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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2026

or

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

For the transition period from _____ to _____

Commission File Number: 001-40603

TSCAN THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**82-5282075**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
830 Winter Street **Waltham, Massachusetts**	**02451**
(Address of principal executive offices)	**(Zip Code)**

(857) 399-9500

(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Voting Common Stock, $0.0001 par value per share	TCRX	The Nasdaq Global Market, LLC

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

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

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

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

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

As of November 5, 2026, the registrant had 63,502,667 shares of voting common stock, $0.0001 par value per share, and 4,276,588 shares of non-voting common stock, $0.0001 par value per share, outstanding.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, or Quarterly Report, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Quarterly Report are forward-looking statements.

In some cases, you can identify forward-looking statements by words such as "may," "can," "will," "should," "would," "expect," "plan," "anticipate," "could," "intend," "target," "project," "seek," "contemplate," "believe," "estimate," "predict," "potential," "possible" or "continue" or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Forward-looking statements contained in this Quarterly Report include, but are not limited to, statements about:

- the beneficial characteristics, safety, efficacy, therapeutic effects and potential advantages of our T cell receptor (TCR)-engineered T cell, or TCR-T, therapy product candidates;
- our expectations regarding our preclinical studies being predictive of clinical trial results;
- the timing of the initiation, progress and expected results of our preclinical studies, clinical trials and our research and development programs;
- the timing of and our ability to submit applications for, and obtain and, if approved, maintain regulatory approvals for our TCR-T therapy product candidates;
- our expectations regarding clinical trial results being predictive of continued development and commercial success of our product candidates;
- our plans relating to developing and commercializing our TCR-T therapy product candidates, if approved, including sales strategy;
- estimates of the size of the addressable market for our TCR-T therapy product candidates;
- our manufacturing capabilities and the scalable nature of our manufacturing process;
- our estimates regarding expenses, future milestone payments and revenue, capital requirements and needs for additional financing;
- our expectations regarding competition;
- our anticipated growth strategies;
- our ability to attract or retain key personnel;
- our ability to establish and maintain development partnerships and collaborations;
- our expectations regarding federal, state and foreign regulatory requirements;
- regulatory developments in the U.S. and foreign countries;
- our ability to obtain and maintain intellectual property protection for our proprietary platform technology and our product candidates;
- the anticipated trends and challenges in our business and the market in which we operate;
- the sufficiency of our existing capital resources to fund our future operating expenses and capital expenditure requirements;
- the effects of rising inflation rates and the impact on operating costs, liquidity and access to credit on any of the foregoing or other aspects of our business operations;
- the effects of global economic uncertainty and financial market volatility caused by political instability, new or increased international tariffs and retaliatory tariffs, changes in U.S. policy, changes in governmental agencies, changes in international trade relationships and conflicts, such as the ongoing conflicts in the Middle East and between Russia and Ukraine, on any of the foregoing or other aspects of our business or operations including our ability to obtain additional financing; and
- our anticipated use of our existing cash resources, our ability to continue as a going concern, and our ability to obtain additional financing in the future.

Any forward-looking statements in this Quarterly Report reflect our current views with respect to future events or to our future financial performance and involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. These forward-looking statements are subject to a number of risks, uncertainties and assumptions included in this Quarterly Report, particularly those described in the "Risk Factors" section in Part II, Item 1A of this Quarterly Report, that could cause actual results or events to differ materially from the forward-looking statements that we make. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time and it is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. In light of these risks, uncertainties and assumptions, the forward- looking events and circumstances discussed in this Quarterly Report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. The forward-looking statements contained in this Quarterly Report are made as of the date of this Quarterly Report, and although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, advancements, discoveries, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. Moreover, except as required by law, neither we nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements. Except as required by law, we assume no obligation to update or revise any forward-looking statements for any reason even if new information becomes available in the future.

You should read this Quarterly Report and the documents that we have filed as an exhibit to this Quarterly Report with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

In addition, this Quarterly Report contains estimates, projections and other information concerning our industry, our business and the markets for our product candidates, including data regarding the estimated size of such markets and the incidence of certain medical conditions. We obtained industry, market and similar data set forth in this Quarterly Report from our internal estimates and research, and from academic and industry research, publications, surveys and studies conducted by third parties, including governmental agencies. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable. Our estimates of the potential market opportunities for our product candidates include key assumptions based on our industry knowledge, industry publications and third-party research, surveys and studies, which may be based on a small sample size and fail to accurately reflect market opportunities. Information based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances that are assumed in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by us and third parties, industry, medical and general publications, government data and similar sources. This Quarterly Report contains summaries of certain provisions contained in some of the documents described herein, but reference is made to the actual documents for complete information. All of the summaries are qualified in their entirety by the actual documents.

Unless stated otherwise, references in this Quarterly Report to "us," "we," "our," "our Company," or "the Company" and similar terms refer to TScan Therapeutics, Inc.

RISK FACTOR SUMMARY

Our business operations are subject to numerous risks that, if realized, could materially and adversely affect our business, financial condition, results of operations, and future growth prospects. These risks are discussed more fully in Part II, Item 1A. "Risk Factors" in this Quarterly Report on Form 10-Q. These risks include, but are not limited to, the following:

Risks Related to Our Business and Industry

- We have incurred significant losses since inception, and we expect to incur losses over the next several years and may not be able to achieve or sustain revenues or profitability in the future.
- We are currently not in compliance with Nasdaq's continued listing requirements. If we are unable to regain compliance with Nasdaq's listing requirements, our common stock could be delisted, which could affect the market price of our common stock and liquidity and reduce our ability to raise capital.
- Our business depends upon the success of our proprietary platform.
- Our limited operating history may make it difficult to evaluate the success of our business to date and to assess our future viability.
- We have never generated any revenue from sales of our TCR-T therapy product candidates, and our ability to generate revenue from product sales and become profitable depends significantly on our success in a number of areas.
- We will need to obtain substantial additional funding to complete the development and any commercialization of our product candidates, if approved. If we are unable to raise this necessary capital when needed, we could be forced to delay, reduce or eliminate our product development programs, commercialization efforts or other operations.
- We have identified conditions that raise substantial doubt about our ability to continue as a going concern.
- Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our intellectual property or product candidates on unfavorable terms to us.
- Global economic uncertainty and financial market volatility caused by political instability, changes in international trade relationships and conflicts could make it more difficult for us to access financing and could adversely affect our business and operations.
- Recent volatility in capital markets and lower market prices for many securities may affect our ability to access new capital through sales of shares of our common stock or issuance of indebtedness, which may impact our liquidity, limit our ability to grow our business, pursue acquisitions or improve our operating infrastructure and restrict our ability to compete in our markets.
- The terms of our loan agreement place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our operating and financial flexibility.
- We have recently reduced the size of our organization, and we may encounter difficulties in managing this development and our strategic prioritization, which could disrupt our operations. In addition, we may not achieve the anticipated benefits and savings from our workforce reductions.

Risks Related to the Development of Our Product Candidates

- Our approach to the discovery and development of product candidates based on our proprietary platform represents a novel approach to cancer treatment, which creates significant challenges for us.
- We are early in our development efforts. If we are unable to advance our product candidates through clinical development, obtain regulatory approval and ultimately commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.
- Although many of our personnel have extensive experience in clinical development at other companies, we have limited direct experience as a company in conducting and completing clinical trials for our product candidates.
- Our preclinical studies and clinical trials may fail to demonstrate adequately the safety, potency and purity of any of our product candidates, which would prevent or delay development, regulatory approval and commercialization.
- Our business could be adversely affected by the effects of health epidemics in regions where we, our partners or other third parties on which we rely have significant manufacturing facilities, concentrations of potential clinical trial sites or other business operations.

- We may rely on third parties to manufacture our clinical product supplies, and we may rely on third parties to produce and process our product candidates, if licensed.
- We cannot guarantee that our product candidates will show any functionality in the solid tumor microenvironment.
- Allogeneic hematopoietic cell transplantation (HCT) is a high-risk procedure that may result in complications or adverse events for patients in our clinical trials including those unrelated to the use of our product candidates.
- Our product candidates may cause undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, require expansion of the trial size, limit their commercial potential, or result in other significant negative consequences.
- If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.
- The market opportunities for our product candidates may be relatively small. In addition, our estimates of the prevalence of our target patient populations may be inaccurate.
- We face significant competition, and our operating results will suffer if we fail to compete effectively.

Risks Related to Manufacturing

- Manufacturing and administering our product candidates is complex and we may encounter difficulties in production, particularly with respect to process development or scaling up of our manufacturing capabilities. If we encounter such difficulties, our ability to provide supply of our TCR-T therapy product candidates for clinical trials or, if approved, for commercial purposes, could be delayed or stopped.
- Although many of our personnel have experience in clinical manufacturing at other companies, we have limited experience as a company managing manufacturing for our product candidates, which will be costly and time-consuming, and which may not be successful.

Risks Related to Government Regulation

- The regulatory approval process is lengthy and time-consuming, and we may experience significant delays in the clinical development and regulatory approval of our product candidates.
- We may be unable to obtain regulatory approval for our product candidates under applicable regulatory requirements. The denial or delay of any such approval would delay commercialization of our product candidates and adversely impact our potential to generate revenue, our business and our results of operations.

Risks Related to Our Intellectual Property

- If we are unable to obtain and maintain patent protection for any product candidates we develop and for our technology, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize products, product candidates and technology similar or identical to ours, and our ability to successfully commercialize any product candidates we may develop and our technology may be adversely affected.
- We are currently, and expect in the future to be, party to material license or collaboration agreements, which may impose numerous obligations and restrictions on us.

Risks Related to Our Reliance on Third Parties

- We rely on third parties to help us conduct our clinical trials. If these third parties do not properly and successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates.

General Risk Factors

- Rising inflation rates may result in increased operating costs and reduced liquidity and affect our ability to access credit.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements.

TScan Therapeutics, Inc.
Condensed Consolidated Balance Sheets
(unaudited, in thousands, except share and per share data)

	September 30, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 73,038	$ 152,406
Prepaid expenses and other current assets	3,746	4,802
Total current assets	76,784	157,208
Property and equipment, net	7,106	8,706
Right of use assets	52,405	57,743
Restricted cash	5,031	5,031
Long-term deposits and other assets	75	101
Total assets	$ 141,401	$ 228,789
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,238	$ 1,241
Accrued expenses and other current liabilities	12,876	7,668
Operating lease liability, current portion	8,003	7,167
Deferred revenue, current portion	—	2,619
Current portion of long-term debt	15,701	—
Total current liabilities	37,818	18,695
Operating lease liability, net of current portion	48,301	54,437
Long-term debt, net	17,271	32,534
Total liabilities	103,390	105,666
Commitments and Contingencies (Note 7)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized; no shares issued and outstanding at September 30, 2026 and December 31, 2025, respectively	—	—
Voting common stock, $0.0001 par value; 600,000,000 shares authorized; 63,502,667 and 52,625,035 shares issued and outstanding at September 30, 2026 and December 31, 2025, respectively	7	5
Non-voting common stock, $0.0001 par value; 10,000,000 shares authorized; 4,276,588 shares issued and outstanding at September 30, 2026 and December 31, 2025	1	1
Additional paid-in capital	634,975	627,979
Accumulated other comprehensive loss	—	—
Accumulated deficit	(596,972)	(504,862)
Total stockholders' equity	38,011	123,123
Total liabilities and stockholders' equity	$ 141,401	$ 228,789

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

TScan Therapeutics, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(unaudited, in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Collaboration and license revenue	$ 586	$ 2,511	$ 2,619	$ 7,758
Operating expenses:				
Research and development	25,291	31,689	70,597	94,111
General and administrative	8,326	7,874	24,685	25,602
Total operating expenses	33,617	39,563	95,282	119,713
Operating loss	(33,031)	(37,052)	(92,663)	(111,955)
Other (expense) income:				
Interest and other income, net	721	2,041	2,716	7,233
Interest expense	(775)	(699)	(2,163)	(2,067)
Total other (expense) income	(54)	1,342	553	5,166
Net loss	$ (33,085)	$ (35,710)	$ (92,110)	$ (106,789)
Other comprehensive income (loss):				
Unrealized gain (loss) on available-for-sale securities	—	6	—	(49)
Total other comprehensive income (loss)	—	6	—	(49)
Comprehensive loss	$ (33,085)	$ (35,704)	$ (92,110)	$ (106,838)
Weighted average shares outstanding-basic and diluted	130,025,962	129,835,938	129,963,151	129,748,897
Net loss per share				
Basic and diluted	$ (0.25)	$ (0.28)	$ (0.71)	$ (0.82)

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

TScan Therapeutics, Inc.
Condensed Consolidated Statements of Stockholders' Equity
(unaudited, in thousands, except share data)

	Common Stock		Non-voting Common Stock				
	Shares	Amount	Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2025	52,625,035	$ 5	4,276,588	$ 1	$ 627,979	$ (504,862)	$ 123,123
Issuance of common stock from exercise of pre-funded warrants	3,199,687	1	—	—	(1)	—	—
Stock-based compensation	—	—	—	—	2,465	—	2,465
Net loss	—	—	—	—	—	(28,666)	(28,666)
Balance at March 31, 2026	55,824,722	6	4,276,588	1	630,443	(533,528)	96,922
Issuance of common stock from employee stock purchase plan	113,655	—	—	—	99	—	99
Issuance of common stock from exercise of pre-funded warrants	7,564,290	1	—	—	(1)	—	—
Stock-based compensation	—	—	—	—	2,357	—	2,357
Net loss	—	—	—	—	—	(30,359)	(30,359)
Balance at June 30, 2026	63,502,667	7	4,276,588	1	632,898	(563,887)	69,019
Stock-based compensation	—	—	—	—	2,077	—	2,077
Net loss	—	—	—	—	—	(33,085)	(33,085)
Balance at September 30, 2026	63,502,667	$ 7	4,276,588	$ 1	$ 634,975	$ (596,972)	$ 38,011

	Common Stock		Non-voting Common Stock					
	Shares	Amount	Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
Balance at December 31, 2024	52,314,039	$ 5	4,276,588	$ 1	$ 616,009	$ (375,096)	$ 51	$ 240,970
Stock-based compensation	—	—	—	—	3,414	—	—	3,414
Net loss	—	—	—	—	—	(34,127)	—	(34,127)
Unrealized loss on available-for-sale securities	—	—	—	—	—	—	(55)	(55)
Balance at March 31, 2025	52,314,039	5	4,276,588	1	619,423	(409,223)	(4)	210,202
Issuance of common stock from employee stock purchase plan	157,366	—	—	—	191	—	—	191
Stock-based compensation	—	—	—	—	3,273	—	—	3,273
Net loss	—	—	—	—	—	(36,952)	—	(36,952)
Balance at June 30, 2025	52,471,405	5	4,276,588	1	622,887	(446,175)	(4)	176,714
Stock-based compensation	—	—	—	—	3,011	—	—	3,011
Net loss	—	—	—	—	—	(35,710)	—	(35,710)
Unrealized gain on available-for-sale securities	—	—	—	—	—	—	6	6
Balance at September 30, 2025	52,471,405	$ 5	4,276,588	$ 1	$ 625,898	$ (481,885)	$ 2	$ 144,021

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

TScan Therapeutics, Inc.
Condensed Consolidated Statements of Cash Flows
(unaudited, in thousands)

	Nine Months Ended September 30,	
	2026	**2025**
Cash flows from operating activities:		
Net loss	$ (92,110)	$ (106,789)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	2,070	2,143
Stock-based compensation expense	6,899	9,698
Accretion of discount on marketable securities	—	(2,354)
Non-cash interest expense and amortization of issuance costs	438	342
Loss on disposal of property and equipment	99	—
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	1,082	378
Right of use assets and lease liabilities, net	38	2,818
Accounts payable	4	2,056
Accrued expenses and other liabilities	5,208	(3,851)
Deferred revenue	(2,619)	(7,758)
Net cash used in operating activities	(78,891)	(103,317)
Cash flows from investing activities:		
Acquisition of property and equipment	(604)	(4,236)
Proceeds from sale of property and equipment	28	—
Purchases of marketable securities	—	(87,471)
Sales and maturities of marketable securities	—	186,250
Net cash (used in) provided by investing activities	(576)	94,543
Cash flows from financing activities:		
Issuance of common stock from employee stock purchase plan	99	191
Cash paid for debt issuance costs	—	(400)
Cash paid for financing costs	—	(200)
Net cash provided by (used in) financing activities	99	(409)
Net decrease in cash, cash equivalents and restricted cash	(79,368)	(9,183)
Cash, cash equivalents and restricted cash at beginning of the period	157,437	183,720
Cash, cash equivalents and restricted cash at end of the period	$ 78,069	$ 174,537
Less: Restricted cash	5,031	5,031
Cash and cash equivalents	$ 73,038	$ 169,506
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 1,725	$ 1,725
Supplemental disclosure of non-cash activities		
Property and equipment included in accounts payable and accrued expenses	$ —	$ 52

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

TSCAN THERAPEUTICS, INC.
NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of Business and Basis of Presentation

Nature of Business

TScan Therapeutics, Inc. and its wholly owned subsidiary, TScan Securities Corporation (the "Company"), is a fully integrated, clinical-stage biotechnology company that was incorporated in Delaware on April 17, 2018 and has a principal place of business in Waltham, Massachusetts. The Company is focused on developing a robust pipeline of T cell receptor ("TCR")-engineered T cell ("TCR-T") therapies for the treatment of patients with cancer. The Company is prioritizing the advancement of its TCR-T therapy candidate for solid tumors, with the goal of delivering life-changing therapies for patients with significant unmet medical needs.

On September 2, 2026, the Company announced a prioritization strategy by which the Company will prioritize the preclinical development of its *in vivo* solid tumor program and pause further enrollment in its Phase 3 ALLOHA-2™ study of TSC-101. Pursuant to such strategy, the Company also implemented a workforce reduction of approximately 75% of the Company's workforce (the "2026 Reorganization"). See Note *11, Reorganization,* to these condensed consolidated financial statements for additional information.

Nasdaq Notice

On August 27, 2026, the Company received written notice (the "Notice") from the Listing Qualifications Department of The Nasdaq Stock Market LLC ("Nasdaq") stating that the Company's voting common stock failed to comply with the $1.00 minimum bid price rule based upon the closing bid price for the 30 consecutive trading days prior to the date of the Notice.

The Company has been provided an initial compliance period of 180 calendar days, or until February 23, 2027, to regain compliance. If the Company does not regain compliance, the Company may be afforded a second 180 calendar day period to regain compliance. To qualify, the Company would be required to transfer to The Nasdaq Capital Market and meet the continued listing requirement for market value of publicly held shares and all other initial listing standards, except for the minimum bid price requirement. In addition, the Company would be required to notify Nasdaq of its intent to cure the deficiency during the second compliance period. If the Staff concludes that the Company will not be able to cure the deficiency, or if the Company does not regain compliance with the minimum bid price requirement within the additional 180 calendar days, the Staff will provide written notification to the Company that the Company's common stock will be subject to delisting. At that time, the Company may appeal the Staff's delisting determination to a Nasdaq Hearings Panel ("Panel"). However, there can be no assurance that, if the Company receives a delisting notice and appeals the delisting determination by the Staff to Panel, such appeal would be successful.

Basis of Presentation

The accompanying unaudited interim condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP") and applicable rules and regulations of the Securities and Exchange Commission (the "SEC") regarding interim financial reporting, and the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. Management believes that these interim financial statements reflect all adjustments, which include only normal recurring adjustments, necessary for the fair presentation of the Company's consolidated financial position, results of operations and cash flows. The unaudited interim condensed consolidated financial statements have been prepared on the same basis as the annual financial statements. The unaudited interim condensed consolidated financial statements include the accounts of TScan Therapeutics, Inc. and its subsidiary, TScan Securities Corporation. All intercompany balances and transactions have been eliminated in consolidation. These unaudited condensed consolidated financial statements are not indicative of any future annual or interim period and should be read in conjunction with the Company's audited consolidated financial statements for the year ended December 31, 2025 in the Company's Annual Report on Form 10-K filed with the SEC on March 4, 2026.

Risks, Uncertainties and Going Concern

The Company is subject to risks common to companies in the biotechnology industry, including, but not limited to, successful development of technology, obtaining additional funding, protection of proprietary technology, compliance with government regulations, risks of failure of preclinical studies and clinical trials, the need to obtain marketing approval for its product candidates and the ability to successfully market any products that receive approval, fluctuations in operating results, economic pressure impacting therapeutic pricing, dependence on key personnel, risks associated with changes in technologies, development by competitors of technological innovations and the ability to scale manufacturing to large scale production. Product candidates currently under development will require significant additional research and development efforts, including preclinical and clinical testing and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure and extensive compliance capabilities. Even if the Company's development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from sales.

These unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles assuming the Company will continue as a going concern. The going concern assumption contemplates the realization of assets and satisfaction of liabilities in the normal course of business.

The Company has primarily funded its operations with proceeds from sales of capital stock, payments received under its license and collaboration agreements and debt financings. Since inception, the Company has incurred recurring net losses, including net losses of $33.1 million and $35.7 million for the three months ended September 30, 2026 and 2025, respectively, and $92.1 million and $106.8 million for the nine months ended September 30, 2026 and 2025, respectively. Net cash used in operations was $78.9 million and $103.3 million for the nine months ended September 30, 2026 and 2025, respectively. As of September 30, 2026, the Company had an accumulated deficit of $597.0 million. As of September 30, 2026, the Company had cash and cash equivalents of $73.0 million, excluding restricted cash of $5.0 million.

In accordance with generally accepted accounting principles, the Company evaluated whether conditions and events, considered in the aggregate, raise substantial doubt about the Company's ability to continue as a going concern for twelve months after the date these condensed consolidated financial statements are issued. The Company has sustained recurring operating losses since inception, used substantial cash in operations, and holds current liabilities due in relation to repayment of its debt. Furthermore, the Company expects to continue to incur operating losses and negative cash flows from operations for the foreseeable future as it executes its strategic plan, including costs related to the research and development of its product candidates. Based on the Company's current operating plan, existing cash and cash equivalents are not expected to be sufficient to fund the Company's obligations for twelve months after the date these condensed consolidated financial statements are issued. These conditions raise substantial doubt about the Company's ability to continue as a going concern.

The Company is evaluating strategies to obtain the required additional funding for future operations. These strategies may include, but are not limited to, entering into collaboration agreements, offerings of the Company's equity securities, the incurrence of debt, or reductions in operating expenditures. However, as discussed within the Nasdaq Notice disclosure above, the Company faces risk of delisting, which may prevent access to capital markets. Accordingly, there can be no assurance that the Company will be successful in obtaining sufficient funding when needed, on acceptable terms, or at all. 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 unaudited condensed consolidated financial statements do not include any adjustments to the carrying amounts and classification of assets, liabilities, and reported expenses that may be necessary if the Company were unable to continue as a going concern.

Emerging Growth Company Status

The Company qualifies as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012 (JOBS Act) and has elected to "opt in" to the extended transition related to complying with new or revised accounting standards, which means that when a standard is issued or revised and it has different application dates for public and nonpublic companies, the Company will adopt the new or revised standard at the time nonpublic companies adopt the new or revised standard and will do so until such time that the Company either (i) irrevocably elects to "opt out" of such extended transition period or (ii) no longer qualifies as an emerging growth company. The Company may choose to early adopt new or revised accounting standards whenever such early adoption is permitted for nonpublic companies. The Company's status as an emerging growth company will end on December 31, 2026, which will be the last day of the fiscal year ending after the fifth anniversary of its initial public offering.

2. Summary of Significant Accounting Policies

Details on the Company's accounting policies are set forth in Note 2, *Summary of Significant Accounting Policies*, in the Company's Annual Report on Form 10-K for the year ended December 31, 2025, filed with the SEC on March 4, 2026.

Recently Adopted Accounting Pronouncements

In November 2024, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2024-04, Debt—Debt with Conversion and Other Options, which is intended to clarify requirements for determining whether certain settlements of convertible debt instruments, including convertible debt instruments with cash conversion features or convertible debt instruments that are not currently convertible, should be accounted for as an induced conversion. This ASU is effective for all entities for annual reporting periods beginning after December 15, 2025, and interim reporting periods within those annual reporting periods, with early adoption permitted. The Company adopted this guidance as of January 1, 2026, and there was no impact on the condensed consolidated financial statements.

Recently Issued Accounting Pronouncements Not Yet Effective

In November 2024, the FASB issued ASU 2024-03, Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures, which is intended to improve disclosures about a public business entity's expenses and provide more detailed information to investors about the types of expenses in commonly presented expense captions. The amendments in this ASU

are effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027, with early adoption permitted. The Company is currently evaluating the potential impact of this guidance on its disclosures.

3. Fair Value Measurements

The following tables set forth by level, within the fair value hierarchy, the assets carried at fair value (in thousands):

	As of September 30, 2026			
	Total	Level 1	Level 2	Level 3
Assets				
Cash equivalents - money market funds	$ 68,855	$ 68,855	$ —	$ —
Total assets	$ 68,855	$ 68,855	$ —	$ —

	As of December 31, 2025			
	Total	Level 1	Level 2	Level 3
Assets				
Cash equivalents - money market funds	$ 146,196	$ 146,196	$ —	$ —
Cash equivalents - government securities	1,987	1,987	—	—
Total assets	$ 148,183	$ 148,183	$ —	$ —

Money market funds and government securities are valued by the Company based on quoted market prices, which represent a Level 1 measurement within the fair value hierarchy. During the nine months ended September 30, 2026, there were no transfers into or out of Level 3.

Assets and Liabilities Not Carried at Fair Value

The carrying value of accounts payable and accrued expenses reported in the condensed consolidated balance sheets approximate fair value due to the short-term nature of these liabilities. Based on the borrowing rates currently available to the Company for bank loans with similar maturities, the fair value of long-term debt is approximately equal to its carrying amount as of September 30, 2026.

4. Accrued Expenses and Other Current Liabilities

The following table summarizes the components of accrued expenses and other current liabilities for each of the periods indicated (in thousands):

	As of September 30, 2026	As of December 31, 2025
Compensation and benefits	$ 6,992	$ 4,145
Research and development	4,424	2,458
Consulting and professional fees	765	568
Legal services and license fee	505	301
Accrued interest	190	196
Total accrued expenses and other current liabilities	$ 12,876	$ 7,668

5. Stockholders' Equity

ATM Program

On May 16, 2023, the Company entered into a sales agreement (the "Sales Agreement") with Wedbush Securities, Inc., as sales agent, pursuant to which the Company could offer, issue and sell up to an aggregate amount of $75.0 million of shares of the Company's voting common stock, par value $0.0001 per share (Voting Common Stock), from time to time in "at-the-market" ("ATM") offerings during the term of the Sales Agreement. No Voting Common Stock has been sold under this Sales Agreement to date.

Equity Offerings

On June 1, 2023, the Company completed an underwritten public offering resulting in the issuance and sale of 23,287,134 shares of Voting Common Stock, at a price of $2.00 per share, and pre-funded warrants to purchase up to 47,010,526 shares of the Voting Common Stock with an exercise price of $0.0001 per share. The pre-funded warrants were issued at a purchase price of $1.9999 per warrant. Aggregate net proceeds were $134.7 million after deducting underwriting discounts, commissions and other offering expenses, with $42.4 million allocated to the Voting Common Stock and $92.3 million allocated to pre-funded warrants.

On April 24, 2024, the Company completed an underwritten public offering resulting in the issuance and sale of 4,958,068 shares of Voting Common Stock, including the partial exercise of the underwriters' option to purchase 2,485,487 additional shares of Voting Common Stock, at the closing market price on April 16, 2024, of $7.13 per share, and pre-funded warrants to purchase up to 18,577,419 shares of the Voting Common Stock with an exercise price of $0.0001 per share. The pre-funded warrants were issued at a purchase price of $7.1299 per warrant. Aggregate net proceeds were $161.4 million after deducting underwriting discounts, commissions and other offering expenses, with $33.1 million allocated to the Voting Common Stock and $128.3 million allocated to pre-funded warrants.

On December 27, 2024, the Company completed a registered direct offering with an existing investor for the issuance of pre-funded warrants to purchase up to 7,500,000 shares of the Company's Voting Common Stock, with an exercise price of $0.0001 per warrant. The pre-funded warrants were issued at a purchase price of $4.00 per warrant. Aggregate net proceeds were $29.8 million.

The pre-funded warrants are immediately exercisable subject to certain ownership limitations, have an exercise price of $0.0001 per share, may be exercised at any time and do not expire. The pre-funded warrants were determined to be equity classified because they are freestanding financial instruments that are legally detachable and separately exercisable from the equity instruments, are immediately exercisable, do not embody an obligation for the Company to repurchase its shares, permit the holders to receive a fixed number of common shares upon exercise, are indexed to the Company's common stock and meet the equity classification criteria. In addition, the pre-funded warrants do not provide any guarantee of value or return. As such, proceeds received from the issuance from the pre-funded warrants were recorded as a component of stockholders' equity within additional paid-in capital. During the nine months ended September 30, 2026, the Company issued an aggregate of 10,763,977 shares of its Voting Common Stock pursuant to the cashless exercise of 10,765,060 pre-funded warrants, respectively, at a weighted average exercise price of $0.0001 per share. The Company did not issue any shares pursuant to the exercise of pre-funded warrants during the nine months ended September 30, 2025.

Common Stock Reserved for Future Issuance

The following table summarizes the shares reserved for future issuance:

	As of September 30, 2026	As of December 31, 2025
Stock options outstanding	18,958,156	16,004,393
Pre-funded warrants outstanding	62,246,707	73,011,767
Shares available for future grant under 2021 Plan	9,674,795	7,432,023
Shares available for future issuance under 2021 ESPP	1,771,927	1,316,566
Total shares of common stock reserved	92,651,585	97,764,749

6. Collaboration and License Agreements

Amgen

On May 8, 2023, the Company entered into a Collaboration Agreement (the "Amgen Agreement") with Amgen Inc. ("Amgen"). The proceeds from the Amgen Agreement included an initial payment of $30.0 million, which was collected in July 2023. In addition, the Company was eligible to earn success-based milestone payments of over $500.0 million. The Company determined the $30.0 million payment to be the entirety of the consideration to be included in the transaction price as of the onset of the arrangement. The potential milestone and royalty payments were also excluded from the transaction price, as they were fully constrained based on the assessed probability of achievement.

On August 12, 2026, the Company received notice from Amgen of their election to terminate the Amgen Agreement, in its entirety. The termination will be effective November 10, 2026. No early termination penalty is payable by the Company in connection with the termination.

During the three months ended September 30, 2026 and 2025, the Company recognized $0.6 million and $2.5 million, respectively, and during the nine months ended September 30, 2026 and 2025, the Company recognized $2.6 million and $7.8 million, respectively, of revenue associated with the Amgen Agreement. As of September 30, 2026, all revenue associated with the Amgen Agreement has been recognized.

7. Commitments and Contingencies

Leases

The Company leases office space under non-cancelable operating lease agreements. There have been no material changes to the Company's leases during the nine months ended September 30, 2026.

Brigham and Women's License Agreement

The Company obtained the worldwide exclusive license to its foundational technology from the Brigham and Women's Hospital, Inc. ("BWH"). The license, as amended, grants worldwide exclusive use to the patent underlying the TargetScan technology in exchange for fees including development milestones and various royalties on product sales should they occur in the future.

Royalty Agreement

In June 2018, the Company amended and restated an existing royalty agreement with one of its founders. Under the amended and restated royalty agreement, the Company agreed to pay the founder an aggregate royalty of 1% of net sales of any product sold by the Company or by any of its direct or indirect licensees for use in the treatment of any disease or disorder covered by a pending patent application or issued patent held or controlled by the Company as of the last date that the founder was providing services to the Company as a director or consultant under a written agreement in perpetuity. Royalties are payable with respect to each applicable product for a defined period of time set forth in the royalty agreement. The founder assigned his rights and obligations under the royalty agreement to one of his affiliated entities in January 2021.

8. Loan and Security Agreements

Silicon Valley Bank

On December 20, 2024 (the "Effective Date"), the Company entered into a Loan and Security Agreement (the "SVB Loan Agreement") with Silicon Valley Bank, a division of First-Citizens Bank & Trust Company ("SVB"). The SVB Loan Agreement, provides for a non-convertible term loan facility of up to $52.5 million, consisting of a first tranche of $32.5 million, which was drawn on the Effective Date, and a second tranche of $20.0 million, available prior to June 30, 2026, which was not drawn.

Under the SVB Loan Agreement, the term loans would mature on September 1, 2029, and would be subject to monthly interest only payments until September 30, 2027, provided the Company achieved both a certain financial and a certain clinical milestone by June 30, 2026, which it did not. The interest-only period ended on September 30, 2026 and monthly payments of principal and interest will begin in October 2026 and continue through maturity on September 1, 2028. The term loan will automatically accelerate upon the occurrence of bankruptcy or insolvency event involving the Company or its subsidiaries.

The term loan accrues interest at a per annum rate equal to the greater of (i) 7.00% and (ii) the prime rate (as last quoted in The Wall Street Journal), minus 0.75%; provided that such interest rate shall not exceed 9.75% per annum. The Company is liable for a final payment of $1.6 million due on the earliest to occur of (i) the maturity, (ii) full repayment, and (iii) acceleration (the "Exit Fee"). In addition, the Company is liable for a prepayment fee equal to 2.0% of principal prepaid during the second year of the term, and 1.0% thereafter.

The SVB Loan Agreement contains customary representations and warranties, events of default and affirmative and negative covenants, including covenants that limit or restrict the Company's and its subsidiaries' ability to, among other things, dispose of assets, make changes to its business, management, ownership or business locations, merge or consolidate, incur additional indebtedness, grant liens on its assets, pay dividends or other distributions, repurchase equity, make investments, and enter into certain transactions with affiliates, in each case subject to certain thresholds and exceptions. The SVB Loan Agreement does not require the Company to comply with a financial maintenance covenant. As collateral for its obligations under the SVB Loan Agreement, the Company granted the lender a first-priority security interest on substantially all of the Company's assets (other than intellectual property), subject to certain exceptions. The Company's obligations under the SVB Loan Agreement will be guaranteed by each of the Company's future direct or indirect subsidiaries, subject to certain exceptions.

The Company recorded $0.8 million and $0.7 million in interest expense for the three months ended September 30, 2026 and 2025, respectively, and $2.2 million and $2.1 million for each of the nine months ended September 30, 2026 and 2025, respectively. The effective interest rate on the SVB Loan Agreement, including the amortization of the debt discount and issuance costs, and accretion of the Exit Fee, was 9.24% as of September 30, 2026.

Future principal payments and the Exit Fee as of September 30, 2026 are as follows (in thousands):

Remainder of 2026	$ 4,062
2027	16,250
2028	13,813
Total payments	34,125
Unamortized debt discount	(1,153)
Total debt, net	32,972
Less current portion, net	(15,701)
Long-term debt, net	$ 17,271

9. Segment Reporting

Operating segments are defined as components of the entity for which separate financial information is made available and that is regularly evaluated by the chief operating decision maker ("CODM") in making decisions regarding resource allocation and assessing performance. The Company's CODM is its Chief Executive Officer and the Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions. The Company is focused on the development of TCR-T therapy product candidates for the treatment of patients with cancer.

