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, 2023

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 **(State or other jurisdiction of incorporation or organization)**	**82-5282075** **(I.R.S. Employer Identification No.)**
830 Winter Street, Waltham, Massachusetts **(Address of principal executive offices)**	**02451** **(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 3, 2023, the registrant had 43,548,092 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 (Quarterly Report) contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (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-engineered T cell (TCR-T), therapy 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 product candidates;
- our plans relating to developing and commercializing our TCR-T therapy candidates, if approved, including sales strategy;
- estimates of the size of the addressable market for our TCR-T therapy 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 United States 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 health epidemics, including the lingering effects of the COVID-19 pandemic, in regions where we, our partners, or other third parties on which we rely, on any of the foregoing or other aspects of our business or operations;
- 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;
- disruptions and instability in the banking industry and other parts of the financial service sector, such as events involving limited liquidity, defaults, non-performance or other adverse events or developments;
- liquidity and/or capital resources changes and the impact of any changes or limitations on factors such as (among others) the company’s ability to borrow funds and/or renew or roll over existing indebtedness and access to private capital sources and public capital markets;
- financial market volatility and declines in financial market prices of equity securities;
- inflation and rising interest rates and resulting impacts financial market prices of debt and equity securities;

- historical and future operating, financial and investment impacts of inflation, rising interest rates and instability in financial and capital markets;
- impacts on customers, distributors, suppliers and others resulting from banking industry disruptions or ongoing or new supply chain and product distribution/logistics issues;
- the effects of global economic uncertainty and financial market volatility caused by political instability, changes in international trade relationships and conflicts, such as the ongoing conflict between Russia and Ukraine, and Israel and Hamas, on any of the foregoing or other aspects of our business or operations; and
- our anticipated use of our existing cash resources 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 these 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 the 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 a number of 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.

•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 cell therapy products and our ability to generate revenue from cell therapy 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 would be forced to delay, reduce or eliminate our product development programs, commercialization efforts or other operations.

•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, such as the ongoing conflict between Russia and Ukraine, and Israel and Hamas, 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 harm 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.

•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.

•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.

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 and manufacturing at other companies, we have limited experience as a company in conducting clinical trials and little direct experience managing a manufacturing facility 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, including any lingering effects of the COVID-19 pandemic, 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.

•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 products or for patients that use any of our product candidates, if approved.

•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 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 as they will be limited to those patients who are ineligible for or have failed prior treatments and 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 candidates for clinical trials or for commercial purposes could be delayed or stopped.

•Although we have expanded our existing manufacturing facility and infrastructure in lieu of relying solely on third parties for the manufacture of our product candidates for certain clinical purposes and many of our personnel have experience in clinical manufacturing at other companies, we have no direct experience as a company managing manufacturing for our product candidates, which will be costly and time-consuming, and which may not be successful.

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

Risks Related to Government Regulation

•The FDA 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.

•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.

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.

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

Risks Related to Our Reliance on Third Parties

•We plan to rely on third parties to 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 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.

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

(in thousands, except share and per share data)

(Unaudited)

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 155,193	$ 120,027
Marketable securities	60,230	-
Prepaid expenses and other current assets	2,144	4,100
Total current assets	217,567	124,127
Property and equipment, net	8,595	10,100
Right-of-use assets	58,539	59,102
Restricted cash	5,031	5,037
Long-term deposit and other assets	1,647	725
Total assets	$ 291,379	$ 199,091
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,196	$ 2,912
Accrued expenses and other current liabilities	9,257	6,838
Operating lease liability, current portion	4,376	3,681
Deferred revenue, current portion	15,212	3,874
Current portion of long-term debt	1,110	-
Total current liabilities	33,151	17,305
Deferred revenue, net of current portion	7,758	-
Operating lease liability, net of current portion	52,662	53,013
Long-term debt and accrued interest	28,835	29,290
Other long term liabilities	12	49
Total liabilities	122,418	99,657
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Voting common stock, $0.0001 par value; 300,000,000 shares authorized; 43,546,528 and 19,082,820 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	4	2
Non-voting common stock, $0.0001 par value; 10,000,000 shares authorized; 4,276,588 and 5,143,134 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	1	1
Additional paid-in capital	396,940	257,810
Accumulated deficit	(227,984)	(158,379)
Total stockholders' equity	168,961	99,434
Total liabilities and stockholders' equity	$ 291,379	$ 199,091

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

TScan Therapeutics, Inc.

Condensed Consolidated Statements of Operations

(in thousands, except share and per share data)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenue				
Collaboration and license revenue	$ 3,887	$ 3,363	$ 13,838	$ 10,440
Operating expenses:				
Research and development	22,741	15,031	65,747	44,215
General and administrative	5,894	4,910	20,192	14,212
Total operating expenses	28,635	19,941	85,939	58,427
Loss from operations	(24,748)	(16,578)	(72,101)	(47,987)
Other (expense) income:				
Interest and other income, net	2,733	534	5,403	690
Interest expense	(982)	(201)	(2,907)	(201)
Total other income	1,751	333	2,496	489
Net loss	$ (22,997)	$ (16,245)	$ (69,605)	$ (47,498)
Net loss per share, basic and diluted	$ (0.24)	$ (0.67)	$ (1.25)	$ (1.98)
Weighted average common shares outstanding—basic and diluted	94,829,844	24,073,935	55,711,252	24,038,257

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

TScan Therapeutics, Inc.

Condensed Consolidated Statements of Stockholders' Equity

(in thousands, except share data)

(Unaudited)

	Common Stock		Non-voting Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount			
Balances at June 30, 2022	18,929,834	$ 2	5,143,134	$ 1	$ 255,060	$ (123,411)	$ 131,652
Exercise of stock options	1,959	-	-	-	5	-	5
Stock-based compensation expense	-	-	-	-	1,246	-	1,246
Net loss	-	-	-	-	-	(16,245)	(16,245)
Balances at September 30, 2022	18,931,793	$ 2	5,143,134	$ 1	$ 256,311	$ (139,656)	$ 116,658
Balances at June 30, 2023	43,542,178	$ 4	4,276,588	$ 1	$ 395,589	$ (204,987)	$ 190,607
Exercise of stock options	4,350	-	-	-	9	-	9
Stock-based compensation expense	-	-	-	-	1,342	-	1,342
Net loss	-	-	-	-	-	(22,997)	(22,997)
Balances at September 30, 2023	43,546,528	$ 4	4,276,588	$ 1	$ 396,940	$ (227,984)	$ 168,961

	Common Stock		Non-voting Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount			
Balances at January 1, 2022	18,764,463	$ 2	5,143,134	$ 1	$ 252,933	$ (92,158)	$ 160,778
Exercise of stock options	50,460	-	-	-	124	-	124
Vesting of restricted common stock	116,870	-	-	-	-	-	-
Stock-based compensation expense	-	-	-	-	3,254	-	3,254
Net loss	-	-	-	-	-	(47,498)	(47,498)
Balances at September 30, 2022	18,931,793	$ 2	5,143,134	$ 1	$ 256,311	$ (139,656)	$ 116,658
Balances at January 1, 2023	19,082,820	$ 2	5,143,134	$ 1	$ 257,810	$ (158,379)	$ 99,434
Exercise of stock options	310,028	-	-	-	692	-	692
Issuance of common stock, net of offering costs	23,287,134	2	-	-	42,412	-	42,414
Issuance of pre-funded warrants, net of offering costs	-	-	-	-	92,318	-	92,318
Conversion of non-voting common stock to voting common stock	866,546	-	(866,546)	-	-	-	-
Stock-based compensation expense	-	-	-	-	3,708	-	3,708
Net loss	-	-	-	-	-	(69,605)	(69,605)
Balances at September 30, 2023	43,546,528	$ 4	4,276,588	$ 1	$ 396,940	$ (227,984)	$ 168,961

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

TScan Therapeutics, Inc.

Condensed Consolidated Statements of Cash Flows

(in thousands)

(Unaudited)

	Nine Months Ended September 30, 2023	2022
Cash flows from operating activities:		
Net loss	$ (69,605)	$ (47,498)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	4,081	3,653
Accretion of marketable securities	(235)	-
Non-cash interest expense related to note payable	655	44
Stock-based compensation	3,708	3,254
Changes in current assets and liabilities:		
Prepaid expenses and other assets	1,034	(235)
Prepaid rent	-	(2,165)
Right-of-use assets and lease liabilities, net	543	(94)
Accounts payable	589	114
Accrued expense and other liabilities	2,542	(591)
Deferred revenue	19,096	(6,975)
Net cash used in operating activities	(37,592)	(50,493)
Cash flows from investing activities:		
Purchases of property and equipment	(2,677)	(2,848)
Purchases of marketable securities	(59,995)	-
Net cash used in investing activities	(62,672)	(2,848)
Cash flows from financing activities:		
Proceeds from issuance of common stock, net of offering costs	42,414	-
Proceeds from issuance of pre-funded warrants, net of offering costs	92,318	-
Proceeds from exercise of stock options	692	124
Proceeds from issuance of term loan, net of issuance costs paid to lender	-	29,354
Payments of debt issuance costs	-	(230)
Net cash provided by financing activities	135,424	29,248
Net increase (decrease) in cash, cash equivalents and restricted cash	35,160	(24,093)
Cash, cash equivalents, and restricted cash - beginning of period	125,064	166,436
Cash, cash equivalents, and restricted cash - end of period	160,224	142,343
Summary of cash, cash equivalents and restricted cash reported within the consolidated balance sheets:		
Cash and cash equivalents	155,193	137,306
Restricted cash	5,031	5,037
Total cash, cash equivalents, and restricted cash	$ 160,224	$ 142,343
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 2,261	$ -
Supplemental disclosure of non-cash investing and financing activities:		
Purchase of property and equipment in accounts payable and accrued liabilities	$ 343	$ 572
Debt issuance costs not yet paid	$ -	$ 94

The accompanying notes are an integral part of these 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 biotechnology company that was incorporated in Delaware on April 17, 2018 and has a principal place of business in Waltham, Massachusetts. The Company is a biopharmaceutical company focused on developing a pipeline of T cell receptor-engineered T cell (TCR-T) therapies for the treatment of patients with cancer.

Basis of Presentation

The accompanying interim unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States (US 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 US GAAP for complete financial statements. Management believes that the interim financial statements reflect all adjustments, which include only normal recurring adjustments necessary for the fair statement of the Company's financial position, results of its operations and cash flows. The 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. The results for the three and nine months ended September 30, 2023 are not necessarily indicative of results to be expected for the year ending December 31, 2023, any other interim periods, or any future year or period. The accompanying condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K, which was filed with the SEC on March 8, 2023. In the opinion of the Company's management, all adjustments (consisting of normal and recurring adjustments) considered necessary for a fair statement of the results for the interim periods presented have been included.

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.

The accompanying unaudited condensed consolidated financial statements have been prepared on the basis of continuity of operations, realization of assets and the satisfaction of liabilities and commitments in the ordinary 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 issuance of a debt facility to K2 HealthVentures LLC. Since its inception, the Company has incurred recurring losses, including net losses of $69.6 million and $47.5 million for the nine months ended September 30, 2023 and 2022, respectively. As of September 30, 2023, the Company had an accumulated deficit of $228.0 million. The Company expects to continue to generate operating losses in the foreseeable future. The Company expects that its cash, cash equivalents and marketable securities as of September 30, 2023 will be sufficient to fund the Company's operations for at least the next twelve months from the date of the issuance of these financial statements.

