common stock during any trading "blackout" period**. Event-driven trading blackout periods may be announced by email.

14. ***If I have an open order to buy or sell Tvardi securities on the date a blackout period commences, can I leave it to my broker to cancel the open order and avoid executing the trade?***

A: No, unless it is in connection with a 10b5-1 trading plan (see Question 27 below). If you have any open orders when a blackout period commences other than in connection with a 10b5-1 trading plan, it is your responsibility to cancel these orders with your broker. If you have an open order and it executes after a blackout period commences not in connection with a 10b5-1 trading plan, you will have violated our insider trading policy and may also have violated insider trading laws.

15. ***Am I allowed to trade derivative securities of Tvardi's common stock?***

A: No. Under our policies, you may not trade in derivative securities related to our common stock, which include publicly traded call and put options. In addition, under our policies, you may not engage in short selling of our common stock at any time.

"Derivative securities" are securities other than common stock that are speculative in nature because they permit a person to leverage their investment using a relatively small amount of money. Examples of derivative securities include "put options" and "call options." These are different from employee options and other equity awards granted under our equity compensation plans, which are not derivative securities for purposes of our policy.

"Short selling" is profiting when you expect the price of the stock to decline, and includes transactions in which you borrow stock from a broker, sell it, and eventually buy it back on the market to return the borrowed shares to the broker. Profit is realized if the stock price decreases during the period of borrowing.

16. ***Why does Tvardi prohibit trading in derivative securities and short selling?***

A: Many companies with volatile stock prices have adopted similar policies because of the temptation it represents to try to benefit from a relatively low-cost method of trading on short-term swings in stock prices, without actually holding the underlying common stock, and encourages speculative trading. We are dedicated to building stockholder value, short selling our common stock conflicts with our values and would not be well-received by our stockholders.

17. ***Can I purchase Tvardi securities on margin or hold them in a margin account?***

A: Under our policies, you may not purchase our common stock on margin or hold it in a margin account at any time.

"Purchasing on margin" is the use of borrowed money from a brokerage firm to purchase our securities. Holding our securities in a margin account includes holding the securities in an account in which the shares can be sold to pay a loan to the brokerage firm.

18. ***Why does Tvardi prohibit me from purchasing Tvardi securities on margin or holding them in a margin account?***

A: Margin loans are subject to a margin call whether or not you possess material nonpublic information at the time of the call. If a margin call were to be made at a time when you were aware of material nonpublic information and you could not or did not supply other collateral, you may be liable under insider trading laws because of the sale of the securities (through the margin call). The sale would be attributed to you even though the lender made the ultimate determination to sell. The U.S. Securities and Exchange Commission takes the view that you made the determination to not supply the additional collateral and you are therefore responsible for the sale.

19. ***Can I pledge my Tvardi shares as collateral for a personal loan?***

A: No. Pledging your shares as collateral for a personal loan could cause the pledgee to transfer your shares during a trading blackout period or when you are otherwise aware of material nonpublic information. As a result, you may not pledge your shares as collateral for a loan.

20. ***Can I hedge my ownership position in Tvardi?***

A: Hedging or monetization transactions, including through the use of financial instruments such as prepaid variable forwards, equity swaps, collars and exchange funds are prohibited by our insider trading policy. Since such hedging transactions allow you to continue to own Tvardi's securities obtained through employee benefit plans or otherwise, but without the full risks and rewards of ownership, you may no longer have the same objectives as Tvardi's other shareholders. Therefore, our insider trading policy prohibits you from engaging in any such transactions.

21. ***Can I gift Tvardi shares during a trading blackout period or when I possess material nonpublic information?***

A: No. Under our policies you may not gift or donate your common stock during a trading blackout period or when you are otherwise aware of material nonpublic information.

22. ***Can I exercise options granted to me under Tvardi's equity compensation plans during a trading blackout period or when I possess material nonpublic information?***

A: Yes. You may exercise the options for cash (or via net exercise transaction with Tvardi) and receive shares, but you may not sell the shares (even to pay the exercise price or any taxes due) during a trading blackout period or any time that you are aware of material nonpublic information. To be clear, you may not effect a broker-assisted cashless exercise (these cashless exercise transactions include a market sale) during a trading blackout period or any time that you are aware of material nonpublic information.