The CODM assesses the Company's performance by reviewing U.S. GAAP net loss and significant expenses by function along with the annual budget. The CODM considers budget-to-actual variances on a quarterly basis when making decisions about the allocation of operating and capital resources.

The following table presents selected information with respect to the Company's single operating segment for each of the periods indicated (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Collaboration and license revenue	$ 586	$ 2,511	$ 2,619	$ 7,758
Less:				
Research and development				
Personnel expenses	7,987	9,441	23,227	27,223
Laboratory supplies, research materials and studies	6,001	9,195	15,576	30,785
Facility-related and other	5,099	4,305	15,032	15,510
Clinical studies	4,608	6,474	11,515	13,890
Stock-based compensation	999	1,683	3,427	5,089
Depreciation expense	597	591	1,820	1,614
General and administrative				
Personnel expenses	3,637	3,172	9,759	9,528
Legal and professional fees	1,947	1,646	6,158	5,641
Facility-related and other	1,583	1,552	5,046	5,295
Stock-based compensation	1,078	1,328	3,472	4,609
Depreciation expense	81	176	250	529
Interest and other income, net	721	2,041	2,716	7,233
Interest expense	(775)	(699)	(2,163)	(2,067)
Net loss	$ (33,085)	$ (35,710)	$ (92,110)	$ (106,789)

10. Net Loss Per Share

Basic and diluted net loss per share was calculated as follows (in thousands, except share and per share data):

	September 30,		September 30,	
	2026	2025	2026	2025
Numerator				
Net loss	$ (33,085)	$ (35,710)	$ (92,110)	$ (106,789)
Denominator				
Weighted average shares outstanding-basic and diluted	130,025,962	129,835,938	129,963,151	129,748,897
Net loss per share				
Basic and diluted	$ (0.25)	$ (0.28)	$ (0.71)	$ (0.82)

As of September 30, 2026 and 2025, common stock issuable upon exercise of the Pre-Funded Warrants totaling 62,246,707 and 73,087,945, respectively, are included as outstanding common stock in the calculation of basic and diluted net loss per share. See Note 5, *Stockholders' Equity*, to these condensed consolidated financial statements for additional information.

The Company has two classes of common stock, each with identical participation rights to earnings and liquidation preferences, and therefore the calculation of net loss per share as calculated above is identical to the calculation under the two-class method. The

Company excluded the following potential common shares from the computation of diluted net loss per share for the periods indicated because including them would have had an anti-dilutive effect:

	September 30,	
	2026	2025
Common stock issuable upon exercise of stock options	18,958,156	18,061,321
Common stock issuable under the employee stock purchase plan	620,051	85,299
Total	19,578,207	18,146,620

11. Reorganization

On November 3, 2025, the Company implemented a workforce reduction of approximately 30% (the "2025 Workforce Reduction"). As of September 30, 2026, there was approximately $0.1 million of accrued severance-related benefits and other costs related to the 2025 Workforce Reduction included in accrued expenses on the consolidated balance sheet. These payments are expected to be completed in the fourth quarter of 2026.

As a result of the 2026 Reorganization, the Company incurred expenses of approximately $4.4 million for wage continuance and severance-related benefits and other costs, of which $3.2 million and $1.2 million is included in research and development and general and administrative expenses, respectively, in the condensed consolidated statement of operations. As of September 30, 2026, there was $3.0 million of accrued severance-related benefits and other costs in accrued expenses on the condensed consolidated balance sheet. These payments are expected to be completed in the fourth quarter of 2027.

The following table summarizes the Company's liability recognized in connection with the 2025 Workforce Reduction and 2026 Reorganization (in thousands):

Balance as of December 31, 2025	$	1,015
Severance-related benefits and other costs		4,424
Cash payments		(2,368)
Balance as of September 30, 2026	$	3,071

12. Subsequent Event

On October 1, 2026, the Company granted 11,013,500 restricted stock units ("RSUs") of which, 6,690,000 are performance based. Stock-based compensation expense will be recorded for RSUs that are expected to vest based on their fair value at grant date and is amortized over the expected vesting period. The service-based RSUs vest annually over three or four years in equal installments commencing on the first anniversary of the grant date. Recognition of stock-based compensation expense associated with performance based RSUs commences when the performance conditions are considered probable of achievement, using management's best estimates.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q (Quarterly Report), and our Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on March 4, 2026. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" and "Special Note Regarding Forward-Looking Statements" sections of this Quarterly Report, our actual results could differ materially from the results described in, or implied by, the forward-looking statements contained in the following discussion and analysis.

Overview

We are a fully integrated, clinical-stage biotechnology company focused on developing a robust pipeline of T cell receptor (TCR)-engineered T cell, or TCR-T, therapies for the treatment of patients with cancer. We are prioritizing the advancement of our *in vivo*-engineered TCR-T therapy candidates for solid tumors, with the goal of delivering life-changing therapies for patients with significant unmet medical needs.

Corporate Updates

In September 2026, we announced a plan to restructure the Company to prioritize development of our *in vivo*-engineered TCR-T therapy candidates for the treatment of patients with solid tumors (the "2026 Reorganization"). As part of this strategic realignment, we implemented a workforce reduction of approximately 75%, which is expected to produce cumulative cost savings of $55.0 million through the end of 2027. We believe concentrating capital resources on the solid tumor program, while preserving the potential value of our other programs through strategic partnerships, provides the strongest path forward to creating long-term value for patients and shareholders. In connection with the workforce reduction, we expect to incur approximately $4.4 million in employee-related costs, consisting primarily of pay continuation and related benefits. We expect to complete the 2026 Reorganization and incur virtually all charges by the end of the fourth quarter of 2027.

Prioritized Solid Tumor Program

To advance our solid tumor program, we are developing *in vivo*-engineered TCR-T therapy candidates that target cancer-specific antigens expressed in various solid tumor indications, including melanoma, ovarian cancer, non-small cell lung cancer, and head and neck cancer. We believe that an *in vivo* engineering approach will overcome the key limitations of *ex vivo*-engineered autologous TCR-T, including the cost and difficulty of patient-specific manufacturing, the delay in getting product to patients, and the need for lymphodepletion. Building on the promise of our prior work, we are reconfiguring our two most active TCRs from our *ex vivo*-manufactured TCR-T program, the Phase 1 PLEXI-T™ study, as *in vivo*-engineered products. As with our *ex vivo* program, we will initially treat patients with single TCR-T candidates (singleplexed therapy). We expect this to be sufficient for cancers with uniform target expression. Many solid tumors, however, are heterogeneous – they express multiple cancer-specific antigens and not every tumor cell expresses a given antigen. To address this challenge, we are also developing what we refer to as multiplex TCR-T therapy, in which we treat a patient with more than one TCR-T candidate at a time. Overall, we believe an *in vivo* approach represents a promising and cost-efficient way to deliver off-the-shelf, multiplexed TCR-T therapy for solid tumors.

Our first two therapeutic candidates, one targeting PRAME and the other targeting MAGE-A4, are advancing through IND-enabling studies. We expect to share preclinical data in Q1 2027 and file our first IND in Q3 2027, with plans to dose our first patient in Q4 2027.

Hematologic Malignancies Program

In September 2026, we provided an update on our hematologic (heme) malignancies clinical program, including updated data from Cohort C of our Phase 1 ALLOHA™ trial evaluating TSC-101, generated with our commercial-ready manufacturing process, in patients with heme malignancies undergoing allogeneic HCT. Despite being at very high risk of relapse, all 14 patients in Cohort C achieved complete donor chimerism at various time-points following treatment with TSC-101. This included two patients who relapsed but subsequently converted to complete donor chimerism after receiving a third infusion of TSC-101, additional targeted agents, or both. One patient was previously disclosed to have a non-relapse mortality, unrelated to TSC-101. TSC-101 infusions continue to be generally well-tolerated and observed adverse events are consistent with post-HCT adverse events.

Despite observing positive clinical data from Cohort C of our Phase 1 ALLOHA™ study, we stopped further enrollment on our Phase 3 ALLOHA-2™ study of TSC-101 due to insufficient funding. Prior to this pause, 7 patients were enrolled on the treatment arm of the study and 5 patients were enrolled on the control arm. Treatment and follow-up of these patients, as well as other study-related activities, will continue at significantly reduced ongoing costs. We remain committed to the care of patients and intend to continue collecting safety and efficacy data while actively exploring strategic partnerships that could continue to move the program forward. Updated data on Cohort C are expected in Q4 2026, followed by data on all patients treated with the commercial-ready manufacturing process in Q2 2027.

Autoimmunity Program

While primarily focused on oncology, we believe our target discovery platform is well suited to identify targets that cause T cell-driven autoimmune disorders. We have previously identified the targets of pathogenic T-cells in HLA-B*27 associated autoimmune disorders, including ankylosing spondylitis. Further discovery efforts have been halted and we are currently evaluating strategic partnerships for this program.

Since our inception in 2018, we have devoted our efforts to raising capital, obtaining financing, filing, prosecuting and maintaining intellectual property rights, organizing and staffing our Company and incurring research and development ("R&D") costs related to the identification of novel targets for TCRs and development of TCR-T therapy product candidates to target and eliminate cancer cells. We do not have any therapies approved for sale and have not generated any revenue from product sales. To date, we have funded our operations primarily with proceeds from sales of capital stock, revenue received under our collaboration agreements, and debt facilities.

We have incurred significant operating losses since our inception. We reported net losses of $33.1 million and $92.1 million for the three and nine months ended September 30, 2026, respectively. As of September 30, 2026, we had an accumulated deficit of $597.0 million. We expect to continue to incur significant expenses and operating losses for the foreseeable future in connection with our ongoing activities, particularly if and as we:

- continue our R&D efforts to identify and develop product candidates and submit IND applications for such product candidates;
- conduct preclinical studies and commence clinical trials for our current and future product candidates based on our proprietary platform;
- conduct clinical trials of our product candidates to evaluate their safety and potential efficacy;
- seek marketing approvals for any product candidates that successfully complete clinical trials;
- build commercial infrastructure to support sales and marketing for our product candidates;
- expand, maintain and protect our intellectual property portfolio;
- hire additional clinical, regulatory and scientific personnel; and
- continue to operate as a public company.

We will not generate revenue from sales of our therapies unless and until we successfully complete clinical development and obtain regulatory approval for one or more of our product candidates. If we obtain regulatory approval for any of our product candidates, we expect to incur significant expenses related to developing our commercialization capability to support the sales, marketing and distribution of those therapies.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from sales of our therapies, if ever, we expect to finance our operations through a combination of equity offerings, debt financings, or other capital sources, including collaborations with other companies, and other strategic transactions. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as, and when, needed, we may have to significantly delay, scale back or discontinue the development and commercialization of one or more of our product candidates.

Because of the numerous risks and uncertainties associated with TCR-T therapy product candidate development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve or maintain profitability. Even if we are able to generate sales of our therapies, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

In accordance with U.S. GAAP, we evaluated whether conditions and events, considered in the aggregate, raise substantial doubt about our ability to continue as a going concern. Based on our current operating plan, existing cash and cash equivalents are expected to fund operations into the fourth quarter of 2027 but are not expected to be sufficient to fund our obligations for at least twelve months after the issuance date of these condensed consolidated financial statements. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. For additional information regarding our liquidity, see "Liquidity and Capital Resources" and "Risk Factors—Risks related to our financial position and need for additional capital." Based on our evaluation, we concluded that substantial doubt exists about our ability to continue as a going concern. See Note 1, *Nature of Business and Basis of Presentation*, to these condensed consolidated financial statements for additional information.

Recent Developments

Nasdaq Compliance

On August 27, 2026, the Company received written notice (the "Notice") from the Listing Qualifications Department of The Nasdaq Stock Market LLC ("Nasdaq") stating that the Company's voting common stock failed to comply with the $1.00 minimum bid price required for continued listing on The Nasdaq Global Market under Nasdaq Listing Rule 5450(a)(1) (the "Minimum Bid Price Rule"). This conclusion was based upon the closing bid price of our common stock for the 30 consecutive trading days prior to the date of the Notice from Nasdaq. The Notice has no effect on the listing of our common stock at this time, and our common stock will continue to trade on The Nasdaq Global Market under the symbol "TCRX."

We have been provided an initial compliance period of 180 calendar days, or until February 23, 2027, to regain compliance with the Minimum Bid Price Rule which requires that the closing bid price of the Common Stock meet or exceed $1.00 per share for a minimum of ten consecutive trading days. If we do not regain compliance by February 23, 2027, we may be afforded a second 180 calendar day period to regain compliance.

Unless cured sooner, to qualify for the additional 180 calendar days, we would transfer to The Nasdaq Capital Market and meet the continued listing requirement for market value of publicly held shares and all other initial listing standards, except for the minimum bid price requirement. In addition, we must notify Nasdaq of our intent to cure the deficiency during the second compliance period. If the Staff concludes we will not be able to cure the deficiency, or if we do not regain compliance, the Staff will provide written notification to us indicating our common stock will be subject to delisting. We may appeal the Staff's delisting determination to a Nasdaq Hearings Panel, but there can be no assurance the appeal would be successful.

We will continue to monitor the bid price of our common stock and consider our available options to regain compliance with the Minimum Bid Price Rule, but there can be no assurance we will be able to regain compliance.

Executive Transition

In connection with the 2026 Reorganization, Jason A. Amello ceased to serve as our Chief Financial Officer and Chrystal Louis, M.D., MPH ceased to serve as our Chief Medical Officer. Following this transition, Gavin MacBeath, Ph.D., our Chief Executive Officer, also serves as our Principal Financial Officer and Principal Accounting Officer.

Results of Operations

Three months ended September 30, 2026 and 2025

The following table summarizes our results of operations for the periods indicated (in thousands):

	Three Months Ended September 30,		Change	
	2026	2025	$	%
Collaboration and license revenue	$ 586	$ 2,511	$ (1,925)	(77%)
Operating expenses:				
Research and development	25,291	31,689	(6,398)	(20%)
General and administrative	8,326	7,874	452	6%
Total operating expenses	33,617	39,563	(5,946)	(15%)
Operating loss	(33,031)	(37,052)	4,021	(11%)
Other (expense) income:				
Interest and other income, net	721	2,041	(1,320)	(65%)
Interest expense	(775)	(699)	(76)	11%
Total other (expense) income	(54)	1,342	(1,396)	(104%)
Net loss	$ (33,085)	$ (35,710)	$ 2,625	(7%)

Revenue

Revenue decreased by $1.9 million for the three months ended September 30, 2026 compared with the same period in the prior year primarily due to the timing of research activities performed pursuant to our collaboration agreement with Amgen, which terminated in August 2026.

Research and development expenses

The following table summarizes our R&D expenses by category for the periods indicated (in thousands):

	Three Months Ended September 30,		Change	
	2026	2025	$	%
Personnel expenses	$ 7,987	$ 9,441	$ (1,454)	(15%)
Laboratory supplies, research materials and studies	6,001	9,195	(3,194)	(35%)
Facility-related and other	5,099	4,305	794	18%
Clinical studies	4,608	6,474	(1,866)	(29%)
Stock-based compensation	999	1,683	(684)	(41%)
Depreciation expense	597	591	6	1%
Total research and development	$ 25,291	$ 31,689	$ (6,398)	(20%)

R&D expenses decreased by $6.4 million for the three months ended September 30, 2026 compared with the same period in the prior year primarily driven by our 2025 workforce reduction. There was a $3.2 million decrease in laboratory supplies, research materials and studies due to the timing and purchase of supplies and consumables and decreased spend on contracted service and a decrease of $1.9 million in clinical studies. In addition, there was a $1.5 million decrease in personnel expenses attributable to the 2025 workforce reduction which was partially offset by the $3.2 million attributable to the 2026 Reorganization and the employee-related costs, consisting primarily of pay continuation and related benefits.

General and administrative expenses

The following table summarizes our general and administrative expenses by category for the periods indicated (in thousands):

	Three Months Ended September 30,		Change	
	2026	2025	$	%
Personnel expenses	$ 3,637	$ 3,172	$ 465	15%
Legal and professional fees	1,947	1,646	301	18%
Facility-related and other	1,583	1,552	31	2%
Stock-based compensation	1,078	1,328	(250)	(19%)
Depreciation expense	81	176	(95)	(54%)
Total general and administrative	$ 8,326	$ 7,874	$ 452	6%

General and administrative expenses increased by $0.5 million for the three months ended September 30, 2026 compared with the same period in the prior year primarily due to increases of $0.5 million in personnel expenses. The increase in personnel expense was primarily due to $1.2 million attributable to the 2026 Reorganization and the employee-related costs, consisting primarily of pay continuation and related benefits which was partially offset by the 2025 workforce reduction. In addition, legal and professional fees increased $0.3 million partially offset by a $0.3 decrease in stock-based compensation.

Other (expense) income

Other income decreased by $1.4 million for the three months ended September 30, 2026 compared to the same period in the prior year primarily due to a decrease in interest income attributable to lower cash balances available for investment.

Nine months ended September 30, 2026 and 2025

The following table summarizes our results of operations for the periods indicated (in thousands):

	Nine Months Ended September 30,		Change	
	2026	2025	$	%
Collaboration and license revenue	$ 2,619	$ 7,758	$ (5,139)	(66%)
Operating expenses:				
Research and development	70,597	94,111	(23,514)	(25%)
General and administrative	24,685	25,602	(917)	(4%)
Total operating expenses	95,282	119,713	(24,431)	(20%)
Operating loss	(92,663)	(111,955)	19,292	(17%)
Other (expense) income:				
Interest and other income, net	2,716	7,233	(4,517)	(62%)
Interest expense	(2,163)	(2,067)	(96)	5%
Total other (expense) income	553	5,166	(4,613)	(89%)
Net loss	$ (92,110)	$ (106,789)	$ 14,679	(14%)

Revenue

Revenue decreased by $5.1 million for the nine months ended September 30, 2026 compared with the same period in the prior year primarily due to the timing of research activities performed pursuant to our collaboration agreement with Amgen, which terminated in August 2026.

Research and development expenses

The following table summarizes our R&D expenses by category for the periods indicated (in thousands):

	Nine Months Ended September 30,		Change	
	2026	2025	$	%
Personnel expenses	$ 23,227	$ 27,223	$ (3,996)	(15%)
Laboratory supplies, research materials and studies	15,576	30,785	(15,209)	(49%)
Facility-related and other	15,032	15,510	(478)	(3%)
Clinical studies	11,515	13,890	(2,375)	(17%)
Stock-based compensation	3,427	5,089	(1,662)	(33%)
Depreciation expense	1,820	1,614	206	13%
Total research and development	$ 70,597	$ 94,111	$ (23,514)	(25%)

R&D expenses decreased by $23.5 million for the nine months ended September 30, 2026 compared with the same period in the prior year primarily driven by our 2025 workforce reduction. There was a $15.2 million decrease in laboratory supplies, research materials and studies due to the timing and purchase of supplies and consumables and decreased spend on contracted service and a decrease of $2.4 million in clinical studies. In addition, there was a $4.0 million decrease in personnel expense and $1.7 million decrease in stock-based compensation primarily driven by our 2025 workforce reduction. The decrease was partially offset by the $3.2 million attributable to the 2026 Reorganization and the employee-related costs, consisting primarily of pay continuation and related benefits.

General and administrative expenses

The following table summarizes our general and administrative expenses by category for the periods indicated (in thousands):

	Nine Months Ended September 30,		Change	
	2026	2025	$	%
Personnel expenses	$ 9,759	$ 9,528	$ 231	2%
Legal and professional fees	6,158	5,641	517	9%
Facility-related and other	5,046	5,295	(249)	(5%)
Stock-based compensation	3,472	4,609	(1,137)	(25%)
Depreciation expense	250	529	(279)	(53%)
Total general and administrative	$ 24,685	$ 25,602	$ (917)	(4%)

General and administrative expenses decreased by $0.9 million for the nine months ended September 30, 2026 compared with the same period in the prior year primarily due to a decrease in stock-based compensation of $1.1 million as a result of our 2025 workforce reduction.

Other (expense) income

Other income decreased by $4.6 million for the nine months ended September 30, 2026 compared with the same period in the prior year primarily due to a decrease in interest income attributable to lower cash balances available for investment.

Liquidity and Capital Resources

Sources of Liquidity

We have not generated any revenue from product sales and have incurred net losses and negative cash flows from our operations. Our primary use of cash is to fund operating expenses, which consist primarily of R&D expenditures, and to a lesser extent, general and administrative expenditures. Under the terms of the Amgen Agreement, we received a payment of $30.0 million in July 2023 which was recognized as revenue over time. On August 12, 2026, we received notice from Amgen of its election to terminate the agreement which will be effective November 10, 2026.

On June 1, 2023, we completed an underwritten public offering of 23,287,134 shares of our voting common stock, inclusive of shares purchased by the underwriters', at a price of $2.00 per share, and pre-funded warrants to purchase up to 47,010,526 shares with

an exercise price of $0.0001 per share. The pre-funded warrants were issued at a purchase price of $1.9999 per warrant. Aggregate net proceeds were $134.7 million after deducting underwriting discounts, commissions and other offering expenses.

On April 24, 2024, we completed an underwritten public offering resulting in the issuance and sale of 4,958,068 shares of our voting common stock, inclusive of shares purchased by the underwriters', at a price of $7.13 per share, and pre-funded warrants to purchase up to 18,577,419 shares with an exercise price of $0.0001 per share. The pre-funded warrants were issued at a purchase price of $7.1299 per warrant. Aggregate net proceeds were $161.4 million after deducting underwriting discounts, commissions and other estimated offering expenses.

Pursuant to the K2 HealthVentures LLC ("K2HV"), Loan Agreement dated September 9, 2022, we had an initial convertible term loan of $30.0 million. On November 20, 2024, K2HV converted $15.0 million outstanding principal into 3,134,796 shares of our voting common stock. On December 20, 2024, we entered into a loan agreement ("SVB Loan") with Silicon Valley Bank, a division of First-Citizens Bank & Trust Company ("SVB"), and repaid all remaining outstanding loan obligations to K2HV.

The SVB Loan Agreement provided for term loans up to an aggregate principal amount of $52.5 million, of which $32.5 million was provided on the closing date. A second tranche of $20.0 million was available prior to June 30, 2026, but was not and can no longer be drawn. The term loan is expected to mature on September 1, 2028 ("Maturity") and was subject to monthly interest only payments through September 30, 2026. Monthly installments of principal and interest began October 1, 2026, and will continue until Maturity. As of September 30, 2026, the $32.5 million term loan remained outstanding. See "Notes to Condensed Consolidated Financial Statements" and "Item 1A. Risk Factors—The terms of our loan agreement place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our operating and financial flexibility" for additional details regarding the SVB Loan Agreement.

On December 27, 2024, we completed a registered direct offering with an existing investor for the issuance of pre-funded warrants to purchase up to 7,500,000 shares of our voting common stock with an exercise price of $0.0001 per warrant. The pre-funded warrants were issued at a purchase price of $4.00 per warrant. Aggregate net proceeds were $29.8 million, after deducting offering expenses.

As of September 30, 2026, we had cash and cash equivalents of $73.0 million, excluding restricted cash of $5.0 million. Based on our current operating plan, existing cash and cash equivalents are expected to fund operations into the fourth quarter of 2027 but are not expected to be sufficient to fund our obligations for at least twelve months after the issuance date of these condensed consolidated financial statements. We have based our current operating plan on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. As a result, management has concluded that substantial doubt exists about our ability to continue as a going concern. See Note 1, *Nature of Business and Basis of Presentation*, to these condensed consolidated financial statements for additional information.

Funding requirements

We expect to continue to incur significant expenses and operating losses for the foreseeable future in connection with our ongoing activities, particularly if and as we:

- continue our R&D efforts to identify and develop product candidates and submit IND applications for such product candidates;
- conduct preclinical studies and commence clinical trials for our current and future product candidates based on our proprietary platform;
- develop processes suitable for manufacturing and clinical development;
- continue to develop and expand our manufacturing capabilities;
- conduct clinical trials of our product candidates to evaluate their safety and potential efficacy;
- seek marketing approvals for any product candidates that successfully complete clinical trials;
- build commercial infrastructure to support sales and marketing for our product candidates;
- expand, maintain and protect our intellectual property portfolio;
- hire additional clinical, regulatory and scientific personnel; and
- continue to operate as a public company.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our

ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends. Any debt financing or additional equity that we raise may also contain terms that are not favorable to us or our stockholders. In the event a convertible debt facility is converted to shares of common stock, such conversion could result in additional and substantial dilution to our existing and future stockholders. If we raise additional funds through additional collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce or terminate our research, product development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

We have not yet received regulatory approval for or commercialized any of our product candidates and do not expect to generate revenue from product sales for several years, if at all. We do not expect to generate any product revenue unless and until we (i) complete development of any of our product candidates; (ii) obtain applicable regulatory approvals; and (iii) successfully commercialize or enter into collaborative agreements for our product candidates. We do not know with certainty when, or if, any of these items will ultimately occur. We expect to incur continuing significant losses for the foreseeable future. We may encounter unforeseen expenses, difficulties, complications, delays and other currently unknown factors that could adversely affect our business.

We will require additional capital to develop our product candidates and fund our operations into the foreseeable future. We anticipate that we will eventually need to raise substantial additional capital, the requirements for which will depend on many factors, including:

- the scope, timing, rate of progress and costs of our drug discovery efforts, preclinical development activities, laboratory testing and clinical trials for our product candidates;
- the number and scope of clinical programs we decide to pursue;
- the cost, timing and outcome of preparing for and undergoing regulatory review of our product candidates;
- the scope and costs of development and manufacturing activities;
- the cost and timing associated with commercializing our product candidates, if they receive marketing approval;
- the amount of revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval;
- the achievement of milestones or occurrence of other developments that trigger payments under any collaboration agreements we might have at such time;
- the extent to which we acquire or in-license other product candidates and technologies;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- our efforts to enhance operational systems and our ability to attract, hire and retain qualified personnel, including personnel to support the development of our product candidates and, ultimately, the sale of our products, following FDA approval;
- our implementation of various computerized information systems;
- impact of health crises and other external disruptions on our clinical development or operations; and
- the costs associated with being a public company.

A change in the outcome of any of these or other variables with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate. Furthermore, our operating plans may change in the future, and we will continue to require additional capital to meet operational needs and capital requirements associated with such operating plans. In addition, adequate funding may not be available to us on acceptable terms or at all. If we are unable to raise capital when needed, it could have a negative impact on our financial condition and our ability to pursue our business strategies. We may need to delay, reduce, or terminate some or all development programs and clinical trials. We may also be required to sell or license our rights to product candidates in certain territories or indications that we would otherwise prefer to develop and commercialize ourselves. See Part II, Item 1A. “Risk Factors” of this Quarterly Report for additional risks associated with our substantial capital requirements.

While we remain an emerging growth company and a smaller reporting company, we are not required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, as we continue to evolve as a business, we will incur increased costs related to legal and financial compliance.

Cash Flows

The following table summarizes net cash flow activity for the periods indicated (in thousands):

	Nine Months Ended September 30,		Change	
	2026	2025	$	%
Net cash used in operating activities	$ (78,891)	$ (103,317)	$ 24,426	-24%
Net cash (used in) provided by investing activities	(576)	94,543	(95,119)	-101%
Net cash provided by (used in) financing activities	99	(409)	508	-124%
Net decrease in cash, cash equivalents and restricted cash	$ (79,368)	$ (9,183)	$ (70,185)	764%

Operating activities

Net cash used in operating activities was $78.9 million for the nine months ended September 30, 2026, and was primarily driven by our net loss of $92.1 million offset by non-cash adjustments of $9.5 million and changes in net working capital of $3.7 million. The change in working capital was partially driven by increased accrued compensation benefits of $2.8 million primarily due to expenses incurred in connection with the 2026 Reorganization. In addition, accrued R&D increased $1.9 million due to the timing of invoices. These increases were partially offset with decreased deferred revenue due to revenue recognition pursuant to the Amgen Agreement.

Net cash used in operating activities was $103.3 million for the nine months ended September 30, 2025, and was primarily driven by our net loss of $106.8 million offset by non-cash adjustments of $9.8 million and a use of $6.4 million related to changes in net working capital. The change in working capital was primarily driven by revenue recognition pursuant to the Amgen Agreement and changes in accrued expenses related to R&D activities.

Investing activities

Net cash used in investing activities was $0.6 million for the nine months ended September 30, 2026, which was driven by the net purchase and sale of property and equipment.

Net cash provided by investing activities was $94.5 million for the nine months ended September 30, 2025, which was driven by the maturities and purchases of marketable securities of $98.8 million partially offset by the purchase of property and equipment of $4.2 million.

Financing activities

Net cash provided by financing activities was $0.1 million for the nine months ended September 30, 2026, which was driven by proceeds from the issuance of common stock under the employee stock purchase plan.

Net cash used in financing activities was $0.4 million for the nine months ended September 30, 2025, which was driven by cash paid for debt issuance and financing costs partially offset by proceeds from the issuance of common stock under the employee stock purchase plan.

Critical Accounting Policies and Estimates

Our condensed consolidated financial statements are prepared in accordance with U.S. GAAP. The preparation of financial statements and related disclosures require us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues, costs and expenses. We base our estimates on historical experience, known trends and events and on various other factors that we believe to be reasonable under the circumstances. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

There have been no material changes to our critical accounting policies and estimates from those disclosed in our financial statements and the related notes and other financial information included in our Annual Report on Form 10-K for the year ended December 31, 2025 filed with the SEC on March 4, 2026.

Emerging Growth Company and Smaller Reporting Company Status

The Jumpstart Our Business Startups Act of 2012 (JOBS Act) permits an “emerging growth company” to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. The Company qualifies as an “emerging growth company” under the JOBS Act and has elected to “opt in” to the extended transition related to complying with new or revised accounting standards, which means that when a standard is issued or revised and it has different application dates for public or private companies, we will adopt the new or revised

standard at the time private companies adopt the new or revised standard and will do so until such time that we either (i) irrevocably elect to "opt out" of such extended transition period or (ii) no longer qualify as an emerging growth company. We may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for private companies. Our status as an emerging growth company will end on December 31, 2026, which will be the last day of the fiscal year ending after the fifth anniversary of our initial public offering.

We are also a "smaller reporting company" meaning that the market value of our stock held by non-affiliates plus the aggregate amount of gross proceeds to us as a result of the IPO is less than $700 million and our annual revenue was less than $100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our common stock held by non-affiliates is less than $250 million, or (ii) our annual revenue was less than $100 million during the most recently completed fiscal year and the market value of our common stock held by non-affiliates is less than $700 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company, as defined in Item 10(f)(1) of Regulation S-K, and are not required to provide the information required under this item.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, under the supervision and with the participation of our Chief Executive Officer who is our Principal Executive Officer and Principal Financial and Accounting Officer, has evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2026. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any disclosure 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. Based on the evaluation of our disclosure controls and procedures as of September 30, 2026, our Chief Executive Officer has concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the three months ended September 30, 2026 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

We are not currently a party to any material legal proceedings. From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity, reputational harm and other factors.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all of the other information in this Quarterly Report on Form 10-Q, and in other documents that we file with the SEC. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of or that we deem immaterial may also become important factors that adversely affect our business. If any of the following risks actually occur, our business, financial condition, liquidity, operating results, and prospects could be materially and adversely affected.

The risk factors denoted with a "", if any, are newly added or have been materially updated from our Annual Report on Form 10-K filed with the SEC on March 4, 2026.*

RISK FACTORS

Risks Related to Our Business and Industry

We have incurred significant losses since inception, and we expect to incur losses over the next several years and may not be able to achieve or sustain revenues or profitability in the future.

Investment in biotechnology product development is a highly speculative undertaking and 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. We are still in the early stages of development of our product candidates and have initiated clinical trials for certain of our product candidates. We have no products licensed for commercial sale and have not generated any revenue from product sales to date, and we continue to incur significant research and development, and other expenses related to our ongoing operations. We have financed our operations primarily through equity and debt issuances, borrowings under secured loan agreements and upfront payments under our existing or previous collaborations.

We have incurred significant net losses in each period since our inception in April 2018. For the three and nine months ended September 30, 2026, and the years ended December 31, 2025 and 2024, we reported net losses of $33.1 million, $92.1 million, $129.8 million, and $127.5 million, respectively. As of September 30, 2026, we had an accumulated deficit of $597.0 million. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase substantially if and as we:

- continue our research and development efforts to identify and develop product candidates and submit additional IND applications for such product candidates;
- conduct preclinical studies and commence and complete clinical trials for our current and future product candidates based on our proprietary platform;
- seek marketing approvals for any of our product candidates that successfully complete clinical trials;
- build commercial infrastructure to support sales and marketing for our product candidates;
- expand, maintain and protect our intellectual property portfolio;
- hire additional personnel; and
- continue to operate as a public company.

Because of the numerous risks and uncertainties associated with biotechnology product research and development, we are unable to accurately predict the timing or amount of the increased expenses we will incur or when, if ever, we will be able to achieve profitability. Even if we succeed in commercializing one or more of our product candidates, we will continue to incur substantial research and development expenses and other expenditures to develop, seek regulatory approval for, and market additional product candidates. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

We are currently not in compliance with Nasdaq's continued listing requirements. If we are unable to regain compliance with Nasdaq's listing requirements, our common stock could be delisted, which could affect the market price of our common stock and liquidity and reduce our ability to raise capital.

Our common stock is currently listed on the Nasdaq Global Market. We cannot assure you that we will be able to maintain a listing of our common stock on any such trading venue. On August 27, 2026, we received written notice (the "Notice") from the Listing

Qualifications Department of The Nasdaq Stock Market LLC ("Nasdaq") stating that our common stock had not maintained the $1.00 minimum closing bid price required for continued listing on the Nasdaq Global Market under Nasdaq Listing Rule 5450(a)(1) (the "Minimum Bid Price Rule") for the 30 consecutive trading days prior to the date of the Notice. The Notice has no immediate effect on the listing of our common stock, which continues to trade on the Nasdaq Global Market under the symbol "TCRX."

We have been provided an initial compliance period of 180 calendar days, or until February 23, 2027, to regain compliance with the Minimum Bid Price Rule, which requires that the closing bid price of our common stock meet or exceed $1.00 per share for a minimum of ten consecutive trading days. Although Nasdaq has granted us this compliance period, there can be no assurance that we will regain compliance and Nasdaq could make a determination to delist our common stock. If we do not regain compliance with the Minimum Bid Price Rule by February 23, 2027, we may be eligible for an additional 180-calendar-day compliance period, provided that we transfer the listing of our common stock to the Nasdaq Capital Market and satisfy the applicable requirements for continued listing on that market, other than the Minimum Bid Price Rule, and we provide written notice of our intention to cure the deficiency during that additional period. If necessary to regain compliance with Nasdaq listing standards, we may implement a reverse stock split, subject to stockholder approval and our board of directors' determination to implement the reverse stock split. Our board of directors has approved, and is seeking stockholder approval at a special meeting for, an amendment to our certificate of incorporation to effect a reverse stock split at a ratio of not less than one-for-two and not more than one-for-fifty, with the exact ratio and timing to be determined by the board of directors in its sole discretion. However, there can be no assurance that a reverse stock split, or any other alternatives we may consider to regain compliance with the minimum bid price requirement, would be approved by our stockholders or would result in a sustained higher stock price that would allow us to meet the Nasdaq stock price listing requirements, and such reverse stock split may limit our ability to conduct subsequent measures to meet Nasdaq listing criteria in accordance with the applicable Nasdaq rules.