Emerging Growth Company Status

The Company qualifies as "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 any new or revised accounting standards whenever such early adoption is permitted for nonpublic companies.

2. Summary of Significant Accounting Policies

The accounting policies of the Company are set forth in Note 2 to the consolidated financial statements contained in the Company's 2022 Annual Report on Form 10-K, the accounting policies followed by the Company for interim financial reporting are consistent with the accounting policies therein.

Available-for-Sale Securities

The Company classifies all of its investments as available-for-sale based upon its intent with regard to such investments. Available-for-sale securities are carried at fair value, with the unrealized gains and losses reported in other comprehensive income (loss). The amortized cost of debt securities in this category is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization is included in interest and investment income. Realized gains and losses and declines in value judged to be other than temporary on available-for-sale securities, are included in interest and investment income.

The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in interest and investment income. To determine whether an other-than-temporary impairment exists, the Company considers whether it has the ability and intent to hold the investment until a market price recovery, and whether evidence indicating the recoverability of the cost of the investment outweighs evidence to the contrary.

3. Fair Value Measurements

During the third quarter of 2023, the Company purchased $60.0 million of U.S. treasury bills with original maturities of six months or less. The Company classified these short-term investments as available-for-sale and are carried at fair value. The fair value of these securities approximate amortized cost as of September 30, 2023. The Company did not hold any marketable securities at December 31, 2022.

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

	Fair value measurements at September 30, 2023 using			
	Level 1	Level 2	Level 3	Total
Cash Equivalents:				
Government securities	$ 108,438	$ -	$ -	$ 108,438
Money market funds	41,568	-	-	41,568
Marketable Securities:				
Government securities	60,230	-	-	60,230
Total	$ 210,236	$ -	$ -	$ 210,236

	Fair value measurements at December 31, 2022 using			
	Level 1	Level 2	Level 3	Total
Cash Equivalents:				
Money market funds	$ 116,946	$ -	$ -	$ 116,946
Total	$ 116,946	$ -	$ -	$ 116,946

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. There were no transfers among Level 1, Level 2, or Level 3 categories in the periods presented.

The carrying value of cash, accounts payable and accrued expenses that are reported on the condensed consolidated balance sheets approximate their fair value due to the short-term nature of these assets and liabilities. The Company entered into long-term debt in September 2022; given the short period to maturity of the debt, the carrying value approximates fair value.

4. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	September 30, 2023	December 31, 2022
Accrued research and development	$ 3,410	$ 1,322
Accrued employee compensation and benefits	4,002	4,357
Accrued consulting and professional services	640	636
Accrued legal services and license fee	777	92
Other	428	431
Total accrued expenses and other current liabilities	$ 9,257	$ 6,838

5. Stockholders' Equity

ATM Program

On May 16, 2023, the Company entered into a sales agreement (the Sales Agreement) with Wedbush Securities, Inc. (Wedbush), 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 under a registration statement on Form S-3 (File No. 333-268260) filed with the SEC, which was declared effective on May 16, 2023. No common stock has been sold under this Sales Agreement to date.

Equity Offering

On June 1, 2023, the Company completed an underwritten public offering of (a) 23,287,134 shares of the Company's Voting Common Stock , at a price of $2.00 per share, and (b) pre-funded warrants to purchase up to 47,010,526 shares of the Voting Common Stock, at a price of $1.9999 per warrant with an exercise price of $0.0001 per share (Pre-Funded Warrants). The Company received aggregate net proceeds of $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.

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. As of September 30, 2023, no Pre-Funded Warrants have been exercised.

6. Collaboration and License Agreements

Novartis

In March 2020, the Company entered into a Collaboration and License Agreement (the Novartis Agreement) with Novartis Institutes For Biomedical Research, Inc. (Novartis) to collaborate on their research efforts to discover and develop novel TCR-T therapies. The Novartis Agreement concluded during the quarter ended March 31, 2023. The Company recognized $5.8 million and $10.4 million of revenue associated with the Novartis Agreement for the nine months ended September 30, 2023 and 2022, respectively.

Amgen

On May 8, 2023, the Company entered into a Collaboration Agreement with Amgen Inc. (the Amgen Agreement) to identify antigens recognized by T cells in patients with Crohn’s disease in accordance with a research plan. Under the terms of the Agreement, Amgen will retain all global development and commercialization rights, as well as an option to expand the collaboration to include target discovery for ulcerative colitis, under certain pre-specified terms. The proceeds from the Amgen Agreements includes an upfront payment of $30.0 million, which was collected in July 2023. In addition, the Company is eligible to earn success-based milestone payments of over $500 million, based upon the achievement of certain clinical development and commercial milestones, as well as

tiered single-digit royalty payments on net sales of products developed from the collaboration, subject to reductions set forth in the Amgen Agreement.

The Company concluded that Amgen meets the definition of a customer, as the Company is delivering research and development activities and a license of intellectual property. The Company identified performance obligations for research and development activities, the license, data reporting and participation in joint steering and research committees, which were determined to be a single combined performance obligation due to the services and licenses being highly interrelated.

For a certain time period during the term of the Amgen Agreement, Amgen has an option to add targets to the collaboration for payments specified in the agreement. Pursuant to the Amgen Agreement, the option for Amgen to select additional targets and to license, develop, and commercialize targets is not a performance obligation at the outset as these are customer options that do not represent material rights.

The Company looked to the promises in the arrangement to determine the method of recognition that best depicted the transfer of the services and the satisfaction of the combined performance obligations. The Company concluded that the performance of the research services over the expected research term was the predominant promise within the performance obligation. The Company will recognize the revenue associated with the performance obligation using an input method. The method of measuring progress towards delivery of the services incorporates actual internal and external costs incurred, relative to total internal and external costs expected to be incurred to satisfy the performance obligation. Changes in estimates of total internal and external costs expected to be incurred are recognized in the period of change as a cumulative catch-up adjustment. As costs are incurred, the Company will recognized revenue over time. At this time, it is estimated that the research term will be approximately 3 years.

The Company determined the $30.0 million upfront payment to be the entirety of the consideration to be included in the transaction price as of the onset of the arrangement. The option to add additional targets was not included in the transaction price as they were assessed to be improbable at this time. The potential milestone and royalty payments that the Company is eligible to receive were also excluded from the transaction price, as all milestone and royalty amounts were fully constrained based on the assessed probability of achievement. The Company will continue to assess the probability of the option to add additional targets and the probability of milestone achievement throughout the research term and will adjust the consideration in the contract accordingly.

The $30.0 million up-front payment was invoiced in June 2023 and was fully collected in July 2023. For the three and nine months ended September 30, 2023, the Company recognized $3.9 million and $7.0 million, respectively, of revenue associated with the Amgen Agreement. As of September 30, 2023, the Company recorded $23.0 million of deferred revenue, of which $7.8 million is classified as long-term.

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 period ended September 30, 2023.

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 Agreement

On September 9, 2022 (the Closing Date), the Company entered into a Loan and Security Agreement (the Loan Agreement) with K2 HealthVentures LLC (K2HV), pursuant to which convertible term loans in an aggregate principal amount of up to $60 million is available to the Company in three tranches, subject to certain terms and conditions. The Company drew the first tranche of $30 million

from K2HV on the Closing Date. The Company has the option to draw the second tranche of $10 million upon the achievement of certain financial and clinical milestones and an uncommitted third tranche of $20 million may be funded by joint agreement of the Company and K2HV. On the Closing Date, the Company paid a facility fee of $0.4 million to K2HV and is subject to an additional 1% of the principal amount of any amount drawn on third tranche.

The term loans mature on September 1, 2026 (the Maturity Date), and will be subject to interest only payments for 24 months, which can be extended to 36 months upon achievement of certain financial and clinical milestones, following which the term loans will amortize in equal monthly installments until maturity. The Company has the ability to repay the loan at any time either in cash or in shares, subject to applicable premiums as specified in the Loan Agreement. The term loans will accrue interest at a per annum rate equal to the greater of (i) 8.75% and (ii) the sum of (A) the prime rate (as last quoted in The Wall Street Journal) and (B) 4.75%, subject to a cap of 9.90%. At September 30, 2023 the applicable interest rate is 9.90%.

The lenders may elect at any time following the closing prior to the payment in full of the term loans to convert any portion of the principal amount of the term loans then outstanding into shares of the Company's common stock. The first tranche of the loan is convertible at the option of K2HV at a conversion price of $4.785 per share and future tranches will be convertible as specified in the agreement, provided that, such price shall be subject to the applicable conversion price floor and other adjustments in accordance with the Loan Agreement. The embedded conversion option meets the derivative accounting scope exception since the embedded conversion option is indexed to the Company’s own common stock and qualifies for classification within stockholders’ equity.

The Company has the option to prepay all, but not less than all, of the outstanding principal balance of the term loans under the Loan Agreement subject to a prepayment fee ranging from 4% to 1% depending upon when the prepayment occurs. The Company is obligated to pay a final fee equal to 6.00% of the aggregate amount of the term loans funded (the Exit Fee), to occur upon the earliest of (i) the maturity date, (ii) the acceleration of the term loans, and (iii) the prepayment of the term loans. If, upon equity conversion, K2HV receives gross proceeds in an amount equal to at least 1.5 multiplied by the principal amount converted from the sale or other disposition of such Conversion Shares (as defined in the Loan Agreement), then as to such principal amount, the Exit Fee will be reduced to zero.

The Company’s obligations under the Loan Agreement are secured by a first priority security interest in substantially all of its assets (other than intellectual property), subject to certain exceptions. The Loan Agreement contains customary representations and warranties, and also includes customary events of default, including payment default, breach of covenants, change of control, and material adverse effects. The Loan Agreement restricts certain activities, such as disposing of the Company’s business or certain assets, incurring additional debt or liens or making payments on other debt, making certain investments and declaring dividends, acquiring or merging with another entity, engaging in transactions with affiliates or encumbering intellectual property, among others. During the term of the Loan Agreement, the Company must maintain minimum unrestricted cash and cash equivalents equal to 5.0 times the average monthly cash burn measured over the trailing three-month period. Upon the occurrence of an event of default, a default interest rate of an additional 5% per annum may be applied to the outstanding loan balances, and K2HV may declare all outstanding obligations immediately due and payable and exercise all of its rights and remedies as set forth in the Loan Agreement and under applicable law.

Future principal debt payments of the convertible term loans funded as of September 30, 2023 are as follows:

2024	$	3,427
2025		14,588
2026		11,985
Total principal payments		30,000
Plus: Final payment fee		1,800
Less: unamortized debt discount and final fee		(1,855)
Total debt		29,945
Less: current portion of long-term debt		(1,110)
Long-term debt, net	$	28,835

9. Net Loss Per Share

Net Loss Per Share

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Numerator:				
Net loss	$ (22,997)	$ (16,245)	$ (69,605)	$ (47,498)
Denominator:				
Weighted-average common shares outstanding, basic and diluted	94,829,844	24,073,935	55,711,252	24,038,257
Net loss per share, basic and diluted	$ (0.24)	$ (0.67)	$ (1.25)	$ (1.98)

The 47,010,526 shares of the Company's common stock issuable upon exercise of the Pre-Funded Warrants described in Note 5 are included as outstanding common stock in the calculation of basic and diluted net loss per share.