23. ***Am I subject to trading blackout periods if I am no longer an employee or consultant of Tvardi?***

A: It depends. If your employment with Tvardi ends during a trading blackout period, you will be subject to the remainder of that trading blackout period. If your employment with Tvardi ends on a day that the trading window is open, you will not be subject to the next trading blackout period. However, even if you are not subject to our trading blackout period after you leave Tvardi, you should not trade in Tvardi securities if you are aware of material nonpublic information. That restriction stays with you as long as the information you possess is material and not publicly disseminated within the meaning of our insider trading policy.

24. ***What if I purchased publicly traded options or other derivative securities before I became a Tvardi employee or consultant?***

A: The same rules apply as for employee stock options. You may exercise the publicly traded options at any time, but you may not sell the securities during a trading blackout period or at any time that you are aware of material nonpublic information.

25. ***May I own shares of a mutual fund that invests in Tvardi?***

A: Yes.

26. ***Are mutual fund shares holding Tvardi common stock subject to the trading blackout periods?***

A: No. You may trade in mutual funds holding Tvardi common stock at any time.

27. ***May I use a "routine trading program" or "10b5-1 plan"?***

A: Subject to the requirements discussed in our insider trading policy and our Rule 10b5-1 Trading Plan Guidelines, eligible persons may use a routine trading program. A routine trading program, also known as a 10b5-1 plan, allows you to set up a highly structured program with your stock broker where you specify ahead of time the date, price, and amount of securities to be traded. If you wish to create a 10b5-1 plan, please contact our team for approval at legal@tvardi.com.

28. ***What happens if I violate our insider trading policy?***

A: Violating our policies may result in disciplinary action, which may include termination of your employment or other relationship with Tvardi. In addition, you may be subject to criminal and civil sanctions.

29. ***Who should I contact if I have questions about our insider trading policy or specific trades?***

A: You should contact our Chief Financial Officer at legal@tvardi.com.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement Nos. 333-290976, 333-277706, 333-270302, 333-263159, 333-253714, 333-236728, 333-230335, 333-223726, 333-216606, 333-210096, 333-203057 and 333-193905 on Form S-8 of our report dated March 31, 2026, relating to the financial statements of Tvardi Therapeutics, Inc. appearing in this Annual Report on Form 10-K for the year ended December 31, 2025.

/s/ DELOITTE & TOUCHE LLP

Houston, Texas

March 31, 2026

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 Annual Report on Form 10-K 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: March 31, 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 Annual Report on Form 10-K 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: March 31, 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 Annual Report on Form 10-K of Tvardi Therapeutics, Inc. (the "Company") for the year ended December 31, 2025, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Imran Alibhai, Chief Executive Officer of the Company, and Dan Conn, Chief Financial Officer of the Company, each hereby certifies, pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), that, to the best of his knowledge, based upon a review of the Report:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ IMRAN ALIBHAI
Name: Imran Alibhai
Title: Chief Executive Officer
(Principal Executive Officer)
Date: March 31, 2026

/s/ DAN CONN
Name: Dan Conn
Title: Chief Financial Officer
(Principal Financial Officer)
Date: March 31, 2026

This certification accompanies the Form 10-K 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-K), irrespective of any general incorporation language contained in such filing.

TVARDI THERAPEUTICS, INC.

INCENTIVE COMPENSATION RECOUPMENT POLICY

1. INTRODUCTION

The Board of Directors (the "***Board***") of Tvardi Therapeutics, Inc., a Delaware corporation (the "***Company***"), has determined that it is in the best interests of the Company and its stockholders to adopt this Incentive Compensation Recoupment Policy (this "***Policy***") providing for the Company's recoupment of Recoverable Incentive Compensation that is received by Covered Officers of the Company under certain circumstances. Certain capitalized terms used in this Policy have the meanings given to such terms in Section 3 below.