If Nasdaq delists our common stock, investors may face material adverse consequences, including, but not limited to, a lack of trading market for the common stock, reduced liquidity, decreased analyst coverage of the Company, and an inability for us to obtain additional financing to fund our operations. While quotation on an over-the-counter market could maintain some degree of a market in our common stock, we could face substantial material adverse consequences, including, but not limited to, the following: limited availability for market quotations for our common stock; reduced liquidity with respect to and decreased trading prices of our common stock; a determination that shares of our common stock are "penny stock" under the SEC rules, subjecting brokers trading our common stock to more stringent rules on disclosure and the class of investors to which the broker may sell the common stock; limited news and analyst coverage for our Company, in part due to the "penny stock" rules; and decreased ability to issue additional securities or obtain additional financing in the future. The perception among investors that we are at heightened risk of delisting could also negatively affect the market price of our securities and trading volume of our common stock.

Even if we regain compliance, we could subsequently fail to satisfy any of Nasdaq's continued listing requirements, such as the corporate governance requirements or the minimum closing bid price requirement, and Nasdaq may take steps to delist our common stock. Such a delisting would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the required minimum bid price or prevent future non-compliance with Nasdaq listing requirements.

Our business depends upon the success of our proprietary platform.

Our success depends on our ability to use our proprietary platform (i) to discover the natural targets of clinically relevant TCRs, (ii) to discover highly active TCRs for known targets, (iii) to genetically engineer patient- or donor-derived T cells safely and reproducibly, (iv) to obtain regulatory approval for product candidates derived from our proprietary platform and related technologies, and (v) to then commercialize our product candidates that address one or more indications. All of our product candidates will require significant additional clinical and non-clinical development, review and approval by the FDA or other regulatory authorities in one or more jurisdictions, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before they can be successfully commercialized. Some of our product candidates are currently being evaluated in humans and may never become commercialized. Moreover, our current product candidates leverage the same or similar technology and use the same or similar manufacturing processes. As a result, an issue with one product candidate could adversely impact our ability to successfully develop and commercialize other product candidates, particularly ones within the same clinical program.

In addition, the success of our proprietary platform in discovering novel targets for TCR-T therapy product candidates is dependent on us obtaining tumor samples from cancer patients who actively respond to cancer immunotherapies. If our ability to obtain a significant amount of such tumor samples in a timely manner is compromised due to unforeseen circumstances, we may not be successful in discovering novel targets and creating new product candidates based on such targets

Our limited operating history may make it difficult to evaluate the success of our business to date and to assess our future viability.

We are a clinical-stage biotechnology company with a limited operating history. We commenced operations in April 2018, and our operations to date have been limited to organizing and staffing our Company, business planning, raising capital, conducting discovery and research activities, filing patent applications, identifying potential product candidates, undertaking preclinical studies and initiating clinical trials, entering into licenses and collaborations, establishing capabilities to manufacture our product candidates, and establishing arrangements for component materials for such manufacturing. Although we have initiated clinical trials for certain of our product candidates, we have not yet demonstrated our ability to successfully conduct or complete any clinical trials, obtain marketing approvals, manufacture clinical or commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales, marketing and distribution activities necessary for successful product commercialization. Consequently, any predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history.

In addition, as a young business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We eventually may need to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

We expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, the results of any quarterly or annual periods should not be relied upon as indications of future operating performance.

We have never generated any revenue from sales of our TCR-T therapy product candidates and our ability to generate revenue from product sales and become profitable depends significantly on our success in a number of areas.

Our ability to become profitable depends upon our ability to generate revenue. To date, we have not generated any revenue from sales of any of our product candidates. We do not expect to generate significant revenue unless or until we successfully complete preclinical and clinical development and obtain regulatory approval of, and then successfully commercialize, at least one of our product candidates. Although we have initiated clinical trials for certain of our product candidates, we have not yet demonstrated an ability to successfully complete clinical trials of our product candidates, obtain marketing approvals, manufacture a commercial-scale medicine, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization to enable us to generate any revenue from product sales. Our other product candidates are in various stages of preclinical development and, as such, we face significant translational risk as we work to advance these product candidates to the clinical stage. Our ability to generate revenue depends on a number of factors, including, but not limited to:

- our ability to develop processes suitable for clinical manufacturing and to obtain related chemistry, manufacturing, and controls (CMC) regulatory approvals;
- timely completion of our preclinical studies and clinical trials, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the performance of third-party contractors;
- our ability to continue to complete IND-enabling studies and to continue to successfully submit INDs or comparable applications;
- 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 and 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, including adverse events, experienced with our product candidates or future product candidates, if any;
- the timely receipt of necessary marketing approvals from the FDA and 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 to treat patients;
- our ability and the ability of our third-party contractors to manufacture adequate clinical and commercial supplies of our product candidates or any future product candidates, to remain in good standing with regulatory authorities and to develop,

validate and maintain commercially viable manufacturing processes that are compliant with current good manufacturing practice (cGMP);

- our ability to successfully develop a commercial strategy and thereafter commercialize our product candidates or any future product candidates in the U.S. and internationally, if licensed for marketing, reimbursement, sale and distribution in such countries and territories, whether alone or in collaboration with others;
- patient demand for our product candidates and any future product candidates, if licensed; and
- our ability to establish, obtain, maintain, protect and enforce intellectual property and proprietary rights in and to our product candidates or any future product candidates.

Many of the factors listed above are beyond our control and could cause us to experience significant delays or prevent us from obtaining regulatory approvals or commercializing our product candidates. Even if we are able to commercialize our product candidates, we may not achieve profitability soon after generating product sales, if ever. If we are unable to generate sufficient revenue through the sale of our product candidates or any future product candidates, we may be unable to continue operations without continued funding.

We will need to obtain substantial additional funding to complete the development and any commercialization of our product candidates, if approved. If we are unable to raise this necessary capital when needed, we could be forced to delay, reduce or eliminate our product development programs, commercialization efforts or other operations.

Since our inception, we have financed our operations through equity issuances, upfront payments under our collaborations and through our debt financings. The development of biotechnology product candidates is capital intensive, and we expect our expenses to increase substantially during the next few years. As our product candidates enter and advance through preclinical studies and clinical trials, we will need substantial additional funds to expand our clinical, regulatory, quality and manufacturing capabilities. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to marketing, sales, manufacturing and distribution. Furthermore, we expect to continue to incur additional costs associated with operating as a public company.

As of September 30, 2026, we had $73.0 million in cash and cash equivalents. We believe that our existing cash and cash equivalents will enable us to fund our current operating plan into the fourth quarter of 2027. Accordingly, our existing cash and cash equivalents will not be sufficient for us to fund any of our product candidates through regulatory approval, and we will need to raise substantial additional capital to complete the development and commercialization of our product candidates through equity offerings, debt financings, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements or other sources. We may also need to raise additional funds sooner if we choose to pursue additional indications for our product candidates or otherwise expand more rapidly than we presently anticipate.

We have based these estimates on assumptions that may prove to be incorrect or require adjustment as a result of business decisions, and we could utilize our available capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including:

- the scope, rate of progress, costs and results of our drug discovery, preclinical or clinical development activities, laboratory testing and clinical trials for our product candidates;
- the number and scope of clinical programs we decide to pursue;
- the scope and costs of manufacturing development and commercial manufacturing activities and our ability to scale them up or out;
- the extent to which we acquire or in-license other product candidates and technologies;
- the cost, timing and outcome of regulatory review of our product candidates, including the potential for regulatory authorities to require that we conduct more studies and trials than those that we currently expect to conduct and the costs of post-marketing studies or risk evaluation and mitigation strategies that could be required by regulatory authorities;
- potential changes in the regulatory environment and enforcement rules;
- the cost and timing of establishing sales and marketing capabilities, if any of our product candidates receive marketing approval;
- the costs of preparing, filing and prosecuting patent applications, maintaining, obtaining, protecting and enforcing our intellectual property and proprietary rights and defending intellectual property-related claims;

- our ability to establish new and maintain existing licensing or collaboration arrangements and the progress of the development efforts of third parties with whom we may enter into such arrangements;
- the impact of any public health crises or other external disruptions on our business, results of operations, development plans (including any supply related matters) and financial position;
- our efforts to enhance operational systems and our ability to attract, hire and retain qualified personnel, including personnel to support the development of our product candidates;
- potential changes in pharmaceutical pricing and reimbursement infrastructure;
- the costs associated with being a public company; and
- the cost associated with commercializing our product candidates, if they receive marketing approval.

Identifying potential product candidates and conducting preclinical studies and clinical trials is a time consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval. In addition, our product candidates, if approved, may not achieve product sales or commercial success. We do not expect to have any products commercially available for sale for many years, if at all. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. Adequate additional financing may not be available to us on acceptable terms, or at all, and may be impacted by the economic climate and market conditions. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, limit, reduce or eliminate our research and development programs or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. In addition, attempting to secure additional financing may divert the time and attention of management from day-to-day activities and distract from our research and development efforts. We may also seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans.

We have identified conditions that raise substantial doubt about our ability to continue as a going concern.

Based on our current operating plan, we believe there is substantial doubt about our ability to continue as a going concern for at least twelve months following the filing of this Quarterly Report on Form 10-Q, and we will need to obtain additional funding. We may be forced to delay or reduce the scope of our product development programs, reduce our research and development costs and/or limit or cease our operations if we are unable to obtain additional funding to support our current operating plan. Our cash forecast contains estimates and assumptions based on the success of our ongoing clinical trials, and management cannot predict the amount or timing of all expenditures with certainty. Nevertheless, our financial statements do not include any adjustments that might result from the outcome of this uncertainty. We will need to raise additional capital to fund our future operations and continue as a going concern. However, we cannot guarantee that we will be able to obtain any or sufficient additional funding or that such funding, if available, will be obtainable on terms satisfactory to us.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our intellectual property or product candidates on unfavorable terms to us.

We may seek additional capital through a variety of means, including through collaboration arrangements, public or private equity or debt financings, third-party (including government) funding and marketing and distribution arrangements, as well as other strategic alliances and licensing arrangements or any combination of these approaches. However, there can be no assurance that we will be able to raise capital on commercially reasonable terms or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholder ownership interest will be diluted, and the terms may include liquidation preferences or other rights, powers or preferences that may adversely affect rights of our stockholders. To the extent that debt financing is available, and we choose to raise additional capital in the form of debt, such debt financing may involve agreements that include covenants limiting or restricting our ability to take certain actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional capital pursuant to collaborations, licensing arrangements or other strategic partnerships, such agreements may require us to relinquish rights to our technologies or product candidates.

If we are unable to raise additional funds through equity or debt financings, or through collaborations, licensing arrangements or strategic partnerships or other sources when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts.

Global economic uncertainty and financial market volatility caused by political instability, changes in international trade relationships and conflicts could make it more difficult for us to access financing and could adversely affect our business and operations.

Our ability to raise capital is subject to the risk of adverse changes in the market value of our stock. Periods of macroeconomic weakness or recession and heightened market volatility caused by adverse geopolitical developments could increase these risks, potentially resulting in adverse impacts on our ability to raise further capital on favorable terms. The impact of geopolitical tension, such as a deterioration in the bilateral relationship between the U.S. and China or in the ongoing conflicts between Russia and Ukraine, and in the Middle East, including resulting sanctions, export controls or other restrictive actions that may be imposed by the U.S. and/or other countries could also lead to disruption, instability and volatility in global trade patterns, which may in turn impact our ability to source necessary reagents, raw materials and other inputs for our research and development operations.

In addition, political developments impacting government spending and international trade, including changes in trade agreements, potential government shutdowns, trade disputes and tariffs, including tariffs that have been or may in the future be imposed by the U.S. or other countries and future legislation or actions taken by the U.S. or other countries that restrict trade, and protectionist or retaliatory measures taken by the U.S. or other countries, may negatively impact markets and cause weaker macroeconomic conditions. For example, in 2025, the U.S. imposed substantial tariffs on imports from its trading partners, including, without limitation, Canada, Mexico, the EU and China. In response to tariffs, other countries have implemented retaliatory tariffs on U.S. goods. While certain tariffs were subsequently suspended, modified, or temporarily reduced, we cannot predict the results of the U.S. government's trade negotiations or the outcome of ongoing legal challenges to specific tariff policies. The impact of tariffs has already been seen, and we expect will continue to be seen, in global markets. In addition, the Trump administration has expressed an intent to impose tariffs on pharmaceutical imports, with the stated policy objective of reshoring pharmaceutical manufacturing to the United States. Among other means, such tariffs may be imposed by the United States under Section 232 of the Trade Expansion Act of 1962, as amended, pursuant to which the U.S. Department of Commerce recently initiated an investigation to determine the effects of importing pharmaceuticals and pharmaceutical ingredients on national security. Historically, tariffs have led to increased trade and political tensions. Political tensions as a result of trade policies could reduce trade volume, investment, technological exchange and other economic activities between major international economies, resulting in a material adverse effect on global economic conditions and the stability of global financial markets. Any of the abovementioned factors could affect our business, prospects, financial condition, and operating results. The extent and duration of any political instability and resulting market disruptions are impossible to predict but could be substantial. Any such disruptions may also have the effect of heightening many of the other risks and uncertainties described elsewhere in this "Risk Factors" section. We are continuing to monitor global capital markets and assessing the potential impact of these factors on our business.

The U.S. Congress and the Trump administration have made and may make substantial changes to fiscal, tax, and other federal policies that may adversely affect our business.

Since the start of the Trump administration in 2025, there have been significant changes to U.S. trade, healthcare, tax, immigration and government regulatory policy. For example, the U.S. government has imposed substantial tariffs on most countries throughout the world and has further threatened to continue to broadly impose tariffs, which could lead to corresponding punitive actions by the countries with which the U.S. trades. Changes to U.S. policy implemented by the U.S. Congress, the Trump administration or any future administration have impacted and may in the future impact, among other things, the U.S. and global economy, international trade relations, unemployment, immigration, healthcare, taxation, the U.S. regulatory environment, inflation and other areas. Although we cannot predict the impact, if any, of these changes to our business, they could adversely affect our business. Until we know what policy changes are made, whether those policy changes are challenged and subsequently upheld by the court system and how those changes impact our business and the business of our competitors over the long term, we will not know if, overall, we will benefit from them or be negatively affected by them.

Recent volatility in capital markets and lower market prices for many securities may affect our ability to access new capital through sales of shares of our common stock or issuance of indebtedness, which may impact our liquidity, limit our ability to grow our business, pursue acquisitions or improve our operating infrastructure and restrict our ability to compete in our markets.

Our operations consume substantial amounts of cash, and we intend to continue to make significant investments to support our business growth, respond to business challenges or opportunities, develop new products, retain or expand our current levels of personnel, support our programs, enhance our operating infrastructure, and potentially acquire complementary businesses and technologies. Our future capital requirements may be significantly different from our current estimates and will depend on many factors, including the need to:

- finance unanticipated working capital requirements, including clinical manufacturing capacity;
- support our discovery and preclinical development activities, and clinical trials for our product candidates;
- pursue acquisitions or other strategic relationships; and

- respond to competitive pressures.

Accordingly, we may need to pursue equity or debt financings to meet our capital needs. With uncertainty in the capital markets and other factors, such financing may not be available on terms favorable to us or at all. If we raise additional funds through further issuances of equity or convertible debt securities, our existing stockholders could suffer significant dilution, and any new equity securities we issue could have rights, preferences, and privileges superior to those of holders of our common stock. Any debt financing secured by us in the future could involve additional restrictive covenants relating to our capital-raising activities and other financial and operational matters, which may make it more difficult for us to obtain additional capital and to pursue business opportunities, including potential acquisitions. If we are unable to obtain adequate financing or financing on terms satisfactory to us, we could face significant limitations on our ability to invest in our operations and otherwise suffer harm to 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 its financial condition and results of operations.

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. Although we are not a borrower or party to any financial instruments with any financial institution currently in receivership, if any of our lenders or counterparties to any such instruments were to be placed into receivership, we may be unable to access such funds.

Although we assess our banking 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 which 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;
- loss of access to revolving existing credit facilities or other working capital sources and/or the inability to refund, roll over or extend the maturity of, or enter into new credit facilities or other working capital resources;
- potential or actual breach of contractual obligations that require us to maintain letters or credit or other credit support arrangements;
- potential or actual breach of financial covenants in our credit agreements or credit arrangements;
- potential or actual cross-defaults in other credit agreements, credit arrangements or operating or financing agreements; or
- termination of cash management arrangements and/or delays in accessing or actual loss of funds subject to cash management arrangements.

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 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 material adverse impacts on our business.

The terms of our loan agreement place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our operating and financial flexibility.

On December 20, 2024 (the SVB Loan Effective Date), we entered into a Loan and Security Agreement (SVB Loan Agreement) with Silicon Valley Bank, a division of First-Citizens Bank & Trust Company (SVB), pursuant to which, SVB will extend up to $52.5 million in a term loan facility, of which $32.5 million was fully funded at the SVB Loan Effective Date. A second tranche of $20.0 million was available to us at SVB's sole discretion on or prior to June 30, 2026. We did not draw the second tranche prior to June 30, 2026, and the second tranche is no longer available. Our obligations under the SVB Loan Agreement, are secured by a first-priority security interest on substantially all of our assets (other than intellectual property), subject to certain exceptions and will be guaranteed by each of our future direct or indirect subsidiaries, subject to certain exceptions. The SVB Loan Agreement contains customary representations and warranties, events of default and affirmative and negative covenants, including covenants that limit or restrict our and our subsidiaries' ability to, among other things, dispose of assets, make changes to its business, management, ownership or business locations, merge or consolidate, incur additional indebtedness, grant liens on its assets, pay dividends or other distributions, repurchase equity, make investments, and enter into certain transactions with affiliates, in each case subject to certain thresholds and exceptions. The SVB Loan Agreement does not require us to comply with a financial maintenance covenant. Upon the occurrence of an event of default, a default interest rate of an additional 3% may be applied to the outstanding loan balance at the sole discretion of SVB and SVB may declare all outstanding obligations immediately due and payable and exercise all of its rights and remedies as set forth in the SVB Loan Agreement and under applicable law. Any declaration by SVB of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline. We may not have enough available cash or be able to raise additional funds through equity or debt financings to repay these outstanding obligations at the time any event of default occurs. Further, if we raise any additional capital through debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

We have recently reduced the size of our organization, and we may encounter difficulties in managing this development and our strategic prioritization, which could disrupt our operations. In addition, we may not achieve the anticipated benefits and savings from our workforce reductions.

On November 3, 2025, the Company announced a prioritization strategy and pursuant to this strategy, the Company also implemented a workforce reduction of approximately 30%, or 66 roles. More recently, on September 2, 2026, the Company announced a prioritization strategy by which the Company is prioritizing the nonclinical development of its *in vivo* solid tumor program and pausing further enrollment in its Phase 3 ALLOHA-2™ study of TSC-101, and, pursuant to such strategy, implemented a workforce reduction of approximately 75% of the Company's workforce. These workforce reductions have resulted in the loss of longer-term employees, the loss of certain institutional knowledge and expertise and the reallocation and combination of certain roles and responsibilities across the organization, all of which could adversely affect our operations. The restructuring and possible additional cost containment measures may yield unintended consequences, such as attrition beyond our intended workforce reductions and reduced employee morale. In addition, we may not achieve anticipated benefits from these workforce reductions. Due to our limited resources, we may not be able to effectively manage our operations or recruit and retain qualified personnel, which may result in weaknesses in our infrastructure and operations, further loss of employees and reduced productivity among remaining employees. If our management is unable to effectively manage this transition and these workforce reductions and additional cost containment measures, our expenses may be more than expected and we may not be able to implement our business strategy. As a result, our future financial performance and our ability to commercialize our future product candidates successfully could be negatively affected.

Risks Related to the Development of Our Product Candidates

Our approach to the discovery and development of product candidates based on our proprietary platform represents a novel approach to cancer treatment, which creates significant challenges for us.

Our future success depends on the successful development of our product candidates, which target solid tumors and heme malignancies utilizing TCR-T therapy product candidates. Advancing our product candidates creates significant challenges for us, including:

- educating medical personnel about the administration of TCR-T therapy product candidates on a stand-alone basis or in combination with built-in immune and tumor modulators;
- educating medical personnel regarding the potential side effect profiles related to our product candidates, such as the potential adverse side effects related to cytokine release syndrome, graft vs host disease (GvHD), neurotoxicity or autoimmune or rheumatologic disorders, which are the most common adverse side effects associated with engineered T cell therapies;
- administering chemotherapy to patients in advance of administering our product candidates, which may increase the risk of adverse side effects;
- sourcing clinical and, if licensed, commercial, supplies for the materials used to manufacture and process our product candidates;
- manufacturing TCR-T therapy product candidates efficiently and consistently without the use of viral vectors using our T-Integrate technology;
- developing a complete shipment lifecycle and supply chain, including efficiently managing the shipment of patient cells from and to clinical sites, minimizing potential contamination to the cell product and effectively scaling manufacturing capacity to meet demand;
- developing processes suitable for clinical manufacturing and obtaining related CMC regulatory approvals;
- managing costs of inputs and other supplies while scaling production;
- using medicines to manage adverse side effects of our product candidates, which may not adequately control the side effects and/or may have a detrimental impact on the potency of our product candidates;
- using medicines to manage adverse side effects of chemotherapy and/or allogeneic stem cell transplantation, used prior to the administration of our product candidates, which may not adequately control the side effects and/or may have a detrimental impact on the potency of our product candidates;
- obtaining and maintaining regulatory approval from the FDA or comparable foreign regulatory authority for our product candidates; and
- establishing sales and marketing capabilities upon obtaining any regulatory approval to gain market acceptance of a novel therapy.

In developing our product candidates, we have not exhaustively explored different options in the design of the TCR construct and in the methods for manufacturing TCR-T therapies. We may find that our existing TCR-T therapy product candidates and manufacturing process may be substantially improved with future design or process changes, necessitating development of new or additional TCR constructs and further clinical testing, which may delay the commercial launch of our product candidates. For example:

- We have made several TCR constructs and used preclinical studies to select product candidates to advance into clinical trials. The preclinical studies are limited in their ability to predict behavior in patients. As we gain experience working with TCR constructs, we may decide to select other TCR constructs for clinical development.
- The process by which patient cells are converted into a TCR-T therapy product candidate has many steps that can influence quality and activity.
- Our efforts to develop an *in vivo* engineering platform for TCR-T therapies for solid tumors are at a very early stage, and it may take substantial time and investment for us to develop this novel capability, and we may not ultimately be successful in doing so.

We have explored a subset of variables and expect to continue to improve and optimize the manufacturing process. Depending upon the nature of the process changes, we may be compelled to perform bridging studies and/or to re-start clinical development, causing delays in time to market and potentially introducing a risk of failure if new processes do not perform as expected.

We are early in our development efforts. If we are unable to advance our product candidates through clinical development, obtain regulatory approval and ultimately commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.

We are early in our development efforts. We have initiated clinical trials for some of our product candidates, and other product candidates are still in preclinical development. Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend significantly on the successful development and eventual commercialization of one or more of our product candidates. The success of our product candidates will depend on several factors, including the following:

- successful development of a process suitable for clinical manufacturing;
- successful completion of preclinical studies;
- successful initiation of clinical trials;
- successful patient enrollment in and completion of clinical trials;
- receipt and related terms of marketing approvals and licensures from applicable regulatory authorities;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- making arrangements with third-party manufacturers, or expanding our manufacturing capabilities, for both clinical and commercial supplies of our product candidates;
- establishing sales, marketing and distribution capabilities and launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others;
- acceptance of our product candidates, if and when approved, by patients, the medical community and third-party payors;
- obtaining and maintaining third-party coverage and adequate reimbursement;
- maintaining a continued acceptable safety profile of our product candidates following licensure; and
- effectively competing with other therapies including other cancer therapies.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or be unable to successfully commercialize our product candidates, which would materially harm our business.

Although many of our personnel have extensive experience in clinical development at other companies, we have limited direct experience as a company in conducting and completing clinical trials and managing a manufacturing facility for our product candidates.

Although many of our personnel have extensive experience in clinical development and manufacturing at other companies, we have limited experience as a company in conducting and completing clinical trials at TScan. In part because of this lack of experience, we cannot be certain that our ongoing preclinical studies or clinical trials will be completed on time or that the planned preclinical studies and clinical trials will begin or be completed on time, if at all. Large-scale clinical trials would require significant additional financial and management resources and reliance on third-party clinical investigators, contract research organizations (CROs) and consultants. Relying on third-party clinical investigators, CROs and consultants may force us to encounter delays that are outside of our control.

Although we have expanded our existing cell manufacturing facility, we have limited direct experience as a company in expanding or managing a manufacturing facility. In part because of this lack of experience, we cannot be certain that any further expansion of our existing manufacturing facility will be completed on time, if at all, or if the planned clinical trials will begin or be completed on time, if at all. In part because of our limited experience, we may have unacceptable or inconsistent product quality success rates and yields, and we may be unable to maintain adequate quality control, quality assurance and qualified personnel. In addition, when we switch from manufacturing in our own facility to manufacturing in a different facility (for example, at an external CDMO) for one or more of our product candidates or make changes to our manufacturing process, we may need to conduct additional preclinical studies to bridge our modified product candidates to earlier versions. Failure to successfully further expand our existing manufacturing capabilities could adversely affect our process and clinical development timelines, regulatory approvals, and the commercial viability of our product candidates.

Our business is highly dependent on our current product candidates, and we must complete IND-enabling studies and clinical testing before we can seek regulatory approval and begin commercialization of any of our product candidates.

There is no guarantee that any of our product candidates will proceed through preclinical or clinical development or achieve regulatory approval. The process for obtaining marketing approval for any product candidate is very long and risky and there will be significant challenges for us to address in order to obtain marketing approval as planned, if at all.

There is no guarantee that the results obtained in current and planned preclinical studies or clinical trials of our current or future product candidates will be sufficient to obtain regulatory approval or marketing authorization for such product candidates. Negative results in the development of our lead product candidates may also impact our ability to obtain regulatory approval for our other product candidates, either at all or within anticipated timeframes because, although other product candidates may target different indications, the underlying proprietary platform, manufacturing process and development process is the same for all of our product candidates. Accordingly, a failure in any one of our programs may affect the ability to obtain regulatory approval to continue or conduct clinical programs for other product candidates.

In addition, because we have limited financial and personnel resources and are placing significant focus on the development of our lead product candidates, we may forgo or delay pursuit of opportunities with other future product candidates that later prove to have greater commercial potential. Our resource allocation decisions, including our recent reprioritization of our pipeline, may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and other future product candidates for specific indications may not yield any commercially viable future product candidates. If we do not accurately evaluate the commercial potential or target market for a particular current or future product candidate, we may relinquish valuable rights to those product candidates through collaborations, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidates.

Our preclinical studies and clinical trials may fail to demonstrate adequately the safety, potency and purity of any of our product candidates, which would prevent or delay development, regulatory approval and commercialization.

Before obtaining regulatory approvals for the commercial sale of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical studies and clinical trials that our product candidates are both safe and effective for use in each target indication. Preclinical and clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the preclinical study and clinical trial processes, and, because our product candidates are in an early stage of development, there is a high risk of failure, and we may never succeed in developing marketable products.

The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through preclinical studies and clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety, potency and purity profile despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biotechnology industry have suffered significant setbacks in advanced clinical trials due to lack of potency or efficacy, insufficient durability of potency or efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that commence preclinical studies and clinical trials are never approved as products.

Any preclinical studies or clinical trials that we may conduct may not demonstrate the safety, potency and purity necessary to obtain regulatory approval to market our product candidates. If the results of our ongoing or future preclinical studies and clinical trials are inconclusive with respect to the safety, potency and purity of our product candidates, if we do not meet the clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with our product candidates, we may be prevented or delayed in obtaining marketing approval for such product candidates. In some instances, there can be significant variability in safety, potency or purity results between different preclinical studies and clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants.

Clinical development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future clinical trial results. If our preclinical studies and clinical trials are not sufficient to support regulatory approval of any of our product candidates, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development of such product candidate.

We cannot be certain that our ongoing and future preclinical study and clinical trial results will be sufficient to support regulatory approval of our product candidates. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Human clinical trials are expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. Failure or delay can occur at any time during the clinical trial process.

We may experience delays in obtaining the FDA's clearance to initiate clinical trials under future IND applications, completing ongoing preclinical studies of our other product candidates, and initiating or completing our planned preclinical studies and clinical trials. Additionally, we cannot be certain that preclinical studies or clinical trials for our product candidates will begin on time, not require redesign, enroll an adequate number of subjects on time, or be completed on schedule, if at all. Clinical trials can be delayed or terminated for a variety of reasons, including delays or failures related to:

- the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical trials;
- delays in obtaining regulatory approval to commence a clinical trial;
- reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- obtaining institutional review board (IRB) approval at each clinical trial site;
- recruiting or retaining an adequate number of suitable patients to participate in a clinical trial;
- having subjects complete a clinical trial or return for post-treatment follow-up;
- clinical trial sites deviating from the approved clinical trial protocol or dropping out of a clinical trial;
- addressing subject safety concerns that arise during the course of a clinical trial;
- adding a sufficient number of clinical trial sites; or
- obtaining sufficient product supply of product candidate for use in preclinical studies or clinical trials from third-party suppliers.

We may experience numerous adverse or unforeseen events during, or because of preclinical studies and clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- we may receive feedback from regulatory authorities that requires us to modify the design of our clinical trials;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon our research efforts for our other product candidates;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of our clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements, fail to maintain adequate quality controls or be unable to provide us with sufficient product supply to conduct and complete preclinical studies or clinical trials of our product candidates in a timely manner, or at all;
- we or our investigators might have to suspend or terminate clinical trials of our product candidates for various reasons, including non-compliance with regulatory requirements, a finding that our product candidates have undesirable side effects or other unexpected characteristics or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- any public health crises may hinder our development or commercialization activities;
- the quality of our product candidates or other materials necessary to conduct preclinical studies or clinical trials of our product candidates may be insufficient or inadequate;
- regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate; and
- our current or future collaborators may conduct clinical trials in ways they view as advantageous to them but that are suboptimal for us.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only moderately positive or if there are safety concerns, our business and results of operations may be adversely affected and we may incur significant additional costs. Accordingly, our clinical trial costs are likely to be significantly higher than those for more conventional therapeutic technologies or drug product candidates.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such clinical trials are being conducted, by the data safety monitoring board for such clinical trial or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical trial protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from the product candidates, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

If we experience delays in the completion, or termination, of any preclinical study or clinical trial of our product candidates, the commercial prospects of our product candidates may be harmed, and our ability to generate revenues from any of these product candidates will be delayed or not realized at all. In addition, any delays in completing our preclinical studies or clinical trials may increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

Our business could be adversely affected by the effects of health epidemics in regions where we, our partners or other third parties on which we rely have significant manufacturing facilities, concentrations of potential clinical trial sites or other business operations.

Public health crises such as pandemics, epidemics, or similar outbreaks could adversely impact our business. For example, our materials suppliers could be disrupted by conditions related to epidemics, possibly resulting in disruption to our supply chain. If our suppliers are unable or fail to fulfill their obligations to us for any reason, we may not be able to manufacture our products and satisfy customer demand or our obligations under sales agreements in a timely manner, and our business could be harmed as a result. Even when such public health crises are largely resolved, the lingering effects of such crises may continue to adversely affect our business operations, and the extent of the impact on our development and regulatory efforts and the future value of and market for our common stock will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time.

We may rely on third parties to manufacture our clinical product supplies, and we may rely on third parties to produce and process our product candidates, if licensed.

We have established facilities and engaged third-party contract manufacturers to manufacture our current product candidates. We rely on outside vendors to manufacture supplies for our manufacturing process, and we expect to rely on outside vendors to help us manufacture our product candidates for registration-enabling clinical trials as well as commercial sales. We have not yet manufactured or processed any product candidates on a commercial scale and may not be able to do so. We plan to optimize the existing manufacturing process to support product commercialization. The process modifications we intend to introduce will require regulatory approval of our product candidates, which could delay the commercialization of the products. We cannot be sure that such changes in the process will result in therapies that are efficacious and viable for commercial sale. In addition, changes in the manufacturing process may result in the need to conduct additional bridging clinical trials to demonstrate product comparability.

The facilities used by us or any third-party contract manufacturers to manufacture and commercialize our product candidates must be approved by the FDA or other foreign regulatory authorities following inspections that will be conducted after we submit a Biologics License Application (BLA) to the FDA or other foreign regulatory authorities to support commercialization. We may not control the manufacturing process of, and may be completely dependent on, third-party contract manufacturing partners for compliance with cGMPs and any other regulatory requirements of the FDA or other regulatory authorities for the manufacture of our product candidates. We have limited control over the ability of any third-party contract manufacturers we engage to maintain adequate quality control, quality assurance and qualified personnel. Even with oversight, the third party may not be able to meet proper quality standards or its contractual obligations. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if licensed.

We, and any third-party contract manufacturers we engage to support our clinical trials, may experience manufacturing difficulties due to limited manufacturing experience, resource constraints or as a result of labor disputes, geopolitical and economic tensions with China, including as a result of the escalation of tariffs or other trade restrictions under the Trump administration, or unstable political environments. The pharmaceutical industry in general, and our suppliers or other third parties on which we rely, may depend on China-based suppliers for certain raw materials, products and services, or other activities. If we or our suppliers are unable to depend on these China-based suppliers or service providers, we may not be able to engage a backup or alternative supplier in a timely manner or at all. This, in turn, could materially and adversely affect our or our suppliers' ability to manufacture or supply products and product candidates which could materially and adversely affect our business. If we or any third-party contract manufacturers we engage were to encounter

any of these difficulties, our ability to manufacture sufficient product supply for our preclinical studies and clinical trials, or to provide products for patients once approved, would be jeopardized.

Many of the materials and regents we expect to use in our processes are single or sole source, and/or have limited stability and as such supply disruptions could materially impact our ability to develop or manufacture products. In addition, certain cell processing equipment, consumables and tubing used in our current manufacturing process are sourced from a single supplier or are otherwise available from a limited number of suppliers. Any interruption in the supply by those single source suppliers could impact our ability to continue development of any and all of our product candidates on the anticipated timelines or at all. We may be unable to obtain these materials and products for an indeterminate period of time if any of these third parties were to cease or interrupt production or otherwise fail to supply these materials or products to us for any reason, including due to regulatory requirements or actions (including recalls), adverse financial developments at or affecting the supplier, or labor shortages or disputes. Regional or single-source dependencies may in some cases accentuate these risks.

We cannot guarantee that our product candidates will show any functionality in the solid tumor microenvironment.

We cannot guarantee that our solid tumor product candidates will show any functionality in the solid tumor microenvironment. The cellular environment in which solid tumor cells thrive is generally hostile to T cells due to factors such as the presence of immunosuppressive cells, humoral factors and limited access to nutrients. Our TCR-T-based product candidates may not be able to access the solid tumor, and even if they do, they may not be able to exert anti-tumor effects in a hostile solid tumor microenvironment. As a result, we have recently decided to focus on developing an *in vivo* engineering platform for TCR-T product candidates for solid tumors, and our efforts are at a very early stage. Therefore, we do not yet know whether this platform will yield viable product candidates with the potential to demonstrate potency in solid tumors. If we are unable to make our product candidates function in solid tumors, our development plans and business may be significantly harmed.