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 described 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,	
	2023	2022
Options to purchase common stock	10,518,779	5,258,027
Common stock issuable upon conversion of Loan Agreement	6,269,592	2,100,027
Potential shares issuable under the ESPP	-	100,768
Total	16,788,371	7,458,822

10. Subsequent Events

On November 8, 2023, we entered into that first amendment (the First Amendment) to Lease by and between PPF OFF 828-830 Winter Street LLC as the landlord and the Company as the tenant, dated August 13, 2019 with respect to certain premises located at 830 Winter Street, Waltham, Massachusetts (830 Winter Street Lease). The First Amendment extends the expiration date of the 830 Winter Street Lease from September 30, 2024 to October 31, 2029 and provides for one option to renew the 830 Winter Streat Lease for a five-year period commencing on November 1, 2029.

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 8, 2023. 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 clinical-stage biopharmaceutical company focused on developing a robust pipeline of T cell receptor-engineered T cell (TCR-T) therapies for the treatment of patients with cancer. Our approach is based on the central premise that we can learn from patients who are winning their fight against cancer in order to treat those who are not. We are continuing to build our ImmunoBank, a repository of therapeutic T cell receptors (TCRs) that recognize diverse targets and are associated with multiple human leukocyte antigen (HLA) types to provide customized multiplexed TCR-T therapy candidates for patients with a variety of solid tumors. We are building our ImmunoBank using our proprietary platform technologies. Using TargetScan, we analyze the T cells of cancer patients with exceptional responses to immunotherapy to discover how the immune system naturally recognizes and eliminates tumor cells in these patients. This allows us to precisely identify the targets of TCRs that are driving these exceptional responses. We aim to use these anti-cancer TCRs to treat patients with cancer by genetically engineering their own T cells to recognize and eliminate their cancer. In addition to discovering TCR-T therapies against novel targets, we are using our ReceptorScan technology to further diversify our portfolio of therapeutic TCRs with TCR-T therapies against known targets. We reduce the risk and enhance the safety profile of these therapeutic TCRs by screening them using SafetyScan to identify potential off-targets of a TCR and eliminate those TCR candidates that cross-react with proteins expressed at high levels in critical organs.

We are advancing a robust pipeline of TCR-T therapy candidates for the treatment of patients with hematologic malignancies and solid tumors. Our lead product candidates, TSC-100 and TSC-101, are in development for the treatment of patients with hematologic malignancies to eliminate residual leukemia and prevent relapse following hematopoietic cell transplantation (HCT). TSC-100 and TSC-101 target HA-1 and HA-2 antigens, respectively, which are well-recognized TCR targets that were identified in patients with exceptional responses to HCT-associated immunotherapy. We have initiated a multi-arm Phase 1 clinical study of TSC-100 and TSC-101 with several clinical sites activated, with planned additional sites to be added in 2023.

In addition, we are developing multiple TCR-T therapy candidates for the treatment of solid tumors. One of the key goals for our solid tumor program is to develop what we refer to as multiplexed TCR-T therapy. We are designing these multiplexed therapies to be a combination of up to three highly active TCRs that are customized for each patient and selected from our bank of therapeutic TCRs, which we refer to as the ImmunoBank. We plan to populate the ImmunoBank with TCRs for multiple targets as well as multiple HLA types for each target, thus helping us to overcome key solid tumor resistance mechanisms of target loss and HLA loss. We are currently advancing five solid tumor programs: TSC-200 (HPV16); TSC-201 (MAGE-C2); TSC-202 (undisclosed target); TSC-203 (PRAME); and TSC-204 (MAGE-A1). We submitted a primary investigational new drug application (IND) for T-Plex, enabling customized mixtures of TCR-Ts to be administered to patients based on cancer-targets and associated common HLA types expressed in their tumors. We have also submitted secondary IND applications for four TCR-T product candidates: TSC-200-A0201, TSC-203-A0201, TSC-204-A0201, and TSC-204-C0702. The United States Food and Drug Administration (FDA) has cleared our INDs for T-Plex, TSC-200-A0201, TSC-203-A0201, TSC-204-A0201, and TSC-204-C0702, allowing us to initiate study start-up activities. We plan to further expand the ImmunoBank by filing INDs for two additional TCRs in the fourth quarter of 2023.

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 costs related to the identification of novel targets for TCRs and development of TCR-T therapies 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, as well as a debt facility with K2HV.

We have incurred significant operating losses since our inception. We reported net losses of $69.6 million and $47.5 million for the nine months ended September 30, 2023 and 2022, respectively. As of September 30, 2023, we had an accumulated deficit of $228.0 million. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. We expect that our expenses and capital expenditure requirements will increase substantially in connection with our ongoing activities, particularly if and as we:

- continue our research and development efforts to identify and develop product candidates and submit INDs 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.

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. Further, we expect to incur additional costs associated with operating as a public company.

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 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.

We believe that our existing cash, cash equivalents and marketable securities will enable us to fund our operating expenses and capital expenditures into 2026. 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.”

Results of Operations

Three months ended September 30, 2023 and 2022

The following table summarizes our results of operations for the three months ended September 30, 2023 and 2022 (in thousands):

	Three Months Ended September 30,		
	2023	2022	Change
Revenue			
Collaboration and license revenue	$ 3,887	$ 3,363	$ 524
Operating expenses:			
Research and development	22,741	15,031	7,710
General and administrative	5,894	4,910	984
Total operating expenses	28,635	19,941	8,694
Loss from operations	(24,748)	(16,578)	(8,170)
Other income:			
Interest and other income, net	2,733	534	2,199
Interest expense	(982)	(201)	(781)
Total other income	1,751	333	1,418
Net loss	$ (22,997)	$ (16,245)	$ (6,752)

Revenue

The revenue recognized during the three months ended September 30, 2023 was driven by recognition of revenue associated with the Amgen Agreement, which commenced in May 2023. The revenue recognized during the three months ended September 30, 2022 was driven by recognition of revenue associated with the Novartis Agreement, which concluded in March 2023. We expect revenue from the Amgen Agreement to result in increased revenues for the remainder of 2023.

Research and Development Expenses

The following table summarizes our research and development expenses for the three months ended September 30, 2023 and 2022 (in thousands):

	Three Months Ended September 30,		
	2023	2022	Change
Laboratory supplies, research materials and studies	$ 7,693	$ 6,250	$ 1,443
Personnel expenses (including stock-based compensation)	7,001	5,383	1,618
Facility-related and other	4,812	2,474	2,338
Clinical studies	3,235	924	2,311
Total research and development expenses	$ 22,741	$ 15,031	$ 7,710

The increase in research and development expenses was primarily attributable to an increase of $2.3 million in clinical studies expense related to Phase 1 study start-up activities and initial enrollment for TSC-100 and TSC-101 as well as Phase 1 study start-up activities for the solid tumor clinical trial. There was a $2.3 million increase in facility-related expenses due to higher lease costs, including the commencement of a new lease in the fourth quarter of 2022, as well as increased depreciation related to purchases of laboratory equipment. The increased facilities costs are driven by the expansion of in-house chemistry, manufacturing, and controls (CMC) labs and equipment as clinical activities ramp up. There was a $1.6 million increase in personnel expenses, driven by expansion of the in-house CMC, clinical and preclinical departments. There was a $1.4 million increase in laboratory supplies, research materials and studies related to increased need for manufacturing consumables.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the three months ended September 30, 2023 and 2022 (in thousands):

	Three Months Ended September 30,		
	2023	2022	Change
Personnel expenses (including stock-based compensation)	$ 2,220	$ 2,864	$ (644)
Facility-related and other	1,832	1,103	729
Legal and professional fees	1,842	943	899
Total general and administrative expenses	$ 5,894	$ 4,910	$ 984

The increase in general and administrative expenses was primarily attributable to a $0.9 million increase in legal and professional fees. In addition, there was an increase of $0.7 million primarily related to increased costs for depreciation expense and facilities-related costs.

Nine months ended September 30, 2023 and 2022

The following table summarizes our results of operations for the nine months ended September 30, 2023 and 2022 (in thousands):

	Nine Months Ended September 30,		
	2023	2022	Change
Revenue			
Collaboration and license revenue	$ 13,838	$ 10,440	$ 3,398
Operating expenses:			
Research and development	65,747	44,215	21,532
General and administrative	20,192	14,212	5,980
Total operating expenses	85,939	58,427	27,512
Loss from operations	(72,101)	(47,987)	(24,114)
Other income:			
Interest and other income, net	5,403	690	4,713
Interest expense	(2,907)	(201)	(2,706)
Total other income	2,496	489	2,007
Net loss	$ (69,605)	$ (47,498)	$ (22,107)

Revenue

The increase in revenue was primarily related to the recognition of remaining revenue associated with the Novartis Agreement, which concluded in March 2023, and the recognition of revenue associated with the Amgen Agreement, which commenced in May 2023. We expect revenue from the Amgen Agreement to result in increased revenues for the remainder of 2023.

Research and Development Expenses

The following table summarizes our research and development expenses for the nine months ended September 30, 2023 and 2022 (in thousands):

	Nine Months Ended September 30,		
	2023	2022	Change
Laboratory supplies, research materials and studies	$ 23,935	$ 20,052	$ 3,883
Personnel expenses (including stock-based compensation)	19,164	14,672	4,492
Facility-related and other	14,815	7,638	7,177
Clinical studies	7,833	1,853	5,980
Total research and development expenses	$ 65,747	$ 44,215	$ 21,532

The increase in research and development expenses was primarily attributable to an increase of $7.2 million in facility-related expenses due to higher lease costs, including the commencement of a new lease in the fourth quarter of 2022, as well as increased depreciation related to purchases of laboratory equipment. These increased facilities costs are driven by the expansion of facilities and equipment for in-house CMC as clinical and preclinical activities ramp up. There was a $6.0 million increase in clinical studies expense related to Phase 1 study start-up activities and initial enrollment for TSC-100 and TSC-101 as well as Phase 1 study start-up activities for the solid tumor clinical trial. There was a $4.5 million increase in personnel expenses, driven by expansion of the in-house CMC, clinical, and preclinical departments. There was a $3.9 million increase in laboratory supplies, research materials and studies related to increased need for manufacturing consumables and license fees.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the nine months ended September 30, 2023 and 2022 (in thousands):

	Nine Months Ended September 30,		
	2023	2022	Change
Personnel expenses (including stock-based compensation)	$ 8,761	$ 8,230	$ 531
Facility-related and other	6,027	3,368	2,659
Legal and professional fees	5,404	2,614	2,790
Total general and administrative expenses	$ 20,192	$ 14,212	$ 5,980

The increase in general and administrative expenses was primarily attributable to a $2.8 million increase in legal and professional fees related to increased legal expense for transactions entered into during 2023. In addition, there was an increase of $2.7 million primarily related to increased costs for depreciation expense and facilities-related costs, and an increase of $0.5 million related to personnel expenses.