This Policy is designed to comply with, and shall be interpreted to be consistent with, Section 10D of the Exchange Act, Rule 10D-1 promulgated thereunder ("***Rule 10D-1***") and Nasdaq Listing Rule 5608 (the "***Listing Standards***").

2. EFFECTIVE DATE

This Policy shall apply to all Incentive Compensation that is received by a Covered Officer on or after October 2, 2023 (the "***Effective Date***"). Incentive Compensation is deemed "***received***" in the Company's fiscal period in which the Financial Reporting Measure specified in the Incentive Compensation award is attained, even if the payment or grant of such Incentive Compensation occurs after the end of that period.

3. DEFINITIONS

"***Accounting Restatement***" means an accounting restatement that the Company is required to prepare due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

"***Accounting Restatement Date***" means the earlier to occur of (a) the date that the Board, a committee of the Board authorized to take such action, or the officer or officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare an Accounting Restatement, or (b) the date that a court, regulator or other legally authorized body directs the Company to prepare an Accounting Restatement.

"***Administrator***" means the Compensation Committee or, in the absence of such committee, the Board.

"***Code***" means the U.S. Internal Revenue Code of 1986, as amended, and the regulations promulgated thereunder.

"***Compensation Committee***" means the Compensation Committee of the Board.

"***Covered Officer***" means each current and former Executive Officer.

"***Exchange***" means the Nasdaq Stock Market.

"***Exchange Act***" means the U.S. Securities Exchange Act of 1934, as amended.

"***Executive Officer***" means the Company's president, principal financial officer, principal accounting officer (or if there is no such accounting officer, the controller), any vice-president of the Company in charge of a principal business unit, division, or function (such as sales, administration, or finance), any other officer who performs a policy-making function, or any other person who performs similar policy-making functions for the Company. Executive officers of the Company's parent(s) or subsidiaries are deemed executive officers of the Company if they perform

such policy-making functions for the Company. Policy-making function is not intended to include policy-making functions that are not significant. Identification of an executive officer for purposes of this Policy would include at a minimum executive officers identified pursuant to Item 401(b) of Regulation S-K promulgated under the Exchange Act.

"***Financial Reporting Measures***" means measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measures derived wholly or in part from such measures, including Company stock price and total stockholder return ("***TSR***"). A measure need not be presented in the Company's financial statements or included in a filing with the SEC in order to be a Financial Reporting Measure.

"***Incentive Compensation***" means any compensation that is granted, earned or vested based wholly or in part upon the attainment of a Financial Reporting Measure.

"***Lookback Period***" means the three completed fiscal years immediately preceding the Accounting Restatement Date, as well as any transition period (resulting from a change in the Company's fiscal year) within or immediately following those three completed fiscal years (except that a transition period of at least nine months shall count as a completed fiscal year). Notwithstanding the foregoing, the Lookback Period shall not include fiscal years completed prior to the Effective Date.

"***Recoverable Incentive Compensation***" means Incentive Compensation received by a Covered Officer during the Lookback Period that exceeds the amount of Incentive Compensation that would have been received had such amount been determined based on the Accounting Restatement, computed without regard to any taxes paid (*i.e.*, on a gross basis without regard to tax withholdings and other deductions). For any compensation plans or programs that take into account Incentive Compensation, the amount of Recoverable Incentive Compensation for purposes of this Policy shall include, without limitation, the amount contributed to any notional account based on Recoverable Incentive Compensation and any earnings to date on that notional amount. For any Incentive Compensation that is based on stock price or TSR, where the Recoverable Incentive Compensation is not subject to mathematical recalculation directly from the information in an Accounting Restatement, the Administrator will determine the amount of Recoverable Incentive Compensation based on a reasonable estimate of the effect of the Accounting Restatement on the stock price or TSR upon which the Incentive Compensation was received. The Company shall maintain documentation of the determination of that reasonable estimate and provide such documentation to the Exchange in accordance with the Listing Standards.

"***SEC***" means the U.S. Securities and Exchange Commission.