Since the number of patients that we plan to dose in our initial clinical trials may be small, the results from such clinical trial, once completed, may be less reliable than results achieved in larger clinical trials, which may hinder our efforts to obtain regulatory approval for our product candidates.

The preliminary results of clinical trials with smaller sample sizes can be disproportionately influenced by various biases associated with the conduct of small clinical trials, such as the potential failure of the smaller sample size to accurately depict the features of the broader patient population, which limits the ability to generalize the results across a broader community, thus making the clinical trial results less reliable than clinical trials with a larger number of patients. As a result, there may be less certainty that such product candidates would achieve a statistically significant effect in any future clinical trials. If we conduct any future clinical trials, we may not achieve a statistically significant result or the same level of statistical significance, if any, that we might have anticipated based on the results observed in our initial clinical trials. In addition, patients who are undergoing allogeneic HCT are very sick and may pass away from complications of their standard clinical transplantation and treatments thus making it difficult to ascertain the beneficial effects of the added T cell therapy. Further, toxicities of the T cell therapy may be difficult to distinguish from the toxicity of the transplantation itself.

Allogeneic HCT is a high-risk procedure that may result in complications or adverse events for patients in our clinical trials including those unrelated to the use of our product candidates.

Stem cell transplantation can cure patients across multiple diseases, but its use carries with it risks of toxicity, serious adverse events and death. Because many therapies are used to prepare or treat patients undergoing allogeneic HCT, patients in our clinical trials or patients that use any of our product candidates may be subject to many of the risks that are currently inherent to this procedure. In particular, stem cell transplant involves certain known potential post-procedure complications that may manifest several weeks or months after a transplant and which may be more common in certain patient populations. For example, autoimmune cytopenia is a known and severe frequent complication of the transplant procedure in certain patients, that can result in death. If these or other serious adverse events, undesirable side effects, or unexpected characteristics are identified during the development of any of our product candidates, we may need to limit, delay or abandon our further clinical development of those product candidates, even if such events, effects or characteristics were the result of stem cell transplant or related procedures generally, and not directly or specifically caused or exacerbated by our product candidates. All serious adverse events or unexpected side effects are continually monitored per the clinical trial's approved protocol. If serious adverse events are determined to be directly or specifically caused or exacerbated by our hematology product candidates, we would follow the clinical trial protocol's requirements, which call for our data safety monitoring committee to review all available clinical data in making a recommendation regarding the trial's continuation.

We may not be able to file IND applications or IND amendments to commence additional clinical trials on the timelines we expect, and even if we are able to, the FDA may not permit us to proceed on the timelines we expect, or at all.

We have initiated clinical trials for some of our product candidates and we expect to submit additional IND applications for our current programs. However, we may not be able to file such IND application on the timelines we expect. For example, we may experience manufacturing delays or other delays with IND-enabling studies. Moreover, we cannot be sure that submission of an IND application will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate clinical trials. Additionally, even if such regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND application, we cannot guarantee that such regulatory authorities will not change their requirements in the future. These considerations also apply to new clinical trials we may submit as amendments to existing IND applications.

In addition, we are planning to develop treatments consisting of a combination of TCR-Ts, which we refer to as multiplex TCR-T. Our plan is to assess the safety and preliminary efficacy of multiplex TCR-T early in the clinical development of our product candidates. While our experience with our T-Plex IND shows that the FDA may clear an IND application, which allows us to combine our product candidates with each other in a multiplex TCR-T, we must still provide safety data for each individual product candidate or each variation or combination of a multiplex TCR-T. Any such requirements could result in material delays in the development timelines of our multiplex TCR-T therapy product candidates.

Our product candidates may cause undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, require expansion of the trial size, limit their commercial potential, or result in other significant negative consequences.

Undesirable side effects caused by our product candidates could cause us or regulatory authorities, including IRBs, to interrupt, delay, or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authorities. Further, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of subjects and limited duration of exposure, rare and severe side effects of our product candidates may only be uncovered with a significantly larger number of patients exposed to the drug. Because of the design of the dose escalation of our planned clinical trials, undesirable side effects could also result in an expansion in the size of our clinical trials, increasing the expected costs and timeline of our clinical trials. Additionally, results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics, which may stem from our therapies specifically or may be due to an illness from which the clinical trial subject is suffering.

For example, there could be an increased risk of GvHD with our TCR-T therapy product candidates in the post-HCT setting. GvHD is a common toxicity in patients undergoing allogeneic HCT, the focus of our heme malignancies program. GvHD occurs because donor T cells, which are part of the standard stem cell product, misrecognize antigens in the patient as foreign and attack tissues and organs that express those antigens. GvHD may be worsened by our TCR-T therapy product candidates because they are derived from donor T cells. While the engineered T cells express a new TCR that is specific for the intended target antigen and is not expected to cause GvHD, those T cells may have low levels of endogenous TCR that have the potential to misrecognize patient antigens as foreign and worsen GvHD.

In solid tumor patients, autoimmunity may occur after TCR-T treatment. TCR-T therapies are generated from a patient's own T cells isolated from their peripheral blood. There is a risk that this process will expand a patient's own T cells that have autoreactivity, or that may recognize healthy cells, and upon re-infusion may trigger an autoimmune reaction resulting in damage to normal tissues and potentially even death.

Autoimmune reaction triggered by an interaction between a patient's naturally occurring antibodies and engineered T cells is a theoretical safety risk of product candidates we develop using our proprietary platform. If a patient's self-generated antibodies were directed to a target expressed on the surface of cells in normal tissue (autoantibodies), engineered T cells would be directed to attack these same tissues, potentially resulting in off-tumor effects. These autoantibodies may be present whether or not the patient has an active autoimmune disorder. In our clinical testing, we plan to take steps to minimize the likelihood that this occurs. There is no guarantee, however, that we will be able to implement interventions to address the risk of autoimmune reactions if and when they occur.

In addition, immunogenicity, which is the reaction between a patient's immune system and a foreign protein outside of the autoimmune context, is an additional theoretical safety risk of product candidates we develop using our proprietary platform. Patients' immune systems may recognize the TCR construct on the TCR-T product as a foreign protein and fight against it, potentially rendering it ineffective, or even provoking an allergic/anaphylactoid response or other adverse side effects. The immunogenic potential of novel therapeutics like TCR-T therapies is difficult to predict. There is no guarantee that we will be able to implement interventions to address the risk of observation of immunogenic reactions if and when they occur.

If unacceptable toxicities arise in the development of our product candidates, we could suspend or terminate our clinical trials or the FDA or comparable foreign regulatory authorities, or local regulatory authorities such as IRBs, could order us to cease clinical trials. Competent national health authorities, such as the FDA, could also deny approval of our product candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the clinical trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff, as toxicities resulting from T cell therapy are not normally encountered in the general patient population and by medical personnel. We expect to have to train medical personnel using our product candidates to understand the side effect profile of our product candidates for both our planned clinical trials and upon any commercialization of any product candidates, if licensed. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient deaths. Any of these occurrences may significantly harm our reputation as well as business, financial condition and prospects.

Our product candidates may target healthy cells expressing target antigens leading to potentially fatal adverse effects.

Our product candidates target specific antigens that are also potentially expressed on healthy cells. Our product candidates may target healthy cells, leading to serious and potentially fatal adverse effects. In our planned clinical trials of our product candidates, we plan to use a dose escalation model to closely monitor the effect of our product candidates on vital organs and other potential side effects. Even though we intend to closely monitor the side effects of our product candidates in both preclinical studies and clinical trials, we cannot guarantee that products will not target and kill healthy cells.

Our product candidates may have serious and potentially fatal cross-reactivity to other peptides or protein sequences within the body.

Our product candidates may recognize and bind to a peptide unrelated to the target antigen to which it is designed to bind. If this peptide is expressed within normal tissues, our product candidates may target and kill the normal tissue in a patient, leading to serious and potentially fatal adverse effects. Detection of any cross-reactivity may halt or delay any ongoing clinical trials for any of our TCR-T therapy product candidates and prevent or delay regulatory approval. Unknown cross-reactivity of the TCR-T binding domain to related proteins could also occur. We have also developed a preclinical screening process to identify cross-reactivity of T cell binders. Any cross-reactivity that impacts patient safety could materially impact our ability to advance our product candidates into clinical trials or to proceed to marketing approval and commercialization.

The vectors used to manufacture our TCR-T therapy product candidates may incorrectly modify the genetic material of a patient's T cells, potentially triggering the development of a new cancer or other adverse events.

Our TCR-T therapy product candidates are manufactured by using a vector to insert genetic information encoding the TCR construct into the patient's T cells. The TCR construct is then integrated into the natural TCR complex and transported to the surface of the patient's T cells. Because the vector modifies the genetic information of the T cell, there is a risk that modification will occur in the wrong place in the T cell's genetic code, leading to vector-related insertional oncogenesis, and causing the T cell to become cancerous. If the cancerous T cell is then administered to the patient with the TCR-T therapy product candidates, the cancerous T cell could trigger the development of a new cancer in the patient. We use non-viral transposon/transposase to insert genetic information into T cells. The risk of insertional oncogenesis remains a concern for gene therapy, and we cannot guarantee that it will not occur in any of our ongoing or planned preclinical studies or clinical trials. There is also the potential risk of delayed adverse events following exposure to gene therapy products due to persistent biological activity of the genetic material or other components of vectors used to carry the genetic material. The FDA has stated that vectors possess characteristics that may pose high risks of delayed adverse events. Non-viral transposon/transposase systems have limited clinical history, and their safety profile is still to be determined. If any such adverse events occur, further advancement of our preclinical studies or clinical trials could be halted or delayed, which would have a material adverse effect on our business and operations.

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

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their approved protocols depends on, among other things, 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 criteria defined in the clinical trial protocol, particularly those who meet the requisite genetic criteria;
- for our heme malignancies program, the ability to find a donor who must be mismatched with the patient either for the HLA type or the antigen type to ensure that the engineered T cell therapy does not recognize donor-derived blood cells;
- any impact of public health crises on clinical trial initiation and enrollment;
- the size of the patient population required for analysis of the clinical trial's primary endpoints;

- 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;
- our ability to obtain and maintain patient consents;
- reporting of the preliminary results of any of our clinical trials;
- risk that patients enrolled in clinical trials will drop out of the clinical trial or pass away from disease-related complications or complications from their standard clinical therapy before they can experience benefits of the engineered T cell therapy;
- the need to obtain sufficient T cells from the patient or allogeneic donor in order for the engineered T cell product to be manufactured; and
- our ability to produce sufficient TCR-T product to meet the dosing requirements of the clinical studies.

In addition, our clinical trials will 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 at such clinical trial sites. Moreover, because our product candidates represent a departure from more commonly used methods for cancer treatment, potential patients and their doctors may be inclined to use conventional therapies, such as chemotherapy and HCT, rather than enroll patients in any future clinical trial. Additionally, because some of our clinical trials are expected to be in patients with relapsed/refractory cancer, the patients are typically in the late stages of their disease and may experience disease progression independent from our product candidates, making them unevaluable for purposes of the clinical trial and requiring additional patient enrollment.

Delays in completing patient enrollment may result in increased costs or may affect the timing or outcome of our ongoing and planned clinical trials, which could prevent completion or commencement of these clinical trials and adversely affect our ability to advance the development of our product candidates.

Research and development of biotechnology products is inherently risky. We may not be successful in our efforts to use and enhance our target discovery platform and TCR technologies to create a pipeline of product candidates and develop commercially successful products, or we may expend our limited resources on programs that do not yield a successful product candidate and fail to capitalize on product candidates or diseases that may be more profitable or for which there is a greater likelihood of success. If we fail to develop additional product candidates, our commercial opportunity will be limited.

We are at an early stage of development, and our target discovery platform has not yet led, and may never lead, to approved or commercially successful products. All our current product candidates are being developed by leveraging the same or similar underlying proprietary platform, manufacturing process and development program. As a result, an issue with one product candidate or failure of any one program to obtain regulatory approval could lead to a failure of our entire pipeline of product candidates.

Even if we are successful in continuing to build our pipeline, obtaining regulatory approvals and commercializing additional product candidates may require substantial additional funding and are prone to the risks of failure inherent in biotechnology product development.

Investment in biotechnology product development involves 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. We cannot provide any assurance that we will be able to successfully advance any of these additional product candidates through the development process. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development or commercialization for many reasons, including the following:

- our research methodology, including our screening technology, may not successfully identify additional product candidates;
- our pursuit of difficult-to-drug targets may make it challenging to design potential product candidates;
- results of clinical trials conducted by others on similar indications or on compounds with similar mechanisms of action could result in our having to conduct additional or cost prohibitive clinical trials, which could delay development and possibly make commercialization prohibitively expensive;

- we may encounter product manufacturing difficulties that limit yield, produce undesirable characteristics, that increase the cost of goods, cause delays, or make the product candidates unmarketable;
- our product candidates may cause adverse effects in patients or subjects, even after successful initial toxicology studies, which may make the product candidates unmarketable;
- our product candidates may not demonstrate a meaningful benefit to patients or subjects; and
- our collaboration partners may change their development profiles or plans for potential product candidates or abandon a therapeutic area or the development of a partnered product.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs, which would have a material adverse effect on our business, operating results and prospects and could potentially cause us to cease operations. Research programs to identify new product candidates require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful.

If we are unable to identify suitable compounds for preclinical and clinical development, we will not be able to obtain revenues from the sale of drugs in future periods, which likely would result in significant harm to our business prospects and financial position.

The market opportunities for our product candidates may be relatively small. In addition, our estimates of the prevalence of our target patient populations may be inaccurate.

Cancer therapies are sometimes characterized as first line, second line, or third line, and the FDA often approves new therapies initially only for a particular line of use. When cancer is detected early enough, first-line therapy is sometimes adequate to cure the cancer or prolong life without a cure. Whenever first-line therapy, usually chemotherapy, antibody drugs, tumor-targeted small molecules, hormone therapy, radiation therapy, surgery, or a combination of these, proves unsuccessful (refractory disease) or the cancer returns after a disease-free interval (relapsed disease), subsequent lines of therapy may be required to manage the disease and/or disease-related side-effects. For our solid tumor product candidates, we expect to initially seek approval in patients with a history of relapsed disease or refractory disease. For those product candidates that prove to be sufficiently safe and beneficial, if any, we would expect to seek approval in earlier lines of therapy, as appropriate, but there is no guarantee that our product candidates would be licensed for an earlier line of therapy, and, prior to any such approvals, we may have to conduct additional clinical trials. We expect to initially seek approval for use of our TCR-T therapy product candidates to treat patients with heme malignancies, including acute myeloid leukemia (AML) and myelodysplastic syndromes (MDS) who are undergoing allogeneic HCT. While HCT provides a potentially curable option for patients with intermediate and high-risk disease, disease relapse remains the main cause of treatment failure and constitutes a significant unmet medical need. Consequently, the potentially addressable patient population for our product candidates may be extremely limited or may not be amenable to treatment with our product candidates.

Our projections of both the number of people who have the cancers we are targeting, as well as the subset of people with these cancers in a position to receive a particular line or type of therapy and who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations or market research, and may prove to be incorrect. Further, new therapies may change the estimated incidence or prevalence of the cancers that we are targeting. Consequently, even if our product candidates are approved, the number of patients that may be eligible for treatment with our product candidates may turn out to be much lower than expected.

Our product candidates rely on the use of protein binding domains, or binders, to target specific cancers, which we may develop, or which may be developed by third parties. We are limited in our ability to apply our product candidates to a wider range of potential target cancers by our ability to develop, partner for or acquire these binders on commercially reasonable terms.

TCR-T therapies require the use of antigen-specific protein binding domains (binders) which guide the TCR-Ts and bind to the antigens on the surface of a tumor to target specific types of cancers. Our ability to develop and commercialize our product candidates will depend on our ability to develop these binders or partner for such binders on commercially reasonable terms for use in clinical trials as well as the availability of such binders for use in commercialized products, if licensed. We cannot ensure that we will have a steady supply of binders that we can utilize in combination with the TCR construct to develop our product candidates. If we are unable to enter into such collaborations on commercially reasonable terms or fail to realize the benefits of any such collaboration, we may be limited to using antibody fragments that we are able to independently develop which may limit the ability of our product candidates to target and kill cancer cells.

The failure to enter into a successful collaboration or to develop our own binders may delay our development timelines, increase our costs and jeopardize our ability to develop future product candidates as a commercially viable drug, which could result in delays in product development and harm our business.

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

We currently have no sales, marketing or distribution capabilities and have no experience as a company in marketing products. We intend to develop an in-house marketing organization and sales force, which will require significant capital expenditures, management resources and time. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel.

If we are unable or decide not to establish internal sales, marketing and distribution capabilities, we will pursue collaborative arrangements regarding the sales and marketing of our product candidates, if licensed. However, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if we are able to do so, that they will have effective sales forces. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We may also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates.

There can be no assurance that we will be able to develop in-house sales and distribution capabilities or establish or maintain relationships with third-party collaborators to commercialize any product in the U.S. or overseas.

Even if we obtain regulatory approval of our product candidates, the products may not gain market acceptance among physicians, patients, hospitals, cancer treatment centers and others in the medical community.

The use of engineered T cells as a potential cancer treatment is a recent development and may not become broadly accepted by physicians, patients, hospitals, cancer treatment centers and others in the medical community. Various factors will influence whether our product candidates are accepted in the market, including:

- the clinical indications for which our product candidates are licensed;
- physicians, hospitals, cancer treatment centers and patients considering our product candidates as a safe and effective treatment;
- the potential and perceived advantages of our product candidates over alternative treatments;
- our ability to demonstrate the advantages of our product candidates over other TCR-T therapies;
- the prevalence and severity of any side effects;
- the prevalence and severity of any side effects for other adoptive cell therapies, TCR-T therapies and public perception of other adoptive cell therapies and TCR-T therapies;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA;
- the timing of market introduction of our product candidates as well as competitive products;
- the cost of treatment in relation to alternative treatments;
- the availability of adequate coverage, reimbursement and pricing by third-party payors and government authorities;
- willingness of patients to pay out-of-pocket in the absence of coverage by third-party payors and government authorities;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts.

In addition, although we are not utilizing embryonic stem cells or replication competent vectors, adverse publicity due to the ethical and social controversies surrounding the therapeutic use of such technologies, and reported side effects from any clinical trials using these technologies or the failure of such clinical trials to demonstrate that these therapies are safe and effective may limit market acceptance of our product candidates. If our product candidates are licensed but fail to achieve market acceptance among physicians, patients, hospitals, cancer treatment centers or others in the medical community, we will not be able to generate significant revenue.

In addition, although our product candidates differ in certain ways from other TCR-T therapy approaches, serious adverse events or deaths in other clinical trials involving engineered TCR, or other T cell products or with our use of licensed TCR-T therapy candidates, even if not ultimately attributable to our product candidates, could negatively impact our business.

Even if our product candidates achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our product candidates, are more cost effective or render our product candidates obsolete.

A variety of risks associated with marketing our product candidates internationally could materially adversely affect our business.

We plan to seek regulatory approval of our product candidates outside of the U.S. and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including:

- differing regulatory requirements in foreign countries;
- unexpected changes in tariffs (including tariffs that have been or may in the future be imposed by the U.S. or other countries), trade barriers (including further legislation or actions taken by the U.S. or other countries that restrict trade), price and exchange controls and other regulatory requirements;
- 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 U.S.;
- potential liability under the Foreign Corrupt Practices Act of 1977 or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the U.S.;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with international operations may materially adversely affect our ability to attain or maintain profitable operations.

We face significant competition, and our operating results will suffer if we fail to compete effectively.

The biotechnology industry is characterized by intense competition and rapid innovation. Our competitors may be able to develop other products or drugs that are able to achieve similar or better results. Our potential competitors include larger biotechnology and pharmaceutical companies with greater resources than us, academic institutions, governmental agencies, public and private research institutions and early stage or smaller companies. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff, experienced marketing and manufacturing organizations and well-established sales forces. Further, our competitors may have more financial resources, greater access to capital and diversified product offerings and revenue sources, which may give our competitors an advantage over us. In addition, many of these competitors are active in seeking patent protection and licensing arrangements in anticipation of collecting royalties for use of technology that they have developed. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors, either alone or with collaborative partners, may succeed in developing, acquiring or licensing on an exclusive basis drug or biologic products that are more effective, safer, more easily commercialized or less costly than our product candidates or may develop proprietary technologies or secure patent protection that we may need for the development of our technologies and products. We believe the key competitive factors that will affect the development and commercial success of our product candidates are safety, potency, purity, tolerability, reliability, convenience of use, price and reimbursement.

Specifically, by genetically engineering T cell therapies, we face significant competition in the T cell immunotherapy space from many companies. For additional information regarding our competition, see “Item 1. Business – Competition” in our Annual Report on Form 10-K filed with the SEC on March 4, 2026. Even if we obtain regulatory approval of our product candidates, the availability and

price of our competitors' products could limit the demand and the price we are able to charge for our product candidates. We may not be able to implement our business plan if the acceptance of our product candidates is inhibited by price competition or the reluctance of physicians to switch from existing methods of treatment to our product candidates, or if physicians switch to other new drug or biologic products or choose to reserve our product candidates for use in limited circumstances. Moreover, the development and manufacturing costs associated with engineered T cell therapies may make it difficult to compete with alternative products that may be simpler and cheaper to develop and manufacture.

Our internal computer systems, or those used by our third-party CROs, our clinical sites, or other contractors or consultants, may fail or suffer cybersecurity incidents, data breaches or other unauthorized or improper access, which could result in a material disruption of the development programs of our product candidates.

Despite the implementation of security measures, our internal computer systems and those of our current and future CROs, our clinical sites, and other contractors and consultants are vulnerable, and like companies in our industry, we have experienced a variety of disruptions and data privacy and information security threats and incidents. These cyberattacks may include cybersecurity incidents, data breaches, attacks by hackers and other malicious third parties (including the deployment of computer viruses, malware, ransomware, denial-of-service attacks, social engineering fraud (including phishing attacks), and other events that affect service reliability and threaten the confidentiality, integrity, and availability of information), unauthorized access, natural disasters, fires, terrorism, war, telecommunications or electrical interruptions or failures, employee error or malfeasance or other malicious or inadvertent disruptions, including inadvertent or intentional wrongful actions by insider employees and vendors. For example, the ongoing conflict between Russia and Ukraine has led to an increase in cyberattacks on Ukraine, including its government, companies, institutions and people, as well on the financial and communications infrastructure of other countries, companies and individuals therein. Additionally, the increased usage of computers operated on home networks may make our or our partners' systems more susceptible to cybersecurity incidents or data breaches. If any such material system failure, cybersecurity incident, or data breach, were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of data from ongoing or completed or future preclinical studies and clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, similar events relating to the computer systems of our third party vendors or manufacturers could also have a material adverse effect on our business, financial condition, results of operations and prospects. Bad actors around the world use increasingly sophisticated methods, including the use of artificial intelligence, to engage in illegal activities involving the theft and misuse of personal information, confidential information and intellectual property. In addition, the potential or current use of artificial intelligence models in our internal or third-party systems may create new attack surfaces or methods for adversaries, which could impact us and our vendors. Any of these effects could damage our reputation, result in the loss of valuable property and information, cause us to breach applicable laws and regulations, and adversely impact our business.

Unauthorized disclosure of sensitive or confidential data, including personally identifiable information, whether through a cybersecurity incident, data breach, systems failure, employee negligence, fraud or misappropriation, or otherwise, or unauthorized access to or through our information systems and networks, whether by our employees or third parties, could result in negative publicity, legal liability and damage to our reputation. Unauthorized disclosure of personally identifiable information could also expose us to sanctions for violations of data privacy laws and regulations around the world.

As we become more dependent on information technologies to conduct our operations, cybersecurity incidents, including deliberate attacks and attempts to gain unauthorized access to computer systems and networks, may increase in frequency and sophistication. These threats pose a risk to the security of our systems and networks and to the confidentiality, availability and integrity of our data, and these risks apply both to us and to third parties on whose systems we rely for the conduct of our business. Because the techniques used to obtain unauthorized access, disable or degrade service or sabotage systems change frequently and often are not recognized until launched against a target, we and our partners or collaborators may be unable to anticipate these techniques or to implement adequate preventative measures. Further, we do not have any control over the operations of the facilities or technology of our cloud and service providers, including any third-party vendors that collect, process and store personal data on our behalf. Our systems, servers and platforms and those of our service providers may be vulnerable to cybersecurity incidents or data breaches, computer viruses or physical or electronic break-ins that our or their security measures may not detect. Individuals able to circumvent such security measures may misappropriate our confidential or proprietary information, disrupt our operations, damage our computers or otherwise impair our reputation and business. We may need to expend significant resources and make significant capital investments to protect against cybersecurity incidents or data breaches or to mitigate the impact of any such cybersecurity incidents or data breaches. There can be no assurance that we or our third-party providers will be successful in preventing cyber-attacks or successfully mitigating their effects. To the extent that any disruption or cybersecurity incident or data 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 and the further development and commercialization of our product candidates could be delayed.

Cybersecurity incidents, loss of data or modification of information, and other disruptions could compromise information related to our business or prevent us from accessing critical information, result in a significant disruption of our activities and expose us to liability, which could adversely affect our business and our reputation.

In the ordinary course of our business, we collect and store information, including personal information, intellectual property and proprietary business information that we own or control or have an obligation to protect. For example, we collect and store research and development information, employee data, commercial information, customer information and business and financial information. We and our service providers, including security and infrastructure vendors, manage and maintain our data using a combination of on-site systems and cloud-based data centers. We face a number of risks related to protecting critical information, including inappropriate use or disclosure, unauthorized access or acquisition, or inappropriate modification of, critical information. We also face the risk of being unable to access our critical information or technology systems due to actual or threats of ransomware, unauthorized encryption, or other malicious activity. We face the risk of being unable to adequately monitor, audit and modify our controls over our critical information. These risks extend to third-party service providers and subcontractors we use to assist us in managing our information or otherwise process it on our behalf. The secure processing, storage, maintenance and transmission of our critical information is vital to our operations and business strategy, and we devote significant resources to protecting such information.

Although we take reasonable measures to protect critical information and other data from unauthorized access, acquisition, use or disclosure, our information technology and infrastructure and that of our service providers handling and storing information on our behalf may be vulnerable to a variety of disruptions, including cybersecurity incidents, data breaches, attacks by hackers and other malicious third parties (including the deployment of computer viruses, malware, ransomware, denial-of-service attacks, social engineering (including phishing attacks), and other events that affect service reliability and threaten the confidentiality, integrity, and availability of information), unauthorized access, natural disasters, fires, terrorism, war, telecommunications or electrical interruptions or failures, employee error or malfeasance or other malicious or inadvertent disruptions. In particular, the risk of a cybersecurity incident, data breach or disruption, particularly through cyber-attacks or cyber intrusion, has generally increased as the number, intensity, and sophistication of attempted attacks and intrusions from around the world have increased. We may not be able to anticipate all types of security threats, and we may not be able to implement preventive measures that are effective against all such security threats. Because the techniques used by cyber criminals change frequently, may not be recognized until launched, and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates or terrorist organizations, we and our service providers and other partners may be unable to anticipate these techniques or implement adequate preventative measures. Further, we do not have any control over the operations of the facilities or technology of third parties that collect, process and store sensitive information on our behalf. Any unauthorized access or acquisition, cybersecurity incident, data breach, or other loss, of information could result in legal claims or proceedings, and liability under federal, state or foreign laws regarding the privacy and protection of information, including personal information, and could disrupt our operations and harm our reputation. In addition, notice of cybersecurity incidents or data breaches may be required to affected individuals, regulators, credit reporting agencies or the media. Any such publication or notice could harm our reputation and our ability to compete. The financial exposure from the events referenced above could either not be insured against or not be fully covered through any insurance that we may maintain, and there can be no assurance that the limitations of liability in any of our contracts would be enforceable or adequate or would otherwise protect us from liabilities or damages as a result of the events referenced above. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to Manufacturing

Manufacturing and administering our product candidates is complex and we may encounter difficulties in production, particularly with respect to process development or scaling up of our manufacturing capabilities. If we encounter such difficulties, our ability to provide supply of our TCR-T therapy product candidates for clinical trials or, if approved, for commercial purposes, could be delayed or stopped.

The process of manufacturing and administering our product candidates is complex and highly regulated. The manufacture of our product candidates involves complex processes, including the manufacture of a transposon containing the genetic information for our TCR construct, a transposase used to insert the transposon genetic information into the T cell genome, and manufacturing operations to ensure the safety, integrity, strength, sterility, purity, and quality of the final product. As a result of the complexities entailed in this process, our manufacturing and supply costs may be higher than those of more traditional manufacturing processes and the manufacturing process may be less reliable and more difficult to reproduce. Additionally, the number of facilities that are capable of harvesting cells for the manufacture of our product candidates and other cell therapy products and product candidates is limited. As the number of cell therapy products and product candidates increases, the limited number of facilities capable of harvesting cells could result in delays in the manufacture and administration of our product candidates.

We currently rely on third parties for the manufacture of components of our manufacturing process, and we have engaged a global third-party manufacturer to support the manufacture of products for our clinical trials. These third-party manufacturers may incorporate their own proprietary processes into our components. We have limited control and oversight of a third party’s proprietary process, and

a third party may elect to modify its process without our consent or knowledge. These modifications could negatively impact our manufacturing, including product loss or failure that requires additional manufacturing runs or a change in manufacturer, both of which could significantly increase the cost of and significantly delay the manufacture of our product candidates. In addition, we are currently reliant on a single manufacturer for our transposon and transposase components, and many of the critical raw materials and reagents used in the process are single or sole source. These third-party providers may not be able to provide adequate resources, capacity to meet our needs, timely delivery of material, or may change internal processes or specifications that adversely affect our process or product candidates.

Our manufacturing process is and will be susceptible to product loss or failure due to logistical issues, manufacturing issues associated with the differences in patients' white blood cells, interruptions in the manufacturing process or supply chain, contamination, equipment or reagent failure, process design flaws, operator error, power failures, supplier error and variability in patient characteristics. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects, product rejection, or other supply disruptions. If for any reason we lose a patient's white blood cells, such material gets contaminated or processing steps fail at any point, the manufacturing process of the TCR-T therapy product candidate will need to be restarted, if possible, and the resulting delay may adversely affect a patient's outcome. If microbial, viral, or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates or critical raw materials or reagents are made or administered, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination.

As our product candidates progress through preclinical studies and clinical trials towards licensure and commercialization, it is expected that various aspects of the manufacturing and administration process will be altered in an effort to optimize processes and results, for example, our efforts to develop an *in vivo* engineering platform for our solid tumor program. We have already identified some improvements to our manufacturing and administration processes, but these changes may not achieve the intended objectives and could cause our product candidates to perform inadequately affecting the results of ongoing or future clinical trials. In addition, any changes may require amendments to be made to regulatory applications or necessitate development of new or additional TCR constructs and further clinical testing, which may further delay the timeframes under which modified manufacturing processes can be used for any of our product candidates.

Developing a commercially viable process is a difficult and uncertain task, and there are risks associated with scaling to the level required for advanced clinical trials or commercialization, including, among others, increased costs, potential problems with process scale-out or scale-up, process reproducibility, stability issues, lot consistency, facility suitability or capacity, staffing, and availability of reagents or raw materials. Competitors have had difficulty reliably producing T cell therapies in the commercial setting. If we experience similar challenges manufacturing product candidates to approved specifications, this may limit our product candidates' utilization and our ability to receive payment for these product candidates once approved. We may ultimately be unable to reduce the expenses associated with our product candidates to levels that will allow us to achieve a profitable return on investment.

Although many of our personnel have experience in clinical manufacturing at other companies, we have limited experience as a company managing manufacturing for our product candidates, which will be costly, time-consuming, and which may not be successful.

We have limited experience as a company in managing a manufacturing facility or manufacturing suite and may never be successful in managing our own manufacturing suite, manufacturing facility or manufacturing capability. We will need to hire additional personnel to manage our operations and facilities and develop the necessary infrastructure to continue the research and development, and eventual commercialization, if licensed, of our product candidates. If we fail to recruit the required personnel, manage our growth effectively, have inadequate facility design or construction, or fail to select the correct location, the development and production of our product candidates could be curtailed or delayed. Although we have established a manufacturing facility, our manufacturing capabilities could be affected by cost-overruns, unexpected delays, equipment failures, design or construction flaws, labor shortages, supply disruptions, natural disasters, power failures and numerous other factors that could prevent us from realizing the intended benefits of our manufacturing strategy and have a material adverse effect on our business.

In addition, the FDA, competent authorities of the EU Member States, and other foreign regulatory authorities may require us to submit samples of any lot of any licensed product together with the protocols showing the results of applicable tests at any time. Under some circumstances, the FDA, competent authorities of the EU Member States, or other foreign regulatory authorities may require that we not distribute a lot until the relevant agency authorizes its release. Slight deviations in the manufacturing process, including those affecting quality attributes and stability, may result in unacceptable changes in the product that could result in lot failures or product recalls, or inability to manufacture product in the future. Lot failures or product recalls could cause us to delay or forgo product launches or clinical trials, which could be costly to us and otherwise harm our business, financial condition, results of operations and prospects. Problems in our manufacturing process or quality control testing could restrict our ability to meet market demand for our product candidates.

We also may encounter problems hiring and retaining the experienced scientific, quality-control and manufacturing personnel needed to operate our manufacturing processes and facility, which could result in delays in production or difficulties in maintaining compliance with applicable regulatory requirements.

We may have difficulty validating our manufacturing process as we manufacture TCR-T therapy product candidates from an increasingly diverse patient population for our clinical trials.

As we develop our clinical products, we may encounter unforeseen difficulties due to quality, quantity, supply timing, or variability issues with donor starting materials and may not be able to develop a robust process or incur additional costs or delays in developing a robust process due to starting material variation or supply.

Although we believe our current manufacturing process is scalable for commercialization, we may encounter challenges in validating our process due to the heterogeneity of the product starting material. While we anticipate that during the early phases of our clinical trials we will be able to adapt our process to account for these differences resulting in a more robust process, we cannot guarantee that issues relating to the heterogeneity of the starting material will not impact our ability to manufacture our product candidates for clinical or commercial distribution.

Risks Related to Government Regulation

The regulatory approval process is lengthy and time-consuming, and we may experience significant delays in the clinical development and regulatory approval of our product candidates.

We have not previously submitted a BLA to the FDA or similar licensure applications to comparable foreign regulatory authorities. A BLA, or similar licensing application, must include extensive preclinical and clinical data and supporting information to establish the product candidate's safety, purity, and potency for each desired indication and must also include significant information regarding the manufacturing controls for the product. We expect the novel nature of our product candidates to create further challenges in obtaining regulatory approval. Accordingly, the regulatory approval pathway for our product candidates may be uncertain, complex, expensive and lengthy, and licensure may not be obtained.