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 research and development expenditures, and to a lesser extent, general and administrative expenditures. Under the terms of the Amgen Agreement, we received an upfront payment of $30.0 million in July 2023. In addition, we are eligible to earn success-based milestone payments of over $500 million, based upon the achievement of certain clinical development and commercial milestones, as well as tiered single-digit royalty payments on net sales of products developed from the collaboration, subject to reductions set forth in the Amgen Agreement.

Pursuant to the Loan Agreement with K2HV (the Loan Agreement), K2HV may provide us with convertible term loans in an aggregate principal amount of up to $60 million, of which $30 million gross proceeds was provided on the closing date. We have the option to draw the remaining tranches subject to certain conditions, including certain clinical milestones. See “Notes to Condensed Consolidated Financial Statements” and “Risk factors—Risks related to our financial position and need for additional capital” for additional details regarding the Loan Agreement.

On May 16, 2023 the Company entered into an the Sales Agreement with Wedbush pursuant to which the Company could sell, from time to time, at its option, up to an aggregate of $75.0 million of shares of its Voting Common Stock, through Wedbush as the sales agent, in “at-the-market” offerings. No common stock has been sold under this Sales Agreement to date.

On June 1, 2023, the Company completed an underwritten public offering of (a) 23,287,134 shares of the Company's Voting Common Stock, inclusive of the underwriters’ 30-day option to purchase 297,660 additional shares of Voting Common Stock, at a price of $2.00 per share, and (b) the Pre-Funded Warrants to purchase up to 47,010,526 shares of the Voting Common Stock, at a price of $1.9999 per warrant with an exercise price of $0.0001 per share. The Company received aggregate net proceeds from the offering of $134.7 million after deducting underwriting discounts, commissions and other offering expenses.

As of September 30, 2023, we had cash, cash equivalents and marketable securities of $215.4 million, excluding restricted cash of $5.0 million.

Funding requirements

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance our research programs into preclinical and clinical development. In addition, we expect to continue to incur additional costs associated with operating as a public company. The timing and amount of our operating expenditures will depend largely on:

- the identification of additional research programs and product candidates;
- the scope, progress, costs and results of preclinical and clinical development of any product candidates we may develop;
- the costs, timing and outcome of regulatory review of any product candidates we may develop;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate a clinical trial;
- our decision to build manufacturing capabilities;
- our decision to invest in facilities to enable growth;
- investing in next-generation T cell engineering capabilities;
- changes in laws or regulations applicable to any product candidates we may develop, including but not limited to clinical trial requirements for approvals;
- the cost and timing of obtaining materials to produce adequate supply for any preclinical or clinical development of any product candidate we may develop;
- the costs and timing of future commercialization activities, including manufacturing, marketing, sales and distribution, for any product candidate we may develop for which we obtain marketing approval;
- the legal costs involved in prosecuting patent applications and enforcing patent claims and other intellectual property claims;
- additions or departures of key scientific or management personnel;

- our ability to establish and maintain collaborations on favorable terms, if at all, as well as the costs and timing of any collaboration, license or other arrangement, including the terms and timing of any milestone payments thereunder; and
- the costs of continuing to operate as a public company.

We believe that our existing cash, cash equivalents and marketable securities will enable us to fund our planned operating expenses and capital expenditure requirements into 2026. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect.

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. In the event the convertible debt facility under the Loan Agreement 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 (1) complete development of any of our product candidates; (2) obtain applicable regulatory approvals; and (3) 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 and our losses to increase as we ramp up our preclinical and clinical development programs. 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;
- 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;

•impact of health epidemics, including the evolving impacts of the COVID-19 pandemic, 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. If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Any future debt financing into which we enter may impose upon us additional covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our common stock, make certain investments or engage in certain merger, consolidation or asset sale transactions. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders.

Adequate funding may not be available to us on acceptable terms or at all. Our potential inability to raise capital when needed could have a negative impact on our financial condition and our ability to pursue our business strategies. If we are unable to raise additional funds as required, 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. If we are required to enter into collaborations and other arrangements to address our liquidity needs, we may have to give up certain rights that limit our ability to develop and commercialize our product candidates or may have other terms that are not favorable to us or our stockholders, which could materially and adversely affect our business and financial prospects. See Part II, Item 1A. “Risk Factors” of this Quarterly Report for additional risks associated with our substantial capital requirements.

Cash Flows

The following table summarizes our sources and uses of cash for each of the periods presented (in thousands):

	Nine Months Ended September 30,		
	2023	2022	Change
Net cash used in operating activities	$ (37,592)	$ (50,493)	$ 12,901
Net cash used in investing activities	(62,672)	(2,848)	(59,824)
Net cash provided by financing activities	135,424	29,248	106,176
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 35,160	$ (24,093)	$ 59,253

Operating Activities

During the nine months ended September 30, 2023, operating activities used $37.6 million of cash, primarily driven by:

•our net loss of $69.6 million.

This was partially offset by:

•non-cash charges of $8.2 million related to depreciation expense, accretion of marketable securities, stock-based compensation, and non-cash interest expense related to note payable,

•an increase in deferred revenue of $19.1 million, due to the initiation of the Amgen collaboration and completion of the Novartis collaboration,

•an increase in accrued expense and other liabilities of $2.5 million, and;

•a decrease in prepaid expenses and other assets of $1.0 million.

During the nine months ended September 30, 2022, operating activities used $50.5 million of cash, primarily driven by:

•our net loss of $47.5 million,

•an increase in prepaid rent of $2.2 million, and;

•a decrease in deferred revenue of $7.0 million, due to recognition of revenue related to the Novartis collaboration.

These were partially offset by:

•non-cash charges of $7.0 million related to depreciation expense, stock-based compensation, and non-cash interest expense related to note payable.

Investing Activities

During the nine months ended September 30, 2023 and 2022, net cash used in investing activities was $62.7 million and $2.8 million, respectively, related to the purchases of property and equipment and marketable securities.

Financing Activities

During the nine months ended September 30, 2023, net cash provided by financing activities was $135.4 million, consisting of net proceeds of $134.7 million from our follow-on public offering in June 2023 and $0.7 million of proceeds from the exercise of stock options.

During the nine months ended September 30, 2022, net cash provided by financing activities was $29.2 million, consisting primarily of net proceeds from the issuance of the convertible debt of $29.3 million under the Loan Agreement.

Critical Accounting Policies and Estimates

We prepare our condensed financial statements in accordance with generally accepted accounting principles in the United States. The preparation of financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues, costs and expenses and related disclosures. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. 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 filed with the SEC on March 8, 2023. The Company has applied the Company's revenue recognition policies to the Amgen Agreement as fully described in Note 6 to the interim condensed consolidated financial statements.

Emerging Growth Company and Smaller Reporting Company Status

The 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 "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.

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 initial public offering 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 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 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 by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, 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 Principal Executive Officer and Principal Financial Officer (our Chief Executive Officer), has evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2023. 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, 2023, our Principal Executive Officer and Principal Financial Officer have 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 period ended September 30, 2023 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 for the year ended December 31, 2022.*

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 biopharmaceutical 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 only recently initiated clinical trials for TSC-100 and TSC-101. 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 private placements of our preferred stock, our public offerings in 2021 and 2023 and borrowings under a secured loan agreement in September 2022.

We have incurred significant net losses in each period since our inception in April 2018. For the nine months ended September 30, 2023 and the years ended December 31, 2022 and 2021, we reported net losses of $69.6 million, $66.2 million and $48.6 million, respectively. As of September 30, 2023, we had an accumulated deficit of $228.0 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 lead product candidates and submit additional investigational new drug applications (INDs) for such lead 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;
- 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 clinical, regulatory and scientific personnel; and
- continue to operate as a public company.

Because of the numerous risks and uncertainties associated with biopharmaceutical 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.

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 through our TargetScan technology, (ii) to discover highly active TCRs for known targets through our ReceptorScan technology, (iii) to genetically engineer patient- or donor-derived T cells safely and reproducibly through our T-Integrate technology, (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 U.S. Food and Drug Administration (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. Our proprietary platform and our product candidates have not yet been evaluated in humans and may never become commercialized. Moreover, all of our current product candidates are being developed using our proprietary platform and leveraging the same or similar technology, 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 adversely impact our ability to successfully develop and commercialize all of our other product candidates.

In addition, the success of our proprietary platform in discovering novel targets for TCR-T therapy 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 biopharmaceutical 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, entering into licenses and collaborations, establishing manufacturing for initial quantities of 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 cell therapy products and our ability to generate revenue from cell therapy 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 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 product candidates or future product candidates to treat hematologic malignancies or solid tumors;
- our ability and the ability of our third parties contractors to manufacture adequate clinical and commercial supplies of our product candidates or any future product candidates, remain in good standing with regulatory authorities and develop, validate and maintain commercially viable manufacturing processes that are compliant with current good manufacturing practices (cGMP);
- our ability to successfully develop a commercial strategy and thereafter commercialize our product candidates or any future product candidates in the United States and internationally, if licensed for marketing, reimbursement, sale and distribution in such countries and territories, whether alone or in collaboration with others;
- 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 would 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 private placements of preferred stock, through our public offerings, and through our debt financing facility. The development of biopharmaceutical 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 incur additional costs associated with operating as a public company.

As of September 30, 2023, we had $215.4 million in cash, cash equivalents and marketable securities. Based on our current operating plan, we believe that our existing cash, cash equivalents and marketable securities will be sufficient to fund our operating expenses and capital expenditure requirements into 2026. Accordingly, our existing cash, cash equivalents and marketable securities 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 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 and maintain collaborations on favorable terms, if at all;
- any continuing impact of the COVID-19 pandemic or other external disruptions on our business, results of operations 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.

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 financing or through collaborations, licensing arrangements or strategic partnerships 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, such as the ongoing conflict between Russia and Ukraine, and Israel and Hamas, 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 US and China or in the ongoing conflict between Russia and Ukraine or between Israel and Hamas, including resulting sanctions, export controls or other restrictive actions that may be imposed by the US and/or other countries against governmental or other entities in, for example, Russia, also could 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. 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.

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 harm 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. For example, on March 10, 2023, Silicon Valley Bank (SVB) was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation (FDIC) as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership. Although a statement by the Department of the Treasury, the Federal Reserve and the FDIC stated all depositors of SVB would have access to all of their money after only one business

day of closure, including funds held in uninsured deposit accounts, borrowers under credit agreements, letters of credit and certain other financial instruments with SVB, Signature Bank or any other financial institution that is placed into receivership by the FDIC may be unable to access undrawn amounts thereunder. Although we are not a borrower or party to any such instruments with SVB, Signature or any other financial institution currently in receivership, if any of our lenders or counterparties to any such instruments, including PacWest or its affiliates, were to be placed into receivership, we may be unable to access such funds. In addition, counterparties to SVB credit agreements and arrangements, and third parties such as beneficiaries of letters of credit (among others), may experience direct impacts from the closure of SVB and uncertainty remains over liquidity concerns in the broader financial services industry. Similar impacts have occurred in the past, such as during the 2008-2010 financial crisis.