4. RECOUPMENT

(a) Applicability of Policy. This Policy applies to Incentive Compensation received by a Covered Officer (i) after beginning services as an Executive Officer, (ii) who served as an Executive Officer at any time during the performance period for such Incentive Compensation, (iii) while the Company had a class of securities listed on a national securities exchange or a national securities association, and (iv) during the Lookback Period.

(b) Recoupment Generally. Pursuant to the provisions of this Policy, if there is an Accounting Restatement, the Company must reasonably promptly recoup the full amount of the Recoverable Incentive Compensation, unless the conditions of one or more subsections of Section 4(c) of this Policy are met and the Compensation Committee, or, if such committee does not consist solely of independent directors, a majority of the independent directors serving on the Board, has made a determination that recoupment would be impracticable. Recoupment is required regardless of whether the Covered Officer engaged in any misconduct and regardless of fault, and the Company's obligation to recoup Recoverable Incentive Compensation is not dependent on whether or when any restated financial statements are filed.

(c) Impracticability of Recovery. Recoupment may be determined to be impracticable if, and only if:

(i) the direct expense paid to a third party to assist in enforcing this Policy would exceed the amount of the applicable Recoverable Incentive Compensation; provided that, before concluding that it would be impracticable to recover any amount of Recoverable Incentive Compensation based on expense of enforcement, the Company shall make a reasonable attempt to recover such Recoverable Incentive Compensation, document such reasonable attempt(s) to recover, and provide that documentation to the Exchange in accordance with the Listing Standards; or

(ii) recoupment of the applicable Recoverable Incentive Compensation would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the requirements of Code Section 401(a)(13) or Code Section 411(a) and regulations thereunder.

(d) Sources of Recoupment. To the extent permitted by applicable law, the Administrator shall, in its sole discretion, determine the timing and method for recouping Recoverable Incentive Compensation hereunder, provided that such recoupment is undertaken reasonably promptly. The Administrator may, in its discretion, seek recoupment from a Covered Officer from any of the following sources or a combination thereof, whether the applicable compensation was approved, awarded, granted, payable or paid to the Covered Officer prior to, on or after the Effective Date: (i) direct repayment of Recoverable Incentive Compensation previously paid to the Covered Officer; (ii) cancelling prior cash or equity-based awards (whether vested or unvested and whether paid or unpaid); (iii) cancelling or offsetting against any planned future cash or equity-based awards; (iv) forfeiture of deferred compensation, subject to compliance with Code Section 409A; and (v) any other method authorized by applicable law or contract. Subject to compliance with any applicable law, the Administrator may effectuate recoupment under this Policy from any amount otherwise payable to the Covered Officer, including amounts payable to such individual under any otherwise applicable Company plan or program, *e.g.*, base salary, bonuses or commissions and compensation previously deferred by the Covered Officer. The Administrator need not utilize the same method of recovery for all Covered Officers or with respect to all types of Recoverable Incentive Compensation.

(e) No Indemnification of Covered Officers. Notwithstanding any indemnification agreement, applicable insurance policy or any other agreement or provision of the Company's certificate of incorporation or bylaws to the contrary, no Covered Officer shall be entitled to indemnification or advancement of expenses in connection with any enforcement of this Policy by the Company, including paying or reimbursing such Covered Officer for insurance premiums to cover potential obligations to the Company under this Policy.

(f) Indemnification of Administrator. Any members of the Administrator, and any other members of the Board who assist in the administration of this Policy, shall not be personally liable for any action, determination or interpretation made with respect to this Policy and shall be indemnified by the Company to the fullest extent under applicable law and Company policy with respect to any such action, determination or interpretation. The foregoing sentence shall not limit any other rights to indemnification of the members of the Board under applicable law or Company policy.

(g) No "Good Reason" for Covered Officers. Any action by the Company to recoup or any recoupment of Recoverable Incentive Compensation under this Policy from a Covered Officer shall not be deemed (i) "good reason" for resignation or to serve as a basis for a claim of constructive termination under any benefits or compensation arrangement applicable to such Covered Officer, or (ii) to constitute a breach of a contract or other arrangement to which such Covered Officer is party.