We may also experience delays in completing planned clinical trials for a variety of reasons, including delays related to:

- the availability of financial resources to commence and complete the planned trials;
- reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- obtaining approval at each clinical trial site by an IRB or ethics committee;
- recruiting suitable patients to participate in a clinical trial;
- having patients complete a clinical trial or return for post-treatment follow-up;
- clinical trial sites deviating from trial protocol or dropping out of a trial;
- adding new clinical trial sites; or
- manufacturing sufficient quantities of qualified materials under cGMPs, including current Good Tissue Practice (cGTPs), and applying them on a subject-by-subject basis for use in clinical trials.

We could also experience delays if physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of our product candidates in lieu of prescribing existing treatments that have established safety, efficacy, potency and purity profiles. Further, a clinical trial may be suspended or terminated by us, the IRBs for the institutions in which such trials are being conducted, the data monitoring committee for such trial, or by the FDA or other regulatory authorities due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience termination of, or delays in the completion of, any clinical trial of our product candidates, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenue will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenue.

Securing regulatory approval also requires the submission of information about the biologic manufacturing process and inspection of manufacturing facilities by the relevant regulatory authority. The FDA or comparable foreign regulatory authorities may fail to approve our manufacturing processes or facilities, whether run by us or our third-party CDMOs. In addition, if we make manufacturing changes to our product candidates in the future, we may need to conduct additional preclinical studies or clinical trials to bridge our modified product candidates to earlier versions.

Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may ultimately lead to the denial of regulatory approval of our product candidates.

We may be unable to obtain regulatory approval for our product candidates under applicable regulatory requirements. The denial or delay of any such approval would delay commercialization of our product candidates and adversely impact our potential to generate revenue, our business and our results of operations.

The research, testing, manufacturing, labeling, licensure, sale, marketing and distribution of biologic products are subject to extensive regulation by the FDA and other regulatory authorities in the U.S. and other countries, and such regulations differ from country to country. We are not permitted to market our product candidates in the U.S. or in any foreign countries until they receive the requisite licensure from the applicable regulatory authorities of such jurisdictions.

The FDA or any foreign regulatory authorities can delay, limit or deny licensure of our product candidates for many reasons, including:

- our inability to demonstrate to the satisfaction of the FDA or the applicable foreign regulatory authority that any of our product candidates are safe, potent and pure;
- the FDA's or the applicable foreign regulatory agency's disagreement with our trial protocol or the interpretation of data from preclinical studies or clinical trials;
- our inability to demonstrate that the clinical and other benefits of any of our product candidates outweigh any safety or other perceived risks;
- the FDA's or the applicable foreign regulatory agency's requirement for additional preclinical studies or clinical trials;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for licensure;
- the FDA's or the applicable foreign regulatory agency's failure to approve our manufacturing processes or facilities or those of third-party manufacturers upon which we rely;
- the potential for approval policies or regulations of the FDA or the applicable foreign regulatory authorities to significantly change in a manner rendering our clinical data insufficient for licensure;
- the data collected from clinical trials of our product candidates may not be sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of a BLA or other comparable submission in foreign jurisdictions or to obtain licensure of our product candidates in the U.S. or elsewhere; or
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Any of these factors, some of which are beyond our control, may result in our failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations, and prospects. Of the large number of biological products in development, only a small percentage successfully complete the FDA or other regulatory approval processes and are commercialized. Even if we eventually complete clinical testing and receive licensure from the FDA or applicable foreign regulatory authorities for any of our product candidates, the FDA or the applicable foreign regulatory agency may grant licensure contingent on the performance of costly additional clinical trials which may be required after licensure. The FDA or the applicable foreign regulatory agency also may license our product candidates for a more limited indication or a narrower patient population than we originally requested, and the FDA, or applicable foreign regulatory agency, may not license our product candidates with the labeling that we believe is necessary or desirable for the successful commercialization of such product candidates.

In addition, even if the trials are successfully completed, preclinical and clinical data are often susceptible to varying interpretations and analyses, and we cannot guarantee that the FDA or comparable foreign regulatory authorities will interpret the results as we do, and more clinical trials could be required before we submit our product candidates for approval. To the extent that the results of the clinical trials are not satisfactory to the FDA or comparable foreign regulatory authorities for support of a marketing application, approval of our product candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional clinical trials in support of potential approval of our product candidates.

Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of our product candidates and would materially adversely impact our business and prospects.

We may seek orphan drug status for some of our current or future product candidates, but we may be unable to obtain such designations or to maintain the benefits associated with orphan drug status, including market exclusivity, which may cause our revenue, if any, to be reduced.

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200,000 in the U.S., or a patient population greater than 200,000 in the U.S. when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the U.S. will be recovered from sales in the U.S. for that drug or biologic. Orphan drug designation must be requested before submitting a BLA. In the U.S., orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a BLA, to market the same biologic for the same approved use or indication for seven years, except in limited circumstances such as a showing of clinical superiority to the product with orphan drug exclusivity or if FDA finds that the holder of the orphan drug exclusivity has not shown that it can 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. As a result, even if one of our product candidates receives orphan exclusivity, the FDA can still approve other drugs that have a different active ingredient for use in treating the same approved use or indication. Furthermore, the FDA can waive orphan exclusivity if we are unable to manufacture sufficient supply of our product.

We may seek orphan drug designation for some or all of our current or future product candidates in additional orphan indications in which there is a medically plausible basis for the use of these products. Even when we obtain orphan drug designation, exclusive marketing rights in the U.S. may be limited if we seek licensure for an indication broader than the orphan designated indication and 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. In addition, although we intend to seek orphan drug designation for other product candidates, we may never receive such designations.

We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted.

A Breakthrough Therapy designation by the FDA, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive marketing approval.

We plan to seek a Breakthrough Therapy designation for our current product candidates and may seek Breakthrough Therapy designation for some or all of our future product candidates. A Breakthrough Therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug, or biologic, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For product candidates that have been designated as Breakthrough Therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Biologics designated as Breakthrough Therapies by the FDA may also be eligible for other expedited approval programs, including Accelerated Approval.

Designation as a Breakthrough Therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a Breakthrough Therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy designation for a product candidate may not result in a faster development process, review or licensure compared to candidate products considered for licensure under non-expedited FDA review procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as Breakthrough Therapies, the FDA may later decide that the product no longer meets the conditions for qualification. Thus, even though we intend to seek Breakthrough Therapy designation for some or all our future product candidates for the treatment of various cancers, there can be no assurance that we will receive Breakthrough Therapy designation.

A Fast Track designation by the FDA, even if granted for any of our current or future product candidates, may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that our product candidates will receive marketing approval.

If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA Fast Track designation for a particular indication. We plan

to seek Fast Track designation for our current product candidates and may seek Fast Track designation for certain of our future product candidates, but there is no assurance that the FDA will grant this status to any of our proposed product candidates. Marketing applications filed 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 approval by the FDA. The FDA has broad discretion whether or not to grant Fast Track designation, so even if we believe a particular product candidate is eligible for this designation, there can be no assurance that the FDA would decide to grant it. Even if we do receive Fast Track designation, we may not experience a faster development process, review or licensure compared to conventional FDA procedures, and receiving a Fast Track designation does not provide assurance of ultimate FDA approval. In addition, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. In addition, the FDA may withdraw any Fast Track designation at any time.

We may seek Accelerated Approval from the FDA for any of our current or future product candidates. Accelerated Approval, even if granted, for any of our current or future product candidates, may not lead to a faster development, or regulatory review or approval process, and it does not increase the likelihood that our product candidates will receive marketing approval.

We may seek approval of our current product candidates or future product candidates using the FDA's Accelerated Approval pathway. A product may be eligible for Accelerated Approval if it treats a serious or life-threatening condition and generally provides a meaningful advantage over available therapies. In addition, it must demonstrate an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality (IMM) that is reasonably likely to predict an effect on IMM or other clinical benefit. As a condition of approval, the FDA requires that a sponsor of a drug or biologic receiving Accelerated Approval perform adequate and well-controlled post-marketing clinical trials. These confirmatory trials must be completed with due diligence. In addition, the FDA currently requires, unless otherwise informed by the agency, pre-approval of promotional materials for products receiving Accelerated Approval, which could adversely impact the timing of the commercial launch of the product. The Food and Drug Omnibus Reform Act of 2022 ("FDORA"), also gives the FDA increased authority to withdraw approval of a drug or biologic granted accelerated approval on an expedited basis if the sponsor fails to conduct such studies in a timely manner, send the necessary updates to the FDA, or if such post-approval studies fail to verify the drug's predicted clinical benefit. Under FDORA, the FDA is empowered to take action, such as issuing fines, against companies that fail to conduct with due diligence any post-approval confirmatory study or submit timely reports to the agency on their progress. Even if we do receive Accelerated Approval, we may not experience a faster development, regulatory review or approval process for that product. Approval of a product may be withdrawn if these trials fail to verify clinical benefit or do not demonstrate sufficient clinical benefit to justify the risks associated with the product. In addition, receiving Accelerated Approval does not provide assurance of ultimate FDA approval.

A Regenerative Medicine Advanced Therapy (RMAT) designation by the FDA, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that our product candidates will receive marketing approval and we may be unable to obtain or maintain the benefits associated with such designation.

We have obtained and may continue to seek an RMAT designation for some of our product candidates. In May 2024, we announced that the FDA granted RMAT designation for TSC-100 and TSC-101 for the treatment of patients with AML, ALL, and MDS undergoing HCT with reduced intensity conditioning. An RMAT is defined as cell therapies, therapeutic tissue engineering products, human cell and tissue products, and combination products using any such therapies or products, except for those regulated solely under Section 361 of the Public Health Service Act. The RMAT program is intended to facilitate efficient development and expedite review of RMATs which are intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition and where preliminary clinical evidence indicates the product has the potential to address unmet medical needs for such disease or condition. A BLA for an RMAT may be eligible for priority review if it meets the criteria for priority review, or for accelerated approval based on surrogate or intermediate endpoints reasonably likely to predict long-term clinical benefit or reliance upon data obtained from a meaningful number of sites. Benefits of RMAT designation include all the benefits of the Fast Track and Breakthrough Therapy designation programs, including early interactions with the FDA, which could include interactions with FDA to discuss any potential surrogate or intermediate endpoint to be used to support accelerated approval. An RMAT that is granted accelerated approval and is subject to post-approval requirements may fulfill such requirements through the submission of clinical evidence, clinical studies, patient registries, or other sources of real-world evidence, such as electronic health records; the collection of larger confirmatory data sets; or post-approval monitoring of all patients treated with such therapy prior to its approval.

RMAT designation is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for RMAT designation and seek RMAT designation for such product candidate, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of RMAT designation for a product candidate may not result in a faster development, review or approval process compared to product candidates considered for approval under non-expedited FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify for RMAT designation, the FDA may later decide that the product candidate no longer meets the conditions for qualification.

We may seek designation for our target discovery platform as a designated platform technology, but we might not receive such designation, and even if we do, such designation may not lead to a faster regulatory review or approval process.

We may seek designation for our target discovery platform as a designated platform technology. Under the Food and Drug Omnibus Reform Act of 2022 (FDORA), a platform technology incorporated within or utilized by a biological product is eligible for

designation as a designated platform technology if (1) the platform technology is incorporated in, or utilized by, a biological product approved under a BLA; (2) preliminary evidence submitted by the sponsor of the licensed biological product, or a sponsor that has been granted a right of reference to data submitted in the application for such biological product, demonstrates that the platform technology has the potential to be incorporated in, or utilized by, more than one biological product without an adverse effect on quality, manufacturing, or safety; and (3) data or information submitted by the applicable person indicates that incorporation or utilization of the platform technology has a reasonable likelihood to bring significant efficiencies to the biological product development or manufacturing process and to the review process. A sponsor may request the FDA to designate a platform technology as a designated platform technology concurrently with, or at any time after, submission of an IND application for a biological product that incorporates or utilizes the platform technology that is the subject of the request. If so designated, the FDA may expedite the development and review of any subsequent original BLA for a biological product that uses or incorporates the platform technology. Even if we believe our target discovery platform technology meets the criteria for such designation, the FDA may disagree and instead determine not to grant such designation. In addition, the receipt of such designation for a platform technology does not ensure that a biological product will be developed more quickly or receive FDA approval. Moreover, the FDA may revoke a designation if the FDA determines that a designated platform technology no longer meets the criteria for such designation. For example, in July 2025, the FDA revoked Sarepta Therapeutics' platform technology designation for AAVrh74 given that new safety information suggested the preliminary evidence on which the designation was based was insufficient to demonstrate that its platform technology had the potential to be incorporated in, or utilized by, more than one drug without an adverse effect on safety.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval and licensure procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the U.S., including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the U.S., a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for any of our product candidates for which we receive marketing approval is also subject to approval.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the U.S. have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our product candidates in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

Even if we receive regulatory approval of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and 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 receive for our product candidates will require surveillance to monitor the safety, potency and purity of the product candidate. The FDA may also require a risk evaluation and mitigation strategy to license our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs, cGTPs and good clinical practices (GCPs) for any clinical trials that we conduct post-licensure. Manufacturers and manufacturers' facilities are required to comply with extensive FDA, and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations and applicable product tracking and tracing requirements. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our manufacturing processes (or those of third parties we engage), or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of our product candidates, withdrawal of the product from the market or voluntary or mandatory product recalls;
- under FDORA, sponsors of approved biologics must provide six months' notice to the FDA of any changes in marketing status, or for discontinuing or interrupting supply of certain drugs, including the withdrawal of a product, and failure to do

so could result in a letter citing such failure to comply as well as the public posting of such letter and redacted company response;

- revisions to the labeling, including limitation on approved uses or the addition of additional warnings, contraindications or other safety information, including boxed warnings;
- imposition of a REMS, which may include distribution or use restrictions;
- requirements to conduct additional post-market clinical trials to assess the safety of the product;
- fines, warning letters, FDA Form 483s, or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;
- product seizure or detention, or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the U.S. or abroad. In addition, the U.S. Supreme Court's July 2024 decision to overturn established case law giving deference to regulatory agencies' interpretations of ambiguous statutory language has introduced uncertainty regarding the extent to which the FDA's regulations, policies, and decisions may become subject to increasing legal challenges, delays, and/or changes. This decision may result in more lawsuits against the FDA to challenge longstanding decisions and policies of the FDA, which could undermine the FDA's authority, lead to uncertainties in the industry, and disrupt the FDA's normal operations, any of which could delay the FDA's review of our regulatory submissions. We cannot predict the full impact of this decision, future judicial challenges brought against the FDA, or the nature or extent of government regulation that may arise from future legislation or administrative action. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

The third-party payer or insurance coverage and reimbursement status of newly approved products are uncertain. Our product candidates may become subject to unfavorable pricing regulations, third-party coverage and reimbursement practices, or healthcare reform initiatives, which would harm our business. Failure to obtain or maintain adequate coverage and reimbursement for new or current products could limit our ability to market those products and decrease our ability to generate revenue.

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drugs vary widely from country to country. In the U.S., recently enacted legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenue we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if any product candidates we may develop obtain marketing approval. For more information, please see "Item 1. Business – Government Regulation – Coverage and Reimbursement" in our Annual Report on Form 10-K filed with the SEC on March 4, 2026.

In the U.S. and markets in other countries, patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Our ability to successfully commercialize our product candidates will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments 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, decide which medications they will pay for and establish reimbursement levels. The availability of coverage and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford treatments such as cell therapy products. Sales of these or other product candidates that we may identify will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize

our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment.

Reimbursement by a third-party payor may depend upon a number of factors, including, but not limited to, 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.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In general, the prices of medicines under such systems are substantially lower than in the U.S. Other countries allow companies to fix their own prices for medicines but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the U.S., the reimbursement for products may be reduced compared with the U.S. and may be insufficient to generate commercially reasonable revenues and profits.

There is also significant uncertainty related to the insurance coverage and reimbursement of newly approved products and coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable foreign regulatory authorities. In the U.S., the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicaid and Medicare Services (CMS), an agency within the U.S. Department of Health and Human Services (HHS). CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. No uniform policy of coverage and reimbursement for products exists among third-party payors and coverage and reimbursement levels for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time consuming and costly process that may require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. It is difficult to predict what CMS will decide with respect to reimbursement for fundamentally novel products such as ours. Reimbursement agencies in Europe may be more conservative than CMS. For example, several cancer drugs have been approved for reimbursement in the U.S. and have not been approved for reimbursement in certain European countries. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale, and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved products we may develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize product candidates, and our overall financial condition.

Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the U.S. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price (ASP) and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs.

We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. In order to obtain reimbursement, physicians may need to show that patients have superior treatment outcomes with our product candidates compared to standard of care drugs, including lower-priced biosimilar versions of standard of care drugs. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

The impact of recent healthcare reform legislation and other changes in the healthcare industry and in healthcare spending on us is currently unknown and may adversely affect our business model.

Our revenue prospects could be affected by changes in healthcare spending and policy in the U.S. and abroad. We operate in a highly regulated industry and new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to healthcare availability, the method of delivery or payment for healthcare products and services could negatively impact our business, operations and financial condition. For more information on healthcare laws and regulations that may impact us, please see "Item 1. Business – Government Regulation – Healthcare Legislative Reform" in our Annual Report on Form 10-K filed with the SEC on March 4, 2026.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future, including significant revisions to the Affordable Care Act and drug pricing reforms. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our product candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our product candidates;
- our ability to obtain coverage and reimbursement approval for a product candidate;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

The Trump Administration has issued executive orders and supported proposed regulatory initiatives in 2025 that could have a significant impact on the prices that we, or any collaborators, may receive for any approved products. On May 12, 2025, President Trump signed an executive order directing the Secretary of HHS to set and communicate most-favored-nation ("MFN") price targets to manufacturers and propose a rulemaking plan to impose MFN pricing if "significant progress" is not made, and also directing the federal government to support regulatory paths to allow direct-to-patient sales for companies that meet these targets. Since this time, multiple drug manufacturers have announced plans to, for certain of their drugs, lower prices to reflect similar pricing around the world, and to sell these reduced-price drugs on a direct-to-consumer purchasing platform developed by the federal government; however, it is not known what results will occur to the extent the recipients of these letters do not reduce their U.S. prices.

On December 19, 2025, CMS released two proposed rules that would incorporate MFN pricing principles into federal reimbursement for prescription drugs: the Global Benchmark for Efficient Drug Pricing Model ("GLOBE") for Medicare Part B and the Guarding U.S. Medicare Against Rising Drug Costs ("GUARD") model for Medicare Part D. On October 2, 2026, CMS finalized the GLOBE regulation, effective November 30, 2026, as a mandatory CMS Innovation Center payment model under Section 1115A of the Social Security Act. As finalized, GLOBE will require manufacturers of specified single source drugs and sole source biologics, within designated therapeutic classes and that have incurred more than $100 million of Medicare Part B spending over a 12-month period) to pay incremental rebates based on an alternative, internationally benchmarked calculation of the existing Medicare Part B drug inflation rebate. The GLOBE Model will begin on January 1, 2027 with the collection of voluntary manufacturer-submitted international drug net pricing data, and will be tested over 5 performance years, running from April 1, 2027 through March 31, 2032. The associated payment period will run from April 1, 2027 through March 31, 2034. GLOBE excludes orphan-only drugs, cell and gene therapy products, plasma-derived products, and drugs with an effective Medicare-negotiated maximum fair price.

GUARD remains a proposed regulation that has not been finalized and, as proposed, would similarly mandate manufacturer rebates for qualifying sole source drugs where the Medicare net price exceeds an MFN benchmark derived from international reference pricing methodologies, with its performance period proposed to begin in 2027. The GLOBE model and the proposed GUARD model will likely be subject to legal challenges that could delay implementation or modify their impact on manufacturer pricing and revenue. Additionally, in November 2025, CMS introduced the GENErating cost Reductions for U.S. Medicaid ("GENEROUS") Model, a voluntary MFN framework for manufacturers participating in the Medicaid Drug Rebate Program. Although it is voluntary, the GENEROUS Model could also impact the drug pricing landscape for manufacturers.

Healthcare reform efforts have been and may continue to be subject to scrutiny and legal challenge. In 2021, the U.S. Supreme Court dismissed the latest judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. As another example, revisions to regulations under the federal anti-kickback statute would remove protection for traditional Medicare Part D discounts offered by pharmaceutical manufacturers to pharmacy benefit managers and health plans. Pursuant to court order, the removal was delayed and subsequent legislation imposed a moratorium on implementation of the rule until January 2032. The IRA drug price negotiation program has also been challenged in litigation filed by various pharmaceutical manufacturers and industry groups.

Individual states have also been increasingly active in passing legislation and implementing 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. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. We expect that additional state and federal healthcare reform measures will be adopted in the future, particularly in light of the new presidential administration, any of which could limit the amounts that federal and state governments will pay for healthcare products and services.

Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability. We expect that the healthcare reform measures that have been adopted and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product and could seriously harm our future revenues. 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 products.

Regulatory requirements in the U.S. and abroad governing cell therapy products have changed frequently and may continue to change in the future, which could negatively impact our ability to complete clinical trials and commercialize our product candidates in a timely manner, if at all.

Regulatory requirements in the U.S. and abroad governing cell therapy products have changed frequently and may continue to change in the future. The FDA has established an office, called the Office of Therapeutic Products within its Center for Biologics Evaluation and Research to meet its growing cell and gene therapy workload. The FDA also established the Cellular, Tissue and Gene Therapies Advisory Committee to advise its review. Under guidelines issued by the National Institutes of Health (NIH) certain gene

therapy clinical trials are subject to review and oversight by an institutional biosafety committee (IBC) a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. Before such a clinical trial can begin, the institution's institutional review board (IRB) and its IBC assess the safety of the research and identifies any potential risk to public health or the environment. While the NIH guidelines are not mandatory unless the research in question is being conducted at or sponsored by institutions receiving NIH funding of recombinant or synthetic nucleic acid molecule research, many companies and other institutions not otherwise subject to the NIH guidelines voluntarily follow them. Moreover, serious adverse events or developments in clinical trials of gene therapy product candidates conducted by others may cause the FDA or other regulatory bodies to initiate a clinical hold on our clinical trials or otherwise change the requirements for approval of any of our product candidates. Although the FDA decides whether individual cell and gene therapy protocols may proceed, the review process and determinations of other reviewing bodies can impede or delay the initiation of a clinical trial, even if the FDA has reviewed the trial and approved its initiation.

Inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key personnel, and substantial changes in leadership, personnel, organizational structure, and policy could 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 staffing, government budget and funding levels, the FDA's ability to hire and retain key personnel and accept the payment of user fees, statutory, regulatory, and policy changes, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC 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. 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, in some instances have had to furlough critical FDA, SEC and other government employees and stop critical activities.

Disruptions at the FDA and other agencies, including substantial leadership departures and changes, personnel cuts and policy changes, may also slow the time necessary for new drugs to be reviewed and/or approved, which would harm our business. Changes and cuts in FDA staffing also could result in delays in the FDA's responsiveness or in its ability to review, or consistency in reviewing, regulatory submissions or applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion or at all. If a prolonged government shutdown or substantial leadership, personnel, and policy changes occur, 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. Such changes could significantly impact the ability of the FDA to timely review and take action on our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, future government shutdowns or substantial leadership, personnel, and policy changes could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

With the change in the U.S. presidential administration in 2025, there is substantial uncertainty as to the extent and nature of how the Trump administration will continue to seek to modify or revise the requirements and policies of the FDA and other regulatory agencies with jurisdiction over our product candidates. This uncertainty could present new challenges and/or opportunities as we navigate development of our product candidates. Additionally, the Trump administration could issue or promulgate executive orders, regulations, policies or guidance that adversely affect us or create a more challenging or costly environment to pursue the development of new product candidates. Also, state governments may seek to address or react to changes at the federal level with changes to their regulatory frameworks in a manner that could impact our operations. Any delay in obtaining, or our inability to obtain, applicable regulatory approvals would delay or prevent development and commercialization of our product candidates and could materially adversely impact our business and prospects.

We are subject to the obligations to and the rights of the U.S. government set forth in the Bayh-Dole Act of 1980 (Bayh-Dole Act). As a result, the U.S. government may have rights in certain inventions developed under these government-funded programs, including a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right to require us to grant exclusive, partially exclusive or nonexclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations, also referred to as "march-in rights."

Any exercise of the march-in rights by the U.S. government could harm our competitive position, business, financial condition, results of operations and prospects. In December 2023, the Biden administration released a proposed framework specifying for the first time that price can be a factor in considering whether an invention is sufficiently available to the public. The proposed framework could potentially enable march-in rights to be used as a tool to regulate drug pricing. The potential inclusion of price as a factor in a march-in determination is expected to draw extensive criticism and challenge, and the ultimate impact is currently unknown. If the U.S.

government exercises such march-in rights, we may receive compensation deemed reasonable by the U.S. government, which may be less than what we might be able to obtain in the open market. IP generated under a government-funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources.

Our employees, independent contractors, consultants, commercial partners 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 and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to: comply with the regulations of the FDA and other similar foreign regulatory authorities, provide true, complete and accurate information to the FDA and other similar foreign regulatory authorities, comply with manufacturing standards we have established, comply with healthcare fraud and abuse laws in the U.S. 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 U.S., our potential exposure under such laws and regulations will increase significantly, and our costs associated with compliance with such laws and regulations are also likely to 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. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. For more information, please see "Item 1. Business – Government Regulation – Anti-Kickback and False Claims Laws and Other Regulatory Matters" in our Annual Report on Form 10-K filed with the SEC on March 4, 2026.

Additionally, we are subject to state and foreign equivalents of each of the healthcare laws described above, among others, some of which may be broader in scope and may apply regardless of the payor.

We have adopted a code of conduct, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent inappropriate conduct 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 be in compliance with such laws or regulations.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. It is possible that governmental authorities will conclude that our business practices may 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 are 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 criminal, civil and administrative sanctions including monetary penalties, damages, fines, disgorgement, individual imprisonment, and exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, reputational harm, and we may be required to curtail or restructure our operations, any of which could adversely affect our ability to operate our business and our results of operations.

The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the EU. The provision of benefits or advantages to induce or reward improper performance generally is governed by the national anti-bribery laws of EU Member States and the Bribery Act 2010 (Bribery Act) in the UK. Infringement of these laws could result in substantial fines and imprisonment. Payments made to physicians in certain EU Member States must be publicly disclosed. EU Directive 2001/83/EC, which is the EU Directive governing medicinal products for human use, further provides that, where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy. This provision has been transposed into the Human Medicines Regulations 2012

and so remains applicable in the UK despite its departure from the EU. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual EU Member States.

These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

We are currently subject to, and may in the future become subject to additional, federal, state and foreign laws and regulations, industry guidelines, and contractual requirements, imposing obligations on how we collect, store, use and process personal information. Our actual or perceived failure to comply with such obligations could harm our business.

We are, and may increasingly become, subject to various laws and regulations, as well as contractual obligations and mandatory industry standards relating to privacy and security in the jurisdictions in which we operate. The regulatory environment related to data privacy and security is increasingly rigorous, with new and constantly changing requirements applicable to our business, and enforcement practices are likely to remain uncertain for the foreseeable future. These laws and regulations may be interpreted and applied differently over time and from jurisdiction to jurisdiction, and it is possible that they will be interpreted and applied in ways that may have a material adverse effect on our business, financial condition, results of operations and prospects.

In the U.S., various federal and state regulators, including governmental agencies like the Federal Trade Commission, have adopted, or are considering adopting, laws and regulations concerning personal information and data security. Certain state laws may be more stringent or broader in scope, or offer greater individual rights, with respect to personal information than federal, international or other state laws, and such laws may differ from each other, all of which may complicate compliance efforts. For example, the California Consumer Privacy Act (CCPA) established privacy rights for California residents for covered companies that process their personal information. Among other things, the CCPA requires covered companies to provide certain disclosures to California residents and provide such residents with new data protection and privacy rights, including the ability to opt-out of certain sales of personal information. The amendments introduced by the California Privacy Rights Act (CPRA) significantly modified the CCPA by expanding privacy rights with respect to certain personal information and created a state agency to oversee implementation and enforcement efforts, among other changes. The CCPA provides for civil penalties for violations, as well as a private right of action for certain data breaches. This may increase the likelihood of, and risks associated with, data breach litigation, including class action litigation and regulatory enforcement.

Similar laws have been passed in numerous other states, and several other states have proposed new privacy laws, some of which are similar to the above discussed recently passed laws. Such proposed legislation, if enacted, may add additional complexity, variation in requirements, restrictions and potential legal risk, require additional investment of resources in compliance programs, impact strategies and the availability of previously useful data and could result in increased compliance costs and/or changes in business practices and policies. The existence of comprehensive privacy laws in different states in the country would make our compliance obligations more complex and costly and may increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance. In addition, laws in all 50 U.S. states require businesses to provide notice to individuals if certain of their personal information has been disclosed because of a qualifying data breach. There are also states that are specifically regulating health information. For example, Washington's My Health My Data Act. The My Health My Data Act imposes new state restrictions and requirements on the processing and sale of consumer health data and creates a private right of action, which further increases the relevant compliance risk. A small number of other states have also passed similar laws regulating consumer health data. In addition, other states have proposed and/or passed legislation that regulates the privacy and/or security of certain specific types of information. For example, a small number of states have passed laws that regulate biometric data specifically. These various privacy and security laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products. State laws are changing rapidly and compliance requirements and enforcement remains unpredictable.

Moreover, U.S. regulators and legislators are increasingly scrutinizing and restricting certain personal data transfers and transactions involving foreign countries. For example, the Department of Justice's April 8, 2025 Final Rule on "Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern" prohibits data brokerage transactions involving certain sensitive personal data categories, including health data, genetic data, and biospecimens, to countries of concern, including China. The regulations also restrict certain investment agreements, employment agreements and vendor agreements involving such data and countries of concern, absent specified cybersecurity controls. Actual or alleged violations of these regulations may be punishable by criminal and/or civil sanctions and may result in exclusion from participation in federal and state programs.

Internationally, laws, regulations and standards in many jurisdictions apply broadly to the collection, use, retention, security, disclosure, transfer, marketing or other processing of personal data. For example, the collection, use, storage, disclosure, transfer, or other processing of personal data regarding individuals in the European Economic Area (EEA), including personal health data, is subject

to the EU General Data Protection Regulation 2016/679 (EU GDPR), and with regards individuals based in the UK, the EU GDPR in such form as incorporated into the laws of the UK (UK GDPR, together with EU GDPR referred to as "GDPR") which became effective on May 25, 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to having a legal basis or condition for processing personal data, stricter requirements relating to the processing of sensitive data (such as health data), where required by GDPR obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, requirements to conduct data protection impact assessments for high risk processing and taking certain measures when engaging third-party processors. The GDPR permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million (£17.5 million in UK) or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. The GDPR increased our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, including as implemented by individual countries. Compliance with the GDPR will be a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities.

The GDPR provides that EEA Member States may make their own further laws and regulations in relation to the processing of genetic, biometric or health data, which could result in differences between EEA Member States, limit our ability to use and share personal data or could cause our costs to increase, and harm our business and financial condition.

Significantly, the GDPR imposes strict rules on the transfer of personal data out of the EEA and UK to other regions outside the EEA/UK, or third countries, that have not been deemed to offer "adequate" privacy protections by the competent data protection authorities, including the U.S. in certain circumstances, unless a derogation exists or adequate international transfer safeguards are put in place, such as, for example, the European Commission approved Standard Contractual Clauses (the EU SCCs) and the UK International Data Transfer Agreement/Addendum (the UK IDTA). Where relying on the EU SCCs or UK IDTA for data transfers, we may also be required to carry out transfer impact assessments on the transfers made pursuant to the EU SCCs and UK IDTA, on a case-by-case basis, to ensure the law in the recipient country provides "essentially equivalent" protections to safeguard the transferred personal data as provided in the EEA and UK, and may be required to adopt supplementary measures if this standard is not met. Further, the EU and the U.S. have adopted its adequacy decision for the EU-U.S. Data Privacy Framework (Framework), which entered into force on July 10, 2023. This Framework provides that the protection of personal data transferred between the EU and the U.S. is comparable to that offered in the EU. This provides a further avenue to ensuring transfers to the U.S. are carried out in line with GDPR. There has been an extension to the Framework to cover UK transfers to the U.S. The Framework could be challenged like its predecessor frameworks. The international transfer obligations under the EEA and UK data protection regimes will require significant effort and cost and may result in us needing to make strategic considerations around where EEA and UK personal data is located and which service providers we can utilize for the processing of EEA and UK personal data. Any inability to transfer personal data from the EEA to the U.S. in compliance with data protection laws may impede our ability to conduct trials and may adversely affect our business and financial position.

Although the UK is regarded as one of the third countries under the EU GDPR, the European Commission has adopted an adequacy decision in favor of the UK, enabling data transfers from EEA member states to the UK without additional safeguards. In December 2025, the European Commission adopted a decision to extend the validity of the UK adequacy decision for six years until December 2031, determining that the UK continues to offer a level of data protection that is "essentially equivalent" to the EU standards. This follows the UK's adoption of the Data (Use and Access) Act 2025 on June 19, 2025. The Data (Use and Access) Act 2025 may have the effect of further altering the similarities between the UK and EEA data protection regime. The competent authorities in the EEA Member States may interpret GDPR obligations slightly differently from country to country and therefore we do not expect to operate in a uniform legal landscape in the EEA. The European Commission has also proposed reforms under the "Digital Omnibus" package, which, if adopted, may further modify EU GDPR-related requirements, including by clarifying the scope of "personal data" and the treatment of coded or de-identified data, potentially requiring further adjustments to our European privacy compliance framework.

The potential of the respective provisions and enforcement of the EU GDPR and UK GDPR further diverging in the future creates additional regulatory challenges and uncertainties for us. All of these evolving compliance and operational requirements impose significant costs, such as costs related to organizational changes, implementing additional protection technologies, training employees and engaging consultants and legal advisors, which are likely to increase over time. In addition, such requirements may require us to modify our data processing practices and policies, utilize management's time and/or divert resources from other initiatives and projects. Any failure or perceived failure by us to comply with any applicable federal, state or foreign laws and regulations relating to data privacy and security could result in damage to our reputation, as well as proceedings or litigation by governmental agencies or other third parties, including class action privacy litigation in certain jurisdictions, which would subject us to significant fines, sanctions, awards, injunctions, penalties or judgments. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Artificial intelligence presents risks and challenges that can impact our business, including by cybersecurity, regulatory, and operational risks.

We may use, and our vendors may incorporate, artificial intelligence ("AI"), both in our own development and implementation of AI and through the adoption of commercially available tools. The use of AI presents risks and challenges that could adversely affect our business and reputation, including cybersecurity, data privacy, IT, confidentiality, regulatory, legal, operational, competitive, reputational, intellectual property and other risks. Our use of certain AI tools may increase the risk of unauthorized disclosure of confidential information, compromise of proprietary intellectual property, or inadvertent inclusion of third-party intellectual property or other protected material, which could result in disputes, claims of infringement, legal liabilities or financial losses. The rapidly evolving regulatory landscape surrounding AI also poses a risk, as new laws and regulations could impose additional compliance burdens, resulting in increased operational costs to comply with U.S. and non-U.S. laws concerning the use of AI, the nature of which cannot be determined at this time.

For example, the EU Artificial Intelligence Act, which entered into force in 2024 and is being phased in on a staggered basis (with certain high-risk obligations recently deferred to 2027 and 2028), may impose significant obligations on companies that deploy AI systems in high-risk contexts, including applications related to clinical development, regulatory submissions, and medical or scientific analysis. To the extent we use or rely on AI tools in such contexts, we may be required to implement additional compliance measures, conduct conformity assessments, or limit or modify our use of certain AI systems, any of which could increase our costs or disrupt our operations. In addition, AI systems, including large language models and other generative AI tools, are known to produce outputs that are factually incorrect, incomplete, or otherwise unreliable, introducing additional operational and regulatory risks into our workflows. In the U.S., the AI regulatory environment is complex and uncertain. Over the past year, states have advanced, and in some cases passed, dozens of laws focusing on automated decision making, including on deployment of AI in healthcare settings. At the federal level, the FDA has advanced guidance and proposed frameworks for regulating AI in drug discovery, marketing submissions, and medical device development. The resulting patchwork of state and federal requirements continues to evolve, remains subject in certain cases to legal challenge, and may be interpreted and applied inconsistently across jurisdictions, any of which could increase our compliance costs or require us to limit or modify our use of AI tools.

Additionally, our vendors may incorporate AI tools into their offerings, and the providers of these AI tools may not meet existing or rapidly evolving regulatory or industry standards, including with respect to privacy and data security. Further, bad actors around the world use increasingly sophisticated methods, including the use of AI, to engage in illegal activities involving the theft and misuse of personal information, confidential information and intellectual property. The use of generative AI models in our internal or third-party systems may create new attack surfaces or methods for adversaries, which could impact us and our vendors. Any of these effects could damage our reputation, result in the loss of valuable property and information, cause us to breach applicable laws and regulations, and adversely impact our business.

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 operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also 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. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

Even if we are able to commercialize any product candidates, the products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which would harm our business.

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. To obtain 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 some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product candidate in a particular country but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues, if any, we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product

candidates obtain marketing approval. For more information, please see "Item 1. Business – Government Regulation – Coverage and Reimbursement" in our Annual Report on Form 10-K filed with the SEC on March 4, 2026.

Our ability to commercialize any product candidates successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government healthcare programs, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, government authorities and third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Coverage and reimbursement may not be available for any product that we commercialize and, even if these are available, the level of reimbursement may not be satisfactory. Reimbursement may affect the demand for, or the price of, any product candidate for which we obtain marketing approval. Obtaining and maintaining adequate reimbursement for our product candidates may be difficult. We may be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of reimbursement relative to other therapies. If coverage and adequate reimbursement are not available or reimbursement is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or similar regulatory authorities outside of the U.S. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, intellectual property, manufacture, sale and distribution expenses. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the U.S. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection for any product candidates we develop and for our technology, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize products, product candidates and technology similar or identical to ours, and our ability to successfully commercialize any product candidates we may develop, and our technology may be adversely affected.

Our success will depend in large part on our ability and the ability of our licensors and collaborators to obtain and maintain patent protection and other intellectual property and proprietary rights in the U.S. and other countries with respect to our technology and our product candidates, their respective components, formulations, combination therapies, methods used to manufacture them and methods of treatment and development that are important to our business, as well as our ability to operate our business without infringing, misappropriating or otherwise violating the intellectual property rights of others.

Given the early stage of development of our product candidates, our patent portfolio is similarly at an early stage. If we do not obtain meaningful patent coverage for our product candidates, their respective components, formulations, combination therapies, methods used to manufacture them and methods of treatment, competitors may be able to erode or negate any competitive advantage we may have, which would likely harm our business and ability to achieve profitability. To establish our proprietary position, we have filed provisional patent applications and corresponding Patent Cooperation Treaty (PCT), national, and regional applications related to our novel product candidates that are important to our business, and we have exclusively licensed a patent family from the Brigham and Women's Hospital, Inc. (BWH); we may in the future also license or purchase issued patents or pending patent applications filed by others. U.S. provisional patent applications are not eligible to become issued patents until, among other things, we file a non-provisional patent application within 12 months of filing of one or more of our related provisional patent applications. With regard to such U.S. provisional patent applications, if we do not timely file any non-provisional patent applications, we may lose our priority date with respect to our provisional patent applications and any patent protection on the inventions disclosed in our provisional patent applications. While we intend to timely file non-provisional patent applications relating to our provisional patent applications, we cannot predict whether any such patent applications will result in the issuance of patents that provide us with any competitive advantage. If we are unable to secure or maintain patent protection with respect to our antibody technology and any proprietary products and technology we develop, our business, financial condition, results of operations, and prospects could be materially harmed.

If the scope of the patent protection we or our existing and potential licensors obtain, if any, is not sufficiently broad, we may not be able to prevent others from developing and commercializing technology and products similar or identical to ours. The degree of patent protection we require to successfully compete in the marketplace may be unavailable or severely limited and may not adequately

protect our business or permit us to gain or keep any competitive advantage. We cannot provide any assurances that any of our owned or exclusively licensed pending patent applications that mature into issued patents will include claims with a scope sufficient to protect our current and future product candidates or otherwise provide any competitive advantage. In addition, to the extent that we license intellectual property now or in the future, we cannot provide any assurances that those licenses will remain in force. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the U.S. Furthermore, patents have a limited lifespan. In the U.S., 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. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product candidate, we may be open to competition. Given the amount of time required for the development, testing and regulatory review of new product candidates, any patents that we may obtain in the future protecting such candidates might expire before or shortly after commercialization of such candidates, if any. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours.

Even if they are unchallenged, our issued patents or pending patent applications, if issued, may not provide us with any meaningful protection or prevent competitors or other third parties from designing around our patent claims to circumvent any patents that may issue by developing similar or alternative technologies or therapeutics in a non-infringing manner. For example, a third party may develop a competitive therapy that provides benefits similar to one or more of our product candidates but that uses a formulation and/or a device that falls outside the scope of our patent claims. If any patent protection that we may obtain in the future from the 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. Similar risks apply to patents or patent applications that we have in-licensed or may in the future in-license.

Patent positions of life sciences companies can be uncertain and involve complex factual and legal questions and are subject of much litigation. No consistent policy governing the scope of claims allowable in the field of binding protein therapeutics, including antibodies and T cell receptors, has emerged in the U.S. The scope of patent protection in jurisdictions outside of the U.S. is also uncertain. Changes in either the patent laws or in their interpretation in any jurisdiction that we seek patent protection may diminish our ability to protect our inventions, obtain, maintain, protect and enforce our intellectual property and other proprietary rights; and, more generally, may affect the value of our intellectual property, including the narrowing of the scope of any patents that we may obtain in the future and any that we may license.

The patent prosecution process is complex, expensive, time-consuming and inconsistent across jurisdictions. We may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patent rights at a commercially reasonable cost or in a timely manner. In addition, we do not intend to pursue, and may not obtain, patent protection in all potentially relevant markets. It is possible that we will fail to identify important patentable aspects of our research and development efforts in time to obtain appropriate or any patent protection or fail to file patent applications covering inventions made in the course of development and commercialization activities before a competitor or another third party files a patent application covering, or publishes information disclosing, a similar, independently developed invention. Such competitor's or other third party's patent application may pose obstacles to our ability to obtain patent protection or limit the scope of the patent protection we may obtain. While we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development efforts, including for example, our employees, corporate collaborators, external academic scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby endangering our ability to seek patent protection. In addition, publications of discoveries in the scientific and scholarly literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Consequently, we cannot be certain that we or our licensors were the first to make the inventions claimed in our owned or in-licensed patent rights and patent applications or were the first to file for patent protection on the inventions claimed in our pending patent applications.

The issuance, scope, validity, enforceability and commercial value of our and our current or future licensors' patent rights are highly uncertain. Our and our licensors' pending and future patent applications may not result in patents being issued that protect our technology or product candidates, in whole or in part, or which effectively exclude others from commercializing competitive technologies and product candidates. Further, the scope of the invention claimed in a patent application can be significantly reduced before the patent is issued, and this scope can be reinterpreted after issuance. Even where patent applications we currently own or that we license now or in the future issue as patents, they may not issue in a form that will provide us with adequate protection to prevent competitors or other third parties from competing with us or otherwise provide us with a competitive advantage. Any patents that eventually issue may be challenged, narrowed or invalidated by third parties. Consequently, we do not know whether any of our product candidates will be protectable or remain protected by valid and enforceable patent rights. Our competitors or other third parties may be able to evade or circumvent our patent rights by developing new alternative technologies or products in a non-infringing manner.

The issuance or grant of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and patents we may obtain in the future may be challenged, invalidated, narrowed or held to be enforceable, including in the courts or patent offices in the U.S. and abroad, or circumvented. There may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim. 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, but which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. We may become subject to a third-party pre-issuance submission of prior art or opposition, derivation, revocation, re-examination, post-grant and *inter partes* review, or interference proceeding and other similar proceedings challenging any patent rights we have or may obtain in the future or the patent rights of others, including based on priority of invention or other features of patentability, in the U.S. Patent and Trademark Office (USPTO) or other foreign patent office. An unfavorable determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, any patent rights we have or may obtain in the future, allow third parties to use or commercialize our technology or product candidates and compete directly with us, without payment to us (as they can now), or extinguish our ability to manufacture or commercialize product candidates without infringing third-party patent rights. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. In addition, there could 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 have a material adverse effect on the price of our common stock.

In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, any patents we have or may obtain in the future protecting such candidates might expire before or shortly after commercialization of such candidates, if any. As a result, our intellectual property may never provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Moreover, any patents or patent applications that we own or may own or in-license in the future may be co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in any such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, thereby enabling our competitors to market competing products and technology. In addition, we or our licensors may need the cooperation of any such co-owners of any patents that we own or may own or in-license in the future in order to enforce such patents against third parties, and such cooperation may not be provided to us or our licensors. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

We could be unsuccessful in obtaining meaningful patent protection on one or more components of our platform technology.

We believe that an important factor in our competitive position is our screening technology platform to identify future product candidates and therapeutic targets. Our screening platform is based in part on technology processes that are (or will be) publicly disclosed in patents and patent applications owned by or licensed to us. Even if such patents and patent applications provide broad protection, it may be difficult or impossible to detect whether a competitor is practicing the proprietary methods claimed in such patents or patent applications to discover their own product candidates and therapeutic targets. In such cases, any existing patents, or patents that may issue from patent applications, owned by or licensed to us would not provide us protection to prevent such activity. Additionally, a competitor may also practice such methods in a jurisdiction where we have no relevant patent protection. Our competitive position could be weakened by competitors or other third parties practicing the methods claimed in these patent applications in a manner we do not detect or in jurisdictions in which we or our licensors do not obtain any relevant patent protection.

If we fail to comply with any of our obligations under existing or future agreements pursuant to which we license intellectual property rights or technology, if the licenses are terminated or if disputes regarding these licenses arise, we could lose significant rights or technology that are material to our business and could interfere with our ability to operate our business.

We are a party to technology licenses, including in-license agreements with BWH and the Provincial Health Services Authority, and we may enter into additional licenses in the future. Such licenses do, and may in the future, impose commercial, contingent payment, royalty, insurance, indemnification, and other obligations on us. If we fail to comply with these obligations, our licensors may have the right to terminate the license, in which event we could lose valuable rights under our collaboration agreements and our ability to develop product candidates could be impaired. Additionally, should any such license agreement be terminated for any reason, there may be a limited number of replacement licensors, and a significant amount of time may be required to transition to a replacement licensor.

Our rights to develop and commercialize our product candidates are subject in part to the terms and conditions of third-party licenses, pursuant to which we have acquired rights from the applicable licensors. Our rights with respect to such intellectual property may terminate, in whole or in part, if we fail to meet applicable requirements or milestones relating to development and commercialization. We may also lose our rights to develop and commercialize our product candidates under such agreements if we fail to pay required milestones or royalties. In the event of an early termination of our license agreements, all rights licensed and developed by us under these agreements may be extinguished, which may have an adverse effect on our business, financial condition, results of operations and prospects.

We rely on certain of our licensors to prepare, file and prosecute patent applications and maintain patents and otherwise protect the intellectual property we license from them and may continue to do so in the future. We have limited or no control over these activities

or any other intellectual property that may be related to our in-licensed intellectual property. For example, we cannot be certain that such activities by these licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. We have limited or no control over how our licensors initiate an infringement proceeding against a third-party infringer of the intellectual property rights, or defend certain of the intellectual property that is licensed to us. It is possible that any licensors' infringement proceeding or defense activities may be less vigorous than had we conducted them ourselves.

These agreements may be complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, a third party may in the future bring claims that our performance under our license agreements, including our sponsoring of clinical trials, interferes with such third party's rights under its agreement with one of our licensors. If any such claim were successful, it may adversely affect our rights and ability to advance our product candidates as clinical candidates or subject us to liability for monetary damages, any of which would have an adverse effect on our business, financial condition, results of operations and prospects.

We are currently, and expect in the future to be, party to material license or collaboration agreements, which may impose numerous obligations and restrictions on us.

We are currently, and expect in the future to be, party to material license or collaboration agreements. These agreements typically impose numerous obligations and restrictions on us, such as various diligence, commercialization, insurance and payment obligations, among others, in order to maintain such licenses. Any of these restrictions or obligations could delay or otherwise negatively impact a transaction that we may wish to enter into. In addition, any termination of these licenses could result in the loss of significant rights and could harm our ability to commercialize our product candidates.

Licensing of intellectual property is of high importance to our business and involves complex legal, business and scientific issues. Disputes may also arise between us and our licensors regarding intellectual property subject to a license or collaboration agreement, including:

- the scope of rights granted under the license or collaboration agreement and other interpretation-related issues;
- whether, and the extent to which, our product candidates, technology and processes infringe on intellectual property of the licensor that is not subject to the licensing or collaboration agreement;
- our right to sublicense patent and other intellectual property rights to third parties under collaborative development relationships;
- the calculation and existence of certain payment obligations under the license or collaboration agreement;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions, know-how and other intellectual property and proprietary rights 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 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.

We are generally also subject to all of the same risks with respect to protection of intellectual property that we license, as we are for intellectual property that we own, and our success will depend in part on the ability of our licensors to adequately obtain, maintain, protect and enforce patent protection for our licensed intellectual property, especially with respect to patent rights which we exclusively in-license. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize products could suffer.

We rely on certain of our licensors to prepare, file and prosecute patent applications and maintain patents and otherwise protect the intellectual property we license from them and may continue to do so in the future. We have limited control over these activities or any other intellectual property that may be related to our in-licensed intellectual property. For example, we cannot be certain that such activities by these licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. We have limited control over how our licensors initiate an infringement proceeding against a third-party infringer of the intellectual property rights or defend certain of the intellectual property that is licensed

to us. It is possible that any licensors' infringement proceeding or defense activities may be less vigorous than had we conducted them ourselves or may not be conducted in accordance with our best interests.

Furthermore, certain of our licenses may not provide us with exclusive rights to use the licensed intellectual property and technology, or may not provide us with exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and product candidates in the future. For example, a portion of our intellectual property portfolio is non-exclusively licensed to us and may be used by our licensors or licensed to third parties, and such third parties may have certain enforcement rights with respect to such intellectual property. Thus, patent rights 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 brought by or against our licensors or another licensee in response to such litigation or for other reasons. As a result, we may not be able to prevent competitors or other third parties from developing and commercializing competitive products, including in territories covered by our licenses.

Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Our proprietary position may depend upon patents that are manufacturing, formulation or method-of-use patents, which may not prevent a competitor or other third party from using the same product candidate for another use.

Composition-of-matter patents are generally considered to be the strongest form of intellectual property protection for drug products because such patents provide protection without regard to any particular method of use or manufacture or formulation of the active pharmaceutical ingredient used. We currently have a limited number of issued patents, but our pending owned U.S. and international patent applications include claims directed to certain compositions-of-matter and certain methods of use of our product candidates. We cannot be certain that claims in any issued patent, or patent that may issue from our pending owned or in-licensed patent applications, will cover the composition-of-matter of any of our current or future product candidates. If we are unsuccessful in obtaining issued patents that cover the composition-of-matter of any of our current or future product candidates, competitors may be able to erode or negate any competitive advantage we may have and our business, financial condition, results of operations and prospects could be materially harmed.

If our efforts to protect the proprietary nature of the intellectual property related to our technologies are not adequate, we may not be able to compete effectively in our market.

Biotechnology and pharmaceutical companies generally, and we in particular, compete in a crowded competitive space characterized by rapidly evolving technologies and aggressive defense of intellectual property. 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 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.

We rely upon a combination of patent rights, confidentiality agreements, trade secret protection and license agreements to protect the intellectual property related to our technologies. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors or other third parties to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market. We, or any partners, collaborators, licensees or licensors may fail to identify patentable aspects of inventions made during development and commercialization activities before it is too late to obtain patent protection on them. Therefore, we may miss potential opportunities to strengthen our patent position.

It is possible that defects of form in the preparation or filing of our patent applications 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 any partners, collaborators, licensees or licensors fail to establish, maintain or protect such patent rights and other intellectual property rights, such rights may be reduced or eliminated. If any partners, collaborators, licensees or licensors are not fully cooperative or disagree 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 applications, any patents that may issue from such patent applications may be invalid and/or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business, financial condition, results of operations and prospects.

Currently, our patents and patent applications are directed to our TCR-T therapy product candidates and accompanying technologies. We seek or plan to seek patent protection for our proprietary platform and product candidates by filing and prosecuting patent applications in the U.S. and other countries as appropriate. Our patent portfolio also includes patent families exclusively licensed from BWH, which include issued and pending U.S. and foreign non-provisional patent applications. Any patents that have issued or may issue from any non-provisional patent applications claiming priority to these provisional patent applications would be expected to expire on various dates from 2038 through 2047, in each case without considering any possible patent term adjustments or extensions.

We anticipate additional patent applications will be filed both in the U.S. and in other countries, as appropriate. However, we cannot predict:

- whether and when any patents will issue;
- the degree and range of protection that any patents that may issue will afford us against competitors;
- whether any of our intellectual property will provide any competitive advantage;
- whether any patents that may issue may be challenged, invalidated, modified, revoked, circumvented or found to be unenforceable;
- whether or not others will obtain patents claiming inventions similar to those covered by our patent applications; or
- whether we will need to initiate or defend litigation or administrative proceedings, which may be costly regardless of whether we win or lose.

Additionally, we cannot be certain that the claims in our pending patent applications covering the composition of matter of our product candidates will be considered patentable by the USPTO or patent offices in foreign countries.

Method-of-use patents protect the use of a product for the specified method. If we obtain any of these types of patents, they would not prevent a competitor from making and marketing a product that is identical to one of our product candidates for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products "off-label." Although off-label prescriptions may induce or contribute to the infringement of method-of-use patents, the practice is common, and such infringement is difficult to prevent or prosecute.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates or uses thereof in the U.S. or in other foreign countries. Even if the patents do successfully issue, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. If the breadth or strength of protection provided by the patent applications we hold with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product candidates. Further, if we encounter delays in our clinical trials, the period during which we could market our product candidates under patent protection would be reduced. Since patent applications in the U.S. and most other countries are confidential for a period after filing, we cannot be certain that we were the first to file any patent application related to our product candidates. Various post-grant review proceedings, such as *inter partes* review and post-grant review, are available for any interested third party to challenge the patentability of claims in any patents issued to us or our licensors. While these post-grant review proceedings have been used less frequently to invalidate biotech patents, they have been successful regarding other technologies, and these relatively new procedures are still changing, and those changes might affect future results. No assurance can be given that, if challenged, any patents that we or our licensors may obtain would be declared by a court to be valid or enforceable or that, even if found valid and enforceable, a competitor's technology or product would be found by a court to infringe any such patent. We may analyze patents or patent applications of our competitors that we believe are relevant and conclude that our activities do not infringe any valid claims of those patents or patent applications, but our conclusions may be erroneous or our competitors may obtain patents with issued claims, including in patents we consider to be unrelated, that block our efforts or that our product candidates or our activities infringe. Others may independently develop products that have the same effect as our product candidates without infringing any patents we may obtain or any of our other intellectual property rights, or they may design around the claims of any patents that we may obtain.

Recent and future patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of any patents we may obtain. In March 2013, under the Leahy-Smith America Invents Act (America Invents Act) the U.S. moved from a "first to invent" to a "first-to-file" system. Under a "first-to-file" system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on the invention regardless of whether another inventor had made the invention earlier. The America Invents Act included several other significant changes to U.S. patent law, including provisions that have affected the way patent applications are prosecuted, redefined prior art and established a new post-grant review system. The effects of these changes are still unclear as the USPTO only recently developed new regulations and procedures in connection with the America Invents Act, and many of the substantive changes to patent law, including the "first-to-file" provisions, only became effective in March 2013. Moreover, the courts have yet to address many of these provisions. Overall, the America Invents Act and its implementation have increased the uncertainties and costs surrounding the prosecution of our patent applications and any enforcement or defense of any patents that we may obtain, which could have a material adverse effect on our business and financial condition.

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:

- others may be able to make or use compounds or cells that are like the biological compositions of our product candidates but that are not covered by the claims of any patents that we may obtain;
- the active biological ingredients in our current product candidates may eventually become commercially available in biosimilar drug products, and no patent protection may be available regarding to formulation or method of use;
- we or our licensors might not have been the first to file patent applications for these inventions;
- there may be prior public disclosures that could invalidate any patents that we or our licensors may obtain;
- the inventors of our owned or in-licensed patent applications may become involved with competitors, develop products or processes that design around any patents that we may obtain, or become adverse to us or patent applications on which they are named as inventors;
- it is possible that our owned or in-licensed patent applications omit individual(s) that should be listed as inventor(s) or include individual(s) that should not be listed as inventor(s), which may cause any patents that may issue from these patent applications to be held invalid or unenforceable;
- we have engaged and may continue to engage in scientific collaborations, and such collaborators may develop adjacent or competing products to ours that are outside the scope of any patents that we may obtain;
- we may not develop additional proprietary technologies for which we can obtain patent protection;
- product candidates or diagnostic tests we develop may be covered by third parties' patents or other exclusive rights; or
- the patents of others may have an adverse effect on our business.

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

In addition to the protection afforded by any patent rights we may obtain, we seek to rely on trade secret protection, confidentiality agreements, and license agreements to protect our proprietary know-how, information, technology and other proprietary information that is not patentable, processes for which patents are difficult to enforce and any other elements of our product discovery and development processes that involve proprietary know-how, information, or technology that we have not sought to protect through patent applications. For example, significant elements of our product candidates, including aspects of sample preparation, methods of manufacturing, cell culturing conditions, computational-biological algorithms, and related processes and software, are based on unpatented trade secrets that are not publicly disclosed. 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 generally provide that all confidential information concerning our business or financial affairs developed or made known to the individual or entity during 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 by the individual, and which are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary technology by third parties. Despite these measures, we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the U.S. Courts outside the U.S. are sometimes less willing to protect trade secrets. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the U.S. and abroad. 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. If we are unable to prevent unauthorized disclosure of our material intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results and financial condition. For more information, see "Risks Related to Our Intellectual Property – We have limited foreign intellectual property rights and may not be able to protect our intellectual property rights throughout the world."

Third-party claims of intellectual property infringement, misappropriation or other violations may prevent or delay our product candidate discovery and development efforts.

Our commercial success depends in part on our avoiding infringement, misappropriation or other violation of the patents and proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries. We may be exposed to, or threatened with, future litigation by third parties having

patent or other intellectual property rights alleging that our product candidates and/or technologies infringe their intellectual property rights. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates or identifying potential product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of drugs, products or their methods of use or manufacture. Because of the large number of patents and patent applications in our fields, there is a risk that third parties may allege that they have patent rights encompassing our product candidates, technologies or methods.

If a third party claims that we infringe, misappropriate or otherwise violate its intellectual property rights, we may face several issues, including, but not limited to:

- infringement, misappropriation and other violation of intellectual property claims which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business;
- substantial damages for infringement, misappropriation or other violation which we may have to pay if a court decides that the product candidate or technology at issue infringes on, misappropriates or otherwise violates the third party's rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees;
- a court prohibiting us from developing, manufacturing, marketing or selling our product candidates, or from using our proprietary technologies, unless the third party licenses its product rights to us, which it is not required to do;
- if a license is available from a third party, we may have to pay substantial royalties, upfront fees and other amounts, and/or grant cross-licenses to intellectual property rights for our product candidates or using our proprietary technologies; and
- redesigning our product candidates or processes so they do not infringe third-party intellectual property rights, which may not be possible or may require substantial monetary expenditures and time.

Some of our competitors or other third parties may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

Third parties may assert that we are employing their proprietary technology without authorization. Generally, conducting preclinical and clinical trials and other development activities in the U.S. is not considered an act of infringement. If any of our product candidates is licensed by the FDA, a third party may then seek to enforce its patent by filing a patent infringement lawsuit against us. While we do not believe that any claims that could otherwise have a materially adverse effect on the commercialization of our product candidates, if licensed, are valid and enforceable, we may be incorrect in this belief, or we may not be able to prove it in litigation. In this regard, patents issued in the U.S. by law enjoy a presumption of validity that can be rebutted only with evidence that is "clear and convincing", a heightened standard of proof. As a result, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. If any third-party patent were held by a court of competent jurisdiction to cover the manufacturing process of our product candidates, constructs or molecules used in or formed during the manufacturing process, or any final product itself, or aspects of our formulations, processes for manufacture or methods of use, including combination therapy or patient selection methods, the holder of any such patent may be able to block our ability to commercialize the product candidate unless we obtained a license under the applicable patent, or until such patent expires or it is finally determined to be held invalid or unenforceable. In any case, such a license may not be available on commercially reasonable terms or at all. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business. Even if we obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. In addition, there could 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 have a material adverse effect on the price of our common stock. Any of the foregoing events could harm our business, financial condition, results of operations and prospects.

Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. Defense of these claims, regardless of their merit, could involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need or may choose to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of

these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our product candidates. Any of the foregoing events could harm our business, financial condition, results of operations and prospects.

We may not be successful in obtaining or maintaining necessary rights to product components and processes for our development pipeline through acquisitions and in-licenses.

Because additional product candidates may require the use of proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to acquire, in-license or use these proprietary rights. In addition, while we have certain patent rights directed to certain TCR constructs, we may not be able to obtain intellectual property to broad T cell or TCR constructs.

Our product candidates may also require specific formulations to work effectively and efficiently and rights to these formulations may be held by others. Similarly, efficient production or delivery of our product candidates may also require specific compositions or methods, and the rights to these may be owned by third parties. We may be unable to acquire or in-license any formulations, compositions, methods of use, processes or other third-party intellectual property rights that we identify as necessary or important to our business operations. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, which would harm our business. We may need to cease use of the compositions or methods covered by such third-party intellectual property rights and may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we can obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. Moreover, the specific antibodies that will be used with our product candidates may be covered by the intellectual property rights of others.

Additionally, we may collaborate with academic institutions to accelerate our preclinical research or development under written agreements with these institutions. In certain cases, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to others, potentially blocking our ability to pursue our program. If we are unable to successfully obtain rights to required third-party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of such program and our business and financial condition could suffer.

The licensing and acquisition of third-party intellectual property rights is a competitive area, and companies that may be more established or have greater resources than we do may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

We may eventually become involved in lawsuits to protect or enforce our intellectual property and proprietary rights, including any patents that we or our licensors may obtain in the future, which could be expensive, time-consuming and unsuccessful.

In the future, competitors or other third parties may infringe any patents that we or our licensors may obtain. To counter any such future infringement or unauthorized use, we may eventually be required to file infringement claims, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents or that our licensors' patents are invalid or unenforceable. In addition, in a patent infringement proceeding, a court may decide that one or more patents that we may obtain in the future is not valid or is unenforceable, in whole or in part, construe the patent's claims narrowly or may refuse to stop the other party from using the technology at issue on the grounds that such patents, if any, do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of such patents, if any, at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. Asserting any patent rights we may obtain in the future, and defending challenges to our rights, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business and we may find it impractical or undesirable to enforce our intellectual property against some third parties.

Post-grant, interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the validity or priority of inventions with respect to our or our licensors' patent applications or any patents that may issue therefrom. An unfavorable outcome could result in a loss of any patent rights we may have. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or proceeding. In addition, there could 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 have a material adverse effect on the price of our common stock. Any of the foregoing events could harm our business, financial condition, results of operations and prospects.

Obtaining and maintaining our patent protection depends on compliance with various procedures, document submission, fee payments and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Some of our patent applications may be allowed in the future. We cannot be certain that an allowed patent application will become an issued patent. There may be events that cause withdrawal of the allowance of a patent application. For example, after a patent application has been allowed, but prior to being issued, material that could be relevant to patentability may be identified. In such circumstances, the applicant may pull the application from allowance for the USPTO or foreign patent agency to review the application in view of the new material. In that circumstance, the USPTO or the other agency may not re-allow an application in view of the new material. Further, periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or patent applications will be due to be paid to the USPTO and foreign patent agencies at several stages over the lifetime of the patents and/or patent applications. The USPTO and various foreign governmental patent agencies also require compliance with several procedural, documentary and other similar provisions during the patent application process and following the issuance of a patent. We also may be dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors and other third parties might be able to enter the market without infringing our or our licensors' patents and patent applications, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we obtain any patents covering our product candidates, they could nonetheless be found invalid or unenforceable if challenged in court or the USPTO.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability. Our owned or in-licensed patents, and any of our owned or in-licensed patent applications that may issue in the future, may be challenged at the USPTO or foreign patent offices in re-examination, *inter partes* review, post-grant review and equivalent proceedings in foreign jurisdictions (such as opposition proceedings). Such proceedings could result in the revocation of or amendment to such patents in such a way that they no longer cover our product candidates or technologies. If we or one of our licensing partners initiates legal proceedings against a third party to enforce a patent that we may obtain in the future covering one of our product candidates, the defendant could counterclaim that such patent is invalid and/or unenforceable. In patent litigation in the U.S., counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the U.S. or abroad, even outside the context of litigation. Such mechanisms include re-examination, *inter partes* review, post-grant review and equivalent proceedings in foreign jurisdictions (such as opposition proceedings). Such proceedings could result in revocation or amendment to any patents we may obtain in the future in such a way that they would no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, or if we are otherwise unable to adequately protect our rights, we would lose at least part, and perhaps all, of any patent protection we may eventually obtain on our product candidates and technologies. Such a loss of patent protection could have a material adverse impact on our business, financial condition, results of operations and prospects and our ability to commercialize or license our technology and product candidates.

Changes to patent law and its interpretation in the U.S. and in foreign jurisdictions could diminish the value of patents in general and may impact the validity, scope or enforceability of our patent rights, thereby impairing our ability to protect our product candidates and technologies.

As is the case with other biotechnology companies, our success is heavily dependent on intellectual property, particularly any patents that may issue from our pending patent applications. Changes in either the patent laws or in their interpretation in any jurisdiction that we seek patent protection may diminish our ability to protect our inventions, obtain, maintain and enforce our intellectual property and proprietary rights and, more generally, may affect the value of our intellectual property and proprietary rights. The U.S. continues to adapt to wide-ranging patent reform legislation that became effective starting in 2012. Moreover, various courts, including the U.S. Supreme Court, have rendered decisions that have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty regarding our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained. Depending on decisions by Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that

would weaken our ability to obtain new patents or to enforce patents that we might obtain in the future. For example, in the case *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.,* the U.S. Supreme Court held that certain claims to DNA molecules are not patentable. We cannot predict how future decisions by the courts, Congress or the USPTO may impact the value of our pending patent applications. Similarly, any adverse changes in the laws and regulations governing patents in other jurisdictions could have an adverse effect on our ability to obtain and effectively enforce our patent rights and have a material adverse effect on our business and financial condition.

We have limited foreign intellectual property rights and may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the U.S. can be less extensive than those in the U.S. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as the laws in the U.S., and we may encounter difficulties in protecting and defending such rights in foreign jurisdictions. Consequently, we may not be able to prevent third parties from practicing our inventions in some or all countries outside the U.S., or from selling or importing products made using our inventions in and into the U.S. or other jurisdictions. Competitors or other third parties may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may also export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as in the U.S. These products may compete with our product candidates and our patent rights or other intellectual property rights may not be effective or sufficient to prevent them from competing. In addition, certain countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to other parties. Furthermore, many countries limit the enforceability of patents against other parties, including government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of any patents. We will need to decide whether, and in which jurisdictions, to pursue protection for the various inventions in our portfolio prior to applicable filing deadlines.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products and biotechnology, which could make it difficult for us to stop the infringement, misappropriation or other violation of our intellectual property rights, including any infringement of any patents we may obtain in the future in such countries, or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce any patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patent applications at risk of not issuing, any patent rights at risk of being invalidated or interpreted narrowly and could 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. Accordingly, our efforts to establish our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

We may be subject to claims challenging the inventorship or ownership of our patent rights and other intellectual property.

We may be subject to claims that former employees, collaborators or other third parties have an interest in our intellectual property as an inventor or co-inventor. It is our policy to enter into confidentiality and intellectual property assignment agreements with our employees, consultants, and contractors. These agreements generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, such agreements may not be honored and may not effectively assign intellectual property rights to us. For instance, the assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against current or former employees, consultants, and contractors, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Moreover, there may be circumstances where we are unable to negotiate for such ownership rights.

Disputes regarding ownership or inventorship of intellectual property can also arise in other contexts, such as collaborations and sponsored research. If we are subject to a dispute challenging our rights in or to inventions or other intellectual property, such a dispute could be expensive and time consuming. If we are unsuccessful in defending such claims, in addition to paying monetary damages, unless we are able to obtain a license, which might not be available on commercially reasonable terms or at all, we could lose valuable rights in intellectual property, such as the exclusive ownership of, or right to use, intellectual property that we regard as our own or that is important to our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees, and certain customers, licensors or partners may defer engaging with us until the particular dispute is resolved. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed trade secrets or other confidential information of their former employers or other third parties or claims asserting ownership of what we regard as our own intellectual property.

We have received, and will continue to receive, confidential and proprietary information from third parties. In addition, we have employed and expect to continue to employ individuals who were previously employed at university or other biotechnology or pharmaceutical companies, including our competitors or potential competitors, in some cases until recently. Although we try to ensure that our employees, consultants, advisors and independent contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we, our employees, advisors, consultants or independent contractors have deliberately, inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information of these former employers, competitors or other third parties, or to claims that we have improperly used or obtained such trade secrets. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of these third parties or our employees' former employers or our consultants' or contractors' current or former clients or customers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management and employees. If we are not successful in defending such claims, in addition to paying monetary damages, we could lose access or exclusive access to valuable intellectual property rights and face increased competition to our business. Any of the foregoing could harm our business, financial condition, results of operations and prospects.

We may be subject to claims, and damages resulting from claims, that we or our employees have wrongfully used or disclosed alleged trade secrets of our competitors or are in breach of non-competition or non-solicitation agreements with our competitors.

Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors, in some cases until recently. We may be subject to claims that we or our employees have inadvertently or otherwise used or disclosed trade secrets or other proprietary information belonging to these former employers or competitors. In addition, we have been and may in the future be subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. If our defense to those claims fails, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Any litigation or the threat thereof may adversely affect our ability to hire employees. A loss of key personnel or their work product could hamper or prevent our ability to commercialize product candidates or potential products, which could have an adverse effect on our business, results of operations, financial condition and prospects.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time. If we do not obtain patent term extension and data exclusivity for any of our current or future product candidates, our business may be materially harmed.

Depending upon the timing, duration, conditions and specifics of any FDA marketing approval of any of our current or future product candidates that we may receive, one or more U.S. patents that we may obtain in the future may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments) and one or more of our foreign patent rights may be eligible for patent term extension under similar legislation, for example, in the EU. In the U.S., the Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for effective patent term lost during product development and the FDA regulatory review process. A 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 may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, there are no assurances that the FDA or any comparable foreign regulatory authority or national patent office will grant such extensions, in whole or in part. For example, we may not be granted an extension if we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply within applicable deadlines, fail to apply prior to the expiration of relevant patents, or otherwise fail to satisfy other applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or term of any such extension is less than we request, the period during which we can enforce our patent rights for the applicable product candidate will be shortened, and our competitors or other third parties may obtain approval to market competing products following expiration of any patents that we may obtain in the future, and our business, financial condition, results of operations, and prospects could be materially harmed.

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

We rely on both registered and common law protection for our trademarks for use in connection with our product candidates and services in various countries. These trademarks may not afford adequate protection. Our trademark applications may be provisionally or ultimately refused by the USPTO or the trademark agencies of other countries, or such applications may be challenged by others. We

also may not have the financial resources to enforce the rights under these trademarks, which may enable others to use the trademarks and dilute their value. Our trademarks may be challenged, infringed, circumvented or declared generic or determined to be infringing the trademarks of others. In such a case, we may not be able to protect or derive any value from such trademarks or may be required to cease using a conflicting mark entirely. The value of our trademarks may also be diminished by our own actions, such as failing to impose appropriate quality control when licensing our trademarks. Any of the foregoing could impair the value of, or ability to use, our trademarks, reduce our ability to compete effectively, and have an adverse effect on our business.

Certain of our in-licensed patent rights are, and our future owned and in-licensed patent rights may be, subject to a reservation of rights by one or more third parties, including government march-in rights with regards to certain patents, that may limit our ability to exclude third parties from commercializing product candidates similar or identical to ours.

Certain of our in-licensed patent rights may be subject to a reservation of rights by one or more third parties. Pursuant to the Bayh-Dole Act, the U.S. government has march-in rights with regards to government-funded technology. For example, the U.S. government has certain rights, including march-in rights, to patent rights and technology funded by the U.S. government and licensed to us from BWH. When new technologies are developed with government funding, in order to secure ownership of such patent rights, the recipient of such funding is required to comply with certain government regulations, including timely disclosing the inventions claimed in such patent rights to the U.S. government and timely electing title to such inventions. Any failure to timely elect title to such inventions may provide the U.S. government with the right to, at any time, take title to such inventions. Additionally, the U.S. government generally obtains certain rights in any resulting patents, including a non-exclusive license authorizing the government to use the invention or to have others use the invention on its behalf. If the government decides to exercise these rights, it is not required to engage us as its contractor in connection with doing so. These rights may permit the U.S. government to disclose our confidential information to third parties and to exercise march-in rights to use or allow third parties to use our licensed technology. The U.S. government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the U.S. Any exercise by the government of any of the foregoing rights could harm our competitive position, business, financial condition, results of operations, and prospects.

Risks Related to Our Reliance on Third Parties

We rely on third parties to help us conduct our clinical trials. If these third parties do not properly and successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates.

We utilize and depend upon independent investigators and collaborators, such as medical institutions, CROs, CDMOs and strategic partners to help us conduct our preclinical studies and clinical trials under agreements with us. We have and expect to have to negotiate budgets and contracts with CROs, trial sites and CDMOs which may result in delays to our development timelines and increased costs. We will rely heavily on these third parties over the course of our clinical trials, and we control only certain aspects of their activities. As a result, we will have less direct control over the conduct, timing and completion of these clinical trials and the management of data developed through clinical trials than would be the case if we were relying entirely upon our own staff. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with 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 GCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot provide assurance that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the GCP regulations. In addition, our clinical trials must be conducted with biologic product produced under cGMP regulations, including cGTP regulations, and will require a large number of test patients. 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 our clinical trials are not and will not be our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our ongoing, clinical and non-clinical product candidates. 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 drug 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 clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials 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.

Switching or adding third parties to conduct our clinical trials involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines.

We have in the past and may in the future form or seek collaborations or strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such collaborations, alliances or licensing arrangements.

We have in the past and may in the future form or seek strategic alliances, create joint ventures or collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business.

In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety, potency and purity and obtain marketing approval.

Further, collaborations involving our product candidates are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization of our product candidates based on clinical trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, 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 product candidates;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;
- collaborators may not properly maintain or defend our intellectual property or proprietary rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our product candidates, or that result in costly litigation or arbitration that diverts management attention and resources;
- the number and type of our collaborations could adversely affect our attractiveness to future collaborators or acquirers;
- there may be conflicts between different collaborators that could negatively affect those collaborations and potentially others;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates; and
- collaborators may own or co-own intellectual property covering our product candidates that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property.

As a result, if we enter into additional collaboration agreements and strategic partnerships or license our product candidates, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that,

following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new collaborations or strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations.

Our collaboration agreements may grant our collaborators exclusive rights under certain of our intellectual property and may therefore preclude us from entering into collaborations with others relating to the same or similar compounds, therapeutic targets, indications or diseases. In addition, if a collaboration agreement is terminated, in whole or in part, we may be unable to continue the development and commercialization of the applicable product candidates, and even if we are able to do so, such efforts may be delayed and result in additional costs.

We may in the future determine to partner with additional pharmaceutical and biotechnology companies for development and potential commercialization of therapeutic products. We face significant competition in seeking appropriate 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 elect to fund and undertake 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 collaborations and 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 or bring them to market or continue to develop our discovery platform and our business, prospects, financial condition and results of operations may be materially and adversely affected.

We have engaged a global third-party manufacturer to manufacture products for our clinical trials. In the future, we may rely on the use of manufacturing suites in third-party GMP facilities or third parties to manufacture our product candidates. Our business could be harmed if we are unable to use third-party manufacturing suites or if the third-party manufacturers fail to provide us with sufficient quantities of our product candidates or fail to do so at acceptable quality levels, prices, or timing.

We have manufacturing capacity at our facilities in Waltham, Massachusetts, but we have not yet manufactured our product candidates on a commercial scale and may not be able to do so for any of our product candidates.

We are using third parties as part of our manufacturing process to support our clinical trials for our product candidates, and we may also use them for product candidates in the future. Our anticipated reliance on a limited number of third-party manufacturers exposes us to the following risks:

- we may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited, and the FDA must inspect any manufacturers for current cGMP and cGTP compliance as part of our marketing application;
- a new manufacturer would have to be educated in, or develop substantially equivalent processes for, the production of our product candidates;
- our manufacturers may have little or no experience with autologous cell products, which are products made from a patient's own cells, and therefore may require a significant amount of support from us in order to implement and maintain the infrastructure and processes required to manufacture our product candidates;
- our third-party manufacturers might be unable to timely manufacture our product candidates or produce the quantity and quality required to meet our clinical and commercial needs, if any;
- our third-party suppliers or collaborators from whom we receive our antibodies used in combination with our product candidates may be unable to timely manufacture or provide the applicable antibody or produce the quantity and quality required to meet our clinical and commercial needs;

- contract manufacturers may not be able to execute our manufacturing procedures and other logistical support requirements appropriately;
- our future contract manufacturers may not perform as agreed, may not devote sufficient resources to our product candidates or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store, and distribute our product, if any;
- manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMP, cGTP and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards;
- we may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our product candidates;
- our third-party manufacturers could breach or terminate their agreements with us;
- raw materials and components used in the manufacturing process, particularly those for which we have no other source or supplier, may not be available or may not be suitable or acceptable for use due to material or component defects;
- our contract manufacturers and critical reagent suppliers may be subject to inclement weather, as well as natural or man-made disasters;
- our contract manufacturers may have unacceptable or inconsistent product quality success rates and yields, and we have no direct control over our contract manufacturers' ability to maintain adequate quality control, quality assurance and qualified personnel; and
- our contract manufacturers may be adversely affected by the geopolitical and economic tensions in the Middle East and with China, the ongoing conflicts between Russia and Ukraine, political unrest in countries where we or our partners operate, earthquakes, flooding, fires, and other natural or man-made disasters, equipment failures, labor shortages, power failures, and numerous other factors.

Each of these risks could delay or prevent the completion of our clinical trials or the approval of any of our product candidates by the FDA, result in higher costs or adversely impact commercialization of our product candidates. In addition, we will rely on third parties to perform certain specification tests on our product candidates prior to delivery to patients. If these tests are not appropriately done and test data are not reliable, patients could be put at risk of serious harm and the FDA could place significant restrictions on our Company until deficiencies are remedied.

The manufacture of cellular-based drug products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of such products often encounter difficulties in production, particularly in scaling up or out, validating the production process and assuring high reliability of the manufacturing process (including the absence of contamination). These problems include logistics and shipping, difficulties with production costs and yields, quality control, including stability of the product, intermediates, or raw materials, product testing, operator error and availability of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Furthermore, if contaminants are discovered in our supply of our product candidates or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot provide assurance that any stability failures or other issues relating to the manufacture of our product candidates will not occur in the future.

We may fail to manage the logistics of collecting and shipping patient material to the manufacturing site and shipping the product candidate back to the patient. Logistical and shipment delays and problems caused by us, our vendors or other factors not in our control, such as weather, could prevent or delay the delivery of product candidates to patients. Additionally, we have to maintain a complex chain of identity and chain of custody with respect to patient material as it moves to the manufacturing facility, through the manufacturing process and back to the patient. Failure to maintain chain of identity and chain of custody could result in patient death, loss of product or regulatory action.

Our product candidates rely on the availability of specialty materials, which may not be available to us on acceptable terms or at all.

Our product candidates require specialty materials, some of which are manufactured by small companies with limited resources and experience to support a commercial product. We may not be able to contract with suppliers on acceptable terms or at all. In addition, a number of our suppliers normally support blood-based hospital businesses and generally do not have the capacity to support commercial products manufactured under cGMP by biotechnology firms or may divert their resources towards hospitals rather than us. Our suppliers may be ill-equipped to support our needs, especially in non-routine circumstances like an FDA inspection or medical

crisis, such as widespread contamination. We may experience delays in receiving key materials to support clinical or commercial manufacturing.

In addition, some of our raw materials are currently sourced from a single supplier, or a small number of suppliers. We also use certain biologic materials that are available from multiple suppliers, but each version may perform differently, requiring us to characterize them and potentially modify the manufacturing process if we change suppliers. We cannot be sure that these suppliers will remain in business, or that they will not be purchased by one of our competitors or another company that is not interested in continuing to produce these materials for our intended purpose. Accordingly, if we no longer have access to these suppliers, we may experience delays in our clinical or commercial manufacturing which could harm our business or results of operations.

Our manufacturing process needs to comply with FDA or other regulatory agency regulations relating to the quality and reliability of such processes. Any failure to comply with relevant regulations could result in delays in or termination of our clinical programs and suspension or withdrawal of any regulatory approvals.

In order to commercially produce our product candidates, we will need to comply with the FDA's or other regulatory agencies' cGMP regulations and guidelines, including cGTPs. We may encounter difficulties in achieving quality control and quality assurance and may experience shortages in qualified personnel. We are subject to inspections by the FDA and comparable foreign regulatory authorities to confirm compliance with applicable regulatory requirements. Any failure to follow cGMP, cGTP or other regulatory requirements or delay, interruption or other issues that arise in the manufacture, fill-finish, packaging, or storage of our TCR-T therapy product candidates as a result of a failure of our facilities or the facilities or operations of third parties to comply with regulatory requirements or pass any regulatory authority inspection could significantly impair our ability to develop and commercialize our TCR-T therapy product candidates, including leading to significant delays in the availability of our TCR-T therapy product candidates for our clinical trials or the termination of or suspension of a clinical trial, or the delay or prevention of a filing or approval of marketing applications for our product candidates. Significant non-compliance could also result in the imposition of sanctions, including warning or untitled letters, fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approvals for our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could damage our reputation and our business.

If our third-party manufacturers use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials, by our third-party manufacturers. Our manufacturing is (and any third-party manufacturers we engage are) subject to federal, state and local laws and regulations in the U.S. governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that our manufacturers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

Risks Related to Employee Matters and Managing Growth

We are highly dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive biotechnology and pharmaceutical 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. The loss of the services of any of our executive officers, other key employees and other scientific and medical advisors, and an inability to find suitable replacements could result in delays in product development and harm our business. In addition, on November 3, 2025, we announced a prioritization strategy that reduced our workforce by approximately 30%, and on September 2, 2026, we announced an additional workforce reduction of approximately 75% of our workforce. These workforce reductions may adversely impact our ability to retain or recruit key personnel.

We conduct our operations at our facility in Waltham, Massachusetts. This region is headquarters to many other biotechnology companies and many academic and research institutions. 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. Changes to U.S. immigration and work authorization laws and regulations, including those that restrain the flow of scientific and professional talent, can be significantly affected by political

forces and levels of economic activity. Our business may be materially adversely affected if legislative or administrative changes to immigration or visa laws and regulations, including as a result of the change in the U.S. presidential administration, impair our hiring processes and goals or projects involving personnel who are not U.S. citizens.

To encourage valuable employees to remain at our Company, in addition to salary and cash incentives, we have provided stock options that vest over time. The value to employees of stock options 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, scientific and development teams may terminate their employment with us on short notice. 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. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical personnel.

We will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As of November 5, 2026, we had 43 full-time employees. As our development and commercialization plans and strategies develop, and as we continue operating as a public company, we expect to need additional managerial, operational, sales, marketing, financial and other personnel, as well as additional facilities to expand our operations. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical and FDA review process for our 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 future financial performance and our ability to commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth, and 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.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including substantially all aspects of regulatory approval, and clinical trial management. There can be no assurance that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, or we are not able to effectively build out new facilities to accommodate this expansion, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

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

We face an inherent risk of product liability as a result of the planned clinical testing of our product candidates 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 testing, 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 ourselves 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:

- decreased demand for our product candidates or products that we may develop;
- injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- 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; and
- a decline in our share price.

Failure to obtain or retain 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, alone or with corporate collaborators. Although we have clinical trial insurance, our insurance policies 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.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

Under Sections 382 and 383 of the Internal Revenue Code of 1986 (IRC), as amended, if a corporation undergoes an "ownership change" (generally defined as one or more shareholders or groups of shareholders who own at least 5 percent of the corporation's equity increasing their equity ownership in the aggregate by a greater than 50 percentage point change (by value) over a three-year period), the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change taxable income may be limited. As a result of our public offerings, our most recent private placements and other transactions that have occurred over the past three years, we have experienced, such an "ownership change." We may also experience ownership changes in the future because of subsequent shifts in our stock ownership or other transactions. As of December 31, 2025, we had U.S. federal net operating loss carryforwards of $174.7 million and U.S. federal research and development tax credit carryforwards of $21.8 million that expire through 2045 and which could be limited if we experience an "ownership change." Under the current law, federal net operating loss carryforwards generated in taxable years beginning after December 31, 2017 will not be subject to expiration. However, any such net operating loss carryforwards may only offset 80% of our annual taxable income in taxable years beginning after December 31, 2020. State net operating loss carryforwards and other tax attributes may be similarly limited. Any such limitations may result in increased tax liabilities that could adversely affect our business, results of operations, financial position and cash flows.

Risks Related to Our Common Stock and Our Status as a Public Company

We do not know whether an active trading market will continue to develop or be sustained for our common stock and, as a result, it may be difficult for our stockholders to sell their shares of our common stock.

Our common stock began trading on the Nasdaq Global Market in July 2021. Prior to July 2021, there was no public market for our common stock, and we cannot assure you that an active trading market for our shares will continue to develop or be sustained. As a result, it may be difficult for our stockholders to sell their shares without depressing the market price of our common stock, or at all.

The price of our common stock is volatile and fluctuates substantially, which could result in substantial losses for our stockholders.

Our stock price has been, and is likely to continue to be, volatile. The stock market in general, and the market for smaller biotechnology companies in particular, have experienced extreme price volatility and volume fluctuations that have often been unrelated to the operating performance of particular companies. As a result of this volatility, our stockholders may not be able to sell their common stock at or above the price they paid for their shares. The market price for our common stock may be influenced by many factors, including:

- overall performance of the equity markets;
- our operating performance and the performance of other similar companies;
- results from our ongoing clinical trials and future clinical trials with our current and future product candidates or of our competitors;
- delays in the commencement, enrollment and the ultimate completion of clinical trials;
- changes in our projected operating results that we provide to the public, our failure to meet these projections or changes in recommendations by securities analysts that elect to follow our common stock;
- regulatory actions with respect to our product candidates;
- regulatory or legal developments in the U.S. and other countries;
- the level of expenses related to future product candidates or clinical development programs;
- our failure to achieve product development or commercialization goals or regulatory approval milestones in the timeframe we announce;
- changes in hospital or emergency care partner practices;
- announcements of acquisitions, strategic alliances or significant agreements by us or by our competitors;
- developments or disputes concerning intellectual property or proprietary rights;
- our ability to obtain, maintain, protect and enforce our intellectual property and proprietary rights;
- recruitment or departure of key personnel;
- the economy as a whole and market conditions in our industry, including conditions resulting from ongoing conflicts in the Middle East and between Russia and Ukraine;
- variations in our financial results or the financial results of companies that are perceived to be similar to us;
- financing or other corporate transactions, or inability to obtain additional funding;
- trading activity by a limited number of stockholders who together beneficially own a substantial amount of our outstanding common stock;
- the expiration of market standoff or contractual lock-up agreements, as applicable;
- the size of our market float; and
- the other factors described in this “Risk Factors” section.

In addition, the stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many biotechnology companies. Stock prices of many biotechnology companies have fluctuated in a manner unrelated or disproportionate to the operating performance of those companies. In the past, stockholders have filed securities class action litigation following periods of market volatility. If we were to become involved in securities litigation, it could subject us to substantial costs, divert resources and the attention of management from our business and adversely affect our business.

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 no or only very few securities analysts commence coverage of us, or if industry analysts cease coverage of us, the trading price for our common stock would be negatively affected. If one or more of the analysts who cover us downgrade our common stock or publish inaccurate or unfavorable research about our business, our common stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for our common stock could decrease, which might cause our common stock price and trading volume to decline.

Substantial amounts of our outstanding shares may be sold into the market. If there are substantial sales of shares of our common stock, the price of our common stock could decline.

The price of our common stock could decline if there are substantial sales of our common stock, particularly sales by our directors, executive officers and significant stockholders, or if there is a large number of shares of our common stock available for sale and the

market perceives that sales will occur. Shares held by directors, executive officers and their affiliates will be subject to volume limitations or other restrictions under Rule 144 under the Securities Act of 1933, as amended (Securities Act) and various vesting agreements.

Certain of our stockholders have rights, subject to some conditions above, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or our stockholders. We also have registered shares of common stock that we have issued and may issue under our employee equity incentive plans. Once we register these shares, they will be able to be sold freely in the public market upon issuance.

The market price of the shares of our common stock could decline as a result of the sale of a substantial number of our shares of common stock in the public market or the perception in the market that the holders of a large number of shares intend to sell their shares.

The concentration of our stock ownership will likely limit our stockholders' ability to influence corporate matters, including the ability to influence the outcome of director elections and other matters requiring stockholder approval.

As of November 5, 2026, our executive officers, directors, and entities affiliated with such persons beneficially owned, in the aggregate, approximately 31% of our outstanding voting stock and approximately 36% of our outstanding common stock. As a result, these stockholders, acting together, have significant influence over all matters that require approval by our stockholders, including the election of directors and approval of significant corporate transactions. Corporate actions might be taken even if other stockholders, oppose them. This concentration of ownership may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you or other stockholders may feel are in your or their best interest as one of our stockholders. This concentration of ownership might also have the effect of delaying or preventing a change of control of our Company that other stockholders may view as beneficial.

We are an "emerging growth company" and a "smaller reporting company," and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies and smaller reporting companies will make our common stock less attractive to investors.

We are an "emerging growth company" as defined in the JOBS Act and we intend to take advantage of some of the exemptions from reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- the option to present only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes Oxley Act;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- not being required to disclose certain executive compensation-related items such as the correlation between executive compensation and performance and comparisons of the chief executive officer's compensation to median employee compensation; and
- not being required to submit certain executive compensation matters to stockholder advisory votes, such as "say-on-pay," "say-on-frequency," and "say-on-golden parachutes."

The JOBS Act permits an "emerging growth company" such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We have elected to take advantage of this extended transition period.

We cannot predict if investors will find our common stock less attractive because we will 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 these reporting exemptions until we are no longer an emerging growth company. We would cease to be an emerging growth company on the date that is the earliest of (i) the last day of the fiscal year in which we have total annual gross revenue of $1.235 billion or more; (ii) December 31, 2026; (iii) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years; or (iv) the last day of the fiscal year in which we are deemed to be a large accelerated filer under the rules of the SEC, which means the market value of our voting and non-voting common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th.

Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company," which would allow us to continue to take advantage of many of the same exemptions from disclosure requirements, including not being required

to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, as amended (Sarbanes-Oxley Act) and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may 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.

Requirements associated with being a public company will increase our costs significantly, as well as divert significant company resources and management attention.

As a public company, and particularly after we are no longer an "emerging growth company," we will 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 also anticipate that we will incur costs associated with relatively recently adopted corporate governance requirements, including requirements of the SEC, and the Nasdaq Global Market. We expect these rules and regulations to increase our legal and financial compliance costs and to make some activities more time-consuming and costly. We also expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors or as executive officers.

If we fail to maintain proper and effective internal controls, our ability to produce accurate and timely financial statements could be impaired, which could result in sanctions or other penalties that would harm our business.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with the Sarbanes-Oxley Act or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock

We are required to disclose changes made in our internal controls and procedures on a quarterly basis and our management will be required to assess the effectiveness of these controls annually. However, for as long as we are an "emerging growth company" under JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to the Sarbanes-Oxley Act. We would cease to be an emerging growth company on the date that is the earliest of (i) the last day of the fiscal year in which we have total annual gross revenue of $1.235 billion or more; (ii) December 31, 2026; (iii) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years; or (iv) the last day of the fiscal year in which we are deemed to be a large accelerated filer under the rules of the SEC, which means the market value of our voting and non-voting common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th. An independent assessment of the effectiveness of our internal controls over financial reporting could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls over financial reporting could lead to financial statement restatements and require us to incur the expense of remediation.

We will have broad discretion in the use of our cash and cash equivalents and may not use them effectively.

We will have broad discretion in the application of our cash and cash equivalents, including working capital and other general corporate purposes, and our stockholders may disagree with how we spend or invest these proceeds. We may spend our funds in ways that do not improve our results of operations or enhance the value of our common stock. The failure by our management to apply these funds effectively could adversely affect our business and financial condition. Pending their use, we may invest our cash and cash equivalents in a manner that does not produce income or that loses value. These investments may not yield a favorable return to our stockholders.

We do not intend to pay dividends for the foreseeable future.

We have never declared nor paid cash dividends on our capital stock. We currently intend to retain any future earnings to finance the operation and expansion of our business, and we do not expect to declare or pay any dividends in the foreseeable future. Consequently, stockholders must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investment.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or our guidance.

Our quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. Our operating results may fluctuate 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, including the nature of the data obtained from such clinical trials, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;
- our ability to successfully recruit patients for preclinical studies and clinical trials, and any delays caused by difficulties in such recruitment efforts;
- our ability to obtain regulatory 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 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, and existing and potential future drugs that compete with our product candidates;
- the changing and volatile U.S., European and global economic 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 our 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.

Delaware law and provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make a merger, tender offer or proxy contest difficult, thereby depressing the trading price of our common stock.

Our status as a Delaware corporation and the anti-takeover provisions of the Delaware General Corporation Law may discourage, delay or prevent a change in control by prohibiting us from engaging in a business combination with an interested stockholder for a period of three years after the person becomes an interested stockholder, even if a change of control would be beneficial to our existing stockholders. In addition, our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that may make the acquisition of our Company more difficult, including the following:

- a classified board of directors with three-year staggered terms, which could delay the ability of stockholders to change the membership of a majority of our board of directors;
- the ability of our board of directors to issue shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of our board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may be called only by a majority vote of our entire board of directors, the chairman of our board of directors or our chief executive officer, which could delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors;
- the requirement for the affirmative vote of holders of at least 66-2/3% of the voting power of all of the then-outstanding shares of the voting stock, voting together as a single class, to amend the provisions of our amended and restated certificate of incorporation or our amended and restated bylaws, which may inhibit the ability of an acquiror to effect such amendments to facilitate an unsolicited takeover attempt; and
- advance notice procedures with which stockholders must comply to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of us.

In addition, as a Delaware corporation, we are subject to Section 203 of the Delaware General Corporation Law. These provisions may prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us for a certain period of time. A Delaware corporation may opt out of this provision by express provision in its original certificate of incorporation or by amendment to its certificate of incorporation or bylaws approved by its stockholders. However, we have not opted out of this provision.

These and other provisions in our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law could make it more difficult for stockholders or potential acquirors to obtain control of our board of directors or initiate actions that are opposed by our then-current board of directors, including delay or impede a merger, tender offer or proxy contest involving our Company. The existence of these provisions could negatively affect the price of our common stock and limit opportunities for stockholders to realize value in a corporate transaction.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the federal district courts of the U.S. 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 employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our certificate of incorporation or our bylaws or any action asserting a claim against us that is governed by the internal affairs doctrine. This provision does not apply to claims brought to enforce a duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Our amended and restated certificate of incorporation provides further that the federal district courts of the U.S. is the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. These choices of forum provisions 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 and may discourage these types of lawsuits. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive-forum provisions, and there can be no assurance that such provisions will be enforced by a court in those other jurisdictions. If a court were to find the exclusive-forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business.

General Risk Factors

Changes in tax legislation could adversely affect our business and financial condition.

The rules dealing with U.S. federal, state, and local and non-U.S. taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department and other taxing authorities. For example, the OBBBA was signed into law on July 4, 2025 and made significant changes to the U.S. federal tax law. Changes to tax laws or tax rulings (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. For example, under Section 174 of the IRC, in taxable years beginning after December 31, 2021, expenses that are incurred for research and development performed outside the U.S. will be capitalized and amortized. The OBBBA provides that for taxable years beginning after December 31, 2024, expenses that are incurred for research and development performed in the U.S. may, at the taxpayer's election, be immediately deducted or capitalized and amortized. In addition, the OBBBA provides that for taxable years beginning after December 31, 2021 and before January 1, 2025, certain eligible taxpayers generally may elect to retroactively deduct expenses for research and development performed in the U.S. in such taxable years by filing amended tax returns for such taxable years, and all other taxpayers that are not eligible to make such an election and that amortized expenses for research and development performed in the U.S. in such taxable years generally may elect to accelerate and deduct the remaining unamortized amounts of such research and development expenses (i) in the first taxable year beginning after December 31, 2024, or (ii) ratably over the two-taxable year period beginning with the first taxable year beginning after December 31, 2024. It cannot be predicted whether, when, in what form, or with what effective dates, new tax laws may be enacted, or regulations and rulings may be promulgated or issued under existing or new tax laws, which could result in an increase in our or our shareholders' tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law or in the interpretation thereof.

Rising inflation rates may result in increased operating costs and reduced liquidity, and affect our ability to access credit.

Increased inflation may result in increased operating costs (including our labor costs), reduced liquidity, and limitations on our ability to access credit or otherwise raise debt and equity capital. In addition, the U.S. Federal Reserve System has repeatedly raised, and may continue to raise, interest rates in response to concerns about inflation. Increases in interest rates, especially if coupled with reduced government spending and volatility in financial markets, may have the effect of further increasing economic uncertainty and heightening these risks.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our CROs, CDMOs and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

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

Recent Sale of Unregistered Equity Securities

Not Applicable

Use of Proceeds

In July 2021, our Registration Statement on Form S-1/A (No. 333-255491) was declared effective by the SEC pursuant to which we issued and sold an aggregate of 6,666,667 shares of Voting Common Stock at a public offering price of $15.00 per share for aggregate net cash proceeds of $89.6 million, after deducting $7.0 million underwriting discounts and commissions, and $3.4 million in offering costs borne by us. No payments for such expenses were made directly or indirectly to (i) any of our officers or directors or their associates, (ii) any persons owning 10% or more of any class of our equity securities or (iii) any of our affiliates. The sale and issuance of 6,666,667 shares closed on July 20, 2021. Morgan Stanley & Co. LLC, Jefferies LLC, Cowen and Company LLC and Barclays Capital Inc. acted as joint book-running managers for the offering. There has been no material change in the planned use of proceeds from our initial public offering as described in our final prospectus filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC.

Item 3. Defaults Upon Senior Securities.

Not Applicable

Item 4. Mine Safety Disclosures.

Not Applicable

Item 5. Other Information.

(c) Insider Trading Arrangements and Policies

During the three months ended September 30, 2026, none of the Company's directors or officers (as defined in Rule 16a-1(f) of the Securities Exchange Act of 1934) adopted, modified or terminated a Rule 10b5-1 trading arrangement or non-Rule 10b5-1 trading arrangement (as such terms are defined in Item 408 of Regulation S-K).

Item 6. Exhibits.

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of TScan Therapeutics, Inc. (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on July 20, 2021)
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of TScan Therapeutics, Inc. (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on May 22, 2026)
3.3	Amended and Restated Bylaws of TScan Therapeutics, Inc. (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on July 20, 2021)
10.1*†	Confidential Separation Agreement and General Release Agreement, by and between the Registrant and Chrystal Louis, M.D., MPH, dated September 24, 2026
10.2*†	Confidential Separation Agreement and General Release Agreement, by and between the Registrant and Jason A. Amello, dated September 25, 2026
31.1*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1**	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.
** Furnished herewith.
• † Portions of this exhibit (indicated by an asterisk) will be omitted in accordance with the rules of the SEC.

SIGNATURES

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

TScan Therapeutics, Inc.

Date: November 12, 2026

By: /s/ Gavin MacBeath

Gavin MacBeath
Chief Executive Officer
(Principal Executive Officer and Principal Financial and Accounting Officer)

Exhibit 10.1

CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL. INFORMATION THAT WAS OMITTED HAS BEEN NOTED IN THIS DOCUMENT WITH A PLACHOLDER IDENTIFIED BY THE MARK "[*]".

TScan Therapeutics 830 Winter Street, Waltham MA 02451 857.399.9500 info@tscan.com
TScan.com

September 2, 2026

Chrystal Louis
[*]
[*]

RE: Confidential Separation Agreement and General Release

Dear Chrystal:

This Confidential Separation Agreement and General Release (the "Agreement") sets forth and confirms the understanding between you and TScan Therapeutics, Inc. (the "Company")[1] relating to the termination of your employment with the Company. The purpose of this Agreement is to establish an amicable arrangement for ending your employment relationship with Company, to permit you to receive severance pay benefits, and to release Company from any claims. This Agreement is entered into in satisfaction of the Company's obligations under Sections 5(b) and 5(d) of the Employment Agreement by and between you and TScan dated as of April 4, 2024 (the "Employment Agreement"), and constitutes the release contemplated by Section 5(b) of the Employment Agreement. If you accept the terms of this Agreement, please sign and return a copy to Ann Hargraves, Chief Human Resources Officer [*] by September 25, 2026.

1. Employment Status, Final Payments and Benefit Eligibility. The following will apply whether or not you sign this Agreement:

a. Termination of Employment. Your employment with Company will end on the earlier of November 1, 2026 or the date on which you commence employment, consulting, or paid board service (the "Separation Date"). Notwithstanding the foregoing, you will not be required to provide any services following September 2, 2026, except that you shall respond to any reasonable questions relating to your work (the "Transition Period"). During the Transition Period, you will continue to receive your base salary at the annual rate of $550,000 through the Company's regular payroll, will continue to accrue paid time off, will continue to vest in your outstanding equity awards, and will continue to participate in the Company's benefit plans on the same basis as immediately prior to the Transition Date. Your salary and benefits will cease as of the Separation Date, and any entitlement you had or might have had under any benefit program provided by Company will also end except as required by federal or state law or as otherwise described below. You and the Company acknowledge and agree that your employment is being terminated as part of a reduction in force and constitutes a Termination without Cause (as defined in the Employment Agreement)

b. Final Wages. You will be paid all wages earned but unpaid through the Separation Date, in accordance with applicable law.

c. Group Medical, Dental and Vision. If you are enrolled in Company-sponsored medical, vision and/or dental plans, coverage for you and any enrolled dependents will end on the last day of the month in which the Separation Date occurs. There will be no lapse in coverage from September 30, 2026 through the last day of the month in which the Separation Date occurs. Any out-of-pocket costs incurred by you in connection with a lapse in coverage after September 2, 2026, if any, including copays and deductibles, will be promptly reimbursed by the Company. The Separation Date will be treated as a qualifying event under the Consolidated Omnibus Budget Reconciliation Act of 1985 ("COBRA"), and you and your dependents may be entitled to continue coverage. You will receive COBRA information under separate cover, including information about the cost for continuation coverage under COBRA.

d. Expenses. Upon submission of all proper documentation and in accordance with Company policy, you will be reimbursed for all reasonable business-related expenses incurred by you prior to your Separation Date. We request that you submit these expenses to ap@tscan.com and copy your manager prior to your Separation Date, but in no event later than

[1] Except for the obligations set forth in Section 2 hereof, which shall be the sole obligation of TScan Therapeutics, Inc., whenever the terms "TScan" or the "Company" are used in this document, they shall be deemed to include TScan Therapeutics, Inc. and any of its parent companies, subsidiaries and related or affiliated entities, and its and their respective officers, directors, employees, agents, successors, and assigns.

September 30, 2026 Requests for expense reimbursement submitted later than September 30, 2026 will not be eligible for reimbursement.

e. Stock Options. As of your Separation Date, all vesting shall cease under any stock option agreements between you and Company and, subject to Section 2.e below, all unvested stock options will be cancelled. Please see your stock option agreements and relevant stock option plan regarding post-termination exercise periods for vested options, which periods shall be measured from the Separation Date. After such period, any unexercised options will be cancelled. You can work directly within E*Trade to exercise options.

f. Company Equipment. All Company-owned equipment, such as laptops, monitors, keyboards, badges, etc., must be immediately returned to the Company on or before the earlier of the Separation Date or the last day of active employment, or such other date requested by the Company. If you have equipment at home, please work with HR to acquire a pre-addressed box to return such equipment. It is Company policy that access for all separated employees, voluntary or involuntary, is discontinued immediately upon termination or the last day in the office. This includes badges, email, shared files and programs. Additionally, if your work at the Company involved using the electronic laboratory notebook, you must close, sign and witness all past and pending experiments prior to the Separation Date. The Company acknowledges that you returned all Company property and equipment on September 2, 2026 and that the condition set forth in Section 5(d) of the Employment Agreement has been satisfied. Nothing in this Agreement or the PIIA prohibits you from retaining copies of documents relating to your own compensation, benefits and terms of employment, as permitted by Section 6 of the Employment Agreement.

g. Non-Disclosure of Confidential Information, Non-Solicitation. The obligations set forth in the Proprietary Information and Inventions Agreement by and between you and Company that was effective as of April 28, 2024 ("PIIA") are incorporated by reference as if fully restated herein. You confirm, reaffirm, acknowledge and agree that all the terms of the PIIA shall remain in full force and effect through the Separation Date, and that your post-termination obligations under the PIIA, including obligations related to non-disclosure and non-solicitation survive the termination of your employment and continue in full force and effect, except as modified herein. For the avoidance of doubt, Company agrees that you are not subject to any noncompete restrictions following the Separation Date.

h. Unemployment Benefits. You have been provided with information describing how to apply for unemployment benefits in Massachusetts under Massachusetts law.

2. Consideration. Provided (i) you comply with paragraphs 1.f and 1.g of this Agreement, and (ii) you execute this Agreement within the time frame set forth above:

a. Severance Payment. Company will pay you on Company's regular payroll schedule your regular base pay for twelve (12) months following the Separation Date, which is equivalent to the gross amount of $550,000 (the "Severance Payments"). Notwithstanding any language to the contrary, no Severance Payments shall be made until the first regularly scheduled payroll date that is at least five (5) business days following the Separation Date of this Agreement (as defined in paragraph 4.d), on which date the Company will provide a lump-sum catch-up payment reflecting the portion of such Severance Payments covering the period from the Separation Date through the date of payment. Company may deduct from the Severance Payments any required withholding taxes, government payments or authorized deductions. The Severance Payments are made in satisfaction of Section 5(b) of the Employment Agreement and are in addition to, and shall not be reduced by or credited against, the base salary, benefits and other amounts payable to you for the period through the Separation Date under Section 1 above.

b. COBRA Benefits. If you timely elect and are eligible to continue receiving group medical, dental, and/or vision insurance pursuant to COBRA the Company will, for a period of twelve (12) months following the last day of coverage under Section 1.c, make contributions to the cost of COBRA coverage for you and your enrolled dependents on the same basis as the Company's contribution to Company-provided health and dental insurance coverage in effect for an active employee with the same coverage elections. If you become eligible to participate in Medicare or a new group health plan (whether you elect coverage under the new group health plan or not), the Company's continued contributions toward COBRA coverage shall end when the new eligibility begins. After Company's obligation to make contributions towards COBRA premiums ends, you shall be responsible for paying all premium costs and applicable administration fees for as long as, and to the extent that, you remain eligible for and elect COBRA continuation coverage.

d. Retention Award. Provided the Company doses a fifth patient in the pivotal trial for TSC-101 on or before November 1, 2026, you will be paid a lump sum in the gross amount of $125,000, subject to required tax withholdings and authorized deductions, in accordance with the retention award granted to you in November 2025.

e. Change in Control. Your termination constitutes an Involuntary Termination (as defined in the Employment Agreement). If a Change in Control (as defined in the Employment Agreement) occurs within the three-month period following the Separation Date, you shall be entitled to the payments, benefits and equity acceleration provided in Section 5(c) of the Employment Agreement, reduced by the Severance Payments and COBRA contributions previously paid to you under this Section 2, and any unvested stock options cancelled under Section 1.e shall be reinstated and vest in full as of the Change in Control. Section 7 of the Employment Agreement shall apply in accordance with its terms.

f. No Offset; New Employment. Your acceptance or commencement of other employment, consulting or board service after the Separation Date, shall not reduce, offset, delay, condition or result in the forfeiture of any payment or benefit under this Agreement, except that the Company's COBRA contributions shall end upon your eligibility for a new group health plan as provided in Section 2.b.

g. Section 409A. The payments and benefits under this Agreement are intended to be exempt from or to comply with Section 409A of the Internal Revenue Code of 1986, as amended, and the regulations thereunder ("Section 409A"), including the short-term deferral and separation pay exemptions, and this Agreement shall be interpreted accordingly. Each installment payment is a separate payment for purposes of Section 409A. Section 11 of the Employment Agreement is incorporated herein by reference and shall apply to the payments and benefits under this Agreement, including, if applicable, the six-month delay for specified employees.

3. Release.

a. You acknowledge and agree that in exchange for the compensation described in paragraph 2 herein, and other good and valuable consideration receipt of which is hereby acknowledged, you are waiving your right to assert any Claim (as defined below) against Company (as defined in footnote 1 of this Agreement) arising from acts or omissions that occurred on or before the date you sign this Agreement. You agree that you are making this release and waiver on behalf of yourself and your representatives, agents, heirs, legatees, successors and assigns.

b. Your waiver and release herein is intended to bar any form of legal claim, charge, complaint or any other form of action (jointly referred to as "Claims") against the Company seeking any form of relief including, without limitation, equitable relief (whether declaratory, injunctive or otherwise), the recovery of any damages or any other form of monetary recovery whatsoever (including, without limitation, back pay, front pay, compensatory damages, emotional distress damages, punitive damages, attorneys' fees and any other costs) against the Company, for any alleged action, inaction or circumstance existing or arising through the date you sign this Agreement. You understand that there could be unknown or unanticipated Claims resulting from your employment with the Company, the cessation of employment or other matters and agree that such Claims are included in this waiver and release.

c. Without limiting the generality of the foregoing, this release includes all claims under any federal, state, or local law or regulation dealing with employment, discrimination, and the payment of wages, including statutes such as federal and state wage and hour laws, federal and state whistleblower laws, Title VII of the Civil Rights Act of 1964, the Civil Rights Act of 1991, the Lilly Ledbetter Fair Pay Act of 2009, the Equal Pay Act, the Americans with Disabilities Act, , the Family and Medical Leave Act, the Employee Retirement Income Security Act (excluding COBRA), the Vietnam Era Veterans Readjustment Assistance Act, the Fair Credit Reporting Act, the Occupational Safety and Health Act, the Sarbanes-Oxley Act of 2002, state and federal False Claims Act, the Worker Adjustment and Retraining Act (WARN), the Massachusetts Law Against Discrimination, the Massachusetts Payment of Wages Statute, the Massachusetts Overtime Statute, the Massachusetts Equal Pay Act, the Massachusetts Civil Rights Act, and the Massachusetts Privacy Statute; each as amended; as well as all claims arising from any contract, whether oral or written, express or implied; promissory estoppel; any tort, including, without limitation, assault, battery, defamation, misrepresentation, intentional interference with contract; any claim for equity or other benefits; or any other statutory and/or common law claim.

d. You specifically and expressly acknowledge that this Agreement is intended to include and extinguish all claims, known and unknown, which exist up to and including the date you sign this Agreement and which arise from or are in any way related to your employment with Company or separation from employment and that no possible claim against Company would materially affect or change your complete and voluntary acceptance of this Agreement, even if such claim were unknown at the time of signing of this Agreement and discovered after that signing.

e. You represent and agree that (i) the payments and benefits set forth in this Agreement, together with payments and benefits previously provided to you, are complete payment, settlement, accord and satisfaction with respect to all obligations and liabilities of the Company to you, and with respect to all claims, causes of action and damages that could be asserted by you against the Company regarding your employment with, change in employment status with, and/or termination from employment, including, without limitation, all claims for wages, salary, commissions, vacation pay, draws,

car allowances, incentive pay, bonuses, business expenses, paid time off, stock and stock options, severance pay, attorneys' fees, compensatory damages, exemplary damages, or other compensation, benefits, costs or sums; and (ii) you have no known workplace injuries or occupational diseases and that you either have been provided or have not been denied any leave requested under the Family and Medical Leave Act.

f. Nothing in this paragraph 3 or in this Agreement generally shall waive, release, or discharge: (i) claims that cannot be waived by private agreement, such as claims for unemployment benefit rights and workers' compensation; (ii) indemnification rights you have or may have against the Company, in accordance with the Section 9 of the Employment Agreement; (iii) any claims relating to age discrimination arising under federal; (iv) any right to file an unfair labor practice charge under the National Labor Relations Act; and (v) any rights to vested benefits, such as pension or retirement benefits, the rights to which are governed by the terms of the applicable plan documents; (vi) your rights under this Agreement (vii) your rights as a holder of vested stock options under the Company's equity incentive plans and your award agreements; and (viii) your rights as a stockholder of the Company. You also acknowledge and agree that, but for providing this waiver and release, you would not be receiving the Consideration provided for in this Agreement.

g. Nothing in this paragraph 3 or in this Agreement generally shall bar or prohibit you from contacting, seeking assistance from, filing a charge with, or participating in any governmental investigation or proceeding before any federal, state or local administrative agency, including the Equal Employment Opportunity Commission, the Securities and Exchange Commission and the Massachusetts Commission Against Discrimination, to the extent permitted by applicable federal, state and/or local law. However, you nevertheless will be prohibited to the fullest extent authorized by law from obtaining monetary damages in any proceeding in which you do so participate, and you hereby irrevocably assign to the United States government any right you may have to any proceeds or awards in connection with any false claim proceedings against Company.

h. THIS RELEASE CONTAINS A WAIVER OF RIGHTS UNDER THE MASSACHUSETTS WAGE ACT: You acknowledge, agree and understand that employees have certain rights under the Massachusetts Wage Act, Mass. Gen. L. ch. 149, et seq. (the "MA Wage Act") regarding when, how, and how much they must be paid, including but not limited to the right to be paid wages earned within timeframes provided in the MA Wage Act; that wages include amounts payable to employee for hours worked, which may include salaries, determined and due commissions, overtime pay, tips, and earned vacation or holiday payments due to employees under oral or written agreements; and that employees have the right to bring private lawsuits for violation of the MA Wage Act. The Company represents that all wages earned by you through the date of this Agreement, have been or will be paid in full when due, and your waiver of rights under the MA Wage Act is conditioned upon, and shall not extend to, any wages (including base salary through the Separation Date) that are not paid when due.

4. Process of Accepting this Agreement.

a. The Company is providing you with seven (7), within which to consider its terms. The Company advises you in writing to consult with an attorney before signing this Agreement, which you represent you have done.

b. At any point prior to the end of this seven (7) day period, you may accept the terms of this Agreement by signing below and returning it to Ann Hargraves, Chief Human Resources Officer [*]. You agree that this seven (7))-day period shall not be restarted by any discussions about or agreed-upon modifications, whether material or immaterial, if any, to this Agreement.

d. The day following the day on which you return a signed copy of this Agreement to Ann Hargraves, provided it is returned within the time frame set forth above, shall be deemed the "Effective Date" of this Agreement.

5. Voluntary Assent. You affirm that no other promises or agreements of any kind have been made to or with you by any person or entity whatsoever to cause you to sign this Agreement, and that you fully understand the meaning and intent of this Agreement. You acknowledge that you have been advised in writing to consult with an attorney, which you have done, and have been afforded a reasonable opportunity to fully discuss and review the terms of this Agreement with an attorney. You further represent that you have carefully read this Agreement, understand the contents herein, freely and voluntarily assent to all of the terms and conditions hereof, and sign your name of your own free will.

6. Employee Representations. You represent and warrant that, you have not reported any illegal or potentially illegal conduct or activities to any supervisor, manager, department head, human resource representative, director, officer, agent, or any representative of Company, and have no knowledge of any such illegal or potentially illegal conduct or activities, including any conduct or activities that may involve false claims to the United States. You understand that nothing in this Agreement prevents you from cooperating with any United States government investigation. In addition, to the fullest extent permitted by law, you hereby irrevocably assign to the

United States government any right you might have to any proceeds or awards in connection with any false claims proceedings against Company.

7. Future Conduct.

a. The parties acknowledge that the Company has publicly disclosed the principal financial terms of your separation in its Current Report on Form 8-K filed September 2, 2026. To the extent not so disclosed, each party agree to keep the financial terms of this Agreement confidential and not to divulge such terms to any person other than to (in your case) your immediate family members and attorneys and financial and tax advisors, and (in the Company's case) its directors, officers, employees, attorneys, accountants, insurers and advisors with a need to know (so long as each such person agrees to be bound by the confidential nature of this Agreement), as required by applicable law, regulation or stock exchange rule, or by court order or subpoena, or as necessary to complete tax returns, or in connection with any action to enforce this Agreement.

b. You agree that neither you nor anyone acting at your request or on your behalf shall maliciously disparage or defame the business, employment or personnel practices of Company or any of its subsidiaries or affiliates, or any of its current, former or future officers, directors, shareholders, investors, employees, representatives, agents or attorneys, except if testifying truthfully in the context of a government investigation or under oath pursuant to a lawful court order or subpoena, or in connection with any action to enforce this Agreement. If you receive such a court order or subpoena, if and to the extent not prohibited by applicable law, you or your attorney shall provide Company with a copy of such court order or subpoena within two (2) business days of your receipt of it and shall notify Company of the content of any testimony or information to be provided and provide Company with copies of all documents to be produced in a reasonable period prior to production. The Company agrees that it shall instruct its directors and executive officers not to maliciously disparage or defame you, your performance or your professional reputation. Nothing in this Section 7 prohibits either party from making truthful statements to any governmental or regulatory agency or as otherwise protected by law.

c. You represent that, as of the date you sign this Agreement, no charges, complaints or actions of any kind have been filed by you or on your behalf against Company with any federal, state or local court or agency.

8. Default. You hereby agree that, upon any material breach or default by you in respect of your obligations under this Agreement, including without limitation, your obligations under Sections 1.g, 3, 4, 6, and 7, provided that the Company has first given you written notice specifying the alleged breach in reasonable detail and, if the breach is capable of cure, thirty (30) days following such notice within which to cure it, Company shall have the following rights and remedies (which shall not be mutually exclusive), in addition to any other rights and remedies which may be available pursuant to other provisions of this Agreement or at law or in equity:

a. Company shall not be required to make any additional payment of the severance benefits described under paragraph 2a and 2.b of this Agreement that remain unpaid; and

b. Company shall have the right and option to require you to reimburse Company for the aggregate amount of all severance benefits previously paid to you pursuant to paragraph 2 of the Agreement, promptly following demand therefor to you.

c. If a court of competent jurisdiction determines that you did not breach or default your obligations under this Agreement, the Company will pay any outstanding severance benefits that were halted or which you reimbursed pursuant to this Section 8.

9. Representations and Governing Law.

a. This Agreement is the complete agreement of the parties on or in any way related to the subject matter addressed in the Agreement and your employment and separation from employment, and it supersedes and cancels all other previous agreements or understandings between the parties, including any previous agreement presented to you, except for (i) the PIIA, which shall remain in full force and effect in accordance with its terms (except as may be modified by Section 1.g above); (ii) Sections 5(c), 6, 7, 9, 10 and 11 of the Employment Agreement, which shall survive and remain in full force and effect in accordance with their terms; (iii) any indemnification agreement between you and the Company; (iv) the Company's equity incentive plans and your award agreements thereunder with respect to your vested stock options; and (v) the Retention Award, each of which shall remain in full force and effect in accordance with its terms. This Agreement specifically incorporates the PIIA, and nothing herein precludes the continued enforcement of the PIIA (except as may be modified by Section 1.g above). This Agreement cannot be modified or rescinded except upon the written consent of both you and Company.

b. If any provision of this Agreement is held to be unenforceable, such provision shall be considered to be distinct and severable from the other provisions of this Agreement, and such unenforceability shall not affect the validity and enforceability of the remaining provisions. If any provision of this Agreement is held to be unenforceable as written but may be made enforceable by limitation, then such provision shall be enforceable to the maximum extent permitted by applicable law. The language of all parts of this Agreement shall in all cases be construed as a whole, according to its fair meaning, and not strictly for or against any of the parties.

c. You represent and warrant that you have the full power, capacity, and authority to enter into this Agreement and have not assigned, pledged, encumbered or in any manner conveyed all or any portion of the potential claims covered by this Agreement. The Company represents and warrants that it has the full power and authority to enter into this Agreement and that the individual signing on its behalf is duly authorized to bind the Company. This Agreement cannot be assigned by you, and it shall be binding upon Company's successors and assigns.

d. The validity, performance and enforceability of this Agreement will be determined and governed by the laws of the Commonwealth of Massachusetts without regard to its conflict of laws principles. The parties agree that any action, demand, claim or counterclaim relating to the terms and provisions of this Agreement, or to its breach, shall be commenced in Massachusetts in a court of competent jurisdiction, and the parties further acknowledge that venue for such actions shall lie exclusively in Massachusetts and that material witnesses and documents would be located in Massachusetts. Both parties hereby waive and renounce in advance any right to a trial by jury in connection with such legal action.

e. The existence and execution of this Agreement shall not be considered as an admission of any liability, violation, error or omission by you or Company.

If you agree to the foregoing, kindly sign and return the enclosed copy of this letter to Ann Hargraves, Chief Human Resources Officer [*] on or before September 25, 2026.

Sincerely,

/s/ Ann Hargraves
Ann Hargraves
Chief Human Resources Officer

I REPRESENT THAT I (A) HAVE READ AND FULLY UNDERSTAND THE TERMS AND CONDITIONS OF THIS AGREEMENT; (B) HAVE HAD SUFFICIENT TIME TO CONSIDER THE AGREEMENT; (C) HAVE BEEN ADVISED IN WRITING TO CONSULT WITH AN ATTORNEY AND HAVE DONE SO; AND (D) AM VOLUNTARILY AND WILLINGLY SIGNING IT.

Agreed and accepted:

/s/ Chrystal Louis	September 24, 2026
Chrystal Louis	Date

Exhibit 10.2

CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL. INFORMATION THAT WAS OMITTED HAS BEEN NOTED IN THIS DOCUMENT WITH A PLACHOLDER IDENTIFIED BY THE MARK "[*]".

TScan Therapeutics 830 Winter Street
Waltham MA 02451
857.399.9500
info@tscan.com TScan.com

September 2, 2026

Jason Amello
[*]
[*]

RE: Confidential Separation Agreement and General Release

Dear Jason:

This Confidential Separation Agreement and General Release (the "**Agreement**") sets forth and confirms the understanding between you and TScan Therapeutics, Inc. (the "**Company**")[1] relating to the termination of your employment with the Company. The purpose of this Agreement is to establish an amicable arrangement for ending your employment relationship with Company, to permit you to receive severance pay benefits, and to release Company from any claims. By virtue of this Agreement, and the Consideration provided to you under this Agreement, TScan is in full compliance with the requirements set forth in Sections 5(b) and 5(d) of the Employment Agreement by and between you and TScan. If you accept the terms of this Agreement, please sign and return a copy to Ann Hargraves, Chief Human Resources Officer [*] by September 25, 2026.

1. *Employment Status, Final Payments and Benefit Eligibility.* The following will apply whether or not you sign this Agreement:

a. *Termination of Employment.* Your employment with Company will end on the earlier of November 1, 2026 or the date on which you commence employment with another company, consulting, or paid board service (the "**Separation Date**"). Notwithstanding the foregoing, you will not be required to provide any services following September 2, 2026, except that you shall respond to any reasonable questions relating to your work. Your salary and benefits (health insurance and all other employer-sponsored contributions, including but not limited to HSA contributions, group life insurance, disability insurance, and 401(k) matching) will continue as an active employee through the Separation Date and will cease as of the Separation Date, and any entitlement you had or might have had under any benefit program provided by Company will also end as of the Separation Date, except as required by federal or state law or as otherwise described below.

b. *Final Wages.* You will be paid all wages earned but unpaid through the Separation Date, in accordance with applicable law.

c. *Group Medical, Dental and Vision.* If you are enrolled in Company-sponsored medical, vision and/or dental plans, coverage for you and any enrolled dependents will end on the last day of the month in which the Separation Date occurs. There will be no lapse in coverage from September 30, 2026 through the last day of the month in which the Separation Date occurs. Any out-of-pocket costs incurred by you in connection with a lapse in coverage after September 2, 2026, if any, including copays and deductibles, will be promptly reimbursed by the Company.

d. The Separation Date will be treated as a qualifying event under the Consolidated Omnibus Budget Reconciliation Act of 1985 ("**COBRA**"), and you and your dependents may be entitled to continue coverage. You will receive COBRA information under separate cover, including information about the cost for continuation coverage under COBRA.

e. *Expenses.* Upon submission of all proper documentation and in accordance with Company policy, you will be reimbursed for all reasonable business-related expenses incurred by you prior to your Separation Date. We request that you submit these expenses to ap@tscan.com and copy your manager prior to your Separation Date, but in no event later than fourteen (14) days following your Separation Date. Requests for expense reimbursement submitted later than fourteen (14) days following your Separation Date will not be eligible for reimbursement.

[1] Except for the obligations set forth in Section 2 hereof, which shall be the sole obligation of TScan Therapeutics, Inc., whenever the terms "TScan" or the "Company" are used in this document, they shall be deemed to include TScan Therapeutics, Inc. and any of its parent companies, subsidiaries and related or affiliated entities, and its and their respective officers, directors, employees, agents, successors, and assigns.

f. *Stock Options.* As of your Separation Date, all vesting shall cease under any stock option agreements between you and Company and all unvested stock options will be cancelled. Please see your stock option agreements and relevant stock option plan regarding post-termination exercise periods for vested options. After such period, any unexercised options will be cancelled. You can work directly within E*Trade to exercise options.

g. *Company Equipment.* All Company-owned equipment, such as laptops, monitors, keyboards, badges, etc., must be immediately returned to the Company on or before the earlier of the Separation Date or the last day of active employment, or such other date requested by the Company. If you have equipment at home, please work with HR to acquire a pre-addressed box to return such equipment. It is Company policy that access for all separated employees, voluntary or involuntary, is discontinued immediately upon termination or the last day in the office. This includes badges, email, shared files and programs. Additionally, if your work at the Company involved using the electronic laboratory notebook, you must close, sign and witness all past and pending experiments prior to the Separation Date.

h. *Non-Disclosure of Confidential Information, Non-Competition and Non-Solicitation.* The obligations set forth in the Proprietary Information and Inventions Agreement by and between you and Company that was effective as of January 29, 2024 ("**PIIA**") are incorporated by reference as if fully restated herein, and you confirm, reaffirm, acknowledge and agree that your post-termination obligations under the PIIA, including obligations related to non-disclosure and non-solicitation survive the termination of your employment and continue in full force and effect, except as modified herein. Because your employment is being terminated as part of a reduction-in-force, the noncompete obligations set forth in Section 4(d)(iii) of the PIIA will not be enforced, and the Company shall have no obligation to pay you the "Post-Termination Compensation" described in Section 5 of the PIIA.

i. *Unemployment Benefits.* Enclosed please find information describing how to apply for unemployment benefits in Massachusetts under Massachusetts law.

2. *Consideration.* Provided (i) you comply with paragraphs 1.f and 1.g of this Agreement, and (ii) you execute this Agreement within the time frame set forth above:

a. *Severance Payment.* Company will pay you on Company's regular payroll schedule your regular base pay for twelve (12) months, which is equivalent to the gross amount of $536,000 (the "**Severance Payments**"). The Severance Payments shall begin no later than the second regularly scheduled payroll date following the Separation Date. The Company may deduct from the Severance Payments any required withholding taxes, government payments or authorized deductions.

b. *COBRA Benefits.* If you timely elect and are eligible to continue receiving group medical, dental, and/or vision insurance pursuant to COBRA the Company will, for a period of twelve (12) months following the Separation Date, make contributions to the cost of COBRA coverage for you on the same basis as the Company's contribution to Company-provided health, vision, and dental insurance coverage in effect for an active employee with the same coverage elections. The Company shall also provide the standard Company-provided contribution for the 2027 plan year towards your deductible for the same period. If you become eligible to participate in Medicare or a new group health plan (whether you elect coverage under the new group health plan or not), the Company's continued contributions toward COBRA coverage shall end when the new eligibility begins. After Company's obligation to make contributions towards COBRA premiums ends, you shall be responsible for paying all premium costs and applicable administration fees for as long as, and to the extent that, you remain eligible for and elects COBRA continuation coverage.

c. *Retention Award.* If the fifth patient in the pivotal trial of TSC-101 is dosed on or before the Separation Date, you will be paid a lump sum in the gross amount of $85,000 (representing 50% of $170,000), subject to required tax withholdings and authorized deductions, in accordance with the terms of the Retention Program offered to you in November 2025.

3. *Release.*

a. You acknowledge and agree that in exchange for the compensation described in paragraph 2 herein, and other good and valuable consideration receipt of which is hereby acknowledged, you are waiving your right to assert any Claim (as defined below) against Company (as defined in footnote 1 of this Agreement) arising from acts or omissions that occurred on or before the Effective Date. You agree that you are making this release and waiver on behalf of yourself and your representatives, agents, heirs, legatees, successors and assigns.

b. Your waiver and release herein is intended to bar any form of legal claim, charge, complaint or any other form of action (jointly referred to as "**Claims**") against the Company seeking any form of relief including, without limitation, equitable relief (whether declaratory, injunctive or otherwise), the recovery of any damages or any other form of monetary recovery whatsoever (including, without limitation, back pay, front pay, compensatory damages, emotional distress damages, punitive damages, attorneys' fees and any other costs) against the Company, for any alleged action, inaction or circumstance existing or arising through the

Effective Date. You understand that there could be unknown or unanticipated Claims resulting from your employment with the Company, the cessation of employment or other matters and agree that such Claims are included in this waiver and release.

c. Without limiting the generality of the foregoing, this release includes all claims under any federal, state, or local law or regulation dealing with employment, discrimination, and the payment of wages, including statutes such as federal and state wage and hour laws, federal and state whistleblower laws, Title VII of the Civil Rights Act of 1964, the Civil Rights Act of 1991, the Lilly Ledbetter Fair Pay Act of 2009, the Equal Pay Act, the Americans with Disabilities Act, the Family and Medical Leave Act, the Employee Retirement Income Security Act (excluding COBRA), the Vietnam Era Veterans Readjustment Assistance Act, the Fair Credit Reporting Act, the Occupational Safety and Health Act, the Sarbanes-Oxley Act of 2002, state and federal False Claims Act, the Worker Adjustment and Retraining Act (WARN), the Massachusetts Law Against Discrimination, the Massachusetts Payment of Wages Statute, the Massachusetts Overtime Statute, the Massachusetts Equal Pay Act, the Massachusetts Civil Rights Act, and the Massachusetts Privacy Statute; each as amended; as well as all claims arising from any contract, whether oral or written, express or implied; promissory estoppel; any tort, including, without limitation, assault, battery, defamation, misrepresentation, intentional interference with contract; any claim for equity or other benefits; or any other statutory and/or common law claim.

d. You specifically and expressly acknowledge that this Agreement is intended to include and extinguish all claims, known and unknown, which exist up to and including the date you sign this Agreement and which arise from or are in any way related to your employment with Company or separation from employment and that no possible claim against Company would materially affect or change your complete and voluntary acceptance of this Agreement, even if such claim were unknown at the time of signing of this Agreement and discovered after that signing.

e. You represent and agree that (i) the payments and benefits set forth in this Agreement, together with payments and benefits previously provided to you, are complete payment, settlement, accord and satisfaction with respect to all obligations and liabilities of the Company to you, and with respect to all claims, causes of action and damages that could be asserted by you against the Company regarding your employment with, change in employment status with, and/or termination from employment, including, without limitation, all claims for wages, salary, commissions, vacation pay, draws, car allowances, incentive pay, bonuses, business expenses, paid time off, stock and stock options, severance pay, attorneys' fees, compensatory damages, exemplary damages, or other compensation, benefits, costs or sums; and (ii) you have no known workplace injuries or occupational diseases and that you either have been provided or have not been denied any leave requested under the Family and Medical Leave Act.

f. Nothing in this paragraph 3 or in this Agreement generally shall waive, release, or discharge: (i) claims that cannot be waived by private agreement, such as claims for unemployment benefit rights and workers' compensation; (ii) indemnification rights you have or may have against the Company; (iii) any right to file an unfair labor practice charge under the National Labor Relations Act; any; (iv) any rights to vested benefits, such as pension or retirement benefits, the rights to which are governed by the terms of the applicable plan documents; (v) your right to enforce this Agreement; or (vi) any claims of age discrimination under the Age Discrimination in Employment Act or the Older Workers Benefit Protection Act. You also acknowledge and agree that, but for providing this waiver and release, you would not be receiving the Consideration provided for in this Agreement.

g. Nothing in this paragraph 3 or in this Agreement generally shall bar or prohibit you from contacting, seeking assistance from, filing a charge with, or participating in any governmental investigation or proceeding before any federal, state or local administrative agency, including the Equal Employment Opportunity Commission and the Massachusetts Commission Against Discrimination, to the extent permitted by applicable federal, state and/or local law. However, you nevertheless will be prohibited to the fullest extent authorized by law from obtaining monetary damages in any proceeding in which you do so participate, and you hereby irrevocably assign to the United States government any right you may have to any proceeds or awards in connection with any false claim proceedings against Company.

h. THIS RELEASE CONTAINS A WAIVER OF RIGHTS UNDER THE MASSACHUSETTS WAGE ACT: You acknowledge, agree and understand that employees have certain rights under the Massachusetts Wage Act, Mass. Gen. L. ch. 149, et seq. (the "**MA Wage Act**") regarding when, how, and how much they must be paid, including but not limited to the right to be paid wages earned within timeframes provided in the MA Wage Act; that wages include amounts payable to employee for hours worked, which may include salaries, determined and due commissions, overtime pay, tips, and earned vacation or holiday payments due to employees under oral or written agreements; and that employees have the right to bring private lawsuits for violation of the MA Wage Act.

4. *Process of Accepting this Agreement.*

a. The Company is providing you until September 25, 2026.

b. At any point prior to September 25, 2026, you may accept the terms of this Agreement by signing below and returning it to Ann Hargraves, Chief Human Resources Officer [*].

c. The day following the day on which you return a signed copy of this Agreement to Ann Hargraves, provided it is returned within the time frame set forth above, shall be deemed the "**Effective Date**" of this Agreement.

5. *Voluntary Assent.* You affirm that no other promises or agreements of any kind have been made to or with you by any person or entity whatsoever to cause you to sign this Agreement, and that you fully understand the meaning and intent of this Agreement. You acknowledge that you have been afforded a reasonable opportunity to fully discuss and review the terms of this Agreement with an attorney. You further represent that you have carefully read this Agreement, understand the contents herein, freely and voluntarily assent to all of the terms and conditions hereof, and sign your name of your own free will.

6. *Employee Representations.* You represent and warrant that you have not reported any illegal or potentially illegal conduct or activities to any supervisor, manager, department head, human resource representative, director, officer, agent, or any representative of Company, and have no knowledge of any such illegal or potentially illegal conduct or activities, including any conduct or activities that may involve false claims to the United States. You understand that nothing in this Agreement prevents you from cooperating with any United States government investigation. In addition, to the fullest extent permitted by law, you hereby irrevocably assign to the United States government any right you might have to any proceeds or awards in connection with any false claims proceedings against Company.

7. *Future Conduct.*

a. You agree to keep the financial terms of this Agreement confidential and not to divulge such terms to any person other than to your immediate family members, financial advisors, and attorneys (so long as each such person agrees to be bound by the confidential nature of this Agreement), as required by court order or subpoena, or as necessary to complete tax returns.

b. You agree that neither you nor anyone acting at your request or on your behalf shall maliciously disparage or defame the business, employment or personnel practices of Company or any of its subsidiaries or affiliates, or any of its current, former or future officers, directors, shareholders, investors, employees, representatives, agents or attorneys, except if testifying truthfully in the context of a government investigation or under oath pursuant to a lawful court order or subpoena. If you receive such a court order or subpoena, if not prohibited by applicable law, you or your attorney shall provide Company with a copy of such court order or subpoena within two (2) business days of your receipt of it and shall notify Company of the content of any testimony or information to be provided and provide Company with copies of all documents to be produced. The Company agrees to instruct all members of the Senior Leadership Team and members of the Board of Directors not to maliciously disparage or defame you, except if testifying truthfully in the context of a government investigation or under oath pursuant to a lawful court order or subpoena.

c. You represent that no charges, complaints or actions of any kind have been filed by you or on your behalf against Company with any federal, state or local court or agency.

8. *Default.* You hereby agree that, upon any material breach or default by you in respect of your obligations under this Agreement, including without limitation, your obligations under Sections 1.g, 3, 4, 6, and 7, Company shall have the following rights and remedies (which shall not be mutually exclusive), in addition to any other rights and remedies which may be available pursuant to other provisions of this Agreement or at law or in equity:

a. Company shall not be required to make any additional payment of the severance benefits described under paragraph 2 of the Agreement; and Company shall have the right and option to require you to reimburse Company for the aggregate amount of all severance benefits previously paid to you pursuant to paragraph 2 of the Agreement, promptly following demand therefor to you.

9. *Representations and Governing Law.*

a. This Agreement is the complete agreement of the parties on or in any way related to the subject matter addressed in the Agreement and your employment and separation from employment, and it supersedes and cancels all other previous agreements or understandings between the parties, including any previous agreement presented to you, except for the PIIA, which shall remain in full force and effect in accordance with its terms (except as may be modified by Section 1.g above). This Agreement specifically incorporates the PIIA, and nothing herein precludes the continued enforcement of the PIIA (except as may be modified by Section 1.g above). This Agreement cannot be modified or rescinded except upon the written consent of both you and Company.

b. If any provision of this Agreement is held to be unenforceable, such provision shall be considered to be distinct and severable from the other provisions of this Agreement, and such unenforceability shall not affect the validity and enforceability of the remaining provisions. If any provision of this Agreement is held to be unenforceable as written but may be made enforceable by limitation, then such provision shall be enforceable to the maximum extent permitted by applicable law. The language of all parts of

this Agreement shall in all cases be construed as a whole, according to its fair meaning, and not strictly for or against any of the parties.

c. You represent and warrant that you have the full power, capacity, and authority to enter into this Agreement and have not assigned, pledged, encumbered or in any manner conveyed all or any portion of the potential claims covered by this Agreement. This Agreement cannot be assigned by you, and it shall be binding upon Company's successors and assigns.

d. The validity, performance and enforceability of this Agreement will be determined and governed by the laws of the Commonwealth of Massachusetts without regard to its conflict of laws principles. You agree that any action, demand, claim or counterclaim relating to the terms and provisions of this Agreement, or to its breach, shall be commenced in Massachusetts in a court of competent jurisdiction, and you further acknowledge that venue for such actions shall lie exclusively in Massachusetts and that material witnesses and documents would be located in Massachusetts. Both parties hereby waive and renounce in advance any right to a trial by jury in connection with such legal action.

e. The existence and execution of this Agreement shall not be considered as an admission of any liability, violation, error or omission by you or Company.

If you agree to the foregoing, kindly sign and return the enclosed copy of this letter to Ann Hargraves, Chief Human Resources Officer [*] on or before **September 25, 2026**.

Sincerely,

/s/ Ann Hargraves
Ann Hargraves
Chief Human Resources Officer

I REPRESENT THAT I (A) HAVE READ AND FULLY UNDERSTAND THE TERMS AND CONDITIONS OF THIS AGREEMENT; (B) HAVE HAD SUFFICIENT TIME TO CONSIDER THE AGREEMENT; AND (C) AM VOLUNTARILY AND WILLINGLY SIGNING IT.

Agreed and accepted:

/s/ Jason Amello	September 25, 2026
Jason Amello	Date

Exhibit 31.1

CERTIFICATION PURSUANT TO RULE 13a-14(a) AND 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Gavin MacBeath, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of TScan 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. I am 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. I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2026

By: /s/ Gavin MacBeath

Name: Gavin MacBeath

Title: Chief Executive Officer

(Principal Executive Officer and Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of TScan Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2026 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: November 12, 2026

By: /s/ Gavin MacBeath
Gavin MacBeath
Principal Executive Officer and Principal Financial and Accounting Officer