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

Although we assess our banking 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 customers or suppliers, which in turn, could have a material adverse effect on our current and/or projected business operations and results of operations and financial condition. For example, a customer may fail to make payments when due, default under their agreements with us, become insolvent or declare bankruptcy, or a supplier may determine that it will no longer deal with us as a customer. In addition, a customer or 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 customer or supplier bankruptcy or insolvency, or the failure of any customer to make payments when due, or any breach or default by a customer or supplier, or the loss of any significant supplier relationships, could result in material losses to us and may 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 September 9, 2022, we entered into the Loan Agreement pursuant to which K2HV may provide us with convertible term loans in an aggregate principal amount of up to $60 million, of which $30 million was fully funded at the closing date in September 2022, $10 million will be funded in the second tranche upon the achievement of certain financial and clinical milestones and $20 million may be funded in the third tranche at K2HV's discretion. Our obligations under the Loan Agreement are secured by a security interest in substantially all of our assets (other than intellectual property), subject to certain exceptions, and will be guaranteed by each of the Company's future direct or indirect subsidiaries, subject to certain exceptions. In addition, during the term of the Loan Agreement, we must maintain minimum unrestricted cash and cash equivalents equal to 5.0 times the average cash burn measured over the trailing three-month period. The Loan Agreement contains customary representations and warranties, and also includes customary events of default, including payment default, breach of covenants, change of control, and material adverse effects. The Loan Agreement restricts certain activities, such as disposing of the Company's business or certain assets, incurring additional debt or liens or making payments on other debt, making certain investments and declaring dividends, acquiring or merging with another entity, engaging in transactions with affiliates or encumbering intellectual property, among others. Upon the occurrence of an event of default, a default interest rate of an additional 5% per annum may be applied to the outstanding loan balances, and K2HV may declare all outstanding obligations immediately due and payable and exercise all of its rights and remedies as set forth in the Loan Agreement and under applicable law. Any declaration by K2HV 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.

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 hematologic malignancies and solid tumors utilizing T cell receptor therapies, or TCR-T therapies. Advancing our product candidates creates significant challenges for us, including:

- educating medical personnel about the administration of TCR-T therapies on a stand-alone basis or in combination with built-in immune and tumor modulators;
- while no such side effects have been observed to date in any of our preclinical or clinical studies, educating medical personnel regarding the potential side effect profile of our product candidates, such as the potential adverse side effects related to cytokine release syndrome (CRS), graft vs. host disease, 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-Ts 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 the treatment;
- 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 method for manufacturing TCR-T therapies. We may find that our existing TCR-T therapy 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 first products. 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 product has many steps that can influence quality and activity.

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 cleared the INDs for TSC-100 and TSC-101, our most advanced product candidates, as well as for T-Plex, TSC-200-A0201, TSC-203-A0201, TSC-204-A0201, and TSC-204-C0702. Our 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;

- effectively competing with other cancer therapies;

- 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.

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 and manufacturing at other companies, we have limited experience as a company in conducting clinical trials and little direct experience 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 clinical trials at the Company. In part because of this lack of experience, we cannot be certain that our ongoing preclinical studies will be completed on time or if the planned preclinical and clinical trials 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 recently expanded our existing cell manufacturing facility for Phase 1 and Phase 2 clinical trials, 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 inexperience, 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, if we switch from manufacturing in our own facility to manufacturing in a different facility (for example, at an external contract manufacturing organization (CMO) for one or more of our product candidates in the future 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 facility 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 or, 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 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 future product candidate, we may relinquish valuable rights to those future 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 future 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 biopharmaceutical 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 authorization to initiate clinical trials under future INDs, completing ongoing preclinical studies of our other product candidates, and initiating 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 as a result 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 continuing effects of the COVID-19 pandemic;
- 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, including any continuing effects of the COVID-19 pandemic, 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 or similar outbreaks could adversely impact our business. In late 2019, a novel strain of a virus named SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2), or coronavirus, which causes COVID-19, emerged in Wuhan, China and has reached most countries across the world, including all 50 states within the U.S., and including Waltham, Massachusetts, where our primary office and laboratory space is located. The coronavirus pandemic led to the implementation of various responses, including government-imposed quarantines, travel restrictions, mask and vaccine mandates and other public health safety measures. Although the U.S. government has declared an end to the Public Health Emergency related to COVID-19, there may be lingering effects of the COVID-19 pandemic on our business. The extent to which COVID-19 may further impact our operations or those of our third party partners, including our preclinical studies or clinical trial operations, will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including new or more severe outbreaks, and the actions to contain the coronavirus or treat its impact, among others. The continued spread of COVID-19 globally and the continued identification of new variants of the SARS-CoV-2 virus could adversely impact our preclinical or clinical trial operations in the U.S., including our ability to recruit and retain patients. For example, as a result of medical complications associated with microsatellite stable colorectal cancer (MSS CRC), the patient populations that our most advanced and other product candidates target may be particularly susceptible to COVID-19, which may make it more difficult for us to identify patients able to enroll in our current and future clinical trials and may impact the ability of enrolled patients to complete any such trials. Any negative impact COVID-19 has to patient enrollment or treatment or the execution of our product candidates could cause costly delays to our clinical trial activities, which could adversely affect our ability to obtain regulatory approval for and to commercialize our product candidates, increase our operating expenses, and have a material adverse effect on our financial results.

The adverse impact of public health crises such as pandemics or similar outbreaks in the countries and regions where we have concentrations of potential clinical trial sites or other business operations and where several of our third party suppliers and contractors are located could adversely affect our business, including by causing significant disruption in the operations of third parties upon whom we rely. The COVID-19 pandemic presented a substantial public health and economic challenge around the world and affected employees, patients, communities and business operations, as well as the U.S. economy and financial markets. While the Company has implemented what it believes to be a reasonable protocol to ensure the safety and wellbeing of employees returning to the office, the effects of our policies may negatively impact productivity, disrupt our business and delay our clinical programs and timelines. In connection with these measures, we may be subject to claims based upon, arising out of or related to COVID-19 and our actions and

responses thereto. These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, financial condition, results of operations and growth prospects.

The ultimate economic impact of the COVID-19 pandemic may be difficult to assess or predict. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

While the COVID-19 pandemic has largely resolved, the downstream effects of the pandemic 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. In addition, to the extent the COVID-19 pandemic adversely affects our business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties described elsewhere in this “Risk Factors” section.

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 to manufacture our clinical scale product candidates for our Phase 1 and Phase 2 clinical trials of our current product candidates. However, we rely on outside vendors to manufacture supplies for our manufacturing process, and we expect to rely on outside vendors to manufacture our product candidates for registration-enabling additional clinical trials as well as commercial sales. We have not yet caused any product candidates to be manufactured or processed on a commercial scale and may not be able to do so for any of our product candidates. We plan to make changes as we work to optimize the manufacturing process. For example, we may switch or be required to switch from research-grade materials to commercial-grade materials in order to get regulatory approval of our product candidates, which could delay receipt of regulatory approval, if any. We cannot be sure that even minor changes in the process will result in therapies that are safe and effective and licensed 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 our product candidates must be approved by the FDA or other foreign regulatory authorities following inspections that will be conducted after we submit an application to the FDA or other foreign regulatory authorities. If we engage third party contract manufacturers, we may not control the manufacturing process of, and may be completely dependent on, such 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 standard 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 for registration-enabling clinical trials, may experience manufacturing difficulties due to limited manufacturing experience, resource constraints or as a result of labor disputes, the COVID-19 pandemic, the U.S.-China trade war or unstable political environments. 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. For example, the type of cell culture media and cryopreservation buffer that we currently use in our manufacturing process for TSC-100 and TSC-101 are each only available from a limited number of suppliers. In addition, the cell processing equipment and tubing that we use in our current manufacturing process is currently sourced from a single supplier. 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 cannot guarantee that our product candidates will show any functionality in the solid tumor microenvironment.

There are no approved TCR-T immunotherapies for solid tumors. While we plan to develop product candidates for use in solid tumors, including the TSC-200 series, we cannot guarantee that our 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, our product candidates may not 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 would 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 products or for patients that use any of our product candidates, if approved.

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 of our 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 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 INDs 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.

We are currently advancing multiple TCRs for five solid tumor targets: HPV16 E7 (TSC-200), MAGE-C2 (TSC-201), PRAME (TSC-203), MAGE-A1 (TSC-204), and an undisclosed target for TSC-202. The most advanced TCRs for each target are as follows: TSC-200-A0201 is an HLA-A*02:01-restricted TCR for HPV16 E7 entering Phase 1 development; TSC-201-B0702 is an HLA-B*07:02-restricted TCR for MAGE-C2 in IND-enabling activities; TSC-202-A0201 is an HLA-A*02:01-restricted TCR for an undisclosed target in discovery; TSC-203-A0201 is an HLA-A*02:01-restricted TCR for PRAME entering Phase 1 development; TSC-204-A0201 is an HLA-A*02:01-restricted TCR for MAGE-A1 entering Phase 1 development; and TSC-204-C0702 is an HLA-C*07:02-restricted TCR for MAGE-A1 entering Phase 1 development. We expect to submit IND applications for two additional TCRs in our solid tumor program in the fourth quarter of 2023. However, we may not be able to file such INDs 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 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, 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 INDs.

In addition, one of our key goals is to develop treatments consisting of a combination of TCR-T therapies, which we refer to as multiplexed TCR-T therapy. Our plan is to assess the safety and preliminary efficacy of multiplexed TCR-T therapy early in the clinical development of our product candidates (e.g., Phase 1). While the FDA has cleared our T-Plex IND, which allows us to combine our product candidates with each other in a multiplexed TCR-T therapy, we must still provide safety data for each individual product candidate or each variation or combination of a multiplexed TCR-T therapy. Any such requirements could result in material delays in the development timelines of our multiplexed TCR-T therapy 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 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 Phase 1 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 graft-versus-host disease (GvHD) with our TCR-T therapy in the post-HCT setting. GvHD is a common toxicity in patients undergoing allogeneic HCT, the focus of our hematologic 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 candidates because they are derived from donor T cells. While the engineered T cells express a new T cell receptor that is specific for the intended target antigen and is not expected to cause GvHD, those T cells may have low levels of endogenous T cell receptors 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 cell that has 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 disease. In our clinical testing, we plan to take steps to minimize the likelihood that this occurs, for example by excluding patients with a history of severe autoimmune disease from our trials. There is no guarantee, however, that we will not observe autoimmune reactions in the future and no guarantee that if we do, that we will be able to implement interventions to address the risk.

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 not observe immunogenic reactions in the future and no guarantee that if we do, that we will be able to implement interventions to address the risk.

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.

Certain patients may lack sufficient T cells for our autologous product candidates to be effective.

For autologous TCR-T therapy, our TCR-T therapy candidates are manufactured by using a vector to insert genetic information encoding the TCR construct into the patient's own T cells. This manufacturing process is dependent on collecting a sufficient number of T cells from the patient. We may not be able to effectively treat some patients if they have an insufficient number of T cells to enable our manufacturing process, which could adversely impact our ability to progress the clinical development of such product candidates and could also adversely impact the commercial viability of such product candidates.

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 candidate 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 therapies 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 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 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 assure 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 such 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 example, for our hematologic malignancies program, patients would have to be HLA-A*02:01 positive and positive for the minor antigen HA-1 or HA-2 to be eligible for treatment with TSC-100 or TSC-101, respectively;
- for our hematologic malignancies program, the ability to find a donor who has to be mismatched with the patient either for the HLA type or the minor antigen type to ensure that the engineered T cell therapy does not recognize donor-derived blood cells;
- any continuing impact of the COVID-19 pandemic 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 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; and
- for patients in our solid tumor program, the patient's need for sufficient T cells in order for the engineered T cell product to be manufactured from their autologous T cells.

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 biopharmaceutical products is inherently risky. We may not be successful in our efforts to use and enhance our TScan technology 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.

A key element of our strategy is to use our TScan technology discovery platform to discover the targets of T cells in oncology, autoimmune and infectious disease applications to build a pipeline of novel product candidates. We and our collaborators are simultaneously pursuing clinical development of multiple product candidates developed employing our TCR technologies.

We are at an early stage of development and our TScan technology discovery platform has not yet led, and may never lead, to approved or commercially successful products. All of 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 medical product development.

Investment in biopharmaceutical 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 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 as they will be limited to those patients who are ineligible for or have failed prior treatments and 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, second line therapy may be administered. Second line therapies often consist of more chemotherapy, radiation, antibody drugs, tumor-targeted small molecules, or a combination of these. Third line therapies can include HCT in certain cancers, chemotherapy, antibody drugs and small molecule tumor-targeted therapies, more invasive forms of surgery and new technologies. We expect to initially seek approval of our product candidates in most instances at least as a second or third line therapy, for use in patients to prevent relapse in patients undergoing HCT. Subsequently, for those product candidates that prove to be sufficiently safe and beneficial, if any, we would expect to seek approval as a second line therapy and potentially as a first line therapy, but there is no guarantee that our product candidates, even if licensed as a second or third or subsequent line of therapy, would be licensed for an earlier line of therapy, and, prior to any such approvals, we may have to conduct additional clinical trials. 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 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 for a second or third line of therapy, 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 future 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 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 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 United States 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, 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 result in increased government regulation, unfavorable public perception and publicity, potential regulatory delays in the testing or licensing of our product candidates, stricter labeling requirements for those product candidates that are licensed, and a decrease in demand for any such product candidates.

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 United States 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, trade barriers, 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 United States;

•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 United States;

•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 biopharmaceutical 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 TCR space from many companies. For additional information regarding our competition, see “Item 1. Business – Competition” in our Annual Report on Form 10-K for the year ended December 31, 2022. 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 or other contractors or consultants, may fail or suffer security 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 and other contractors and consultants are vulnerable to a variety of disruptions and data privacy and information security incidents, including data breaches, attacks by hackers and other malicious third parties (including the deployment of computer viruses, malware, ransomware, denial-of-service attacks, social engineering, 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. For example, the ongoing conflict between Russia and Ukraine has led to an increase in cyberattacks on the 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 due to shelter-in-place, stay-at-home advisories or similar restrictions related to the COVID-19 pandemic may make our or our partners' systems more susceptible to security breaches. While we have not experienced any such material system failure or security breach to date, if such an event 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 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, to the extent we rely on third parties for the manufacture of our product candidates and to conduct clinical trials, similar events relating to their computer systems could also have a material adverse effect on our business, financial condition, results of operations and prospects.

Unauthorized disclosure of sensitive or confidential data, including personally identifiable information, whether through a breach of computer systems, 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, cyber 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 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 security breaches or to mitigate the impact of any such 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 security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidates could be delayed.

Security 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 data breaches, attacks by hackers and other malicious third parties (including the deployment of computer viruses, malware, ransomware, denial-of-service attacks, social engineering, 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 security 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 services 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, 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 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 candidates for clinical trials or 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, purity, and quality of the final product. More specifically, the manufacture of our product candidates includes harvesting white blood cells from the patient, isolating certain T cells from the white blood cells, combining patient T cells with our delivery vector through a process known as transduction, selection of modified T cells from the population, expanding the selected transduced T cells to obtain the desired dose, aseptically filling product into vessels suitable for storage, distribution, and clinical dosing, and ultimately infusing the modified T cells back into the patient's body. As a result of the complexities entailed in this process, our manufacturing and supply costs will be higher than those at more traditional manufacturing processes and the manufacturing process is less reliable and more difficult to reproduce. Additionally, the number of facilities that are capable of harvesting patients' cells for the manufacture of our product candidates and other autologous cell therapy products and product candidates is limited. As the number of autologous cell therapy products and product candidates increases, the limited number of facilities capable of harvesting patients' cells could result in delays in the manufacture and administration of our product candidates.

We currently rely on our internal manufacturing facility for clinical manufacturing, and any disruption to this facility could impact our ability to advance our clinical trials. We currently rely on third parties for the manufacture of our vector and other components of our manufacturing process. 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, 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 candidate for that patient will need to be restarted, if possible, and the resulting delay may adversely affect that 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. 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, such 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 we have expanded our existing manufacturing facility and infrastructure in lieu of relying solely on third parties for the manufacture of our product candidates for certain clinical purposes and many of our personnel have experience in clinical manufacturing at other companies, we have no direct experience as a company managing manufacturing for our product candidates, which will be costly, time-consuming, and which may not be successful.

We have expanded our existing manufacturing capacity to support our Phase 1 and Phase 2 clinical trials of our product candidates. We have no prior experience as a company in setting up, building or managing a manufacturing facility or manufacturing suite, and may never be successful in developing 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, the European Medicines Agency (EMA), 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, the EMA 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 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.

Any problems in our manufacturing process or facilities could make us a less attractive collaborator for potential partners, including larger pharmaceutical companies and academic research institutions, which could limit our access to additional attractive development programs.

We may have difficulty validating our manufacturing process as we manufacture TCR-T therapy 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 FDA 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 Biologics License Application (BLA) to the FDA or similar licensure applications to comparable foreign regulatory authorities. A BLA must include extensive preclinical and clinical data and supporting information to establish the product candidate's safety, purity, and potency for each desired indication. The BLA 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 Practices (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 CMOs. 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 United States and other countries, and such regulations differ from country to country. We are not permitted to market our product candidates in the United States 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 United States 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, many 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 United States, or a patient population greater than 200,000 in the United States when there is no reasonable expectation that the cost of developing and making available the

drug or biologic in the United States will be recovered from sales in the United States for that drug or biologic. Orphan drug designation must be requested before submitting a BLA. In the United States, 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 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 indication or disease. 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 United States 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.

On August 3, 2017, the Congress passed the FDA Reauthorization Act of 2017 (FDARA). FDARA, among other things, codified the FDA's pre-existing regulatory interpretation, to require that a drug sponsor demonstrate the clinical superiority of an orphan drug that is otherwise the same as a previously approved drug for the same rare disease in order to receive orphan drug exclusivity. The new legislation reverses prior precedent holding that the Orphan Drug Act unambiguously requires that the FDA recognize the orphan exclusivity period regardless of a showing of clinical superiority. Moreover, in the Consolidated Appropriations Act of 2021, Congress did not further change this interpretation when it clarified that the interpretation codified in FDARA would apply in cases where FDA issued an orphan designation before the enactment of FDARA but where product approval came after the enactment of FDARA. The FDA may further reevaluate the Orphan Drug Act and its regulations and policies. 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 of 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 plan to seek approval of our current product candidates, and may seek approval of future product candidates using 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 may require 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. Even if we do receive Accelerated Approval, we may not experience a faster development, regulatory review or approval process for that product. In addition, receiving Accelerated Approval does not provide assurance of ultimate FDA approval.

We may seek designation for our TargetScan 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 TargetScan 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 an 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 TargetScan 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.

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 United States, 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 United States, 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 United States 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.

In addition, we could face heightened risks with respect to seeking marketing approval in the United Kingdom (UK) as a result of the withdrawal of the UK from the European Union (EU), commonly referred to as Brexit. The UK is no longer part of the European Single Market and European Union Customs Union. As of January 1, 2021, the Medicines and Healthcare products Regulatory Agency(MHRA) became responsible for supervising medicines and medical devices in Great Britain, comprising England, Scotland and Wales under domestic law, whereas Northern Ireland will continue to be subject to EU rules under the Northern Ireland Protocol. The MHRA will rely on the Human Medicines Regulations 2012 (SI 2012/1916) (as amended) (the HMR) as the basis for regulating medicines. The HMR has incorporated into the domestic law of the body of EU law instruments governing medicinal products that pre-existed prior to the UK's withdrawal from the EU. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, may force us to restrict or delay efforts to seek regulatory approval in the UK for our product candidates, which could significantly and materially harm our business.

Furthermore, following the Brexit vote, the EU moved the European Medicines Agency's headquarters from the UK to the Netherlands. This transition may cause disruption in the administrative and medical scientific links between the European Medicines Agency and the UK Medicines and Healthcare products Regulatory Agency, including delays in granting clinical trial authorization or marketing authorization, disruption of import and export of active substance and other components of new drug formulations and disruption of the supply chain for clinical trial product and final authorized formulations. The cumulative effects of the disruption to the regulatory framework may add considerably to the development lead time to marketing authorization and commercialization of products in the EU and/or the UK.

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 in order 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 drugs and biologics must provide 6 months' notice to the FDA of any changes in marketing status, such as the withdrawal of a product, and failure to do so could result in the FDA placing the product on a list of discontinued products, which would revoke the product's ability to be marketed;
- 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 Risk Evaluation and Mitigation Strategy (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 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 United States or abroad. 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 insurance coverage and reimbursement status of newly-approved products is 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 United States, 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 for the year ended December 31, 2022.

In the United States 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 is not available, or is 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 United States. 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 United States, the

reimbursement for products may be reduced compared with the United States 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 United States, the principal decisions about reimbursement for new medicines are typically made by Centers for Medicare & Medicaid 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, a number of cancer drugs have been approved for reimbursement in the United States 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.

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 United States 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, please see “Item 1. Business – Government Regulation – Healthcare Legislative Reform” in our Annual Report on Form 10-K for the year ended December 31, 2022.

The Inflation Reduction Act of 2022 (IRA) includes several provisions that may impact our business to varying degrees, including provisions that reduce the out-of-pocket spending cap for Medicare Part D beneficiaries from $7,050 to $2,000 starting in 2025, thereby effectively eliminating the coverage gap; impose new manufacturer financial liability on certain drugs under Medicare Part D, allow the U.S. government to negotiate Medicare Part B and Part D price caps for certain high-cost drugs and biologics without generic or biosimilar competition; require companies to pay rebates to Medicare for certain drug prices that increase faster than inflation; and delay until January 1, 2032 the implementation of the HHS rebate rule that would have limited the fees that pharmacy benefit managers can charge. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one orphan designation and for which the only approved indication is for that disease or condition. If a product receives multiple orphan designations or has multiple approved indications, it may not qualify for the orphan drug exemption. The implementation of the IRA is currently subject to ongoing litigation challenging the constitutionality of the IRA’s Medicare drug price negotiation program. The outcome of these challenges on the IRA, and the effects of the IRA on our business and the healthcare industry in general are not yet known.

In addition, President Biden has issued multiple executive orders that have sought to reduce prescription drug costs. In February 2023, HHS also issued a proposal in response to an October 2022 executive order from President Biden that includes a proposed prescription drug pricing model that will test whether targeted Medicare payment adjustments will sufficiently incentivize manufacturers to complete confirmatory trials for drugs approved through FDA’s accelerated approval pathway. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may

reverse or otherwise change these measures, both the Biden administration and Congress have indicated that they will continue to seek new legislative measures to control drug costs.

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 repeal, replacement or significant revisions to the Affordable Care Act. 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.

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.

Regulatory requirements in the United States 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 United States and abroad governing cell therapy products have changed frequently and may continue to change in the future. The FDA has established an office, now 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.

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

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the 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.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, 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.

Since March 2020 when foreign and domestic inspections of facilities were largely placed on hold, the FDA has been working to resume pre-pandemic levels of inspection activities, including routine surveillance, bioresearch monitoring and pre-approval inspections. Should FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, and the FDA does not determine a remote interactive evaluation to be adequate, the agency has stated that it generally intends to issue, depending on the circumstances, a complete response letter or defer action on the application until an inspection can be completed. During the COVID-19 public health emergency, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities.

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 United States and similar foreign fraudulent misconduct laws or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws 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 for the year ended December 31, 2022.

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 business conduct and ethics, 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 physicians is governed by the national anti-bribery laws of EU Member States, such as the U.K. Bribery Act 2010 (Bribery Act). Infringement of these laws could result in substantial fines and imprisonment. Payments made to physicians in certain EU Member States must be publicly disclosed. 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. Ensuring compliance with such laws could also impair our efforts to maintain and expand our customer base, and thereby decrease our revenue.

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 United States, 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) as amended by the California Privacy Rights Act (CPRA) creates individual privacy rights for California residents and imposes obligations on companies that process their personal information and meet certain revenue or volume processing thresholds. Among other things, the CCPA requires covered companies to provide new disclosures to California residents and provide such residents new data protection and privacy rights, including the ability to opt-out of certain sales of personal information. The amendments introduced by the CPRA significantly modify the CCPA by expanding residents' rights with respect to certain personal information and creates a new 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 private right of action may increase the likelihood of, and risks associated with, data breach litigation, including class action litigation.

Similar laws have been passed in twelve other states and a number of 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 as a result of a qualifying data breach. There are also states that are specifically regulating health information. For example, Washington state recently passed a health privacy law that will regulate the collection and sharing of health information, and the law also has a private right of action, which further increases the relevant compliance risk. Connecticut and Nevada 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 there is discussion in the U.S. Congress of a new comprehensive federal data privacy law to which we may likely become subject, if enacted.

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 (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 processing health and other sensitive data, 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 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 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 United States in certain circumstances, unless a derogation exists or adequate international transfer safeguards (for example, the European Commission approved Standard Contractual Clauses (the EU SCCs) and the UK International Data Transfer Agreement/Addendum (the UK IDTA) are put in place. 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. 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 United States 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. The UK government has confirmed that personal data transfers from the UK to the EEA remain free flowing. The relationship between the UK and the EU in relation to certain aspects of data protection law remains unclear, and it is unclear how UK data protection laws and regulations will develop in the medium to longer term, and how data transfers to and from the UK will be regulated in the long term. Further, the UK Government has introduced a Data Protection and Digital Information Bill (the UK Bill) into the UK legislative process. The aim of the UK Bill is to reform the UK’s data protection regime following Brexit. If passed, the final version of the UK Bill may have the effect of further altering the similarities between the UK and EEA data protection regime and threaten the UK adequacy decision from the European Commission. In addition, EEA Member States have adopted national laws to implement the GDPR that may partially deviate from the GDPR. Further, 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 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. This lack of clarity on future UK laws and regulations and their interaction with EU laws and regulations could add legal risk, complexity and cost to our handling of personal data and our privacy and data security compliance programs and could require us to implement different compliance measures for the UK and the EEA.

It is unclear how UK data protection laws and regulations will develop in the medium to longer term, and how data transfers to and from the UK will be regulated in the long term. Although the EU GDPR and the UK GDPR currently impose substantially similar obligations, it is possible that over time the UK GDPR could become less aligned with the EU GDPR. In addition, EEA Member States have adopted national laws to implement the EU GDPR that may partially deviate from the EU GDPR. Further, the competent authorities in the EEA Member States may interpret the EU 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 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. The lack of clarity on future UK laws and regulations and their interaction with EU laws and regulations could add legal risk, uncertainty, complexity and cost to our handling of European personal data and our privacy and data security compliance programs and could require us to implement different compliance measures for the UK and the EEA. 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.

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 for the year ended December 31, 2022.

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 United States. 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 United States. 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 United States 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. In particular, we do not exclusively license any issued patents and most of the patent applications we own are provisional applications. 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 certain patent applications 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 United States. Furthermore, patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. 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 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 antibodies has emerged in the United States. The scope of patent protection in jurisdictions outside of the United States 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 United States 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 our 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 United States 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 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 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 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 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 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 patent applications owned by or licensed to us and we do not currently own or in-license any issued patents that protect our screening platform. Even if these patents issue from these patent applications and provide broad protection, it may be difficult or impossible to detect whether a competitor is practicing the proprietary methods claimed in such patent applications in order to discover their own product candidates and therapeutic targets. In such case, any 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 Provincial Health Services Authority (PHSA), 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 the manner in which 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, which we describe below, 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 the manner in which 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 API used. We currently have a limited number of issued patents, but our pending owned U.S. and international patent applications include claims that cover compositions of matter and methods of use of our product candidates. We cannot be certain that claims in any 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 in the course of 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 patent applications are directed to our TCR-T therapy 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 United States and other countries as appropriate. Our patent portfolio also includes patent families exclusively licensed from BWH, which include pending U.S. and foreign non-provisional patent applications. Any patents that 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 2043, in each case without taking into account any possible patent term adjustments or extensions.

We anticipate additional patent applications will be filed both in the United States 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 United States 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 of time during which we could market our product candidates under patent protection would be reduced. Since patent applications in the United States and most other countries are confidential for a period of time 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 United States 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 a number of 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 similar to 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 with regard to formulation or method of use;
- we or our licensors, as the case may be, 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 course of the party's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all

inventions conceived 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 United States. Courts outside the United States 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 United States 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 “Risk Factors – 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 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 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 a number of 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 United States 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 United States 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-T 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 are able to 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 in order 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 a number of 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 United States, 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 United States 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 United States 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 biopharmaceutical 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 United States 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 with regard to 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 the U.S. 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 United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as the laws in the United States, 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 United States, or from selling or importing products made using our inventions in and into the United States 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 United States. 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. Most of our patent portfolio is at the very early stage. 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 biopharmaceutical 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 we may obtain in the future 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 patents we obtain in the future 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 cost 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 other 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 of 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 United States, 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, and have filed applications to register various trademarks, including “TSCAN THERAPEUTICS” and “TSCAN,” 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 United States. 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 plan to rely on third parties to 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 plan to utilize and depend upon independent investigators and collaborators, such as medical institutions, CROs, CMOs and strategic partners to conduct our preclinical studies and clinical trials under agreements with us. We expect to have to negotiate budgets and contracts with CROs, trial sites and CMOs 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. As of March 31, 2023, our Collaboration and License Agreement with Novartis Institutes for BioMedical Research, Inc. (Novartis) concluded. Our Amgen Agreement, to identify antigens recognized by T cells in patients with Crohn's disease, grants Amgen options to evaluate a variety of modalities to create therapeutics based on targets discovered by us and Amgen will retain all global development and commercialization rights, as well as an option to expand the collaboration to include target discovery for ulcerative colitis, under certain pre-specified terms. Amgen may terminate the Amgen Agreement in its entirety for our insolvency, uncured material breach, or failure to comply with specified compliance provisions or subject to a specified negotiation mechanism. Amgen may terminate the Amgen Agreement in its entirety upon ninety (90) days' prior written notice to us. 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.

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

We expect to use third parties as part of our manufacturing process for registrational trials for our current pipeline, 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 COVID-19 pandemic, the ongoing U.S.-China trade war, political unrest in countries where we or our partners operate, earthquakes 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 biological drug products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of biologic 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 our manufacturing site (or that of any third party we engage) 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 do not have long-term contracts with many of these suppliers and may not be able to contract with them 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 biopharmaceutical 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. For example, in 2020, we experienced significant delays in receiving shipments of materials utilized in our cell expansion process as a result of the distributor prioritizing distribution of such products for medical use, rather than product candidate development, and, subsequently, increased demand following the easing of state and federal workplace restrictions.

In addition, some of our raw materials are currently sourced from a single supplier, or a small number of suppliers. For example, the type of cell culture media and cryopreservation buffer that we currently use in our manufacturing process for TSC-100 and TSC-101 are each only sourced from a limited number of suppliers. In addition, the cell processing equipment and tubing that we use in our current manufacturing process is only sourced from a single supplier. 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 some of our protocols 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 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 either at our own facility or at a third party's facility, we will need to comply with the FDA's 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 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 programs, including leading to significant delays in the availability of our TCR-T therapy 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 United States 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.

We conduct our operations at our facility in Waltham, Massachusetts. This region is headquarters to many other biopharmaceutical 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 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 3, 2023, we had 145 full-time employees and 10 part-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, 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 may have experienced, such an “ownership change.” We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As of December 31, 2022, we had U.S. federal net operating loss carryforwards of $86.3 million and U.S. federal research and development tax credit carryforwards of $6.9 million that expire through

2042 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 biopharmaceutical 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 United States 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 the COVID-19 pandemic; or the ongoing conflict 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 biopharmaceutical companies. Stock prices of many biopharmaceutical 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, or the 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. In addition, the Loan Agreement provides the lenders with certain registration rights with respect to the Conversion Shares (as defined in the Loan Agreement). Pursuant to the terms of the Loan Agreement, we are obligated to prepare and file with the SEC a registration statement to register the Conversion Shares for resale upon request of K2HV. 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 3, 2023, our executive officers, directors, and entities affiliated with such persons beneficially owned, in the aggregate, approximately 31% of our outstanding voting stock and approximately 37% 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.

In addition, we entered into a nominating agreement with Baker Brothers Life Sciences, L.P. and 667, L.P. (collectively, the BBA Funds) which was subsequently amended and restated on April 22, 2021), pursuant to which, among other things, we agreed to support the nomination of, and cause our board of directors (or the nominating committee thereof) to include in the slate of nominees recommended to our stockholders for election as directors at each annual or special meeting of our stockholders at which directors are to be elected, one person designated from time to time by the BBA Funds, subject to the requirements of fiduciary duties under applicable law and the terms and conditions of such nominating agreement. The agreement only applies for the three years following our initial public offering, as long as (1) the BBA Funds and their affiliates, collectively, beneficially own at least 75% of the shares of our common stock issued upon conversion of the Series C convertible preferred stock purchased by the BBA Funds in our Series C convertible preferred stock financing, and (2) the BBA Funds and their affiliates, collectively, beneficially own at least 2% of our then outstanding voting common stock.

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 will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) ending December 31, 2026, (b) in which we have total annual gross revenue of at least $1.235 billion or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

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 could be an "emerging growth company" until December 31, 2026. 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 United States 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 United States 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 income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (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 Internal Revenue Code of 1986, as amended, in taxable years beginning after December 31, 2021, expenses that are incurred for research and development in the U.S. will be capitalized and amortized, which may have an adverse effect on our cash flow. 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 United States 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 biopharmaceutical 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, CMOs 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 (No. 333-257938) 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.

During the three months ended September 30, 2023, none of the Company's directors or officers (as defined in Rule 16a-1(f) of the Securities Exchange Act of 1934) adopted, terminated or modified 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).

On November 8, 2023, we entered into that first amendment (the First Amendment) to Lease by and between PPF OFF 828-830 Winter Street LLC as the landlord and the Company as the tenant, dated August 13, 2019 with respect to certain premises located at 830 Winter Street, Waltham, Massachusetts (830 Winter Street Lease). The First Amendment extends the expiration date of the 830 Winter Street Lease from September 30, 2024 to October 31, 2029 and provides for one option to renew the 830 Winter Streat Lease for a five-year period commencing on November 1, 2029.

The foregoing summary of the First Amendment is qualified in its entirety by reference to the lease amendment, a copy of which is filed as Exhibit 10.1 to this Quarterly Report.

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	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*	First Amendment to Lease by and between PPF OFF 828-830 Winter Street LLC and the Registrant, dated November 8, 2023.
31.1*	Certification of Principal Executive 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.
31.2*	Certification of 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
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.
** Furnished herewith

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 9, 2023

By: /s/ Gavin MacBeath
Gavin MacBeath
Chief Executive Officer
(Principal Executive Officer and Interim Principal Financial Officer)

Date: November 9, 2023

By: /s/ Leiden Dworak
Leiden Dworak
Vice President, Finance
(Principal Accounting Officer)

Exhibit 10.1

830 WINTER STREET
WALTHAM,
MASSACHUSETTS
(the "Building")

FIRST
AMENDMENT
("First Amendment")

EXECUTION DATE:	November 8, 2023 (the "Execution Date")
LANDLORD:	PPF OFF 828-830 Winter Street LLC, a Delaware limited liability company
TENANT:	TScan Therapeutics, Inc., a Delaware corporation
PREMISES:	Approximately 25,472 rentable square feet of space in the Building, consisting of approximately 24,826 rentable square feet of space on the third (3rd) floor of the Building and approximately 646 rentable square feet of space in the basement of the Building, as more particularly described in the Existing Lease (as defined below).
DATE OF EXISTING LEASE:	August 13, 2019 (the "Existing Lease").
CURRENT EXPIRATION DATE:	September 30, 2024
EXTENDED EXPIRATION DATE:	October 31, 2029

BACKGROUND

WHEREAS, Landlord and Tenant desire to amend the Existing Lease to reflect, among other provisions, the extension of the term of the Existing Lease, upon the terms and conditions hereinafter set forth.

NOW, THEREFORE, the Existing Lease is hereby amended as follows (the Existing Lease, as further amended by this First Amendment, shall hereafter be referred to as the "Lease"). Any capitalized terms used herein shall have the same definition as set forth in the Existing Lease, except to the extent otherwise set forth in this First Amendment.

1.Term. The term of the Lease is hereby extended for a term (the "First Extension Term") commencing on October 1, 2024 (the "First Extension Term Commencement Date") and ending on October 31, 2029 (the "Extended Expiration Date"), unless sooner terminated, in accordance with and subject to the terms and conditions set forth in the Lease. Without limitation, all

references in the Lease to the “Term” shall be deemed to include the First Extension Term in all respects and all references to the “Expiration Date” shall be deemed to refer to the Extended Expiration Date. The demise and use of the Premises shall be upon and subject to the terms and conditions of the Existing Lease, except as expressly set forth in this First Amendment.

2.First Extension Term Rent. Until the First Extension Term Commencement Date, Rent shall be payable as set forth in Section 5 of the Existing Lease. Commencing on the First Extension Term Commencement Date, Base Rent shall be payable as follows:

Lease Period	Annual Base Rent	Monthly Base Rent Payments
10/1/2024-10/31/2024	$0.00	$0.00
11/1/2024-10/31/2025:	$1,986,816.00	$165,568.00
11/1/2025-10/31/2026:	$2,046,420.48	$170,535.04
11/1/2026-10/31/2027:	$2,107,813.09	$175,651.09
11/1/2027-10/31/2028:	$2,171,047.49	$180,920.62
11/1/2028-10/31/2029:	$2,236,178.91	$186,348.24

3.Operating Costs and Taxes. From and after the Execution Date, Tenant shall continue to pay Tenant’s Share of Operating Costs and Tenant’s Share of Taxes in the same manner and at the same times set forth in Article 5 of the Existing Lease.

4.Second Extension Option. Tenant shall have one (1) option to renew the Lease for a five (5) year period (the “Second Extension Term”) commencing on November 1, 2029, subject to and in accordance with the terms and conditions of Section 1.2 of the Lease; provided, however, that all references to the “Extension Term” therein shall be considered to be references to the “Second Extension Term”.

5.Condition of the Premises. The parties acknowledge that Tenant is currently in occupancy of the Premises. On the First Extension Term Commencement Date, Tenant shall continue in occupancy of the Premises in its “as-is” condition subject to and in accordance with Article 3 of the Existing Lease. Tenant may perform Alterations in the Premises in accordance with Article 11 of the Existing Lease, at Tenant’s sole cost and expense (but subject to Landlord’s First Amendment Contribution). Landlord shall provide to Tenant a tenant improvement allowance (“Landlord’s First Amendment Contribution”) of up to $509,440 (i.e., $20.00 per rentable square foot of the Premises). The provisions of Sections 5 and 6 of Exhibit 4 of the Existing Lease shall govern the requisition and payment of Landlord’s First Amendment Contribution, except that:

a.All references to Landlord’s Contribution shall be considered to be references to Landlord’s First Amendment Contribution;

b.All references to Tenant’s Work shall be considered to be references to the Alterations approved by Landlord;

c.The last sentence of Section 5 of Exhibit 4 shall not apply and in lieu thereof, after the full and final completion of Tenant’s Alterations, Tenant shall also have the right to use a portion of the Landlord’s First Amendment Contribution, but in no event more than

$254,720 (i.e., $10.00 per rentable square foot of the Premises), to offset Base Rent due under the Lease; and

d.The Outside Requisition Date with respect to Landlord's First Amendment Contribution shall be the date which is eighteen (18) months after the First Extension Term Commencement Date.

6.Security Deposit. The parties hereby acknowledge that Landlord is currently holding a Security Deposit in the amount of $595.408.00 pursuant to the Existing Lease. Landlord shall continue to hold the Security Deposit during the First Extension Term pursuant to and in accordance with Article 7 the Existing Lease.

7.Miscellaneous

(a)Broker. Tenant and Landlord each warrants and represents that it has dealt with no broker in connection with the consummation of this First Amendment other than Cresa and CBRE (collectively, the "First Amendment Broker"). Tenant and Landlord each agrees to defend, indemnify and save the other harmless from and against any claims arising in breach of the representation and warranty set forth in the immediately preceding sentence. Landlord shall be solely responsible for the payment of any brokerage commission to First Amendment Broker.

(b)Ratification; Representations. In all other respects, except as expressly modified herein, the Existing Lease is hereby ratified and confirmed. The submission of drafts of this document for examination and negotiation does not constitute an offer, or a reservation of or option for any of the terms and conditions set forth in this First Amendment, and this First Amendment shall not be binding upon Landlord or Tenant unless and until Landlord shall have executed and delivered a fully executed copy of this First Amendment to Tenant. Tenant hereby represents and warrants to Landlord as follows: (i) the execution and delivery of this First Amendment by Tenant has been duly authorized by all requisite limited liability company action,
(ii) neither the Lease nor the interest of Tenant therein has been assigned, sublet, encumbered or otherwise transferred; (iii) to the best knowledge of Tenant, there are no defenses or counterclaims to the enforcement of the Lease or the liabilities and obligations of Tenant thereunder; (iv) except as set forth herein, Tenant is not entitled to any offset, abatement or reduction of rent under the Lease; (v) to the best knowledge of Tenant, neither Landlord or Tenant is in breach or default of any of its respective obligations under the Lease; (vi) Landlord has performed all work and constructed all improvements required pursuant to the Lease and, except for Landlord's First Amendment Contribution, has provided all allowances and contributions required pursuant to the Lease; and (vii) Landlord has made no representations or warranties, except as expressly and specifically set forth in this First Amendment or as expressly and specifically set forth in the Lease as of the date of the Lease. To the best knowledge of Landlord, neither Landlord or Tenant is in breach or default of any of its respective obligations under the Lease.

(c)Conflict. In the event that any of the provisions of the Existing Lease are inconsistent with this First Amendment or the state of facts contemplated hereby, the provisions of this First Amendment shall control.

(d)Counterparts. This First Amendment may be executed in any number of counterparts and by each of the undersigned on separate counterparts, which counterparts taken together shall constitute one and the same instrument. This First Amendment may be executed by

electronic signature, which shall be considered as an original signature for all purposes and shall have the same force and effect as an original signature. Without limitation, in addition to electronically produced signatures, “electronic signature” shall include faxed versions of an original signature or electronically scanned and transmitted versions (e.g., via pdf) of an original signature.

[BALANCE OF PAGE INTENTIONALLY LEFT BLANK;
SIGNATURES ON FOLLOWING PAGE]

EXECUTED as of the date first above written.

LANDLORD:
PPF OFF 828-830 WINTER STREET, LLC,
a Delaware limited liability company

By: PPF MASS REIT, LLC, a Delaware limited liability company, its Sole Member

By: PPF OP, LP, a Delaware limited partnership, its Sole Partner

By: PPF OPGP, LLC, a Delaware limited liability company, its General Partner

By: Prime Property Fund, LLC, a Delaware limited liability company, its Sole Member

By: Morgan Stanley Real Estate Advisor, Inc., a Delaware corporation, its Investment Adviser

By: /s/ Tricia Moore

Name: Tricia Moore

Title: Vice President

TENANT:

TSCAN THERAPEUTICS, INC., a Delaware corporation

By: /s/ Gavin MacBeath
Name: Gavin MacBeath
Title: CEO

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.The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a.designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b.designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c.evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d.disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5.The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

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

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

Date: November 9, 2023	By:	/s/ Gavin MacBeath
	Name:	Gavin MacBeath
	Title:	Chief Executive Officer
		(Principal Executive Officer)

Exhibit 31.2

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.The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a.designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b.designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c.evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d.disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5.The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

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

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

Date: November 9, 2023	By:	/s/ Gavin MacBeath
	Name:	Gavin MacBeath
	Title:	Chief Executive Officer
		(interim Principal Financial 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, 2023 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 9, 2023

By:

/s/ Gavin MacBeath
Gavin MacBeath
(Principal Executive Officer and interim Principal Financial Officer)