5. ADMINISTRATION

Except as specifically set forth herein, this Policy shall be administered by the Administrator. The Administrator shall have full and final authority to make any and all determinations required under this Policy. Any determination by the Administrator with respect to this Policy shall be final, conclusive and binding on all interested parties and need not be uniform with respect to each individual covered by this Policy. In carrying out the administration of this Policy, the Administrator is authorized and directed to consult with the full Board or such other committees of the Board as may be necessary or appropriate as to matters within the scope of such other committee's responsibility and authority. Subject to applicable law, the Administrator may authorize and empower any officer or employee of the Company to take any and all actions that the Administrator, in its sole discretion, deems necessary or

appropriate to carry out the purpose and intent of this Policy (other than with respect to any recovery under this Policy involving such officer or employee).

6. SEVERABILITY

If any provision of this Policy or the application of any such provision to a Covered Officer shall be adjudicated to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provisions of this Policy, and the invalid, illegal or unenforceable provisions shall be deemed amended to the minimum extent necessary to render any such provision or application enforceable.

7. NO IMPAIRMENT OF OTHER REMEDIES

Nothing contained in this Policy, and no recoupment or recovery as contemplated herein, shall limit any claims, damages or other legal remedies the Company or any of its affiliates may have against a Covered Officer arising out of or resulting from any actions or omissions by the Covered Officer. This Policy does not preclude the Company from taking any other action to enforce a Covered Officer's obligations to the Company, including, without limitation, termination of employment and/or institution of civil proceedings. This Policy is in addition to the requirements of Section 304 of the Sarbanes-Oxley Act of 2002 ("**SOX 304**") that are applicable to the Company's Chief Executive Officer and Chief Financial Officer and to any other compensation recoupment policy and/or similar provisions in any employment, equity plan, equity award, or other individual agreement, to which the Company is a party or which the Company has adopted or may adopt and maintain from time to time; provided, however, that compensation recouped pursuant to this Policy shall not be duplicative of compensation recouped pursuant to SOX 304 or any such compensation recoupment policy and/or similar provisions in any such employment, equity plan, equity award, or other individual agreement except as may be required by law.

8. AMENDMENT; TERMINATION

The Administrator may amend, terminate or replace this Policy or any portion of this Policy at any time and from time to time in its sole discretion. The Administrator shall amend this Policy as it deems necessary to comply with applicable law or any Listing Standard.

9. SUCCESSORS

This Policy shall be binding and enforceable against all Covered Officers and, to the extent required by Rule 10D-1 and/or the applicable Listing Standards, their beneficiaries, heirs, executors, administrators or other legal representatives.

10. REQUIRED FILINGS

The Company shall make any disclosures and filings with respect to this Policy that are required by law, including as required by the SEC.

TVARDI THERAPEUTICS, INC.

INCENTIVE COMPENSATION RECOUPMENT POLICY

FORM OF EXECUTIVE ACKNOWLEDGMENT

I, the undersigned, agree and acknowledge that I am bound by, and subject to, the Tvardi Therapeutics, Inc. Incentive Compensation Recoupment Policy, as may be amended, restated, supplemented or otherwise modified from time to time (the "***Policy***"). In the event of any inconsistency between the Policy and the terms of any employment agreement, offer letter or other individual agreement with Tvardi Therapeutics, Inc. (the "***Company***") to which I am a party, or the terms of any compensation plan, program or agreement, whether or not written, under which any compensation has been granted, awarded, earned or paid to me, the terms of the Policy shall govern.

In the event that the Administrator (as defined in the Policy) determines that any compensation granted, awarded, earned or paid to me must be forfeited or reimbursed to the Company pursuant to the Policy, I will promptly take any action necessary to effectuate such forfeiture and/or reimbursement. I further agree and acknowledge that I am not entitled to indemnification, and hereby waive any right to advancement of expenses, in connection with any enforcement of the Policy by the Company.

Agreed and Acknowledged:

_____

Name:
Title:
Date: