UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2021

OR

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

Commission File Number 001-40603

TSCAN THERAPEUTICS, INC.

(Exact name of Registrant as specified in its Charter)

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

Registrant's telephone number, including area code: (857) 399-9500

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

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

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

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

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

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

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

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

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 June 30, 2021, the last business date of the registrant's most recently completed second quarter, there was no public market for the registrant's common stock. The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, based on the closing price of the shares of common stock on The NASDAQ Stock market on March 4, 2022, was approximately $64,227,891.

The number of shares of Registrant's Common Stock outstanding as of March 4, 2022 was 23,976,942.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's proxy statement for the 2022 annual meeting of stockholders to be filed pursuant to Regulation 14A within 120 days after the registrant's fiscal year ended December 31, 2021, are incorporated by reference in Part III of this Form 10-K.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, or Annual Report, including the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations," as well as information included in oral statements or other written statements made or to be made by us, 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, that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this Annual Report, including statements regarding our future results of operations and financial position, future revenue, business strategy, prospects, product candidates, planned preclinical studies and clinical trials, results of clinical trials, research and development costs, regulatory approvals, timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that are in some cases beyond our control and may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

The words "may," "will," "should," "would," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions are intended to identify forward-looking statements. Forward-looking statements contained in this Annual Report include, but are not limited to, express or implied statements about:

- the beneficial characteristics, safety, efficacy, therapeutic effects and potential advantages of our T cell receptor-engineered T cell, or 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;
- 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 effect of the COVID-19 pandemic, including mitigation efforts and political, economic, legal and social effects, 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.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in the section titled "Risk Factors" and elsewhere in this Annual Report. 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. In light of these risks, uncertainties and assumptions, the forward- looking events and circumstances discussed in this Annual 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 Annual Report are made as of the date of this Annual 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. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this Annual Report to conform these statements to actual results or to changes in our expectations.

You should read this Annual Report and the documents that we reference in this Annual Report and have filed with the SEC 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 Annual 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 Annual 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.

PART I

Item 1. Business

Overview

We are a clinical-stage biopharmaceutical company focused on developing a robust pipeline of T cell receptor-engineered T cell, or 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. Using one of our proprietary platform technologies, 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 T cell receptors, or 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 believe this three-pronged approach will enable us to discover and develop a wide array of potential treatment options for patients with cancer.

We are advancing a robust pipeline of TCR-T therapy candidates for the treatment of patients with hematologic and solid tumor malignancies. Our lead liquid tumor 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 stem cell transplantation, or 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 submitted Investigational New Drug, or IND, applications with the U.S. Food and Drug Administration, or FDA, for each of TSC-100 and TSC-101 in the fourth quarter of 2021. The FDA has cleared the IND for TSC-100 while the IND for TSC-101 remains on clinical hold pending additional assessment of the potential for off-tumor reactivity in certain tissues. We plan to initiate the Phase 1 clinical study of TSC-100 in the first half of 2022. Pending clearance of the IND for TSC-101, we will initiate the TSC-101 arm of the trial. 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 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 the key solid tumor resistance mechanisms of target loss as well as HLA loss. We are currently advancing five solid tumor programs: TSC-200 in IND-enabling activities; TSC-204 advancing to IND-enabling studies; and TSC-201, TSC-202, and TSC-203, in lead optimization. We expect to submit two IND applications for our solid tumor TCR-T therapy candidates in the second half of 2022, with additional IND applications expected to be submitted in 2023.

T cells are an essential component of the adaptive immune system and provide protection against cancer, infection, and autoimmune disease. Multiple approaches have been and are continuing to be explored to develop effective T cell-based therapies for the treatment of cancer, including tumor infiltrating lymphocyte, or TIL, therapy and chimeric antigen receptor T cell, or CAR-T, therapy. The success of TIL therapy depends on the specific T cells present in the patient. If their TILs do not have appropriate anti-cancer specificities, the therapy is unlikely to be effective. In addition, TIL therapy has, to date, shown limited applicability for the treatment of liquid tumors. In contrast, CAR-T therapy has proven effective in certain hematological malignancies of lymphoid origin but have not yet shown efficacy or safety in myeloid malignancies. Additionally, this type of treatment is limited to targets on the surface of tumor cells and has not yet been shown to effectively penetrate solid tumors. Both TIL and CAR-T therapies, as well as other immunotherapies such as checkpoint inhibitors, harness the power of cytotoxic T cells in fighting cancer. Despite demonstrating compelling efficacy, they are only effective in a subset of patients. To address a broader patient population, we believe additional T cell-based approaches are needed that more closely mimic the way the immune system recognizes and fights cancer in patients who are responding to immunotherapy.

Our decision to develop TCR-T therapies for the treatment of cancer is based on our conviction that we can learn from the natural interaction between T cells and tumor cells and harness this information to treat patients by reprogramming their immune systems. We believe that TCR-T therapy combines the benefits of TIL and CAR-T therapies while uniquely addressing their key limitations.

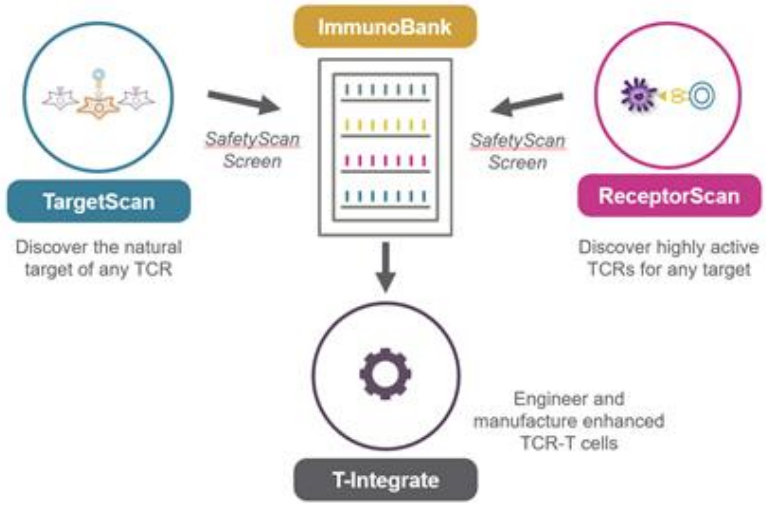
The development of TCR-T therapy requires three key prerequisites: (i) an effective anti-cancer TCR; (ii) knowledge of the precise peptide antigen, a protein or other molecule to which an antibody binds, that is recognized by the TCR; and (iii) confirmation that the TCR does not recognize problematic off-targets. We believe that our approach provides us with the following key advantages:

- *Our TCR-T therapies are based on highly active TCRs that are clinically relevant.* Many other approaches to T-cell therapy rely on specifically expanding T cells that are already present in the patient. Our platform analyzes anti-cancer T cells from a wide variety of patients who are responding to immunotherapy in order to find the most active and clinically relevant TCRs against each target. We believe that we can develop TCR-T therapies for a wide range of patients, including those who do not have T cells that efficiently recognize their cancers.

- *Our TCR-T therapies are designed to be used in combination with each other.* We are building our diverse ImmunoBank of TCRs to allow for multiplexed TCR-T therapy, which has the potential to address the heterogeneous nature of solid tumors and to prevent resistance developing due to loss of a single target. We believe this approach may allow us to overcome the limitations and challenges of TCR-T therapy development to date. We plan to populate ImmunoBank with TCRs for multiple targets as well as multiple HLA types for each target, thus helping us to overcome the key solid tumor resistance mechanisms of target loss as well as HLA loss.

- *Our approach is expandable.* ImmunoBank has the flexibility to be used with new and optimized methods of T cell engineering that we may develop over time. We are building ImmunoBank to be compatible with both autologous and allogeneic engineering technologies in order to potentially transition to generating off-the-shelf, allogeneic T cells that have been pre-engineered with our TCRs for direct administration to patients.

Our proprietary platform is designed to: (i) discover anti-cancer TCRs from patients with exceptional responses to immunotherapy; (ii) determine novel targets of clinically relevant TCRs; (iii) discover novel TCRs that recognize clinically validated targets; (iv) identify off-targets of TCRs to eliminate candidates that could potentially pose a safety risk; and (v) manufacture TCR-T therapies efficiently and consistently without the use of viral vectors using our T-Integrate technology. The central elements of our platform that differentiate us from other cell therapy companies are TargetScan, ReceptorScan, SafetyScan, ImmunoBank and T-Integrate.



TargetScan. At the core of our proprietary platform is TargetScan, which enables us to identify natural targets of TCRs using an unbiased, genome-wide high-throughput screen. We have developed this technology to be extremely versatile and applicable across multiple therapeutic areas, including cancer, autoimmune disorders, and infectious diseases. It can be applied to virtually any TCR that plays a role in the cause or prevention of disease. Using TargetScan, we have identified more than 60 shared antigens in patient tumors, and over 90% of these targets have not previously been publicly identified as targets for TCR-T therapy. We believe this provides us with a competitive advantage, because not only are we among the first to identify these targets as tumor-specific antigens, but also we have already identified highly active TCRs that recognize these targets.

SafetyScan. SafetyScan is designed to identify potential off-target interactions of a given TCR and eliminate those TCR candidates that cross-react with proteins expressed at high levels in critical organs. We believe this will allow us to reduce the risk and enhance the potential safety profile of our TCR-T therapy candidates early in development before we initiate clinical trials.

ReceptorScan. To further expand our ability to discover and develop therapeutic TCRs, we have developed our proprietary ReceptorScan technology to enable us to identify and clone highly active TCRs that recognize known or clinically validated targets. We co-culture hundreds of millions of CD8+ T cells from either healthy donors or cancer patients with dendritic cells, also referred to as antigen-presenting cells, that display the target antigen of interest to the T cells. T cells that recognize the target of interest proliferate and are subsequently isolated based on their ability to recognize a fluorescently labeled version of the target. We then use single cell sequencing to identify the specific TCR sequences that recognize the target. Our novel technologies allow us to gene-synthesize hundreds of TCRs simultaneously and to rapidly sort through hundreds of target-specific TCRs in a single high-throughput screen to identify the most active clones. Using ReceptorScan, we have identified our two lead TCR-T therapy candidates, TSC-100 targeting HA-1 and TSC-101 targeting HA-2, as well as our other pipeline programs.

ImmunoBank. We are building ImmunoBank, our diverse bank of therapeutic TCRs, to allow for multiplexed TCR-T therapy, which has the potential to address the heterogeneous nature of solid tumors and to prevent resistance developing due to loss of a single haplotype target. We believe this approach may allow us to overcome the limitations and challenges of TCR-T therapy development to date. 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 the key solid tumor resistance mechanisms of target loss as well as HLA loss. Finally, we are building ImmunoBank to have the flexibility to be used with new and optimized methods of T-cell engineering that we may develop over time. We are building ImmunoBank to be compatible with both autologous and allogeneic engineering technologies in order to potentially transition to generating off-the-shelf, allogeneic T cells that have been pre-engineered with our TCRs for direct administration to patients.

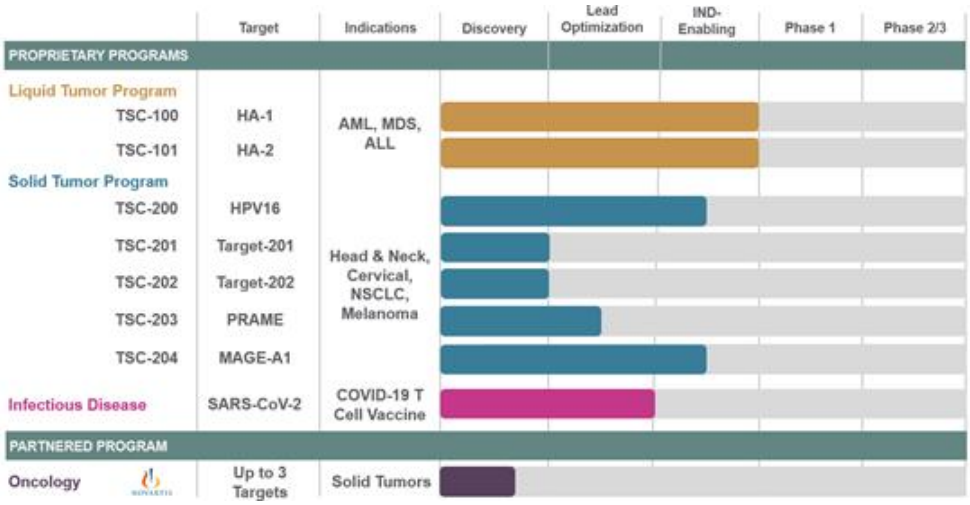
T-Integrate. Manufacturing cell therapies is highly complex, and associated challenges have led to significant delays or failures in the development of many cell therapies. To enable the rapid, cost-effective, and consistent manufacturing of TCR-Ts, we have developed a non-viral vector delivery system that we refer to as T-Integrate. Our TCR-T therapy candidates are manufactured using a transposon/transposase system, in which the DNA encoding the TCR is manufactured as a Nanoplasmid™, a non-viral vector. The Nanoplasmid, together with an mRNA sequence encoding a transposase enzyme, is introduced into the T cell by electroporation. After the T cell translates the mRNA into protein, the transposase enzyme inserts the TCR sequence from the Nanoplasmid into the genome of the T cell. This system is highly reproducible, as the only required components are a Nanoplasmid, which is different for each TCR product, and an mRNA, which is constant for all TCR products. Unlike lentivirus, both of these components are routinely manufactured in a cost-effective manner without the need for extensive process development.

We have completed the construction and validation of a 7,000 square-foot state-of-the-art good manufacturing practices, or GMP, manufacturing facility to manufacture all necessary Phase 1 and 2 supply for our TCR-T therapies. We expect that this facility will provide sufficient production capacity to supply product for all planned Phase 1 and 2 clinical studies for the liquid and solid tumor programs. Approval of our IND for TSC-100 validates our facility for human manufacturing of our T cell therapies. We believe our manufacturing platform will enable us to efficiently develop and manufacture many different TCR-T therapies, allowing us to deliver customized multiplexed therapy to patients with cancer.

Our Pipeline

We are building ImmunoBank with the goal of delivering customized multiplexed TCR-T therapies to a wide range of patients with cancer. In addition, we are applying our platform to identify targets and TCRs in therapeutic areas outside of oncology, such as

autoimmune disorders and infectious disease, through strategic partnerships. Our current proprietary pipeline is summarized in the figure below.



In addition to our proprietary pipeline programs noted above, we have also entered into collaborations with strategic partners for applications of our platform technologies. We have a collaboration and license agreement with Novartis Institutes for BioMedical Research, Inc., or Novartis, to identify novel cancer antigens from the T cells of patients with a certain specific type of cancer. Novartis has the option to license and develop therapies for up to three of the targets discovered in the collaboration. Should Novartis license a target, we are eligible for a payment of $10 million per target as well as future milestones and royalties. In addition, we have partnered with QIAGEN Sciences, LLC to develop a highly specific diagnostic test to determine prior exposure to SARS-CoV-2 based on the presence of anti-viral T cells.

With our differentiated platform as the foundation, we are building a three-pillar research and development strategy to create transformational TCR-T therapies for patients.

1. *Our Liquid Tumor Program.* We are developing our liquid tumor program to treat patients with hematologic malignancies who are undergoing allogeneic HCT. In the first phase of our clinical development strategy, we are initially focusing on clinically validated cancer targets that have been discovered in patients with exceptional responses to HCT-associated immunotherapy, including HA-1 and HA-2.

In the fourth quarter of 2021, we submitted IND applications with the FDA for our lead TCR-T therapy candidates, TSC-100 and TSC-101. The FDA cleared the IND for TSC-100 in January 2022, while the IND for TSC-101 remains on clinical hold. For TSC-101, we received written communication from the FDA asking for additional assessment of the potential for off-tumor reactivity in certain tissues and are working with the agency to resolve its questions as quickly as possible. The liquid tumor trial is based on an umbrella protocol, which will allow us to begin the TSC-100 and control arms of the trial in the near term and to open the TSC-101 arm to the ongoing trial upon clearance of the IND. We plan to initiate the Phase 1 clinical study of TSC-100 in the first half of 2022. Pending clearance of the IND for TSC-101, we will then initiate the TSC-101 arm of the trial, allowing for us to advance TSC-100 into Phase 1 clinical trials. The study protocol allows us to conduct clinical trials of TSC-100 and TSC-101 in parallel, with patients enrolled in treatment arms based on their genotype. Patients who are positive for the target antigen, HA-1 or HA-2, as well as the HLA-A*02:01 allele, which is the HLA type required to display HA-1 and HA-2 on the cell surface for recognition by a T cell, will be eligible for enrollment. Furthermore, eligible patients will require donors who are negative for either the target antigen or the HLA-A*02:01 allele.

Through the development of our liquid tumor program, we are building a foundation of manufacturing, clinical, and regulatory capabilities, which will be applied to the future development of our broader portfolio of TCR-T therapy candidates for solid tumors. With the FDA clearance of our IND for TSC-100, we believe our approach has been validated.

2. *Our Solid Tumor Program.* We are developing a portfolio of autologous TCR-T therapy candidates that are designed to be used in combination with each other to treat and eliminate solid tumors. Our TSC-200 series of product candidates are designed to elicit anti-tumor responses in patients by targeting cancer-specific antigens in their tumor cells. Our TCR-T therapy candidates

include: (i) either well-recognized cancer targets that have demonstrated anti-tumor activity in clinical trials or novel targets that were identified by TargetScan from the T cells of patients responding to immunotherapy, and (ii) naturally occurring TCRs specific to a patient's HLA type that recognize these cancer-specific targets. Such targets are not only commonly shared among patients with the same cancer type, but also frequently expressed in multiple solid tumor types, enabling clinical development across multiple indications. Our first five product candidates include a combination of known targets, such as HPV16 for TSC-200, PRAME for TSC-203, and MAGE-A1 for TSC-204, as well as targets that are novel antigens for TCR-T therapy, such as for TSC-201 and TSC-202. In addition to our five lead product candidates, we have identified over 60 novel antigens based on tumor samples from patients who are actively responding to immunotherapy using our TargetScan technology. We are in early stages of analyzing these additional novel antigens and plan to advance those that we believe have the best potential as a TCR-T product candidate into preclinical development.

Our vision is to create and continuously expand ImmunoBank to enable customized multiplexed TCR-T therapy for a wide range of solid tumor patients. For each patient with a solid tumor malignancy, we plan to analyze their tumor to determine which targets are expressed at high levels in each patient's particular cancer. We will then access ImmunoBank and select up to three TCRs that match their HLA type and address the most highly expressed targets in their tumor. We will use this set of TCRs to genetically reprogram their T cells to recognize these targets, and the resulting T cells will be infused back into the patient as a multiplexed TCR-T therapy.

3. *Strategic Partnerships and Collaborations.* T cells play a fundamental role in many other therapeutic areas beyond cancer, such as autoimmune disorders and infectious disease. We believe that our TargetScan technology is well suited to discover novel antigens for the development of therapeutics, diagnostics, and vaccines in these other therapeutic areas. We intend to opportunistically pursue collaborations with strategic partners for applications of our platform technologies outside our core focus of oncology.

Our Strategy

Our mission is to create life-changing T cell therapies for patients by unleashing the untapped potential of the human immune system. Our goal is to use our proprietary platform technologies for the identification of novel tumor-specific antigens and clinically active TCRs to become a leader in the development of engineered T cell therapies for the treatment of liquid and solid tumors. Our strategy includes the following key elements:

- ***Leverage our proprietary platform technologies to build our diverse ImmunoBank of therapeutic TCRs to treat a wide range of tumor types***. Our TargetScan technology enables us to identify novel antigens that are broadly expressed across multiple types of solid tumors. In order to ensure that the antigens identified are clinically relevant, we use TCRs from tumor samples of patients with exceptional responses to immunotherapy. Our platform allows us to assess the specificity and cytotoxicity of these TCRs to develop a portfolio of TCR-T therapy candidates with therapeutic potential. As we continue to expand our screening technology, we believe we will be able to generate our ImmunoBank of therapeutic TCRs with the diversity required to treat many solid tumors using multiplexed therapy. 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 the key solid tumor resistance mechanisms of target loss as well as HLA loss.

- ***Advance our lead liquid tumor product candidates, TSC-100 and TSC-101, through clinical development.*** Our two lead programs, TSC-100 and TSC-101, are designed to target HA-1 and HA-2, respectively, both of which are antigens with clinically demonstrated anti-tumor effects in patients who naturally develop T cells specific to these targets. Using our ReceptorScan technology, we generated hundreds of highly active TCRs that recognize HA-1 and HA-2. We selected TSC-100 and TSC-101 based on their superior potency and lack of off-target effects. In the fourth quarter of 2021 we submitted INDs for each of TSC-100 and TSC-101 to the FDA. The FDA cleared the IND for TSC-100 in January 2022 enabling us to move forward with Phase 1 clinical development, while the IND for TSC-101 remains on clinical hold pending additional assessment of the potential for off-tumor reactivity in certain tissues. We plan to initiate the Phase 1 clinical study of TSC-100 in the first half of 2022. Pending clearance of the IND for TSC-101, we will then initiate the TSC-101 arm of the trial. The study protocol allows us to conduct clinical trials of TSC-100 and TSC-101 in parallel, with patients enrolled in treatment arms based on their genotype. In addition, through our liquid tumor programs, we have established a foundation of manufacturing, clinical and regulatory capabilities to support the development of our broad portfolio of TCR-T therapies.

- ***Apply experience from our liquid tumor program to efficiently develop our solid tumor program targeting both novel and previously identified antigens.*** Using TargetScan, we have identified over 60 novel antigens based on tumor samples from patients who are actively responding to immunotherapy. We are initially developing our TSC-200 series of TCR-T therapies against five selected target antigens that are frequently expressed across multiple solid tumor types. Our first five solid tumor TCR-T therapy candidates include a combination of known targets, such as HPV16 for TSC-200, PRAME for TSC-203, and MAGE-A1 for TSC-204 as well as targets that are novel antigens for TCR-T therapy, such as for TSC-201 and TSC-202. We

believe that the treatment of solid tumors will require a combination of several TCR-T therapeutics, which we refer to as 'multiplexed therapy.' We plan to leverage the foundation built from our liquid tumor programs to efficiently develop a robust portfolio of TCR-T therapy candidates and expand ImmunoBank to enable multiplexed TCR-T therapies for solid tumors.

- ***Continue to develop manufacturing capabilities based on our non-viral T-Integrate system.*** We believe that in-house manufacturing capabilities substantially facilitate the successful early development of cell therapies. For our TCR-T therapy candidates, we have developed a non-viral gene delivery system, which we refer to as T-Integrate, based on transposons that are designed to enable cost-effective and consistent cell manufacturing with short development times. We have built an internal, fully operational GMP manufacturing facility that we expect will provide sufficient capacity to support all of our clinical programs in both liquid and solid tumors through Phase 2 clinical trials. With the FDA clearance of our IND for TSC-100, we believe our approach has been validated.

- ***Develop next generation T cell engineering capabilities.*** Our long-term vision is to build an allogeneic repository of off-the-shelf, genetically engineered T cells and provide multiplexed TCR-T therapies to patients with a wide range of malignancies. Although our initial solid tumor programs are autologous, we are developing T-cell engineering technologies and in-house manufacturing capabilities to transition our therapeutic TCRs to allogeneic therapies based on T cells derived from healthy donors or induced pluripotent stem cells. We are also exploring additional next generation technologies, such as *in vivo* T-cell engineering, to further advance our T-cell engineering capabilities.

- ***Opportunistically pursue strategic partnerships and collaborations to maximize the full potential of our platform.*** Our platform represents a powerful tool to identify targets and TCRs in therapeutic areas outside of oncology, such as autoimmune disorders and infectious disease. We intend to seek strategic partners with proven clinical development and commercialization capabilities for certain targets and/or assets that do not overlap with our internal programs or our core focus. To date, we have a collaboration and license agreement with Novartis to identify novel cancer antigens from the T cells of patients with a specific type of cancer. Novartis has the option to license and develop therapies for up to three discovered targets. Should Novartis license a target, we are eligible for a payment of $10 million per target as well as future milestones and royalties. Additionally, we have established a partnership for the development of a T cell-based COVID-19 diagnostic with QIAGEN Sciences, LLC.

Background on T Cell Therapies

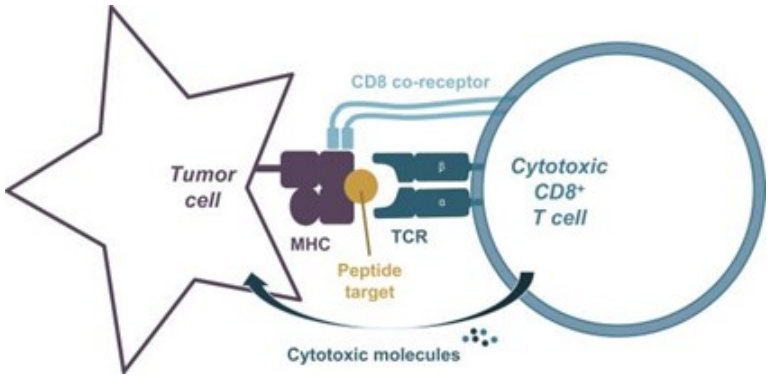
The human immune system constantly provides a natural and highly effective defense against cancer, which only forms when tumor cells find a way to evade the immune system. The treatment of cancer was revolutionized over a decade ago with the advent of immunotherapy – therapeutic approaches designed to re-enable or re-direct immune cells to recognize and fight cancer. Over the past 10 years, a suite of immuno-oncology drugs has been approved and adopted as part of routine clinical practice. Successes in immuno-oncology came initially from the approval of immune checkpoint inhibitors and more recently from the development of cellular therapies, such as CAR-T and TIL therapies. These therapies all harness the power of cytotoxic T cells in fighting both hematologic malignancies and solid tumors. Although these therapies have demonstrated compelling efficacy, they are only effective in a subset of patients. To address a broader patient population, we believe additional T cell-based approaches are needed that more closely mimic the way the immune system recognizes and fights cancer in patients who are responding to immunotherapy.

Overview of T Cell Biology

T cells are an essential component of the adaptive immune system and provide protection against cancer, infection, and autoimmune disease. T cells are classically divided into two primary types of activating cells: helper T cells and cytotoxic T cells. Helper T cells, which express the CD4 co-receptor, function by providing signals to other immune cells for activation and recruitment. Cytotoxic T cells, which express the CD8 co-receptor, function by killing any cells in the human body that are expressing unnatural proteins, including proteins that are not expressed in normal tissue, proteins that arise from mutated genes, or proteins derived from pathogens. By definition, tumor cells are abnormal and make a wide variety of unnatural proteins. T cells are activated and exert their helper or cytotoxic function when their T cell receptors, or TCRs, recognize antigens displayed on the surface of malignant or infected cells.

Virtually every cell in the body has a mechanism for displaying on its surface a sampling of every protein that is being made by the cell. This includes all normal proteins as well as aberrant proteins if the cell is cancerous or proteins from pathogens if the cell has been infected. Cellular proteins are broken down into short fragments, or peptides, by the proteasome, and these peptides are loaded into Major Histocompatibility Complexes, or MHCs, to be displayed on the outside of the cell. These peptide/MHC complexes are recognized by TCRs on cytotoxic CD8+ T cells, as shown in the graphic below. Because the TCR recognizes both the peptide and the MHC, a TCR only functions correctly when both the peptide and the correct MHC are present.

TCRs on Cytotoxic CD8+ T Cells Recognize the Peptide/MHC Complexes of Tumor Cells



MHC proteins, which present different peptides to the human immune system, are highly variable among people. An individual's MHC proteins are determined by their Human Leukocyte Antigen, or HLA, type. Although there are many different HLA types, some are quite common. For example, 42% of individuals in the United States are positive for the HLA-A*02:01 allele, or variant. TCRs are often referred to as "HLA-restricted" because they are only able to interact with specific HLA types. For this reason, TCR-T therapy harnesses the specificity of the TCR-peptide-MHC interaction to selectively target tumor cells.

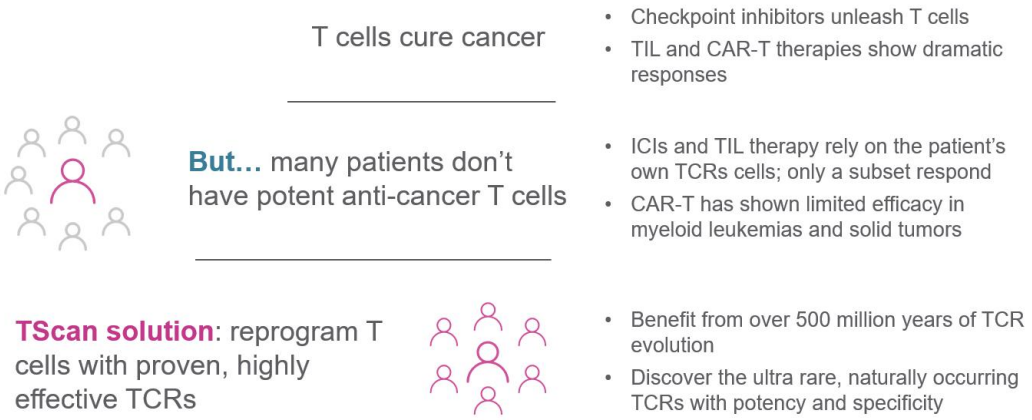
Current Approaches to T Cell Therapy

Multiple approaches are being explored to develop effective T cell-based therapies for the treatment of cancer. One approach is to isolate naturally occurring T cells from a patient's tumor, referred to as tumor-infiltrating lymphocytes, or TILs, expand and activate those cells *ex vivo*, and then return them to the patient via intravenous infusion. Although the targets of these T cells are not known, it is presumed that T cells isolated from a tumor are enriched in T cells directed against cancer cells. This approach, however, depends on the anti-cancer T cells present in the patient. If the patient's TILs do not have appropriate anti-cancer specificities or if their anti-cancer TILs cannot be adequately expanded *ex vivo*, the therapy is unlikely to be effective.

A different approach that has proven effective in certain hematological malignancies is to identify targets that are highly expressed on the surface of tumor cells, such as CD19. Antibody fragments that recognize these targets are used to create an artificial construct that links the antibody to key signaling elements required for T cell activation. The resulting chimeric antigen receptor, or CAR, is incorporated genetically into a patient's T cells, thereby redirecting those cells to recognize and fight the patient's cancer. Although CAR-T therapies have been highly effective in certain tumor types, leading to multiple approved products, the benefit of these therapies and the addressable cancer indications have been limited by several factors. First, it is likely that there is a relatively limited set of truly tumor-specific cell surface antigens. In general, most antigens expressed on the surface of tumor cells are also expressed on normal cells, resulting in therapies that, even if effective, have a narrow therapeutic window and are vulnerable to potentially life-threatening toxicities. Second, CAR-T cells rely on antibody fragments that recognize cell-surface proteins, precluding intracellular proteins as potential targets. Third, CAR-T therapies generally do not efficiently penetrate solid tumors, which to date has limited their applicability to hematologic malignancies.

In contrast to CAR-T therapies, naturally occurring TCRs offer two important benefits compared to antibody-containing artificial receptors. First, TCRs are the natural receptors used by the T cell to recognize foreign antigens. As such, they are optimized to stimulate the T cell appropriately when they engage their targets on a tumor cell. An appropriately stimulated T cell will not only kill the tumor cell, but also produce cytokines that stimulate other immune cells and make copies of itself, or proliferate, to further augment the immune response. Balancing all the cellular responses of a T cell is something that has been finely tuned over millions of years of evolution and is best mediated by naturally occurring TCRs, rather than by artificial constructs. Second, TCRs can recognize a much broader set of antigens, including peptides derived from both cell surface and intracellular proteins, whereas CARs are restricted to recognizing only cell surface proteins. MHC-I peptides are predominantly derived from intracellular proteins rather than extracellular proteins, which dramatically increases the universe of potential cancer-specific antigens that can be recognized by TCRs compared to CARs. We believe TCR-T therapy combines the benefits of TIL and CAR-T therapies while uniquely addressing their key limitations, as shown below.

Reprogramming T cells with proven, highly effective TCRs comprehensively treats all cancer patients



The development of TCR-T therapy requires three key prerequisites: (i) an effective anti-cancer TCR; (ii) knowledge of the precise peptide antigen that is recognized by the TCR; and (iii) confirmation that the TCR does not recognize problematic off-targets. Each of these prerequisites is technically challenging. Historically, targets of anti-cancer T cell clones were identified through a manual and labor-intensive process, and the identification of each target was often a multi-year project. As a result, only a few dozen targets have been identified to date and most clinical development efforts are focused on a short list of the most promising targets.

Our Approach

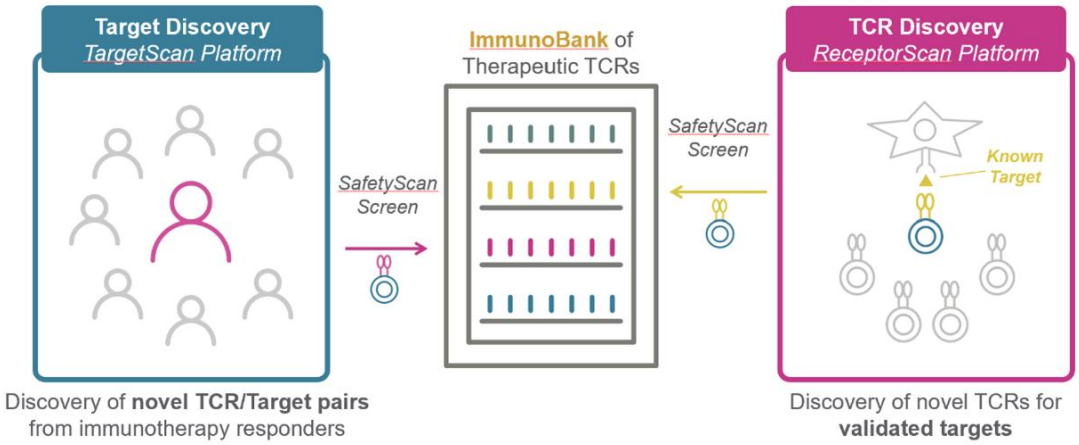
Our approach is based on the central premise that we can *learn* from patients who are winning their fight against cancer in order to *treat* those who are not. Using our proprietary platform technologies, we are analyzing the T cells of cancer patients with exceptional responses to immunotherapy to discover clinically relevant targets and TCRs. We are building ImmunoBank with the goal of delivering customized multiplexed TCR-T therapy to a wide range of patients with cancers.

Learning

When a patient responds to an immunotherapy drug such as an immune checkpoint inhibitor, their tumor shrinks because T cells in their tumor become activated and drive an anti-tumor cytotoxic response. The TCRs of their T cells recognize tumor-specific antigens on tumor cells and signal the T cell to kill the cancer cells. Our approach starts with isolating clinically active anti-cancer T cells from tumor samples of patients who are actively responding to immunotherapy agents. We then use our proprietary TargetScan technology to determine the precise targets being recognized by their TCRs. This provides us with a novel TCR/target pair that can be developed into a TCR-T therapy candidate. The advantage of our approach is that when we identify a new target, we know the target is immunologically relevant – the human immune system has already used that target to recognize and fight cancer. Furthermore, we have already identified a TCR that recognizes the target and, importantly, is associated with a meaningful clinical response in a patient. To de-risk clinical development of the TCR, we use our SafetyScan technology to scan across every peptide sequence in the entire human proteome with the goal of ensuring that it does not have any problematic off-target effects. We then select TCRs that are highly active with no apparent problematic off-target effects to be added to ImmunoBank.

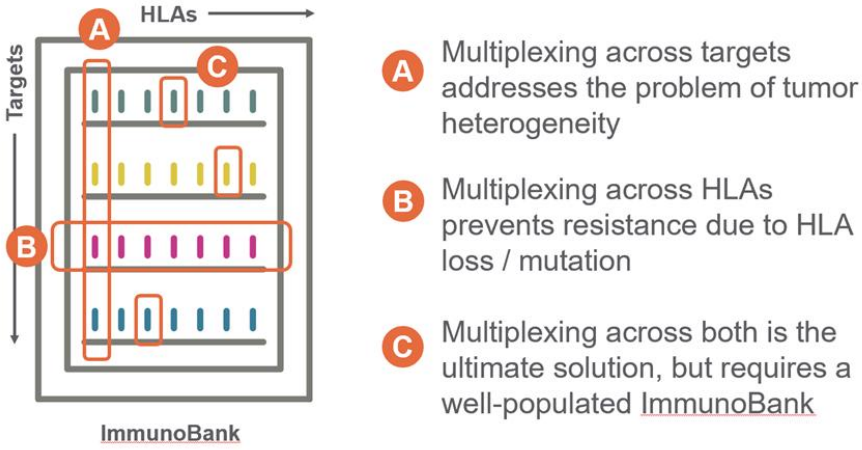
In addition to discovering novel TCR/target pairs, we are leveraging our proprietary ReceptorScan technology to identify highly active TCRs against previously identified and clinically validated targets. Once we identify these highly active TCRs, we use our SafetyScan technology to reduce the risk that they exhibit problematic off-target effects, which de-risks their subsequent clinical development. The diagram below illustrates our proprietary discovery process where therapeutic TCR candidates are discovered using either TargetScan or ReceptorScan and those that we characterize as the best TCRs after screening with SafetyScan are added to ImmunoBank.

Our Proprietary Target and TCR Discovery Process



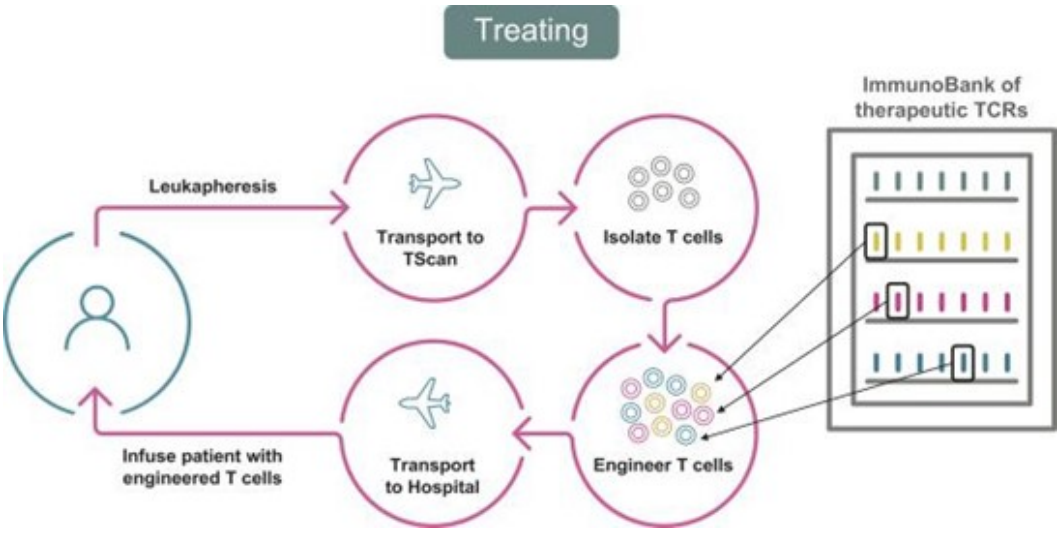
Treating

Our discovery process enables us to build and expand ImmunoBank with what we believe represents the most active TCRs isolated from a large group of diverse patients who are responding to immunotherapy. We are developing TCR-T therapies that use these clinically relevant TCRs to reprogram the T cells of patients who do not spontaneously generate effective anti-cancer T cells and thus do not respond to immunotherapy. Such patients will first have their tumors undergo HLA typing and testing for the presence of tumor-specific targets. Next, to manufacture engineered T cells, white blood cells will be obtained from either the patient or a healthy donor using a procedure called leukapheresis. We will then transport these white blood cells to our in-house manufacturing facility, where we isolate the T cells and genetically engineer them using TCR sequences from ImmunoBank. We believe the continued expansion and diversification of ImmunoBank will enable us to deliver customized multiplexed TCR-T therapy to patients, where each patient's T cells are engineered with multiple TCRs that are matched to their specific tumor and HLA type. For example, if a patient's tumor expresses high levels of a particular cancer target, their T cells will be reprogrammed with a TCR that recognizes that particular cancer target.



Once the T cells are engineered with a combination of the most relevant TCRs, they will be transported back to the hospital and reintroduced into the patient by intravenous infusion. Following the infusion, the engineered T cells, which are designed to recognize multiple targets expressed by the patient's tumor, will proliferate *in vivo* and mount an anti-cancer immune response. Our patient treatment and manufacturing process is summarized in the graphic below.

Our Patient Treatment and Manufacturing Process



Key Features of Our Approach

We believe there are three key advantages to our approach:

- *Our TCR-T therapies are based on highly active TCRs that are clinically relevant.* Many other approaches to T-cell therapy rely on specifically expanding T cells that are already present in the patient. Our platform analyzes anti-cancer T cells from a wide variety of patients who are responding to immunotherapy in order to find the most active and clinically relevant TCRs against each target. We believe that we can develop TCR-T therapies for a wide range of patients, including those who do not have T cells that efficiently recognize their cancers.

- *Our TCR-T therapies are designed to be used in combination with each other.* We are building our diverse ImmunoBank of TCRs to allow for multiplexed TCR-T therapy, which has the potential to address the heterogeneous nature of solid tumors and to prevent resistance developing due to loss of a single target. We believe this approach may allow us to overcome the limitations and challenges of TCR-T therapy development to date. We plan to populate ImmunoBank with TCRs for multiple targets as well as multiple HLA types for each target, thus helping us to overcome the key solid tumor resistance mechanisms of target loss as well as HLA loss.

- *Our approach is expandable.* ImmunoBank has the flexibility to be used with new and optimized methods of T cell engineering that we may develop over time. We are building ImmunoBank to be compatible with both autologous and allogeneic engineering technologies in order to potentially transition to generating off-the-shelf, allogeneic T cells that have been pre-engineered with our TCRs for direct administration to patients.

Our Platform

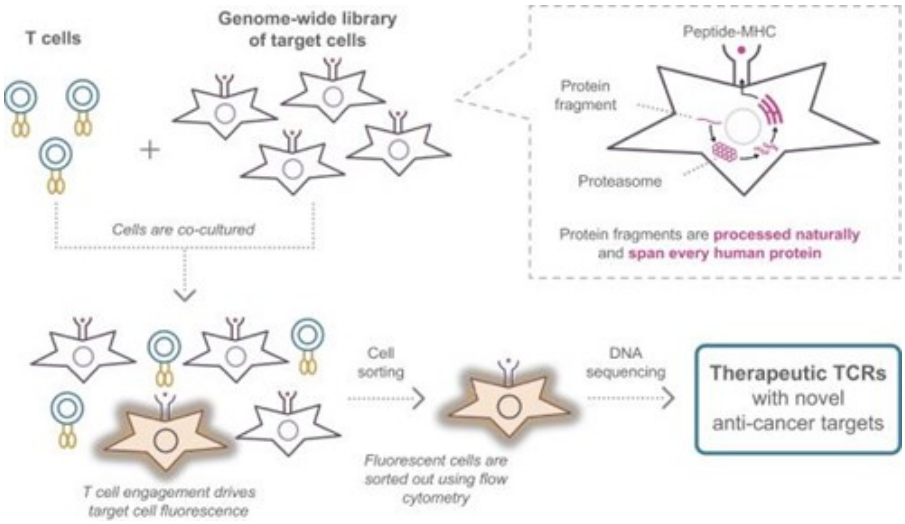
Our proprietary platform is designed to: (i) discover anti-cancer TCRs from patients with exceptional responses to immunotherapy; (ii) determine novel targets of clinically relevant TCRs; (iii) discover novel TCRs that recognize clinically validated targets; (iv) identify off-targets of TCRs to eliminate candidates that could potentially pose a safety risk; (v) multiplex treatments through inclusion of clinically relevant targets with HLA type to customize treatments and (vi) manufacture TCR-T therapies efficiently and consistently without the use of viral vectors using T-Integrate. The central elements of our platform that differentiate us from other cell therapy companies are our proprietary platform technologies: TargetScan, ReceptorScan, SafetyScan, ImmunoBank and T-Integrate.

TargetScan—Identification of Novel Targets of Clinically Active TCRs

At the core of our proprietary platform is our TargetScan technology that enables us to identify the natural target of a TCR using an unbiased, genome-wide, high-throughput screen. We have developed this technology to be extremely versatile and applicable across multiple therapeutic areas, including cancer, autoimmune disorders, and infectious diseases. It can be applied to virtually any TCR that plays a role in the cause or prevention of disease.

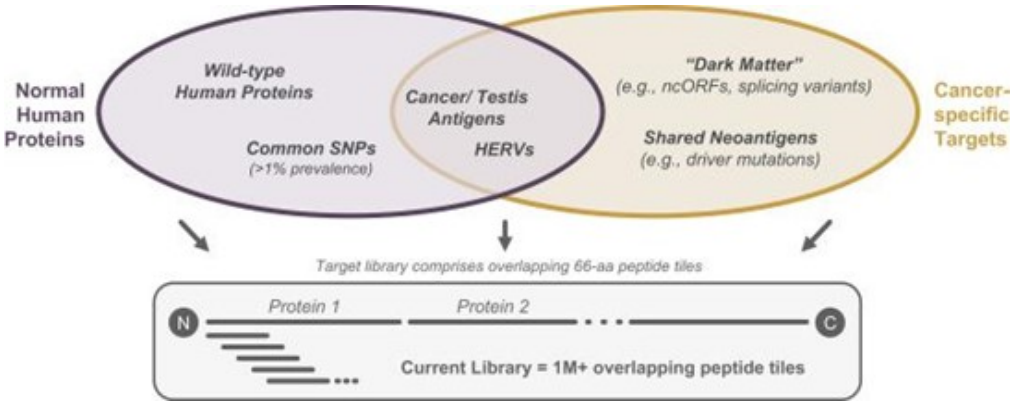
To identify the target of a clinically active TCR found in the T cells of a patient actively responding to immunotherapy, we mix T cells expressing that TCR with a genome-wide library of target cells where every cell in the library expresses a different protein fragment. In each target cell, the protein fragment is processed naturally by the proteasome or immunoproteasome and the resulting peptides are displayed on cell-surface MHC proteins. If a T cell recognizes the peptide-MHC complex on a target cell, it attempts to kill the target cell, thereby activating a proprietary fluorescent reporter in the target cell. By isolating fluorescent target cells and sequencing their expression cassettes, TargetScan reveals the natural target(s) of the T cell, as shown below. This technology was published as a feature article in *Cell* in 2019.

Overview of Our Proprietary TargetScan Technology



Central to this technology is the library of protein fragments used for any given TargetScan screen. Our proprietary libraries comprise hundreds of thousands of specific sequences that collectively include most or all of the targets that a TCR could potentially recognize. For example, our current Oncology Target Discovery Library (version 3.0) comprises over one million clones, each expressing a unique protein fragment. Collectively, these fragments span every human protein encoded in the human genome, along with all single nucleotide polymorphisms, or SNPs, which are single amino acid variations in naturally occurring proteins, observed at over 1% frequency in the human population. In addition, the library includes elements that are specific to cancer cells, which are particularly interesting to us as potential targets: common oncogenic driver mutations, cancer/testis antigens, human endogenous retroviruses, or HERVs, and a large collection of sequences that are not translated in normal tissue but frequently translated in human cancers. We constructed our libraries using a tiling pattern of overlapping fragments to provide complete and redundant coverage of every targeted sequence, as shown in the graphic below.

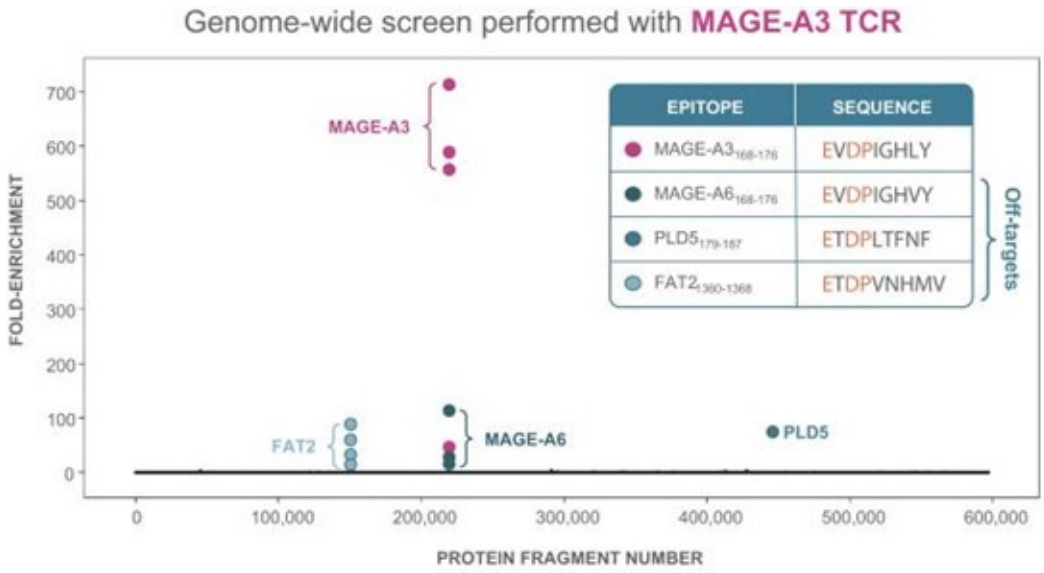
Oncology Target Discovery Library (Version 3.0)



Our Oncology Target Discovery Library allows us to precisely identify the novel targets recognized by TCRs from patients who are actively responding to immunotherapy. In addition, because the library comprehensively covers every non-mutated human protein sequence, we are also able to fully characterize all potential off-target interactions for any given TCR, which we believe will help us reduce the risk and enhance the potential safety profile of our TCR-T therapy candidates before we advance them to clinical development. Furthermore, we can use our screen for any HLA type, enabling target discovery across a wide range of patient demographics.

To validate our TargetScan technology, we performed the following proof-of-concept screens using our Oncology Target Discovery Library (version 2.0), which includes approximately 600,000 protein fragments spanning every human protein. In the first screen, we used a naturally occurring TCR that is known to recognize the protein MAGE-A3. As shown below, our screen correctly identified the primary target of this TCR, and also identified three off-targets, including two that are unrelated at the gene level to MAGE-A3 and would likely not have been identified in a bioinformatic search.

TargetScan Proof-of-Concept:
Target Screen of MAGE-A3 Specific TCR Identifies MAGE-A3 and Three Off-Target

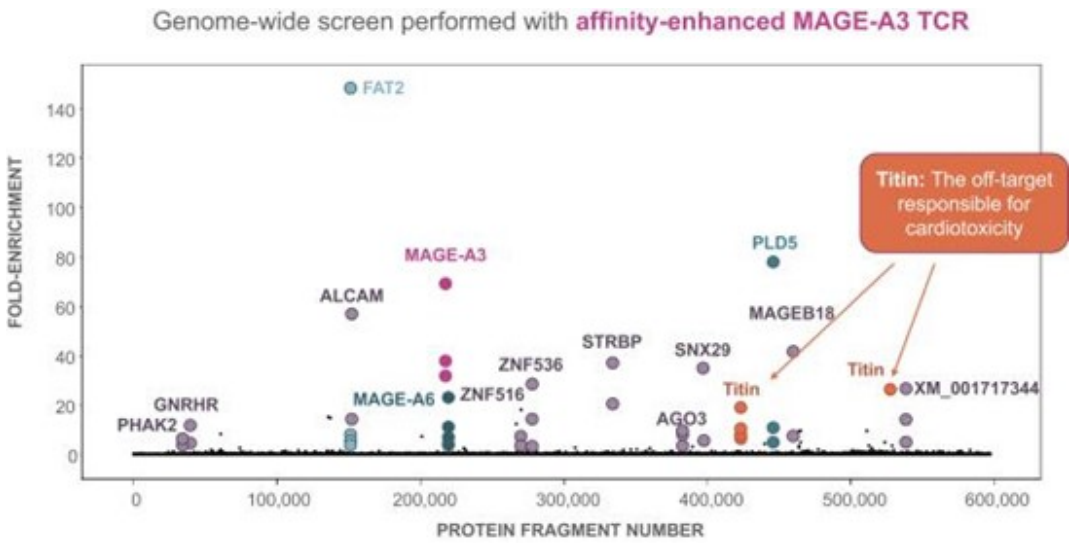


SafetyScan—Elimination of Off-Target Activity

SafetyScan is designed 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 believe this will allow us to reduce the risk and enhance the potential safety profile of our TCR-T therapy candidates early in development before we initiate clinical trials.

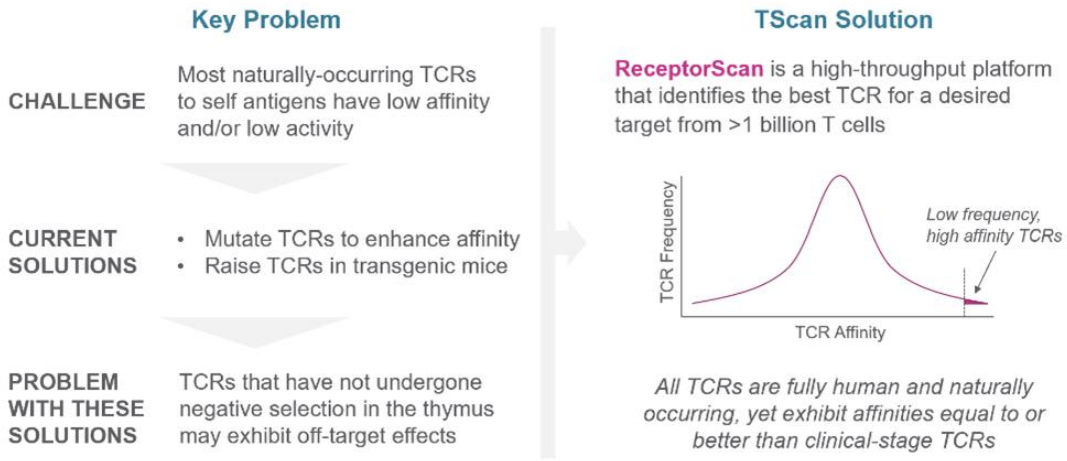
The ability to identify problematic off-targets is critical as TCR-T therapies engineered with TCRs that recognize off-targets expressed at high levels in critical organs could cause toxicities, thereby limiting their therapeutic potential. To further validate this application of our technology, we used SafetyScan to screen an affinity-enhanced version of the MAGE-A3 TCR described above. Affinity enhancement is a process by which a naturally occurring TCR is mutated in order to generate a more potent therapeutic construct. The affinity-enhanced TCR that we screened had previously entered clinical trials with a different sponsor, but human testing of the TCR was halted abruptly because two patients treated with T cells engineered to express this affinity-enhanced TCR died of acute cardiac failure within five days of T cell administration. Subsequent studies revealed that this TCR recognized an off-target derived from the muscle protein Titin, which is abundantly expressed in cardiac tissue. When we screened this same affinity-enhanced TCR using our SafetyScan technology, we identified a variety of potential additional off-targets which were not seen in our screen of the natural TCR, including the protein Titin, as shown below. This experiment demonstrates why we believe that our SafetyScan technology provides a significant competitive advantage, because it enables us to rapidly and efficiently eliminate from our preclinical pipeline TCRs that are identified as recognizing potentially problematic off-targets. Importantly, this includes off-targets that may not be identified through standard bioinformatics or *in-vitro* tissue assays. We believe that SafetyScan thereby has the potential to enable us to decrease the risk of encountering unexpected toxicities in our clinical trials by providing a genome-wide understanding of off-target effects.

SafetyScan Proof-of-Concept: Target Screen of Affinity-Enhanced MAGE-A3-Specific TCR Identifies Clinically Relevant Off-target Linked to Toxicity



Using TargetScan, we have identified more than 60 shared antigens in patient tumors, and over 90% of these targets have not previously been identified as targets for TCR-T therapy. We believe this provides us with a competitive advantage, because not only are we among the first to identify these targets as tumor-specific antigens, but also we have already identified highly active TCRs that recognize these targets.

ReceptorScan identifies ultrahigh affinity, naturally occurring TCRs with low risk of off-target effects



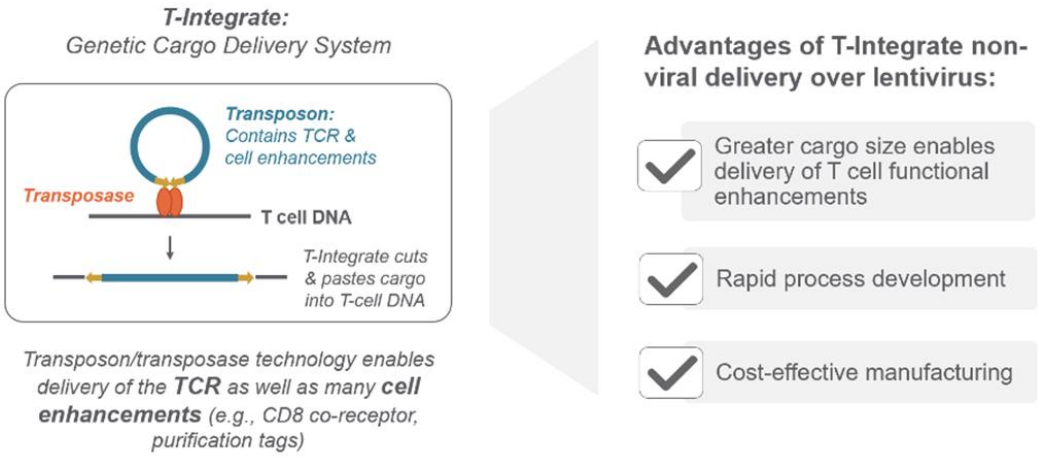
T-Integrate—Genetic Engineering of T Cells Using Transposons

Cell therapy manufacturing is highly complex, and associated challenges have led to significant delays or failures in the development of many cell therapies. To enable the rapid, cost-effective, and consistent manufacturing of TCRs, we have developed a non-viral vector delivery system that we refer to as T-Integrate. Our manufacturing platform enables us to introduce any of the TCRs from ImmunoBank, along with additional genetic elements such as CD8 that further augment T cell function, into the genomes of patient- or donor-derived T cells.

Genetically engineering a T cell requires two steps: (1) delivering DNA encoding the TCR into the nucleus of a T cell and (2) integrating that DNA into the genome of the T cell. These two steps are often accomplished through the use of retroviral vectors, such as lentivirus, by packaging RNA encoding the TCR into lentiviral particles, which are then used to infect T cells. Although effective, manufacturing lentiviral particles is time-consuming, costly, and often highly variable. In addition, each new TCR requires extensive process development, as the TCR sequence affects the efficiency with which it is packaged into the lentivirus.

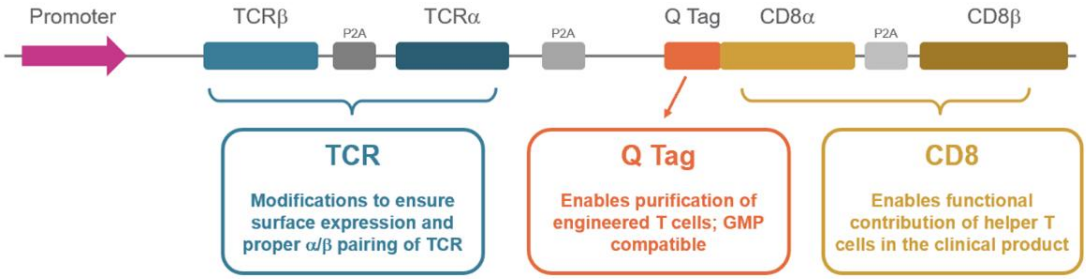
As a more efficient and reproducible alternative to lentivirus, we have developed T-Integrate to genetically engineer T cells using a transposon/transposase system, as shown in the graphic below. In this system, DNA encoding the TCR is manufactured as a Nanoplasmid™ and enables DNA delivery using a smaller plasmid footprint. The Nanoplasmid, together with an mRNA sequence encoding a transposase enzyme, is introduced into the T cell by electroporation. After the T cell translates the mRNA into protein, the transposase enzyme inserts the TCR sequence from the Nanoplasmid into the genome of the T cell. This system is highly reproducible, as the only required components are a Nanoplasmid, which is different for each TCR product, and mRNA, which is constant for all TCR products. Unlike lentivirus, both of these components are routinely manufactured in a cost-effective manner without the need for extensive process development. We believe our manufacturing platform will enable us to efficiently develop and manufacture many different TCR-T therapies, allowing us to deliver customized multiplexed therapy to patients with cancer.

Our T-Integrate Manufacturing Platform



Our transposon vector includes both the beta and alpha chains of the TCR under the control of a strong promoter. This is designed to ensure that high levels of the TCR are produced on the surface of the T cells and that the TCRs that are normally expressed in the patient or donor's T cells, or the 'endogenous' TCRs, are suppressed. We have also introduced specific alterations in the constant region of the TCR to further augment its stability. In addition to the TCR, our transposon construct includes genes encoding the alpha and beta chains of the cell-surface protein CD8. CD8 forms a complex with the TCR and is necessary for the TCR to recognize its target on tumor cells. Including the CD8 co-receptor in our construct enables us to genetically reprogram both major types of T cells: cytotoxic T cells that naturally make their own CD8 and helper T cells that do not make CD8. Our final TCR-T therapies are a mixture of both cytotoxic and helper T cells that have been reprogrammed to recognize and eliminate tumor cells expressing the relevant targets. We also included a short peptide tag at the beginning of CD8 alpha in our construct. This tag does not interfere with the function of CD8 alpha but provides a way to easily purify the engineered T cells during our manufacturing process. We plan to further enhance our T cell therapies with the addition of a TGFβ blocker to overcome the immunosuppressive tumor microenvironment. An illustration of the construct of our TCR-T therapies is shown below.

Construct of our TCR-T Therapies



Another important advantage of T-Integrate, our manufacturing platform, is that its greater carrying capacity than the commonly used lentiviral approach enables us to introduce additional genes that augment T cell function along with the gene that encodes the TCR itself. As our programs advance, we intend to introduce additional elements to our products with the goal of further improving their performance in the solid tumor setting, including features designed to increase the penetration of our T cells into solid tumors, with the aim of keeping our T cells active for a longer time and rendering our T cells more impervious to the hostile tumor microenvironment.

Our Programs

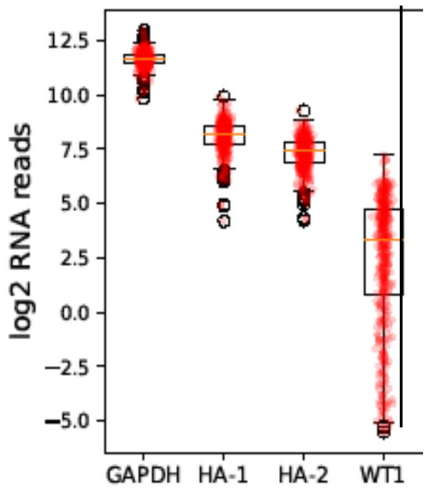
With our differentiated platform as our foundation, we are building a three-pillar research and development strategy to create transformational TCR-T therapies for patients, as shown below.

Our Liquid Tumor Program

We are developing our liquid tumor program to treat patients with hematologic malignancies who are undergoing allogeneic HCT. In the first phase of our clinical development strategy, we are initially focusing on well-recognized cancer targets that have been discovered in patients with exceptional responses to HCT-associated immunotherapy, including HA-1 and HA-2. Our program is based on the well-established observation that patients who are mismatched with their donors for minor histocompatibility antigens such as HA-1 or HA-2, and naturally mount a T cell response against those antigens, show significantly lower relapse rates following HCT. By developing TSC-100 and TSC-101, TScan aims to recreate this natural graft versus leukemia response in order to prevent relapse in patients undergoing HCT.

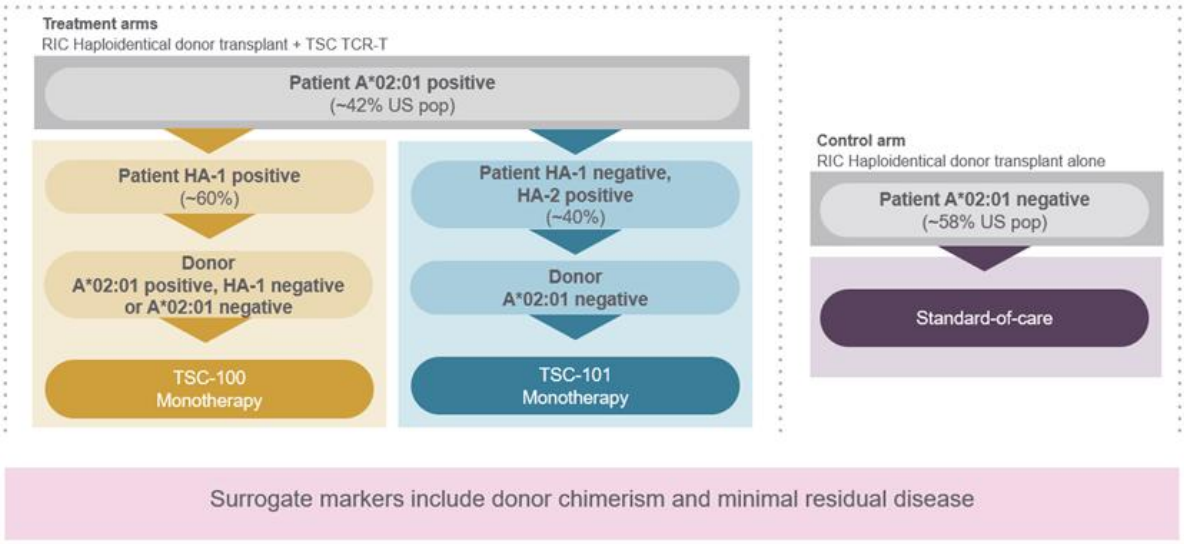
Minor histocompatibility antigens like HA-1 and HA-2 are distinct from other cancer-associated antigens such as WT1 previously targeted by TCR-T therapies in hematologic malignancies. As shown below, cancer-associated antigens like WT1 have low and heterogenous expression and were previously selected so that normal blood cells in the patient would be relatively spared. WT1-targeted TCR-T therapies proved to have relatively poor efficacy in patients with AML, potentially due to the rapid emergence of resistant tumor cells that had lacked WT1 expression and thus escaped killing by engineered T cells. HA-1 and HA-2 in contrast have high and homogenous expression (see below) making it less likely for tumors cells to escape due to low antigen expression. While HA-1 and HA-2 are also expressed in normal blood cells, treating HA-1/ HA-2 positive patients who receive stem cell transplantation from donors who are negative for HA-1/ HA-2, ensures that the engineered T cells selectively eliminate all the patient's blood cells, cancerous or normal, while sparing donor-derived normal blood cells. This strategy therefore enables high levels of anti-cancer efficacy with what we believe to be less risk of life-threatening toxicities to normal cells.

Target Expression in AML



We plan to conduct clinical trials of our lead TCR-T therapy candidates, TSC-100 and TSC-101, in parallel, with patients enrolled in treatment arms based on their genotype, as shown below. Patients who are positive for the target antigen, HA-1 or HA-2, as well as the HLA-A*02:01 allele, which is the HLA type required to display HA-1 and HA-2 on the cell surface for recognition by a T cell, will be eligible for enrollment. Furthermore, eligible patients will require donors who are negative for either the target antigen or the HLA-A*02:01 allele.

Our Clinical Development Strategy for Multiple TCR-T Therapies

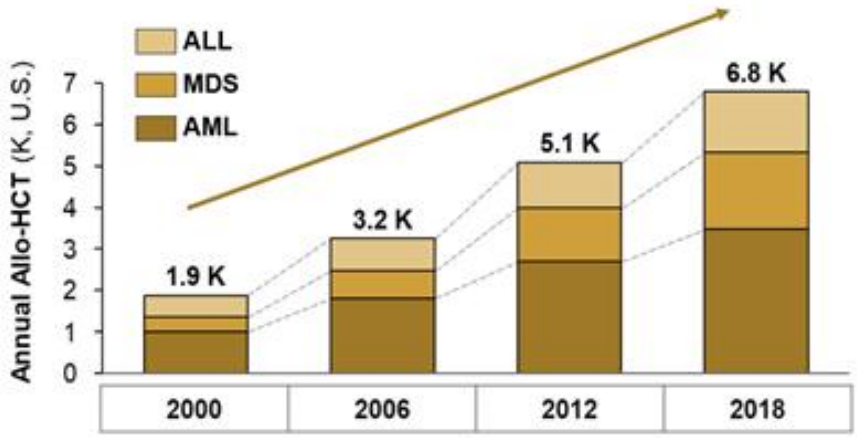


Background on Hematologic Malignancies

Hematopoietic stem cell transplantation, or HCT, has become the standard of care for many hematologic malignancies. When a patient with leukemia undergoes HCT, they start by receiving a conditioning regimen of high dose chemotherapy with or without radiation. This regimen is intended to kill both the patient's leukemia cells as well as their native blood cells and blood cell precursors, including hematopoietic stem cells in their bone marrow. The patient then receives hematopoietic stem cells from an HLA-matched donor. The stem cells engraft in their bone marrow and start to repopulate their body with new blood cells, which are now genetically identical to the donor. HCT has demonstrated the rare opportunity in cancer treatment to generate long-term remissions or cures. For example, patients with acute myeloid leukemia, or AML, who receive HCT have a five-year post-transplant survival rate of 44%.

Approximately 7,000 allogeneic HCT procedures are performed yearly in the United States, primarily in patients with AML, MDS, or ALL. As a curative therapy for many hematologic malignancies, use of HCT has been steadily increasing over the last two decades, as shown below, with increased use driven largely by increasing donor qualification, an increase in disease prevalence due to aging populations, and improved conditioning regimens permitting broader use in older and frailer patient segments. In addition, newer, more effective leukemia therapies continue to drive an increasing use of HCT in patients who previously failed to achieve proper remission prior to transplant. While the approval of CAR-T therapies has significantly impacted the treatment of B-cell malignancies over the last decade, HCT in non-B cell malignancies is anticipated to remain the standard of care for patients. An example of the limitations associated with CAR-T therapy is the difficulty differentiating tumor from normal cells of CD19-targeted CAR-T therapies. CD19 is a target highly expressed on the surface of tumor cells and is also expressed on normal B cells which are also eliminated by CD19 targeted CAR-T cells. While loss of B cells does not generally lead to serious complications, toxicity on other normal myeloid blood cell types such as neutrophils would cause a life-threatening complication called febrile neutropenia in which bacterial infections occur due to the loss of neutrophils. This is one reason why CAR-T therapies cannot be used in non-B cell hematologic malignancies such as myeloid leukemias and HCT remains the standard of care for those patients.

The Number of Allogeneic HCT Procedures in the U.S. Continues to Rise



However, despite the increasing use of HCT and the resulting clinical benefits or cures, approximately 40% of the patients who receive HCT relapse, at which point there are limited treatment options and the prognosis is very poor. Clinical observations have shown that if the T cells of the donor recognize certain minor histocompatibility antigens, or miHAs, in the patient's leukemia cells, such as proteins that have single amino acid differences between the patient and the donor, the T cells of the donor drive a specific graft vs. leukemia, or GvL, effect, whereby the engrafted donor T cells detect remaining leukemia as foreign and eliminate the remaining disease. As a result, the patient often experiences a long-term remission from their cancer, or even a complete cure. If the miHAs are also expressed in non-hematopoietic tissues, the patient may develop graft vs. host disease, or GvHD, but if the miHAs are only expressed in blood cells, a specific GvL effect is observed without an increase in GvHD. Our liquid tumor program is focused on targeting miHAs that are exclusively expressed in hematopoietic cells in order to induce the GvL effect while potentially mitigating the risk of GvHD.

TSC-100

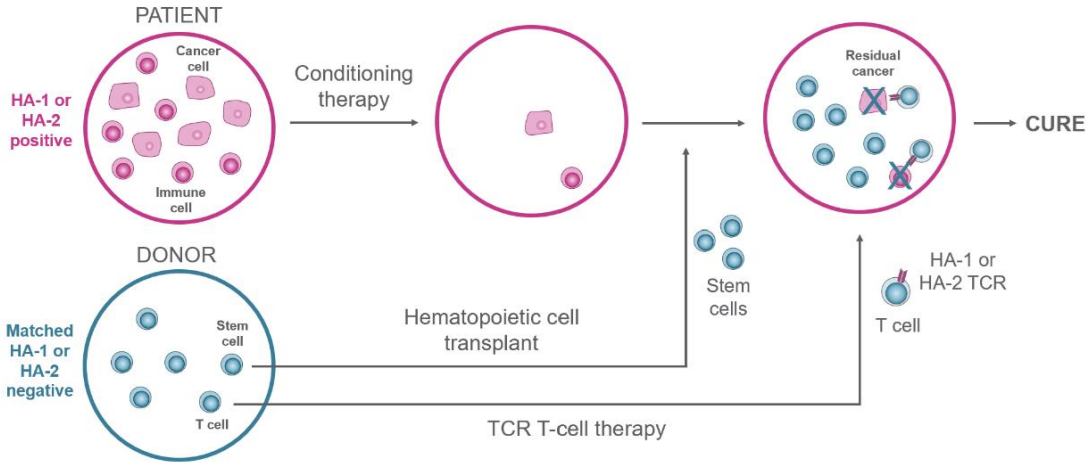
TSC-100 is an allogeneic TCR-T therapy candidate directed at eliminating all native blood cells, including residual cancer cells, in HA-1-positive and HLA-A*02:01-positive patients with hematologic malignancies who undergo HCT using a donor who is either HA-1-negative or HLA-A*02:01-negative. Using ReceptorScan, we screened over a hundred million CD8+ T cells and identified and assessed hundreds of highly active TCRs that recognize the HA-1 antigen. We selected TCR-100a based on its superior affinity, cytotoxic activity, and specificity compared to the others. TSC-100 is designed to elicit an anti-tumor response in patients by targeting HA-1, which is present on malignant and normal blood cells of HA-1-positive patients but not on any of the new, donor-derived blood cells they receive from a donor who is either HA-1-negative or HLA-A*02:01-negative. We believe that donor T cells specifically engineered to express TCR-100a will generate an anti-tumor effect in patients, leading to a reduction in relapse rates and an increase in long-term survival. In the fourth quarter of 2021, we filed an IND for TSC-100 with the FDA. The FDA cleared our IND for TSC-100, enabling us to move forward with Phase 1 clinical development.

HA-1 was one of the first miHAs to be discovered in a patient undergoing HCT. HA-1 is a peptide antigen derived from the protein ARHGAP45, which is an intracellular protein expressed at high levels in all blood cells but not in any other tissue. ARHGAP45 comes in two forms. In HA-1-positive individuals, the peptide has the sequence VLHDDLLEA and, if the individual has the HLA type A*02:01, the antigen is efficiently displayed on the surface of blood cells. In HA-1-negative individuals, the peptide has the sequence VLRDDLLEA, and the HA-1 antigen is not displayed. Approximately 60% of people have the VLHDDLLEA sequence and approximately 42% of people in the United States have the HLA type A*02:01, which means that approximately 25% of individuals in the United States are HA-1-positive with the specific HLA type required for antigen expression. Studies of patients receiving HCT have shown that in cases where the T cells of an HA-1-negative donor naturally develop a response to HA-1 in an HA-1-positive patient, the T cells mediate a specific GvL effect and the patient often experiences a long-term remission. TSC-100 is based on this clinical observation and is designed to specifically cause this GvL effect in patients receiving HCT.

We are developing TSC-100 as a treatment for patients with cancer who are HA-1-positive and have been deemed eligible for HCT. For each patient, a healthy donor who is HA-1-negative or HLA-A*02:01-negative will be identified. Hematopoietic stem cells isolated from that donor will be used as the source of transplant material. In parallel, T cells isolated from the same donor will be genetically engineered to recognize HA-1. Once engraftment of donor stem cells is established in the patient, TSC-100 will be infused

into the patient with the goal of eliciting a highly specific anti-tumor effect. The engineered donor T cells are designed to recognize and eliminate all of the patient's native blood cells, including residual leukemia cells, which are HA-1-positive, thereby preventing relapse and potentially promoting complete cures. Because the patient's new healthy blood cells are derived from the donor and are therefore either HA-1-negative or HLA-A*02:01-negative, we believe that TSC-100 should have minimal toxic side effects. A summary of the treatment paradigm for TSC-100 is illustrated below.

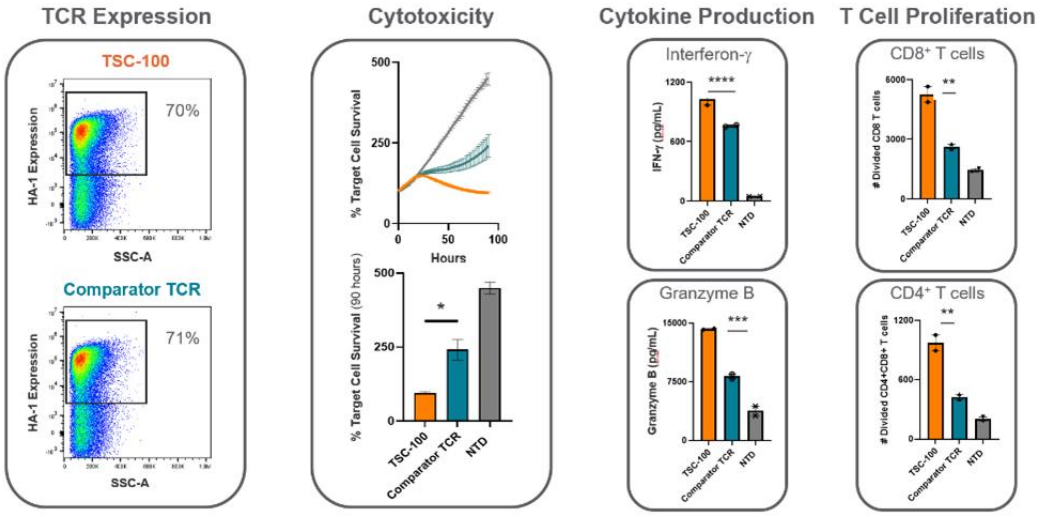
TSC-100 Treatment Paradigm



Preclinical Data

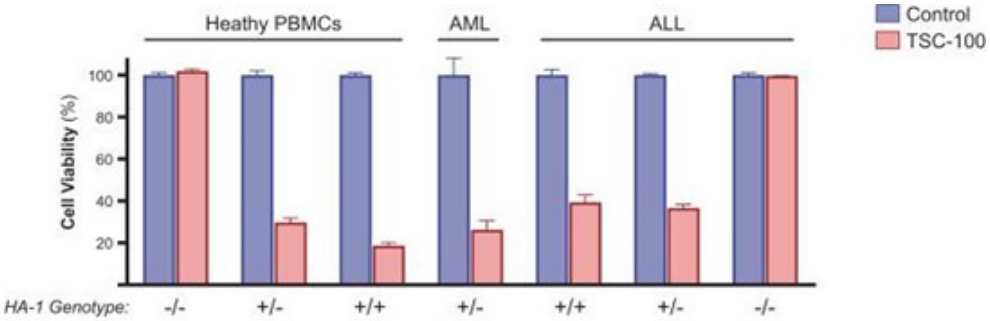
Using ReceptorScan, we screened over 175 million T cells from six healthy donors to identify naturally occurring TCRs specific for HA-1. We then extensively characterized over 300 of these TCRs for their ability to specifically recognize and kill tumor cells that express HA-1. We prioritized TCRs with the highest potency in cytotoxicity assays and in their production of cytokines associated with increased T-cell activation and function. Through this screening process, we identified TCR-100a, which exhibited superior potency compared to the other TCRs. We assessed the *in vitro* HA-1-specific cytotoxicity of TCR-100a using cell lines with various levels of HA-1 expression, as shown below. THP1, a cell line that expresses moderate levels of HA-1, was susceptible to cell killing by multiple TCRs we tested. However, TF1, a cell line that expresses less than half the level of HA-1 expressed by THP1, was sensitive to cell killing by TCR-100a but was resistant to almost all other HA-1-specific TCRs, including TCRs reported in the literature. Our preclinical studies also demonstrated that SUDHL1 cells, which lack HA-1 expression, were resistant to all tested HA-1-specific TCRs, as expected, highlighting the high selectivity and potential safety of TCR-T therapies.

In Vitro Studies Demonstrate Superior HA-1-Specific Cytotoxicity of TCR-100a Compared to Other TCRs



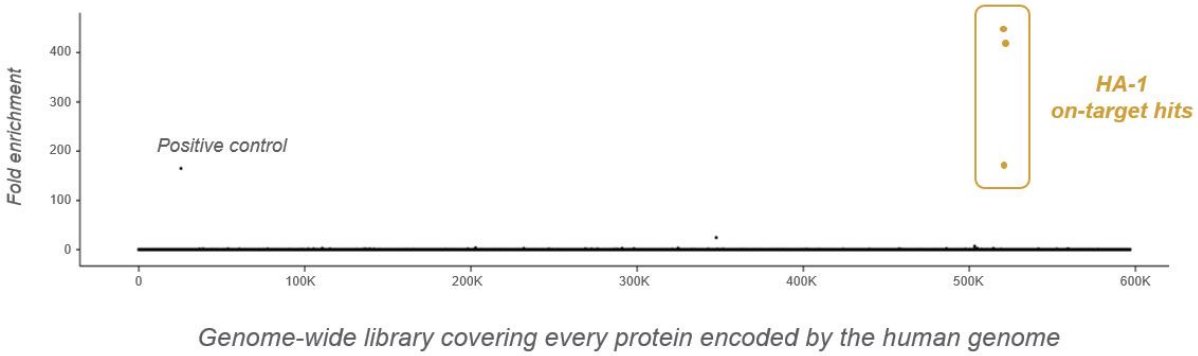
Because people inherit two copies of every chromosome, one from their mother and one from their father, everyone has two copies of the ARHGAP45 gene. HA-1-positive patients can therefore be either homozygous for HA-1 (+/+), with both genes encoding the HA-1-positive peptide (VLHDDLLEA), or heterozygous for HA-1 (+/-), with one gene encoding the HA-1-positive peptide and the other encoding the HA-1-negative peptide (VLRDDLLEA). To ensure that TSC-100 is able to effectively eliminate healthy blood cells and leukemia cells that are either homozygous HA-1-positive (+/+) or heterozygous HA-1-positive (+/-), we assessed the activity of TSC-100 against blood cells derived from a variety of healthy donors and patients with AML and ALL. As shown below, TSC-100 eliminates both homozygous and heterozygous HA-1-positive healthy blood cells and leukemia cells.

TSC-100 Displays Specific Cytotoxic Activity Towards HA-1-positive Cells



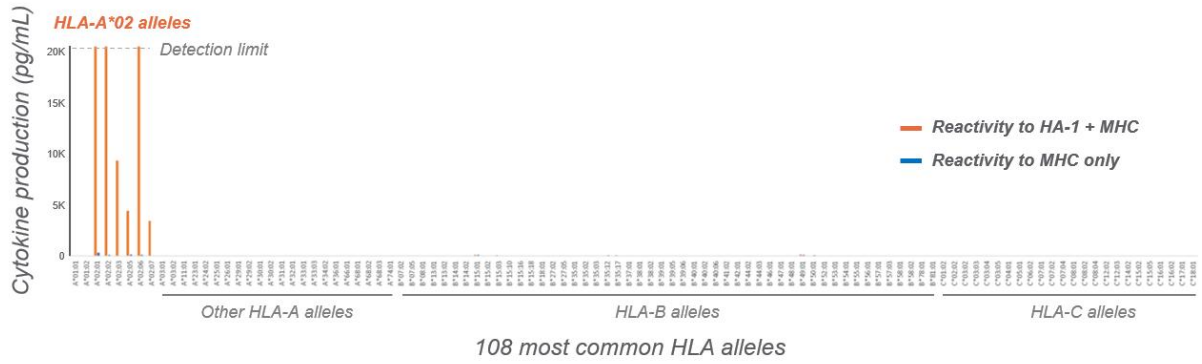
It is known in the cell therapy field that TCRs which exhibit off-target effects can potentially cause toxicity. In order to reduce the potential for TCR-100a to exhibit problematic off-target effects, we used SafetyScan to comprehensively scan for any other potential targets recognized by TCR-100a. This screen was performed using a subset of our Oncology Target Discovery Library (version 2.0), which includes approximately 600,000 protein fragments and collectively spans every protein encoded in the human proteome as well as all common SNPs. As shown below, all three protein fragments in the library that contain the HA-1-positive peptide antigen were strongly enriched in the screen, and no significant off-target interactions were observed. In contrast, some of the other HA-1-specific TCRs identified by ReceptorScan did exhibit off-target effects, highlighting our ability to select candidates that we believe have favorable risk/benefit profiles.

SafetyScan Screen Reveals No Significant Off-Targets for TCR-100a



To further evaluate the potential safety profile of TSC-100, we screened TCR-100a against HA-1-positive and HA-1-negative cells that individually express each of the 108 most common HLA alleles. In the HA-1-positive cells, TCR-100a was able to mediate efficient recognition in cells expressing HLA-A*02:01 as well as in cells expressing two related HLA types, HLA-A*02:02 and HLA-A*02:06. This suggests that patients with any of these three HLA types could potentially benefit from TSC-100. Notably, TCR-100a showed no recognition of HA-1-negative cells across all 108 HLA types, indicating low risk of alloreactivity or misrecognizing other antigens on other HLA types, as shown below.

TSC-100 Shows No Detectable Alloreactivity Across 108 Different HLA Types



TSC-101

Similar to TSC-100, TSC-101 is an allogeneic TCR-T therapy candidate directed at eliminating residual cancer cells in HA-2-positive and HLA-A*02:01-positive patients with hematologic malignancies who undergo HCT using a donor who is either HA-2-negative or HLA-A*02:01-negative. HA-2, which is derived from the protein MYO1G, is another miHA that has been identified to be clinically relevant. In patients who naturally develop HA-2-specific T cells, a GvL effect has been observed and these patients experience long-term remissions. Using ReceptorScan, we have identified a highly active TCR, which we refer to as TCR-101a, that recognizes HA-2. In the fourth quarter of 2021, we filed an IND for TSC-101. The FDA placed a clinical hold on the TSC-101 IND; we received written communication from the FDA asking for additional assessment of the potential for off-tumor reactivity in certain tissues and are working with the agency to resolve its questions as quickly as possible.

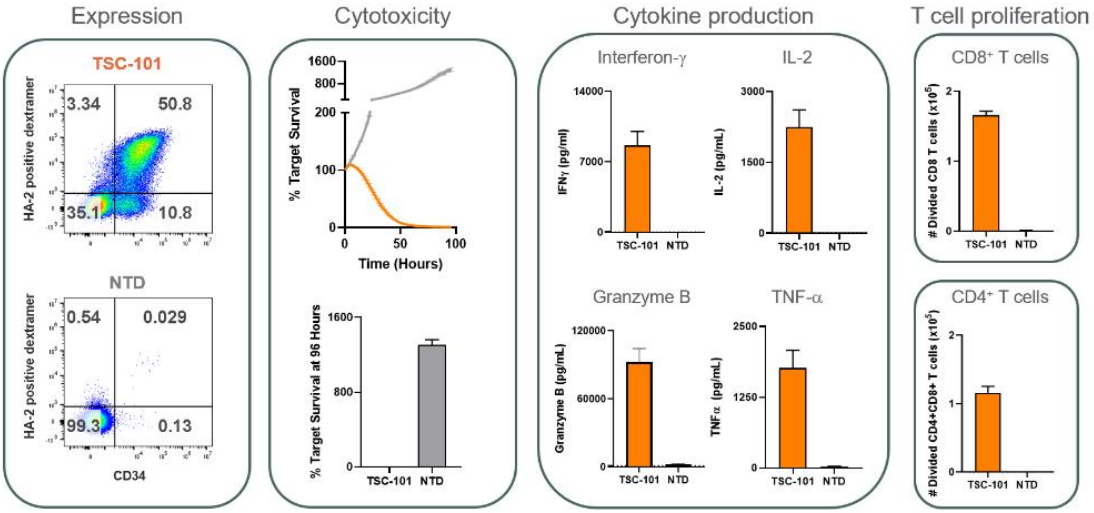
Unlike HA-1, the HA-2 antigen is highly prevalent, with approximately 95% of individuals in the United States being HA-2-positive. However, as with HA-1, a specific HLA type, HLA-A*02:01, which is present in approximately 42% of individuals in the United States, is required to display the HA-2 antigen on the cell surface for recognition by a T cell. As a result, approximately 40% of

HCT patients would be positive for both HA-2 and HLA-A*02:01 and therefore be eligible for treatment with TSC-101 using a donor who is negative for HLA-A*02:01, regardless of whether the donor is HA-2-positive or HA-2-negative. Such donors are straightforward to identify and should be available to most patients who undergo half-matched, or haploidentical, transplantation using family members as donors, as patients typically have between two and three potential haploidentical donors.

Preclinical Data

Similar to TCR 100a, we used ReceptorScan to identify TCR 101a. We screened approximately 237 million CD8+ cells from five healthy HA-2 negative donors and identified approximately 1,302 natural TCRs that recognize HA-2. These were then narrowed down to 15 TCRs with the highest surface expression and greatest affinity for the HA-2 peptide. We further evaluated the top five TCRs for off-target cross-reactivity against the entire human proteome using SafetyScan, identifying TCR-101 as the most active TCR with the lowest off-target activity and cleanest cross-reactivity profile against 108 other HLA alleles. Finally, TSC-101, our TCR-T therapy candidate which is T cells manufactured to express TCR-101, was tested on a panel of normal cell types representing all vital organs and did not recognize any normal non-hematologic cell type. In contrast, TSC-101 demonstrated efficient cell killing of both normal and malignant primary hematologic samples confirming a high degree of selectivity for hematologic cells. The discovery of TCR-101 was presented at the 63rd American Society of Hematology Annual Meeting and Exposition, in December 2021.

TCR-101a Demonstrates High Activity Similar to TSC100a



Clinical Development Plan for Our Liquid Tumor Program

Background on Types of HCT

Patients with acute leukemias who undergo allogeneic HCT have heterogeneous outcomes that are primarily related to two main variables: (i) the intensity or doses of the conditioning regimen they receive prior to the stem cell infusion and (ii) the type of donor who provides the stem cells.

High-intensity conditioning regimens are called myeloablative conditioning and associated with higher mortality rates. They are therefore reserved for young and relatively fit patients. Lower-intensity regimens are called reduced-intensity conditioning, or RIC, and better tolerated, but are associated with higher relapse rates. TSC-100 and TSC-101 are both designed to substantially reduce relapse rates, and we plan to enroll patients who are eligible for RIC-based HCT with the goal of improving clinical outcomes for these patients.

There are different types of donors who are eligible for allogeneic HCT procedures. Donors who are siblings of the patient and are perfectly matched for eight out of eight HLA alleles are considered the highest priority donor type for patients undergoing allogeneic HCT, but these types of donors are available for less than a third of patients. For the majority of patients, the choice is between an unrelated donor who is perfectly matched for eight out of eight HLA alleles, referred to as a matched unrelated donor, or MUD, or a

family member such as a sibling, parent or child who has a half-match with the patient, referred to as a haploidentical donor, or haplo. Historically, haplo donor transplantation was associated with much higher GvHD than MUD-transplants, but a recent treatment regimen that uses chemotherapy given three days after stem cell infusion called post-transplantation cyclophosphamide, or PTCy, specifically kills immune cells that cause GvHD. As a result, haplo transplants with PTCy have recently achieved equivalent outcomes as MUD transplants and are rapidly increasing in usage in the United States and worldwide.

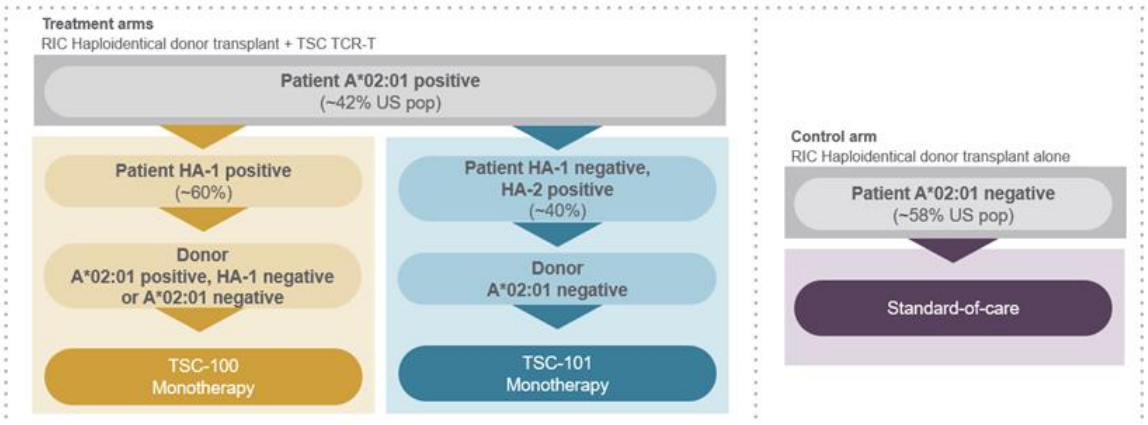
The use of haplos greatly expands the donor pool for patients undergoing HCT and provides patients with the optionality to choose donors who are mismatched on specific HLA types, such as A*02:01, as opposed to being mismatched on certain minor antigens, such as HA-1 or HA-2. We are developing TSC-100 and TSC-101 with a specific focus on patients undergoing haplo donor transplantation with donors who are negative for either the miHA or the specific HLA type. We believe the engineered donor T cells will recognize any residual leukemia cells, which are target-positive, in the patient and prevent relapse with the potential to promote complete cures. Because the patient's new healthy blood cells are derived from the donor and are therefore either target-negative or not able to express the target, we believe TSC-100 and TSC-101 should have minimal toxic side effects.

Planned Phase 1 Clinical Trial

We are planning to conduct clinical studies for TSC-100 and TSC-101 within a multi-arm, controlled, Phase 1, 'umbrella' design clinical trial to investigate the safety and efficacy of TSC-100 and TSC-101 in patients with ALL, AML, and MDS, that are undergoing HCT following RIC.

Our Phase 1 clinical trial is designed to include measurements of early surrogate markers of efficacy, such as chimerism, or the percentage of blood cells that are donor-derived, and whether patients continue to have detectable residual leukemia in their post-transplant bone marrow biopsy, both of which are predictors of relapse. As shown in the graphic below, we also plan to include a control arm, comprising patients who do not meet the HLA or miHA genetic criteria and are treated with standard RIC haplo transplantation alone. Comparisons of both safety and efficacy outcomes with this control arm will potentially enable all patients treated with TSC-100 or TSC-101 to be included as part of the efficacy analysis for the initial Phase 1 trial prior to transitioning the program into a registrational Phase 2 trial towards a future biologics license application, or BLA, filing.

Planned Multi-Arm Phase 1 Clinical Trial Design



Anticipated timeline

We filed INDs on TSC-100 and TSC-101 in the fourth quarter of 2021. The FDA has cleared our IND for TSC-100, enabling us to move forward with our clinical development plan for TSC-100. We anticipate dosing the first patient in the TSC-100 arm of our Phase 1 clinical trial in the first half of 2022; and presenting initial clinical data on our Phase 1 trial in the second half of 2022. The FDA placed a clinical hold on our IND for TSC-101. We received written communication from the FDA asking for additional assessment of the potential for off-tumor reactivity in certain tissues and are working with the agency to resolve its questions as quickly as possible. The liquid tumor trial is based on an umbrella protocol, which will allow us to begin the TSC-100 and control arms of the trial in the near term and to open the TSC-101 arm to the ongoing trial upon clearance of the TSC-101 IND.

Future market expansion opportunities

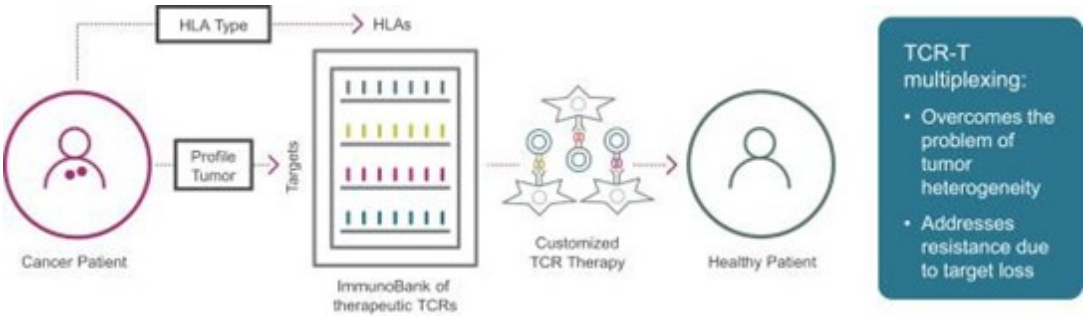
If TSC-100 and TSC-101 demonstrate the ability to significantly reduce relapse rates after hematopoietic cell transplantation, there could potentially be new opportunities to expand the curative potential of HCT combined with TSC products to greater numbers of patients. Currently, only about 7,000 patients undergo HCT per year in the United States out of approximately 40,000 patients diagnosed each year with AML, MDS and ALL. There are two reasons for this relatively modest rate of transplant utilization. First, only patients who achieve a clinical complete remission (CR) are referred for HCT since the relapse rates of patients not in CR are considered too high to safely use HCT. If HCT combined with TSC products markedly reduce relapse rates, patients who do not achieve CR could still undergo HCT and benefit from its curative potential. This market expansion would require a separate clinical trial. Second, while reduced intensity conditioning has enabled many more elderly and frail patients to undergo transplantation, the chemotherapy and radiation doses used for conditioning are still high and considered too toxic for most patients over the age of 65 or those with underlying comorbidities. This is because the conditioning regimen of HCT is considered the primary modality to eliminate residual leukemia cells and reducing doses further would result in greater relapse rates. If however, the relapse rates could be reduced by a TSC product post HCT, a clinical trial could test the use of minimal intensity conditioning prior to HCT. If successful, this would further expand the curative potential of HCT combined with TSC therapy to older, frailer patients. A final market expansion opportunity could occur from the use of TSC products as a chemotherapy andradiation free conditioning regimen for non-malignant diseases such as sickle cell anemia which are currently treated with HCT. Since chemotherapy and radiation are associated with the risk of long-term toxicities such as cancer, heart damage, lung damage and infertility, cellular therapies such as TSC-100 or TSC-101 could reduce those risks and increase the numbers of patients willing to undergo HCT.

Solid Tumor Program

We are developing a portfolio of autologous TCR-T therapy candidates that are designed to be used in combination with each other to treat and eliminate solid tumors. Our TSC-200 series of product candidates are designed to elicit an anti-tumor response in patients by targeting cancer-specific antigens in their tumor cells. Our TCR-T therapy candidates include: (i) either well-recognized cancer targets that have demonstrated anti-tumor activity in clinical trials or novel targets that were identified by TargetScan from the T cells of patients responding to immunotherapy and (ii) naturally occurring TCRs specific to a patient's HLA type that recognize these cancer-specific targets. Such targets are not only commonly shared among patients with the same cancer type, but also frequently expressed in multiple solid tumor types, enabling clinical development across multiple indications. Our first five solid tumor TCR-T therapy candidates include a combination of known targets, such as HPV16 for TSC-200, PRAME for TSC-203, and MAGE-A1 for TSC-204, as well as novel TCR-T therapy targets that have not yet been tested in the clinic, such as TSC-201 and TSC-202. We are currently advancing our five solid tumor TCR-T therapy candidates through lead optimization, and we expect to submit IND applications for two candidates in the second half of 2022, with additional IND submissions expected to be filed in 2023. In addition to our five lead solid tumor TCR-T therapy candidates, we have identified over 60 novel antigens based on tumor samples from patients who are actively responding to immunotherapy using our TargetScan technology. We are in early stages of analyzing these additional novel antigens and plan to advance those that we believe have the best potential as a TCR-T therapy candidate into preclinical development.

We are building ImmunoBank, a collection of highly active TCRs, to enable multiplexed TCR-T therapy. Our vision is to expand ImmunoBank with TCRs that recognize diverse targets and are associated with multiple HLA types in order to provide a broad array of therapeutic options for patients with various types of solid tumors. For patients with a solid tumor malignancy, we plan to analyze their tumor to determine which targets are expressed at high levels in their particular cancer. We will then access ImmunoBank and select up to three TCRs that match their HLA type and address the most highly expressed targets in their tumor. We will use this set of TCRs to genetically reprogram their T cells to recognize these targets and the resulting engineered T cells will be infused back into the patient as a multiplexed TCR-T therapy.

Our Strategy to Treat Solid Tumors with Multiplexed TCR-T Therapy



TCR-T Therapy for the Treatment of Solid Tumors

Immunotherapy has reshaped the treatment of solid tumors by demonstrating that tumor shrinkage, eradication, and long-term durable responses can be obtained by stimulating the patient's own immune system to attack their cancer cells. Immune checkpoint inhibitors, such as nivolumab or pembrolizumab, work by unleashing anti-cancer T cells that are already present in a patient's tumor, enabling those T cells to recognize and eliminate their cancer. For patients who respond to checkpoint inhibitors, these agents have been shown to be very effective. However, only a subset of patients responds to checkpoint inhibitors, highlighting the need for T cell-based therapies that can treat those patients who do not respond. Despite their efficacy in only a subset of patients, checkpoint inhibitors have annual sales well in excess of $20 billion.

One reason why patients do not respond to current immunotherapy treatments is that they lack T cells with highly active TCRs that recognize cancer-specific antigens in their tumors. By reprogramming the patient's own T cells to recognize these targets, we believe that we can expand the dramatic responses observed with checkpoint inhibitor therapy to the patients for whom these therapies are ineffective.

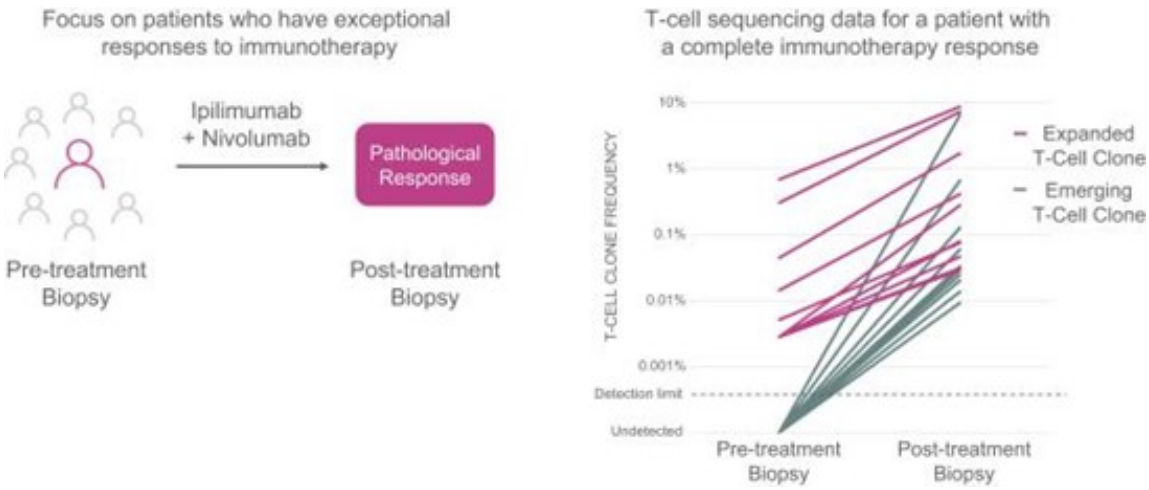
Our Solution

Our solid tumor program is based on the premise that if we can understand how T cells naturally fight cancer, we can use this information to design life-changing TCR-T therapies for virtually any patient with cancer. Our discovery process begins with identifying patient T cells that are actively driving their clinical response to immunotherapy. We then use TargetScan to determine the precise targets of these highly active TCRs. Our discovery efforts are initially focused on patients with head and neck cancer who respond to checkpoint inhibitor therapy and patients with melanoma who respond to TIL therapy. These cancers represent tumor types with a high degree of T cell infiltration and strong responses to immunotherapy, which provides us with clinically active T cells from which we can discover novel TCR/target pairs. We have found that targets discovered in one type of cancer are often expressed in other cancers as well, enabling broader clinical development of our TCR-T therapy candidates. The tumor types we are focused on also express several known targets that were previously discovered from patient T cells. We are using ReceptorScan to discover highly active TCRs for these previously identified targets to complement the discovery of our novel TCR/target pairs. Finally, ImmunoBank will allow us to target multiple HLA types to prevent target loss and increase durability of response.

Novel Targets Identified from Patients with Head and Neck Cancer

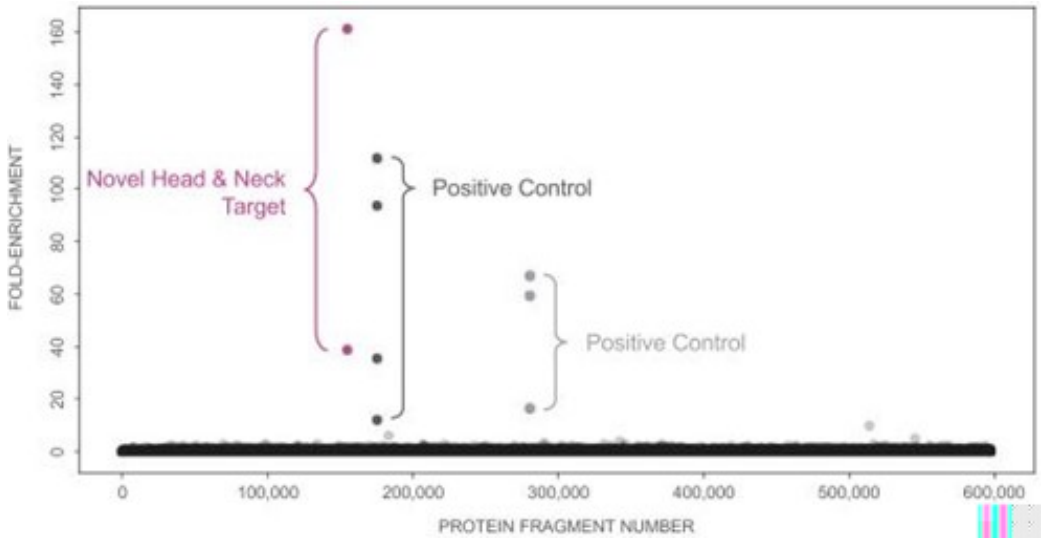
One of the ways we identify anti-cancer TCRs is by focusing on T cells that clonally expand in a tumor when the patient responds to checkpoint inhibitor therapy. Some of this work is being performed under collaborative research agreements with various academic institutions. Using single cell sequencing, our collaborators determined the TCR sequences of thousands of T cells in the tumors of patients with head and neck cancer before and after immunotherapy. This analysis also revealed the frequency of each T cell clone in the tumor samples. As an example, if a particular TCR sequence is observed at 0.05% frequency in the tumor before the patient receives immunotherapy and then increases to 5% after the tumor starts to shrink, the T cell has clonally expanded 100-fold and is likely to have played a causal role in driving the patient's clinical response. Certain TCR sequences are not detectable in the pre-treatment biopsy but are observed at high frequency in the post-treatment tumor. These emerging clones are also potential candidates for driving the patient's clinical response. An illustrative example of T cell sequencing data from one patient with head and neck cancer who had a complete response to immunotherapy.

Clinically Relevant Anti-Cancer T Cells Identified Through T Cell Sequencing



We have performed genome-wide TargetScan screens on over 100 TCRs derived from T cells that clonally expanded in the tumors of patients with head and neck cancer who are responding to immune checkpoint inhibitors, which has resulted in our discovery of over 60 novel shared antigens. An example of one such screen is shown below. This screen was performed with our Oncology Target Discovery Library (version 2.0), which comprises over 600,000 protein fragments. Two protein fragments, shown in dark pink, were specifically recognized by the TCR. Due to the redundancy built into our library through its overlapping tiling pattern, both of the identified clones contain the same nine amino acid-long peptide antigen that we determined to be the target of this TCR. Notably, no off-targets were observed in the screen, highlighting the value of the SafetyScan technology in identifying TCRs with clean specificity profiles.

Identification of a Novel Target from a Patient with Head and Neck Cancer



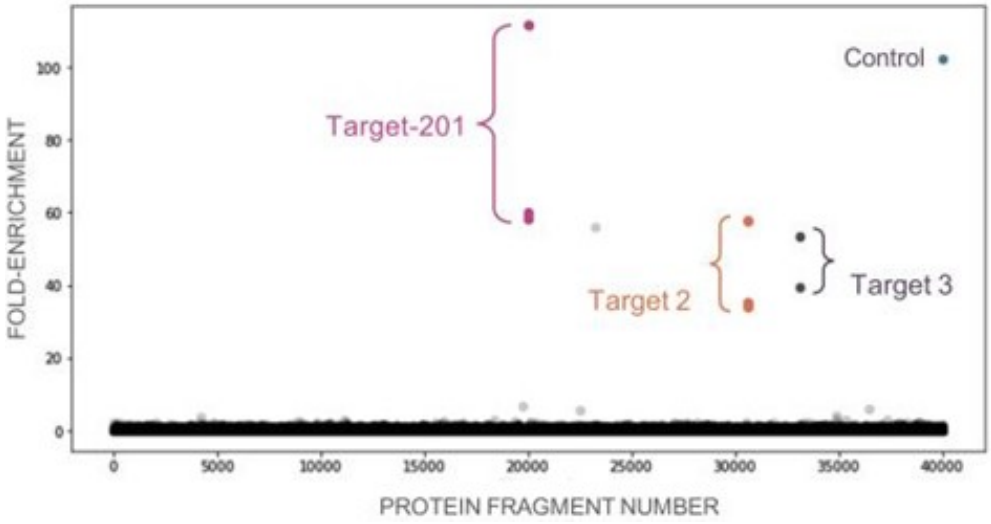
Novel Targets Identified from Patients with Melanoma

Another approach we use to identify clinically relevant anti-cancer T cells is to analyze T cells from patients with melanoma who respond to TIL therapy. Using single cell sequencing, we determine the TCR sequences of the T cells in the responding patient's TIL therapy product and focus on the most abundant T cell clones. We have found that TIL therapy products are often dominated by as few as two or three clones, further increasing our confidence that these TCRs played a causal role in fighting the patient's cancer.

To increase the throughput of our discovery efforts, we have used TargetScan in a more directed manner to screen sub-libraries of protein fragments that focus on particular classes of tumor antigens. For example, we built a sub-library that focuses on cancer/testis antigens, or CTAs, which are genes that typically play a role in embryonic development but are not expressed in any adult tissues other than testes. T cells do not infiltrate testes and cells in the testes have very low levels of MHC proteins, making testes an immune-privileged site that will not be targeted by engineered T cells in the context of cell therapy. CTA genes are frequently found to be expressed in tumor cells and often play a role in causing cancer. Several well-recognized targets in development for TCR-T therapy are CTAs, including NY-ESO-1 and MAGE-A4.

We are focused on the discovery of novel targets within this class of antigens and have built a TargetScan library comprising 40,000 fragments that cover 1,600 CTA genes. Because this library is substantially less complex than our genome-wide Oncology Target Discovery Library, we can screen the TargetScan library with dozens of TCRs simultaneously. For example, the screen shown below was conducted with 35 TCRs derived from 11 patients with melanoma who received TIL therapy. In a single screen, we identified three TCR/target pairs that recognize CTAs, including the antigen target for one of our lead solid tumor product candidates, TSC-201, which we refer to as Target-201, as well as two other antigens that have not previously been identified as targets for TCR-T therapy.

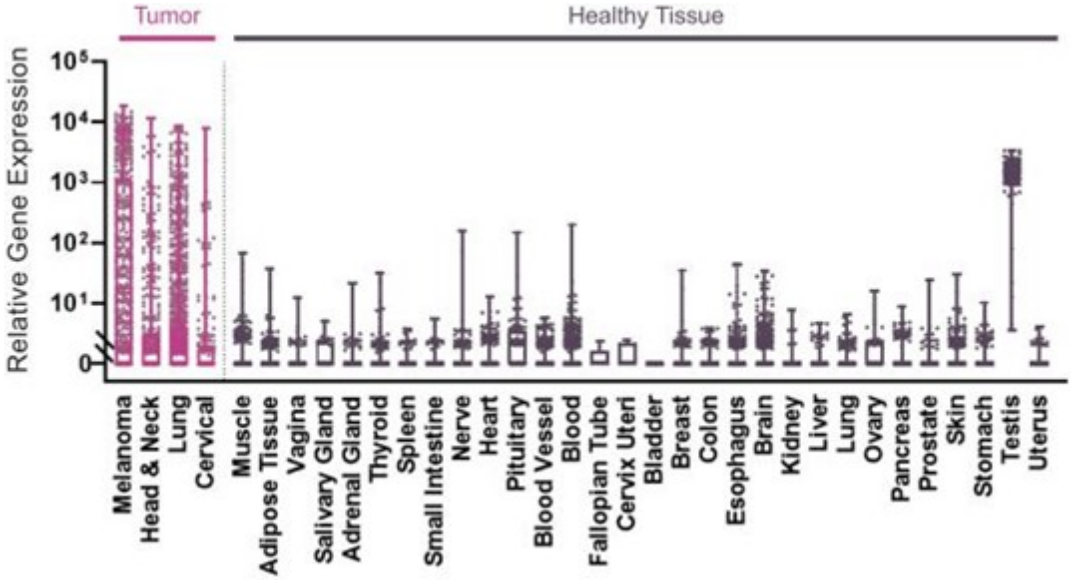
Three Novel Cancer/Testis Antigen Targets Identified from TIL-Responsive Patients



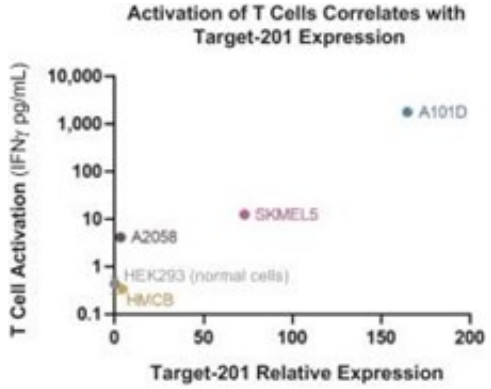
TCR and Target Validation Process

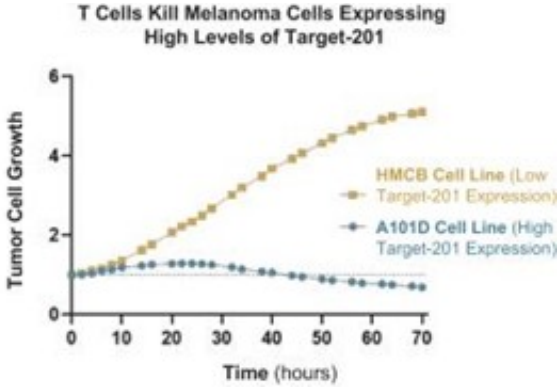
When we discover novel TCR/target pairs, we first determine if the gene that encodes the target is expressed at high levels in normal tissue. As shown below, Target-201 is exclusively expressed in testis, which is an immune privileged tissue and, as a result, should not pose a significant safety concern. We also examine how frequently the target is expressed in various solid tumors. As shown below in dark pink, Target-201 is overexpressed in a high percentage of melanoma tumor samples as well as in several other tumor types, including non-small cell lung cancer, or NSCLC, head and neck cancer, and cervical cancer.

Selective Expression of Target-201 in Multiple Tumor Types vs. Normal Tissues



Next, as part of our discovery process, we test if the TCRs discovered with our approach are able to kill cancer cells that naturally express the relevant target and specific HLA type. As shown below on the left, when T cells expressing the TCR that recognizes Target-201 are cultured with melanoma cell lines that naturally express different levels of Target-201, such as A101D and SKMEL5, the degree to which the T cells get activated correlates with the expression level of Target-201 in the melanoma cells. In addition, the T cells kill melanoma cells expressing high levels of Target-201, as shown below on the right but do not kill cells that express low levels of Target-201, which highlights the selectivity of the TCR for Target-201.

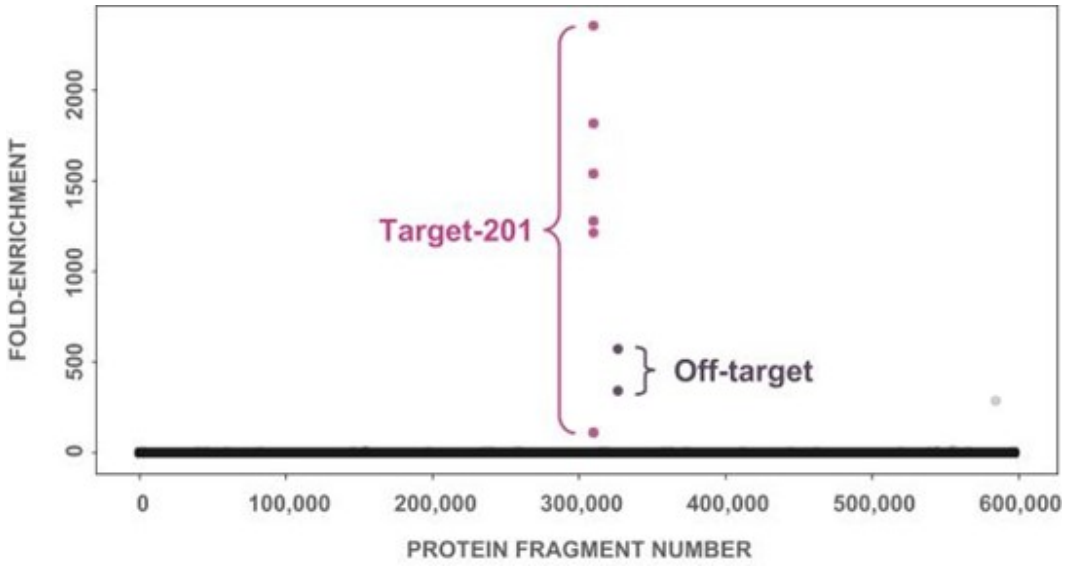




Finally, to reduce the risk that a TCR discovered in a targeted screen recognizes any problematic off-targets, we re-screen the TCR using SafetyScan and our genome-wide library. As shown below, when the TCR that recognizes Target-201 was re-screened using our Oncology Target Discovery Library (version 2.0), which includes protein fragments spanning every normal protein encoded in the human genome, only one potential off-target was observed. We subsequently identified several cell lines that naturally express the full-length protein from which the off-target antigen was derived and found that T cells engineered with the TCR do not recognize or kill these cells. Although the TCR recognizes target cells overexpressing protein fragments containing this off-target antigen, it does not recognize cells expressing the full-length protein at normal levels. This shows that our genome-wide screen detects potential off-targets with very high sensitivity, and that not all off-targets detected in this manner are problematic. In the event, however, that a TCR exhibits

problematic off-target effects, we can use ReceptorScan to discover alternative TCRs that have similar anti-cancer effects but do not cross-react with proteins expressed at high levels on normal tissue or critical organs.

Genome-Wide Safety Screen of Target-201 TCR Using SafetyScan



To further expand the pool of addressable patients with our TSC-200 series of product candidates, we can also use ReceptorScan to identify TCRs recognizing antigens on the same target protein that are presented by different HLA alleles. Ultimately, we believe this strategy has the potential to enable multiplexed TCR-T therapy in which a patient is treated with more than one TCR for the same target protein, presented on two different HLA alleles. This approach could reduce the risk of resistance arising from loss, downregulation, or mutation of individual HLA genes.

TSC-200 Series

Our first five solid tumor TCR-T therapy candidates include a combination of known targets, such as HPV16 for TSC-200, PRAME for TSC-203, and MAGE-A1 for TSC-204, as well as targets that are novel antigens for TCR-T therapy, such as for TSC-201 and TSC-202. All of these targets are frequently expressed in the solid tumors of interest to us, including melanoma, head and neck cancer, NSCLC, and cervical cancer. In 2021, it is estimated that in the U.S., approximately 100,000 patients are diagnosed with melanoma, 66,000 with head and neck cancer, 185,000 with NSCLC, and 15,000 with cervical cancer. We plan to advance a combination of known and novel targets into clinical development, which will allow us to use the product candidates targeting known antigens as backbones for our initial clinical trials evaluating multiplexed TCR-T therapy. For example, we plan to evaluate TSC-200, which targets well-known and clinically-validated oncogenic proteins derived from HPV16, in combination with TSC-201 and TSC-202, which target antigens that have not yet been tested for TCR-T therapy.

TSC-200

In parallel with our TargetScan discovery efforts in head and neck cancer, we are using ReceptorScan to discover highly active TCRs that target antigens in human papilloma virus, or HPV, for our TSC-200 program. Over 25% of head and neck cancers are caused by HPV infection, including up to 70% of oropharangeal cancers. HPV antigens are a particularly compelling set of targets due to the fact that HPV proteins drive tumorigenesis in these cancers, which means that these proteins are (1) present in every tumor cell in an HPV-positive tumor and (2) essential to the survival of the tumor cell. In addition to head and neck cancers, HPV is found in more than 90% of cervical and anal cancers as well as over 60% of vaginal, vulval, and penile cancers. Recent Phase 1 clinical data from the National Cancer Institute showed tumor regression with objective clinical responses in 50% of patients with metastatic HPV-positive cancers who were treated with a TCR-T candidate targeting HPV16, which we believe provides clinical support for the inclusion of an HPV16-targeting TCR, TSC-200, in our multiplexed TCR-T therapy strategy. We have identified over a thousand TCRs that recognize HLA-A*02:01- specific antigens derived from HPV16, and we are currently identifying the most active TCR with a de-risked safety profile to advance to IND-enabling studies. We also intend to extend our discovery efforts to include additional HPV16-derived antigens presented on other HLA types as the program advances.

TSC-201

As detailed above, using our TargetScan technology, we have identified what we refer to as Target-201, as one of three targets from the T cells of melanoma patients responding to TIL therapy. Target-201 is a CTA that is exclusively expressed in testis and is not expressed in normal adult tissues. The testis is an immune-privileged tissue and, as a result, we believe that targeting Target-201 should not pose a significant safety concern. In addition, Target-201, which contributes to tumorigenesis by suppressing the cellular mechanisms responsible for controlling cell division, is selectively expressed across multiple different types of tumors, including approximately 50% of melanomas, approximately 25% of head and neck cancers, and approximately 50% of non-small cell lung cancers. Tumors expressing Target-201 have been shown to be associated with metastasis and poor patient survival. We have identified two clinically active TCRs that recognize novel epitopes derived from Target-201 presented on two common HLA alleles, and we are currently evaluating which TCR/Target-201 antigen pair to advance to IND-enabling studies. We are also using ReceptorScan to identify additional TCRs for Target-201 epitopes presented on other HLA alleles to further expand the addressable patient population.

TSC-202

We have also identified clinically active TCRs targeting what we refer to as Target-202, which is a protein involved in cell invasion and migration that plays a role in the metastasis of tumors. Target-202 is a CTA that is expressed only in the placenta, with very low expression in testis and no expression in any other adult tissue. Increased expression of Target-202 is positively correlated with the degree of tumor invasion, lymph node metastasis, distant metastasis, and poor prognosis. Expression of Target-202 is especially high in HPV-positive tumors. Target-202 expression is repressed in normal tissue by the tumor suppressor protein p53. In HPV-driven carcinomas, however, the viral protein E6 causes degradation of p53, leading to increased expression of Target-202. As a result, high expression of Target-202 is observed in over 90% of cervical cancers and approximately 75% head and neck cancers. Target-202 is also expressed in HPV-negative tumors, including approximately 40% of NSCLCs, over 95% of melanomas, and up to 80% of primary breast cancers. Using ReceptorScan, we have identified thousands of TCRs that recognize multiple HLAA*02:01-specific epitopes derived from Target-202, and we are currently identifying the most active TCR to advance to IND-enabling studies.

TSC-203

We are developing TSC-203 as a TCR-T therapy candidate targeting a known cancer antigen, Preferentially Expressed Antigen in Melanoma, or PRAME. Similar to Target-201, PRAME contributes to tumorigenesis by suppressing cellular signals that control cell division, and higher expression levels of PRAME in tumors correlate with increased metastasis and poor patient outcomes. PRAME is a CTA that, like Target-201 and Target-202, is absent in adult tissues except in the ovaries and testis. Approximately 50% of NSCLCs, approximately 25% of cervical cancers, and approximately 90% of melanomas and head and neck cancers express PRAME. Moreover, PRAME expression is homogeneous within these tumors, which we believe make it an attractive target for multiplexed TCR-T therapy. Using ReceptorScan, we have identified thousands of TCRs across multiple PRAME-derived epitopes presented on HLA-A*02:01, and we are currently identifying the most active TCR to advance to IND-enabling studies. In addition, we are using TargetScan on clinically active TCRs from patients with melanoma and head & neck cancer to identify novel PRAME epitopes presented on other HLA types.

In addition to our five lead solid tumor TCR-T therapy candidates, we have identified more than 60 novel antigens using TargetScan, of which over 90% have not previously been publicly disclosed as targets for TCR-T therapy. Although target validation naturally results in attrition, it is clear that tumor-resident T cells recognize many more shared antigens than have been reported to date. Many of the antigens we have identified are expressed across multiple solid tumor types and some have expression levels comparable or superior to targets currently in clinical development by others such as NY-ESO-1. We are currently in the process of validating several of these additional novel antigens and identifying potential TCR/target pairs using our platform technologies. We plan to continuously expand ImmunoBank with TCRs for both known and novel targets as well as address different HLA types to enable customized multiplexed TCR-T therapy while also addressing the potential issue of HLA loss leading to resistance for a wide range of solid tumor patients.

TSC-204

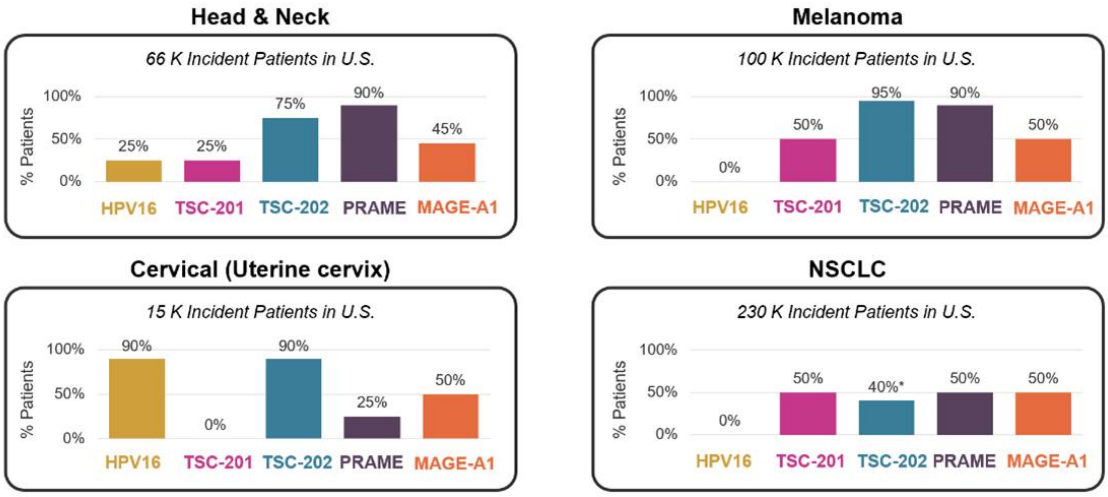
We are developing TSC-204 as a TCR-T therapy candidate targeting a known cancer antigen, melanoma-associated antigen 1, or MAGE-A1, that will include multiple TCRs for different HLA-restricted epitopes on this target. Using our TargetScan platform we have identified MAGE-A1 as one of the targets of T cells from a head and neck cancer patient responding to checkpoint inhibitor therapy. From this patient, we discovered multiple different TCRs recognizing a novel HLA-C*07:02 restricted epitope of MAGE-A1 which is a cancer/testis gene frequently overexpressed in a wide variety of solid tumors, including approximately 45% of head & neck cancers, 50% of melanomas, 50% of cervical cancers and 50% of non-small cell lung cancers. In addition to these highly active HLA-C*07:02 restricted TCRs, we are also using ReceptorScan to identify additional clinical TCRs for MAGE-A1 epitopes presented on multiple

other HLA alleles to further expand the addressable patient population. TScan believes that it is the only company with a disclosed TCR program in MAGE-A1 for HLA types other than A*02:01. The Company anticipates filing an IND for TSC-204 in the second half of 2022.

Clinical Development Plan for Our Solid Tumor Program

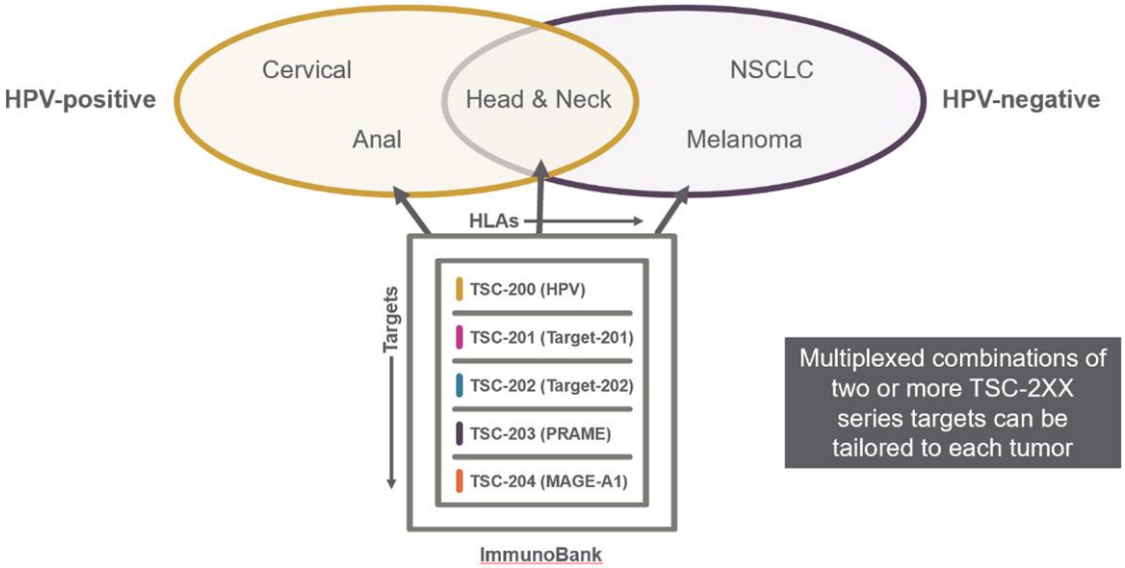
For the initial first-in-human studies for our TSC-200 series of TCR-T therapy candidates, we plan to evaluate multiple TCRs in parallel to determine the safety and preliminary efficacy of multiplexed TCR-T therapy. We envision using TSC-200 as the backbone therapy for patients with HPV-positive malignancies, including head and neck, cervical, and anal cancers. According to the Centers for Disease Control, the incidence of HPV-positive cancers in the U.S. is approximately 46,000 cases per year, with five-year survival rates ranging from approximately 50% to 70%. The targets of TSC-201, TSC-202, TSC-203, and TSC-204 are also frequently expressed in the solid tumors of interest to us, as shown below.

Cancer Expression Levels for the Targets of our Lead Solid Tumor Programs



After establishing single agent safety for each of our initial solid tumor TCR-T therapy candidates in a multi-arm Phase 1 clinical trial, we plan to test TSC-200 in combination with TSC-201, TSC-202, or TSC-203 in patients who are positive for the respective targets of these therapies. We will also explore three-TCR combinations in patients who are positive for the three respective targets. Because the targets of TSC-201, TSC-202, TSC-203, and TSC-204 are also frequently expressed in melanoma and NSCLC, we will also explore various combinations of these TCR-T therapy candidates in patients with HPV-negative head and neck cancer, melanoma, and NSCLC. A summary of our planned Phase 1 clinical strategy is shown below.

TSC-200 Series Phase 1 Clinical Strategy



Anticipated timeline

As we advance our solid tumor program, we anticipate presenting pre-clinical data at a major scientific meeting in the first half of 2022; filing INDs for two solid tumor TCR-T therapy candidates in the second half of 2022 with additional IND filings in 2023; and presenting initial clinical data on our multi-arm Phase 1 clinical trial in 2023. As we continue to discover and validate TCR/target pairs, we aim to continue to file additional INDs and introduce those solid tumor TCR-T therapy candidates into this multi-arm basket-style Phase 1 clinical trial. We believe this trial will serve as the first step towards our long-term goal of building and expanding ImmunoBank to provide customized multiplexed TCR-T therapy for virtually any patient with a solid tumor malignancy.

ImmunoBank – Flexible Content for Diverse Platforms

Our current clinical development strategy is based on autologous T cell engineering, which is the basis for approved CAR-T products such as Kymriah and Yescarta. As the field of T cell engineering evolves, a wide variety of additional manufacturing platforms are being developed that may further improve TCR-T cell products. For example, companies such as Lyell Immunopharma, Inc. are developing methods to enhance autologous T cell engineering to provide improved duration of efficacy, while companies such as Allogene Therapeutics, Inc. are developing ways to engineer allogeneic T cells and companies such as Sana Biotechnology, Inc. are developing ways to engineer T cells *in vivo*. All of these engineering platforms require validated “content” – TCRs that recognize tumor-specific antigens on cancer cells without recognizing problematic off-targets. As we advance our ImmunoBank of TCRs through clinical development, we intend to continue to build our own manufacturing platform, while simultaneously investigating novel T cell engineering platforms once they have established safety and efficacy. Ultimately, we aspire to build the largest collection of validated TCR “content” that can be used with a variety of T cell engineering platforms.

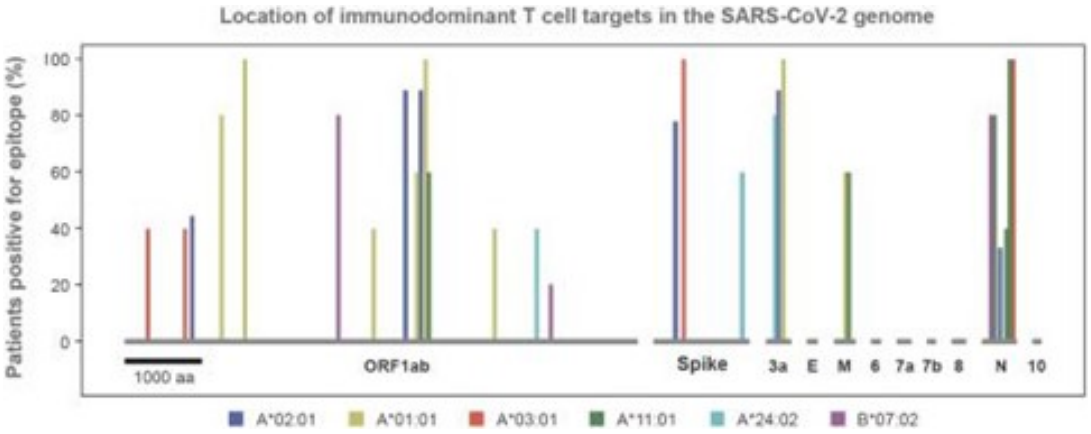
Expansion Opportunities Beyond Oncology

Our primary focus is on the development of T cell therapies to treat cancer. However, T cells play a fundamental role in many other disease areas, such as infectious disease and autoimmune disease. We believe that our TargetScan technology is well suited to discover novel antigens for the development of therapeutics, diagnostics, and vaccines in these other areas. We intend to build additional corporate value by opportunistically pursuing collaborations with strategic partners for applications of our platform technologies outside our core focus.

COVID-19

As a proof-of-concept for TargetScan's applicability and antigen discovery capabilities in infectious disease, we applied our technology to identify the antigens most frequently recognized by the T cells of patients who had recovered from COVID-19. We screened the entire genome of SARS-CoV-2, the virus that causes COVID-19, as well as the genomes of SARS-CoV and the four seasonal coronaviruses that cause the common cold. We found that the antigens recognized by CD8+ T cells were largely derived from segments of the virus that are not part of the spike protein, which is the current target of COVID-19 vaccines. Additionally, patient T cells were generally not found to be cross-reactive with seasonal coronaviruses, suggesting that prior coronavirus exposure is unlikely to confer immunity to COVID-19. We published the details of these studies in the journal *Immunity* in 2020.

T Cell Targets in SARS-CoV-2 Are Primarily Located
In Proteins Other Than the Spike Protein



We have partnered with QIAGEN Sciences, LLC to develop a highly specific diagnostic test to determine prior exposure to the virus based upon the presence of anti-viral T cells.

We believe that our findings can also be used to develop next-generation vaccines for COVID-19 that confer durable immune protection from SARS-CoV-2 infection and potentially provide protection against future variants. Most current vaccine efforts elicit a response to the SARS-CoV-2 spike protein. While these first-generation vaccines are able to elicit neutralizing antibodies and provide effective protection against infection, it is not clear how durable these responses will be given that antibody levels have been shown to rapidly decline after a few months and numerous coronavirus variants have now been discovered with mutations in the spike protein. Notably, none of the mutations observed in these variants occurs in the 29 T cell targets that we identified, suggesting that vaccines delivering these target antigens may be less susceptible to vaccine-resistant strains emerging in the future. We have partnered with Akagera Medicines to develop an mRNA lipid nanoparticle (LNP) vaccine candidate which includes not only the spike protein that elicits neutralizing antibodies but also all the non-spike T cell epitopes we discovered which would elicit a protective T cell response. The LNP vaccine candidate utilizes Akagera's novel LNP technology which is designed to better target lymph nodes thereby reducing the risk of local toxicity such as injection site swelling, reduce the vaccine dose by up to 10-fold and have improved stability requiring a -20°C cold chain rather than the more onerous -80°C cold chain that existing mRNA LNP vaccines require. Preclinical testing of this vaccine candidate has demonstrated efficient eliciting of a broad T cell response mimicking the T cell responses observed in convalescent COVID-19 patients.

Other Diseases

TargetScan can also be used for novel target discovery in additional infectious and autoimmune diseases. For example, infections such as tuberculosis, influenza, and HIV have been shown to be T cell-mediated and are associated with high mortality rates. In addition, many autoimmune diseases such as rheumatoid arthritis, psoriasis, and scleroderma are largely T cell-mediated, but with poorly defined instigating self-antigens. Our TargetScan technology, which provides an unbiased, genome-wide method to discover the natural targets of disease-relevant T cells, is well positioned to identify these self-antigens. We believe the discovery of these targets could enable the development of novel, more targeted therapeutic approaches to treat these diseases.

License and Collaboration Agreements

Collaboration and License Agreement with Novartis

On March 27, 2020, we entered into a Collaboration and License Agreement with Novartis Institutes for BioMedical Research, Inc. (Novartis) (such agreement, the Novartis Agreement). Pursuant to the Novartis Agreement, we have received an aggregate of $20.0 million of cash representing the upfront payment and have receivables for reimbursement of expenditures under the arrangement of $0.9 million as of December 31, 2021. We granted Novartis and its affiliates options to obtain exclusive, royalty-bearing, sublicensable, transferable, worldwide licenses to certain target antigens identified in performance of the Novartis Agreement and corresponding T-cell receptors for such target antigens to make, have made, import, use, sell or offer for sale, including to develop, manufacture, commercialize, register, hold or keep, have used, export, transport, distribute, promote, market or have sold or otherwise dispose of such target antigens and corresponding T-cell receptors. Novartis can exercise each option by paying us $10.0 million and can exercise up to three options (each target antigen for which Novartis exercises an option, an "Optioned Program"). In addition, we granted Novartis and its affiliates an option to obtain a non-exclusive, royalty-bearing, sublicensable, transferable, worldwide license under our intellectual property corresponding to products associated with such Optioned Program and improvements to our platform created in performance of activities under the Novartis Agreement, in each case, solely as necessary to exploit products associated with such Optioned Program.

The ownership of inventions (and resulting patent rights) created in performance of the collaboration will be determined by inventorship (i.e., inventions invented solely by us in performance of the collaboration and inventions invented solely by Novartis in performance of the collaboration will be owned by Novartis and inventions invented jointly by us and Novartis in performance of the collaboration will be jointly owned). We retain our rights to (i) our intellectual property, (ii) programs that are not selected by Novartis and (iii) our platform improvements, which will not be considered collaboration technology.

Each party has the sole right (but not the obligation) in its sole discretion and cost, to prepare, file, prosecute and maintain all patents and patent applications that are owned solely by such party. For any collaboration patents or patent applications owned by us, if we elect not to file a patent application or to cease the prosecution or maintenance of any of our collaboration patents or patent applications, we must notify Novartis immediately of such decision, at which point Novartis will become permitted to file or continue prosecution or maintenance of such patent or patent application in our name. For joint collaboration patents and patent applications, Novartis has the first right (but not the obligation) to prepare, file, prosecute and maintain any joint collaboration patent or patent applications and/or optioned program patents or patent applications.

For each Optioned Program, as between the parties Novartis is solely responsible for the clinical development of such Option Program. Novartis is required to pay us up to an aggregate of $230.0 million upon achievement of certain clinical milestones and milestones for the first commercial sale in certain countries with respect to products directed to the corresponding target antigen for each Optioned Program. Novartis is also required to pay us up to an aggregate of $260.0 million upon achievement of certain annual net sales milestones for products directed to the corresponding target antigen for each Optioned Program. In addition, for each Optioned Program, Novartis is required to pay us, on a product-by-product and country-by-country basis, tiered royalties in the low-single-digit to mid-single-digit percentage on Novartis', its affiliates' and sublicensees' net sales of certain products directed to target antigens for each Optioned Program and a percentage in the mid-single-digits to low-teens on Novartis' net sales of products directed to such antigens and containing a T-cell receptor we identified to Novartis in our performance of the Novartis Agreement, subject to certain customary reductions. Royalties will be payable on a product-by-product and country-by-country basis during the period of time commencing on the first commercial sale of an applicable product in a country and ending upon the later of: (a) 10 years from the date of first commercial sale of such product in such country; (b) expiration of the last-to-expire valid claim of patents licensed by us to Novartis under the Novartis Agreement covering the manufacture, use or sale of such product in such country; or (c) the expiration of any regulatory or marketing exclusivity in such country with respect to such product (the "Royalty Term"). Novartis may terminate the Novartis Agreement entirely or on a program-by-program basis at any time for convenience upon 90 days' notice; provided, however, that Novartis will be required to fulfill any payment obligations that accrued prior to termination.

For a period of up to 180 days after the end of the collaboration period (which collaboration period will end no later than March 2023), we agree to notify Novartis if we intend to seek a third party partner to exclusively license or similarly grant rights to patents or know-how developed by us under the collaboration to allow for the development or commercialization of products directed to any programs that Novartis has not exercised an option to prior to the expiration of such option (a ROFN Notice). Upon receiving such notice, Novartis will have 90 days to provide us with a term sheet to exclusively license such collaboration technology to develop or commercialize products directed to such previously declined program, which will trigger Novartis's right of first negotiation. If Novartis delivers such term sheet, then Novartis will have 270 days following the ROFN Notice to negotiate a license for such collaboration technology.

The Novartis Agreement will remain in effect until (i) all options expire unexercised or (ii) if any options are exercise, on a product-by-product and country-by-country basis for each Optioned Program, upon the expiration of the Royalty Term for all products

associated with such Optioned Program in such country. Either party may terminate the Novartis Agreement upon an uncured material breach of the agreement or insolvency of the other party. We may terminate the Novartis Agreement immediately upon written notice to Novartis if Novartis challenges the validity, enforceability or scope of any of the patents we license to Novartis under the agreement. Novartis may terminate the agreement, either in its entirety or on a program-by-program basis, for convenience at any time with 90 days' prior written notice.

Exclusive Patent License Agreement with BWH

On December 5, 2018, we entered into an Exclusive Patent License Agreement with The Brigham and Women's Hospital, Inc. ("BWH"), as amended on July 26, 2019 and further amended and restated on April 20, 2021 (collectively, the "BWH Agreement"), pursuant to which we obtained an exclusive, sublicensable, worldwide license to practice under certain of BWH's patent rights for identifying T Cell epitopes, which are relevant to our TargetScan technology for identifying potential therapeutic products. The original 2018 BWH Agreement granted us the right to practice BWH's patent rights in a certain field of use ("MHC Class I License Field"). In connection with the amended and restatement of the BWH Agreement in 2021, we expanded the field of use in which we are authorized to practice BWH's patent rights to include MHC Class II uses and applications in exchange for certain additional payments to BWH. We are obligated to use commercially reasonable efforts to develop and commercialize at least one product or process that practices the licensed patent rights and at least one therapeutic or diagnostic product or process directed to an epitope identified through practicing the licensed patent rights.

Upon execution of the amendment of the BWH Agreement dated April 20, 2021, we paid an additional one-time fee of $466,500. We are required to pay BWH up to an aggregate of $12.72 million upon the achievement of certain clinical, regulatory and sales milestones for therapeutic products and processes. We are obligated to pay a low double-digit percentage of all non-royalty income we receive under sublicenses of BWH's patent rights. We are also obligated to pay a low single-digit percentage of all non-royalty income we receive under agreements with third parties ("Collaborators") where we practice under BWH's patent rights in connection with the research or development one or more therapeutic products or processes with or for such third party ("Collaboration Agreements"). We are also obligated to pay tiered royalties in the high single-digit percentage range on annual net sales of products and processes that practice the licensed patent rights and in the low single-digit percentage range on annual net sales of therapeutic and diagnostic products and processes directed to an epitope identified through practicing the licensed patent rights (other than those sold by Collaborators), with the royalty percentage for such products and processes decreasing to lower than one-percent royalties if directed to epitopes identified through practicing the licensed patent rights after December 31, 2019. For therapeutic and diagnostic products and processes directed to an epitope identified through practicing the licensed patent rights and sold by a Collaborator, we are obligated to pay lower than one-percent royalties of the Collaborator's annual net sales of such products and processes. For products and processes sold by us, our affiliates or sublicensees, such royalties only apply to products and processes directed to epitopes in a defined field of use MHC Class I field identified prior to December 31, 2022 and products and processes based on epitopes in the MHC Class II field identified prior to September 30, 2023. For products or processes directed to epitopes identified under a Collaboration Agreement, such royalties apply regardless of when the epitopes were identified. For each applicable product or process, the royalty term continues until the tenth (10^{th}) anniversary of the first commercial sale of such product or process. The royalty rates are also subject to reduction upon certain other events. Within sixty (60) days of each anniversary of December 5^{th}, we are obligated to pay BWH a non-refundable, mid five figure minimum annual royalty, which amount is creditable against royalties subsequently due on net sales of products and processes in such calendar year.

The BWH Agreement will terminate upon the later of (a) the last to expire or abandoned valid claim within the licensed patents, and (b) one year after the last sale for which a royalty is due. The current expected expiration date for the last-to-expire licensed patent right is June 8, 2038 (absent any adjustments or extensions of term). We also have the right to terminate the BWH Agreement in its entirety or on a country-by-country basis, for any reason upon 90 days' prior written notice to BWH. BWH may terminate the BWH Agreement: (1) without notice if we fail to maintain insurance required by the BWH Agreement; (2) upon notice within 60 days of our bankruptcy; (3) upon notice within 60 days after notice by BWH of our default in the performance of any obligation under the BWH Agreement that is not cured within such 60-day period; (4) if we fail to make any payments due under the BWH Agreement and do not cure such failure within 10 days after receiving BWH notice thereof; or (5) if we or any of our affiliates challenge the validity, enforceability or scope of any of the patent rights licensed to us under the BWH Agreement.

Option and Exclusive License Agreement with Qiagen

On November 5, 2020, we entered into an Option and Exclusive License Agreement with QIAGEN Sciences, LLC (Qiagen) (such agreement, the Qiagen Agreement). Pursuant to the Qiagen Agreement, Qiagen paid us a one-time non-refundable, non-creditable $150,000 option fee (Option Fee) in exchange for an option to obtain an exclusive, royalty-bearing, sublicensable, worldwide license under our rights to patents and patent applications related to certain SARS- CoV-2 peptides to use, make and otherwise commercialize products containing such SARS-CoV-2 peptides (the Option). Qiagen exercised the Option on April 14, 2021 and paid us an additional $150,000 option exercise fee. Qiagen may freely sublicense its rights through multiple tiers so long as it binds each sublicensee to terms

consistent with the Qiagen Agreement and remains responsible for any breaches of such terms by its sublicensees. We expressly reserved the right to conduct research or develop or commercialize products for or related to the treatment of SARS-CoV-2.

In addition, Qiagen is required to pay us a one-time, non-refundable, non-creditable $300,000 milestone payment upon launch of the first in vitro diagnostic product containing the licensed peptides. Qiagen is also required to pay us, on a product-by-product and country-by-country basis, royalties in the low-single-digit to mid-single-digit percentage on Qiagen's and its affiliates' net sales of products containing the licensed peptides, subject to certain customary reductions, for as long as such products are covered by a valid claim of the patents licensed by us to Qiagen under the Qiagen Agreement.

We are solely responsible for managing patent maintenance, prosecution and enforcement during the term of both the Option Exercise Period (defined below) and term of the Qiagen Agreement.

The Qiagen Agreement will expire upon the later to occur of (i) expiration of the last to expire valid claim of patents we license to Qiagen under the Qiagen Agreement or (ii) 15 years from the effective date of the Qiagen Agreement. Should any patents issue from any non-provisional patent applications claiming priority to any of the licensed U.S. provisional patent applications, the current expected expiration date for the last-to-expire licensed patent right is June 17, 2041 (absent any adjustments or extensions of term). Qiagen may terminate the Qiagen Agreement for any reason upon 60 days' prior written notice to us; provided, however, that Qiagen will be required to fulfill any payment obligations that accrued prior to termination.

Non-Exclusive License Agreement with Provincial Health Services Authority

On October 15, 2020, we entered into a Non-Exclusive License Agreement with the Provincial Health Services Authority of British Columbia (PHSA) (such agreement, the PHSA Agreement). Pursuant to the PHSA Agreement, we obtained a non-exclusive, perpetual, non-transferable, sublicensable, worldwide license to practice certain of PHSA's patent rights for identifying T Cell epitopes, which epitopes are relevant to our platform for identifying potential TCR-T therapies. Any sublicenses we grant to PHSA's patent rights must also include a license of our own IP; we are not permitted to sublicense PHSA's rights on a standalone basis.

Pursuant to the PHSA Agreement, we paid PHSA a one-time, non-refundable upfront fee of $500,000 as well as a reimbursement for previously incurred patent prosecution costs of approximately $50,000. Starting on the first anniversary of the effective date of the PHSA Agreement and continuing for five years thereafter, we are required to pay PHSA a mid-five-figure annual license fee, of which the first installment has been paid. In addition, we are obligated to pay a mid-six-figure fee for each sublicense and each further sublicense granted by one of our sublicensees or a sublicensee of our sublicensee (through multiple tiers) of the rights granted to us under the PHSA Agreement.

The PHSA Agreement will terminate upon the last to expire patent licensed under the PHSA Agreement. We also have the right to terminate the PHSA Agreement at any time, but such termination will not be effective until the later of (a) October 16, 2023, and (b) the date we have paid PHSA total aggregate fees equal to the upfront fee plus five years of annual license fees totaling $750,000. PHSA may terminate the PHSA Agreement upon giving us two separate written notices at least 30 days apart if: (i) we or any of our affiliates challenge the validity, enforceability or scope of any of the patents licensed to us under the PHSA Agreement; (ii) we owe unpaid fees due under the PHSA Agreement in excess of $100,000; or (iii) we breach material terms of the PHSA Agreement regarding sublicense restrictions (such as failing to pay the sublicense fee or sublicensing PHSA technology on a standalone basis) or our obligation to indemnify PHSA for damages resulting from our research or commercialization of PHSA's patent rights and, in each case described above, such termination will be effective only if we fail to cure such breach after receiving PHSA's two separate notices.

Royalty Agreement

In connection with our incorporation in April 2018, we entered into a royalty agreement with one of our founders. We amended and restated this royalty agreement in June 2018 and our founder assigned his rights and obligations under the royalty agreement to one of his affiliated entities in January 2021. Pursuant to the royalty agreement, we are required to pay him a royalty of 1% of net sales (as defined in the royalty agreement) of any product sold by us or by any of our 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 us as of the last date that the founder was providing services to us as a director or consultant under a written agreement. Royalties are payable with respect to each applicable product on a country-by-country and product-by-product basis, beginning on the first commercial sale of the first royalty-bearing product and ending on the later of (i) the date on which the exploitation of such royalty-bearing product is no longer covered by such patent in such country or (ii) the 15th anniversary of the first commercial sale of the first royalty-bearing product in such country. We may not assign our rights and obligations under the royalty agreement except in the event of a change in control relating to our company. The term of the royalty agreement continues until expiration of the last applicable royalty term.

Manufacturing

We have built in-house cell therapy manufacturing capabilities as one of the key components of our platform. The manufacturing of cell therapies requires the integration of several distinct components. Primary human blood cells are the source of T cells, along with a vector that delivers the desired genetic elements into these T cells. As a more operationally flexible and cost-efficient alternative to lentivirus, we have developed a manufacturing platform to genetically engineer T cells using a transposon/transposase system, which we refer to as T-Integrate.

We are designing our programs to use a transposon vector and corresponding transposase enzyme, which is derived from sfR fall armyworm, to deliver our TCRs into the genome of T cells. Our transposon/transposase system effectively inserts our TCRs and other exogenous genes, such as CD8, at random locations in the genome. The transposon will be delivered as a Nanoplasmid™, which was developed by Nature Technology, an Aldevron Company, and has no antibiotic selection element, reducing the risk of inadvertent transmission of antibiotic resistance into T cells. The transposase will be delivered as mRNA. mRNA is transiently expressed in the cell, reducing exposure of cells to prolonged transposase activity, which could result in multiple transposition events where the transposon would be moved around the genome. Aldevron has a license from Nature Technology to manufacture research-grade and GMP-grade transposon and transposase. The initial batch of research-grade and GMP-grade transposon and transposase which we intend to use in connection with our near-term pre-clinical studies and clinical trials will be manufactured by Aldevron pursuant to a non-exclusive, fee-for-service supply arrangement pursuant to which we may purchase materials from time-to-time, subject to normal market pricing.

We are developing our manufacturing process using industry standard instrumentation to enable direct transfer of methods from process development to manufacturing. These devices also allow for functionally closed processes in a small footprint. For product manufacturing, we use single-use bag and tubing kits, supplies, and process reagents that are available from well-established vendors who specialize in supplying clinical grade reagents for the cell and gene therapy industry. Our TCR-T therapies will be characterized and released using well-developed analytic methods. The final product will be cryopreserved, simplifying logistics and reducing risk of delivery failures. We plan to have controls and safeguards throughout the entire process to ensure product identity, integrity, and chain of custody. A clearly defined and documented manufacturing process, performed by trained operators using specialized instrumentation in an appropriately designed, commissioned, and operated manufacturing facility, are all critical for the manufacturing of safe, effective, and well-characterized cell therapies.

Our cell product manufacturing facility in Waltham, MA was designed and built to support multiple programs through Phase 1 and Phase 2 clinical development, with a projected capacity to support treating over 300 patients per year. We believe internalizing our manufacturing process enables us to better control this key aspect of clinical development and reduces the risk of program delay due to third party reliance. We expect to revisit our manufacturing process prior to commencing registrational trials and may use third-party CMOs to manufacture product candidates for our registrational trials.

Competition

We believe our novel and proprietary platform technologies, TargetScan and ReceptorScan, and our in-house cell therapy expertise constitute a meaningful competitive advantage in successfully developing novel and highly effective treatments for cancer. However, the biopharmaceutical industry in general, and the cell therapy field in particular, is characterized by rapidly advancing and changing technologies, intense competition, and a strong emphasis on intellectual property. We face substantial and increasing competition from many different sources, including large and specialty biopharmaceutical companies, academic research institutions, governmental agencies, and public and private research institutions. Competitors may compete with us in hiring scientific and management personnel, establishing clinical study sites, recruiting patients to participate in clinical trials, and acquiring technologies complementary to, or necessary for, our programs.

We face competition from segments of the pharmaceutical, biotechnology and other related markets that pursue the development of TCR-T or other cell therapies for the treatment of cancer. We expect to compete with a number of other T-cell therapy companies, including those with target discovery platforms, such as Adaptive Therapeutics, Inc., Immatics N.V., Enara Bio Ltd., Repertoire Immune Medicines, Inc., and 3T Biosciences Inc. In addition, we may face competition from other TCR companies such as Adaptimmune Therapeutics, Plc., Medigene AG, GlaxoSmithKline Pharmaceuticals Ltd, T-Knife GmbH, and Alaunos Therapeutics, Inc. We may also face competition from companies focused on CAR-T, TIL, gammadelta T cell, and other T cell therapies, such as Kite Pharma, Inc., a subsidiary of Gilead, Inc. (including Yescarta, which is approved for the treatment for large B-cell lymphoma or follicular lymphoma, two types of non-Hodgkin lymphoma), Juno Therapeutics, Inc., a subsidiary of Bristol-Myers Squibb, Inc., Iovance Biotherapeutics, Inc., Instil Bio, Inc., Achilles Therapeutics plc, Sana Biotechnology, Inc., 2seventy Bio, Inc., Atara Biotherapeutics, Inc., Lyell Immunopharma, Inc., Allogene Therapeutics, Inc., PACT Pharma, Inc., Gadeta B.V., and Adicet Bio, Inc. There are also companies utilizing other cell-based approaches that may be competitive to our product candidates. For example, companies such as Takeda Pharmaceutical Company, Ltd., Celyad, S.A., ImmunityBio, Inc., Celularity, Inc., Fate Therapeutics, Inc., and Nkarta, Inc. are developing therapies that target and/or engineer natural killer, or NK, cells. In addition, for our lead liquid tumor programs, TSC-100

and TSC-101, we may face competition from HighPass Bio, Inc. NexImmune, Inc., VOR Biopharma, Inc., and Marker Therapeutics, Inc., who are also developing cell therapies in the post-HCT setting.

Immunocore's KIMMTRAK is the first TCR-based therapeutic to receive FDA approval, potentially establishing a regulatory pathway, pricing benchmark, and commercial uptake pattern for TCR-based therapeutics. However, KIMMTRAK is a bispecific antibody indicated for use in a rare patient population with unresectable or metastatic uveal melanoma, which is not directly competitive to TScan. Immunocore's other programs using TCR-mimic bispecifics in other indications such as cutaneous melanoma may be a more direct competitor to TScan's products.

Furthermore, we also face competition more broadly across the oncology market for cost-effective and reimbursable cancer treatments. The most common methods of treating patients with cancer are surgery, radiation, and drug therapy, including chemotherapy, hormone therapy, biologic therapy, such as monoclonal and bispecific antibodies, immunotherapy, cell-based therapy, and targeted therapy, or a combination of any such treatments. There are a variety of available drug therapies marketed for cancer. In many cases, these drugs are administered in combination to enhance efficacy. While our TCR-T therapy candidates, if any are approved, may compete with these existing drugs and other therapies, to the extent they are ultimately used in combination with or as an adjunct to these therapies, our TCR-T therapies may not be competitive with them. Some of these drugs are branded and subject to patent protection, and others are available on a generic basis. As a result, obtaining market acceptance of, and gaining significant share of the market for, and commanding a certain price for any of our TCR-T therapies that we successfully introduce to the market may pose challenges. In addition, many companies are developing new oncology therapeutics, and we cannot predict what the standard of care will be as our product candidates progress through clinical development.

We could see a reduction or elimination in our commercial opportunity if our competitors develop and commercialize drugs that are safer, more effective, have fewer or less severe side effects, are more convenient to administer, are less expensive, are more accessible, or receive a more favorable label than our TCR-T therapy candidates. Our competitors also may obtain FDA or other regulatory approval for their drugs more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. The key competitive factors affecting the success of all of our TCR-T therapy candidates, if approved, are likely to be their efficacy, safety, convenience, price, and the availability of reimbursement from government and other third-party payors.

Intellectual Property

Our success depends in part on our ability to obtain, maintain and protect our proprietary technology and intellectual property and proprietary rights and to operate our business without infringing, misappropriating and otherwise violating the intellectual property and proprietary rights of third parties. We rely on a combination of patent applications, trademarks, trade secrets, and other intellectual property rights and measures to protect the intellectual property rights that we consider important to our business. We also rely on know-how and continuing technological innovation to develop and maintain our competitive position. We also seek to protect our proprietary rights by entering into confidentiality agreements and proprietary information agreements with suppliers, employees, consultants and others who may have access to our proprietary information. The steps we have taken to protect our trade secrets, trademarks, patent applications and other intellectual property and proprietary rights may not be adequate, and third parties could infringe, misappropriate or misuse our intellectual property. If this were to occur, it could harm our reputation and adversely affect our business, competitive position, financial condition or results of operations.

As of the date hereof, our patent portfolio consisted of a patent family exclusively licensed from BWH, including a pending U.S. non-provisional patent application and multiple pending foreign non-provisional patent applications, relating to methods and compositions for identifying target antigens specific to T cells. In addition, we have filed multiple patent families including multiple pending U.S. provisional patent applications and more than ten pending international and foreign patent applications. The claims of these patent applications are directed toward various aspects of our therapy candidates and research programs, including compositions of matter directed to SARS-CoV-2 immunodominant antigens, anti-SARS-CoV-2 TCRs, anti-SARS-CoV-2 vaccines, anti-HA-1 TCRs (including the TSC-100 TCR-T therapy candidate), anti-HA-2 TCRs (including the TSC-101 TCR-T therapy candidate), TCRs targeting the antigen of TSC-200, anti-HPV TCRs (including the TSC-200 TCR-T therapy candidate), and TCRs targeting the antigen of TSC-204 (including the TSC-204 TCR-T therapy candidate), as well as a phospholipid scrambling reporter-based T cell antigen screening platform and certain screening methods thereof. These patent applications, if issued, are expected to expire on various dates from 2038 through 2042, in each case without taking into account any possible patent term adjustments or extensions and assuming that appropriate maintenance and governmental fees are paid.

Liquid Tumor Program Product Patent Families

We have filed multiple pending patent applications covering our liquid tumor programs including claims to the composition-of-matter of TSC-100, TSC-101, as well as other anti-HA-1 and anti-HA-2 TCRs and related T cell therapies. The pending patent

applications will begin to enter the PCT international phase by April 2022. The pending international Patent Cooperation Treaty (PCT), Argentine, and Taiwanese patent applications claim the benefit of priority from earlier-filed U.S. priority provisional patent applications filed in 2020 and 2021. We expect any patents within this family, if issued, to expire the earliest in 2041 (without taking into account any possible patent term adjustments or extensions and assuming that appropriate maintenance and governmental fees are paid).

Solid Tumor Program Product Patent Families

We have filed multiple pending U.S. provisional patent applications covering our solid tumor programs including claims to the composition-of-matter of anti-HPV, anti-MAGE-A1 TCRs and related T-cell therapies. The pending patent applications will begin to enter the PCT international phase by April 2022. We expect any patents within this family, if issued, to expire the earliest in 2042 (without taking into account any possible patent term adjustments or extensions and assuming that appropriate maintenance and governmental fees are paid).

Infectious Disease Product Patent Families

We have filed multiple pending patent applications covering our infectious disease programs including claims to the composition-of-matter of SARS-CoV-2 immunodominant antigens, anti-SARS-CoV-2 TCRs, and composition-of-matter of certain SARS-CoV-2 vaccines. These pending international PCT, Argentine, Bangladeshi, Democratic Republic of the Congo, Pakistani, and Taiwanese patent applications claim the benefit of priority from earlier-filed U.S. priority provisional patent applications filed in 2020. We expect any patents within this family, if issued, to expire the earliest in 2041 (without taking into account any possible patent term adjustments or extensions and assuming that appropriate maintenance and governmental fees are paid). Certain of these pending patent applications are jointly owned by us and AHS Hospital Corporation ("AHS"). AHS has exclusively licensed their interest to us in such patent applications.

Platform Technology

We own a pending PCT patent application with claims that cover reporter-based T cell antigen screening platform. We expect any claims within this family, if issued, to expire the earliest in 2041 (without taking into account any possible patent term adjustments or extensions and assuming that appropriate maintenance and governmental fees are paid).

Our pending patent applications may not result in issued patents and we can give no assurance that any patents that might issue in the future will protect our future products or provide us with any competitive advantage. Moreover, 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. For more information regarding the risks related to our intellectual property, please see "Risk Factors—Risks Related to Our Intellectual Property". We rely on certain technology and intellectual property rights that we in-license from third parties.

Third-Party Intellectual Property Rights

We have an exclusive patent license from The Brigham and Women's Hospital, Inc. (BWH) to a patent family directed to a granzyme B (GzB)-based antigen screening technology platform, as well as compositions-of-matter and certain screening methods thereof (consisting of one pending U.S. patent application and six foreign patent applications pending in Australia, Canada, China, Europe, Hong Kong, and Japan). Any patents issuing from the U.S. and foreign patent applications are expected to expire in 2038 (without taking into account any possible patent term adjustments or extensions and assuming that appropriate maintenance and governmental fees are paid). We also have a non-exclusive, perpetual, non-transferable patent license from the Provincial Health Services Authority of British Columbia (PHSA) to a patent family directed to granzyme-based antigen screening methods consisting of an issued U.S. patent that is expected to expire August 4, 2035, a pending U.S. patent application, and issued Canadian patent that is expected to expire March 25, 2035 (assuming that appropriate maintenance and governmental fees are paid). We do not have any additional material licenses to any technology or intellectual property rights.

As of the date hereof, we own or have rights to two pending U.S. trademark applications, 14 foreign trademark registrations, and three pending foreign trademark applications.

Government Regulation

FDA Regulation and Marketing Approval

In the U.S., the FDA regulates drugs under the Federal Food, Drug and Cosmetic Act ("FDCA"), and biologics under the Public Health Service Act, the regulations promulgated under both laws and other federal, state, and local statutes and regulations. Failure to comply with the applicable U.S. regulatory requirements at any time during the product development process, approval process or after approval may subject an applicant to administrative or judicial sanctions and non-approval of product candidates. These sanctions could include, among other things, the imposition by the FDA of a clinical hold on trials, the FDA's refusal to approve pending applications or related supplements, withdrawal of an approval, untitled or warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, restitution, disgorgement, civil penalties, or criminal prosecution. Such actions by government agencies could also require us to expend a large amount of resources to respond to the actions. Any agency or judicial enforcement action could have a material adverse effect on us.

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the clinical development, approval, manufacture, distribution and marketing of pharmaceutical products. These agencies and other federal, state and local entities regulate R&D activities and the testing, manufacture, quality control, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, post-approval monitoring, advertising, promotion, sampling and import and export of our products. Rocket's drugs must be approved by the FDA as biologics through the BLA approval process applicable to gene therapy product candidates, before they may be legally marketed in the U.S.

Within the FDA, the FDA's Center for Biologics Evaluation and Research ("CBER") regulates gene therapy products and has published guidance documents with respect to the development these types of products. The FDA also has published guidance documents related to, among other things, gene therapy products in general, their preclinical assessment, observing subjects involved in gene therapy studies for delayed adverse events, potency testing, and chemistry, manufacturing and control information in gene therapy INDs.

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

- completion of non-clinical laboratory tests, animal studies and formulation studies conducted according to Good Laboratory Practice ("GLP"), or other applicable regulations;
- submission of an IND, which allows clinical trials to begin unless FDA objects within 30 days;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug or biologic for its intended use or uses conducted in accordance with FDA regulations and Good Clinical Practices ("GCP"), which are international ethical and scientific quality standards meant to ensure that the rights, safety and well-being of trial participants are protected, and that the integrity of the data is maintained;
- preparation and submission to the FDA of a BLA;
- submission of a user fee for FDA review of the BLA;
- review of the product by an FDA advisory committee, where appropriate or if applicable;
- satisfactory completion of pre-approval inspection of manufacturing facilities and clinical trial sites at which the product, or components thereof, are produced to assess compliance with current Good Manufacturing Practice ("cGMP") requirements, and if applicable, the FDA's current Good Tissue Practice ("cGTP") requirements, and of selected clinical trial sites to assess compliance with GCP requirements; and
- FDA approval of a BLA which must occur before a biologic can be marketed or sold.

Preclinical Studies

Preclinical studies include laboratory evaluation of the purity and stability of the manufactured drug substance or active pharmaceutical ingredient and the formulated drug or drug product, as well as in vitro and animal studies to assess the safety and activity of the drug for initial testing in humans and to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations. The results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical studies, among other things, are submitted to the FDA as part of an IND.

Companies usually must complete some long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the drug in commercial quantities in accordance with ("cGMP") requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality, and purity of the final drug product. Additionally, appropriate packaging must be

selected and tested, and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

IND and Clinical Trials

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCP requirements. Clinical trials are conducted under written study protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Prior to commencing the first clinical trial, an initial IND, which contains the results of preclinical testing along with other information, such as information about product chemistry, manufacturing and controls and a proposed protocol, must be submitted to the FDA. The IND automatically becomes effective 30 days after receipt by the FDA unless the FDA within the 30-day time period raises concerns or questions about the drug product or the conduct of the clinical trial and imposes a clinical hold. A clinical hold may also be imposed at any time while the IND is in effect. In such a case, the IND sponsor must resolve any outstanding concerns with the FDA before the clinical trial may begin or re-commence. Accordingly, submission of an IND may or may not result in the FDA allowing clinical trials to commence or continue.

In addition to the submission of an IND to the FDA before initiation of a clinical trial in the United States, certain human clinical trials involving recombinant or synthetic nucleic acid molecules are subject to oversight of institutional biosafety committees(“IBC’s”), as set forth in the National Institutes for Health(“NIH”), Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, or NIH Guidelines. Under the NIH Guidelines, recombinant and synthetic nucleic acids are defined as: (i) molecules that are constructed by joining nucleic acid molecules and that can replicate in a living cell (i.e., recombinant nucleic acids); (ii) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules (i.e., synthetic nucleic acids); or (iii) molecules that result from the replication of those described in (i) or (ii). Specifically, under the NIH Guidelines, supervision of human gene transfer trials includes evaluation and assessment by an IBC, a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment, and such review may result in some delay before initiation of a clinical trial. While the NIH Guidelines are not mandatory unless the research in question is being conducted at or sponsored by institutions receiving NIH funding of recombinant or synthetic nucleic acid molecule research, many companies and other institutions not otherwise subject to the NIH Guidelines voluntarily follow them.

A sponsor who wishes to conduct a clinical trial outside the U.S. may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of a BLA or IND so long as the clinical trial is conducted in compliance with GCP, and the FDA is able to validate the data from the study through an onsite inspection if the agency deems it necessary.

A separate submission to the existing IND must be made for each successive clinical trial to be conducted during product development. Further, an independent Institutional Review Board (“IRB”) for each site at which the clinical trial will be conducted must review and approve the clinical trial before it commences at that site. Informed written consent must also be obtained from each trial subject. Regulatory authorities, including the FDA, or IRB, or the sponsor, may suspend or terminate a clinical trial at any time on various grounds, including a finding that the participants are being exposed to an unacceptable health risk or that the clinical trial is not being conducted in accordance with FDA requirements. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization as to whether or not a trial may move forward at designated check points based on access to certain data from the trial and may recommend halting the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy.

Human clinical trials for BLA approval typically involve a three-phase process, although some phases may overlap or be combined. Phase 1, the initial clinical evaluations, consists of administering the drug and testing for safety and tolerated dosages and in some indications such as rare disease, as preliminary evidence of efficacy in humans. Phase 2 involves a study to evaluate the effectiveness of the drug for a particular indication and to determine optimal dosage and dose interval and to identify possible adverse side effects and risks in a larger patient group. When a product is found safe, and initial efficacy is established in Phase 2, it is then evaluated in Phase 3 clinical trials. Phase 3 trials consist of expanded multi-location testing for efficacy and safety to evaluate the overall benefit-to-risk index of the investigational drug in relationship to the disease treated. The results of preclinical and human clinical testing are submitted to the FDA in the form of a BLA for approval to commence commercial sales.

All clinical trials must be conducted in accordance with FDA regulations, GCP requirements and their protocols in order for the data to be considered reliable for regulatory purposes. Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. Phase 1, Phase 2 and Phase 3 clinical trials may not be

completed successfully within any specified period, or at all. Government regulation may delay or prevent marketing of product candidates or new drugs for a considerable period of time and impose costly procedures upon our activities.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of FDA-regulated products, including drugs, are required to register and disclose certain clinical trial information. Information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to disclose the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed until the new product or new indication being studied has been approved up to a maximum of two years. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

The BLA Approval Process

In order to obtain approval to market a drug in the U.S., a marketing application must be submitted to the FDA that provides data establishing to the FDA's satisfaction the safety and effectiveness of the investigational drug for the proposed indication. The application includes all relevant data available from pertinent non-clinical or preclinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls and proposed labeling, among other things. Data can come from company-sponsored clinical trials intended to test the safety and effectiveness of a use of a product, or from a number of alternative sources, including studies initiated by investigators that meet GCP requirements.

During the development of a new drug, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to submission of an IND, at the End-of-Phase 1 or 2, and before a BLA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice and for the sponsor and the FDA to reach agreement on the next phase of development.

The results of product development, non-clinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information are submitted to the FDA as part of a BLA requesting approval to market the product for its intended indication. The FDA reviews all BLAs submitted to ensure that they are sufficiently complete for substantive review before it accepts them for filing. It may request additional information rather than accept a BLA for filing. In this event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. The FDA has 60 days from its receipt of a BLA to conduct an initial review to determine whether the application will be accepted for filing based on the agency's threshold determination that the application is sufficiently complete to permit substantive review. The FDA reviews a BLA to determine, among other things, whether the proposed product is safe and potent, or effective, for its intended use, and has an acceptable purity profile, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, safety, strength, quality, potency and purity. The FDA has agreed to specific performance goals on the review of BLA's. Specifically, FDA under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, as amended, the FDA has 10 months, from the filing date, in which to complete its initial review of an original BLA and respond to the applicant, and six months from the filing date of an original BLA designated for priority review. The review process may be extended by the FDA for three additional months to consider certain late-submitted information or information intended to clarify information already provided in the submission. After the FDA completes its substantive review of a BLA, it will communicate to the sponsor that the drug will either be approved, or it will issue a complete response letter to communicate that the BLA will not be approved in its current form and inform the sponsor of changes that must be made or additional clinical, non-clinical or manufacturing data that must be received before the application can be approved, with no implication regarding the ultimate approvability of the application or the timing of any such approval, if ever. If or when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the BLA, the FDA may issue an approval letter. FDA has committed to reviewing such resubmissions in two to six months depending on the type of information included. The FDA may refer applications for novel drug products or drug products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation, and a recommendation as to whether the application should be approved and, if so, under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving a BLA, the FDA typically will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA may inspect one or more clinical sites to assure compliance with GCP. For a gene therapy product, the FDA also will not approve the product if the manufacturer is not in compliance with the cGTPs. These are FDA regulations that govern the methods used in, and the facilities and controls used for, the manufacture of human cells, tissues, and cellular and tissue-based products, or HCT/Ps, which are

human cells or tissue intended for implantation, transplant, infusion, or transfer into a human recipient. The primary intent of the +cGTP requirements is to ensure that cell and tissue-based products are manufactured in a manner designed to prevent the introduction, transmission and spread of communicable disease. FDA regulations also require tissue establishments to register and list their HCT/Ps with the FDA and, when applicable, to evaluate donors through appropriate screening and testing. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it typically will outline the deficiencies and often will request additional testing or information. This may significantly delay further review of the application. If the FDA finds that a clinical site did not conduct the clinical trial in accordance with GCP, the FDA may determine the data generated by the clinical site should be excluded from the primary efficacy analyses provided in the BLA. Additionally, notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

The FDA may require, or companies may pursue, additional clinical trials after a product is approved. These so-called Phase 4 or post-approval trials may be made a condition to be satisfied for continuing drug approval. The results of Phase 4 trials can confirm the effectiveness of a product candidate and can provide important safety information. In addition, the FDA has authority to require sponsors to conduct post-marketing trials to specifically address safety issues identified by the agency. See “Post-Marketing Requirements” below.

The FDA also has authority to require a Risk Evaluation and Mitigation Strategy (“REMS”), from manufacturers to ensure that the benefits of a drug outweigh its risks. A sponsor may also voluntarily propose a REMS as part of the BLA submission. The need for a REMS is determined as part of the review of the BLA. Based on statutory standards, elements of a REMS may include “Dear Doctor letters,” a medication guide, more elaborate targeted educational programs, and in some cases distribution and use restrictions, referred to as elements to assure safe use (“ETASU”). ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patient registries. These elements are negotiated as part of the BLA approval, and in some cases the approval date may be delayed. Once adopted, REMS are subject to periodic assessment and modification.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, manufacturing processes or facilities, require submission and FDA approval of a new BLA or BLA supplement before the change can be implemented. A BLA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing BLA supplements as it does in reviewing BLAs.

Even if a product candidate receives regulatory approval, the approval may be limited to specific disease states, patient populations and dosages, or might contain significant limitations on use in the form of warnings, precautions or contraindications, or in the form of onerous risk management plans, restrictions on distribution or use, or post-marketing trial requirements. Further, even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product, including safety labeling or imposition of a REMS, the requirement to conduct post-market studies or clinical trials or even complete withdrawal of the product from the market. Delay in obtaining, or failure to obtain, regulatory approval for our products, or obtaining approval but for significantly limited use, would harm our business. In addition, we cannot predict what adverse governmental regulations may arise from future U.S. or foreign governmental action.

The Hatch-Waxman Amendments

Under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments, a portion of a product’s U.S. patent term that was lost during clinical development and regulatory review by the FDA may be restored by returning up to five years of patent life for a patent that covers a new product or its use. This period is generally one-half the time between the effective date of an IND (falling after issuance of the patent) and the submission date of a BLA, plus the time between the submission date of a BLA and the approval of that application, provided that the sponsor acted with diligence. Patent term restorations, however, cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended and the extension must be applied for prior to expiration of the patent. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration.

Market Exclusivity

The Affordable Care Act, or ACA, signed into law on March 23, 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or the BPCIA, which created an abbreviated approval pathway for biological products shown to be similar to, or interchangeable with, an FDA-approved reference biological product. Bio similarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical trial or trials. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the biologic and the reference biologic may be switched after one has been previously

administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. However, complexities associated with the larger, and often more complex, structure of biological products, as well as the process by which such products are manufactured, pose significant hurdles to implementation that are still being worked out by the FDA.

A reference biological product is granted four (4) and twelve (12) year exclusivity periods from the time of first licensure of the product. FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product, and FDA will not approve an application for a biosimilar or interchangeable product based on the reference biological product until twelve (12) years after the date of first licensure of the reference product. "First licensure" typically means the initial date the particular product at issue was approved in the United States. Date of first licensure does not include the date of licensure of (and a new period of exclusivity is not available for) a biological product if the licensure is for a supplement for the biological product or for a subsequent application by the same sponsor or manufacturer of the biological product (or licensor, predecessor in interest, or other related entity) for a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength, or for a modification to the structure of the biological product that does not result in a change in safety, purity, or potency. Therefore, one must determine whether a new product includes a modification to the structure of a previously approved product that results in a change in safety, purity, or potency to assess whether the licensure of the new product is a first licensure that triggers its own period of exclusivity. Whether a subsequent application, if approved, warrants exclusivity as the "first licensure" of a biological product is determined on a case-by-case basis with data submitted by the sponsor.

In addition, under the Orphan Drug Act, FDA may designate a biologic product as an "orphan drug" if it is intended to treat a rare disease or condition (generally meaning that it affects fewer than 200,000 individuals in the U.S., or more in cases in which there is no reasonable expectation that the cost of developing and making a biologic product available in the U.S. for treatment of the disease or condition will be recovered from sales of the product). Orphan product designation must be requested before submitting a BLA. After FDA grants orphan product designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by FDA. Orphan product designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. If a product with orphan status receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, meaning that FDA may not approve any other applications to market the same drug or biologic product for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity or if the party holding the exclusivity fails to assure the availability of sufficient quantities of the drug to meet the needs of patients with the disease or condition for which the drug was designated. Competitors, however, may receive approval of different products for the same indication than that for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity. Orphan medicinal product status in the EU has similar, but not identical, benefits.

Pediatric exclusivity is another type of non-patent marketing exclusivity in the U.S. and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity, including the non-patent exclusivity. This six-month exclusivity may be granted if a BLA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data.

Rare Pediatric Disease Designation and Priority Review Vouchers

Under the FDCA, the FDA incentivizes the development of drugs and biological products that meet the definition of a "rare pediatric disease," defined to mean a serious or life-threatening disease in which the serious of life-threatening manifestations primarily affect individuals aged from birth to 18 years and the disease affects fewer than 200,000 individuals in the United States or affects more than 200,000 in the United States and for which there is no reasonable expectation that the cost of developing and making in the United States a drug or biological product for such disease or condition will be received from sales in the United States of such drug or biological product. The sponsor of a product candidate for a rare pediatric disease may be eligible for a voucher that can be used to obtain a priority review for a subsequent human drug or biological product application after the date of approval of the rare pediatric disease drug or biological product, referred to as a priority review voucher ("PRV"). A sponsor may request rare pediatric disease designation from the FDA prior to the submission of its BLA. A rare pediatric disease designation does not guarantee that a sponsor will receive a PRV upon approval of its BLA. Moreover, a sponsor who chooses not to submit a rare pediatric disease designation request may nonetheless receive a PRV upon approval of their marketing application if they request such a voucher in their original marketing application and meet all of the eligibility criteria. If a PRV is received, it may be sold or transferred an unlimited number of times. Congress has extended the PRV program through September 30, 2024, with the potential for PRVs to be granted through September 30, 2026.

Expedited Development and Review Programs

FDA is authorized to expedite the review of BLAs in several ways. Under the Fast Track program, the sponsor of a biologic product candidate may request FDA to designate the product for a specific indication as a Fast Track product concurrent with or after

the filing of the IND. Biologic products are eligible for Fast Track designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to the combination of the product candidate and the specific indication for which it is being studied. In addition to other benefits, such as the ability to have greater interactions with FDA, FDA may initiate review of sections of a Fast-Track BLA before the application is complete, a process known as rolling review.

Any product submitted to FDA for marketing, including under a Fast Track program, may be eligible for other types of FDA programs intended to expedite development and review, such as regenerative medicine advanced therapy ("RMAT") designation, priority review and accelerated approval. To qualify for RMAT designation, the product candidate must be a regenerative medicine therapy, which is defined as a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, except for those regulated solely under Section 361 of the Public Health Service Act and part 1271 of Title 21, Code of Federal Regulations; is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and preliminary clinical evidence indicates that the product has the potential to address unmet medical needs for such disease or condition. A gene therapy product may meet the definition of a regenerative medicine therapy for purposes of RMAT designation. A BLA for a product candidate that has received RMAT designation may be eligible for priority review or accelerated approval through use of surrogate or intermediate endpoints reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of sites. Benefits of RMAT designation also include early interactions with FDA to discuss any potential surrogate or intermediate endpoint to be used to support accelerated approval. A product candidate with RMAT designation that is granted accelerated approval and is subject to post-approval requirements may fulfill such requirements through the submission of clinical evidence from clinical studies, patient registries, or other sources of real-world evidence, such as electronic health records; the collection of larger confirmatory data sets; or post-approval monitoring of all patients treated with such therapy prior to its approval.

A product candidate including one that received Fast Track or RMAT designation is eligible for priority review if it treats a serious condition and, if approved, it would be a significant improvement in the safety or effectiveness of the treatment, diagnosis or prevention of a serious condition compared to available therapies. FDA aims to complete its review of priority review applications within six months as opposed to 10 months for standard review.

Additionally, a biologic product may be eligible for accelerated approval if it is designed to treat a serious or life-threatening disease or condition and demonstrates an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity and prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, FDA may require that a sponsor of a drug or biologic product candidate receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. In addition, FDA currently requires, unless otherwise informed by the agency, pre-approval of promotional materials intended for dissemination or publication within 120 days of marketing approval.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or the time period for FDA review or approval may not be shortened. Fast Track designation, priority review and accelerated approval do not change the standards for approval but may expedite the development or approval process.

Post-Marketing Requirements

Following approval of a new product, a pharmaceutical company and the approved product are subject to continuing regulation by the FDA, including, among other things, monitoring and recordkeeping activities, reporting to the applicable regulatory authorities of adverse experiences with the product, providing the regulatory authorities with updated safety and efficacy information, product sampling and distribution requirements, and complying with promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting drugs for uses or in patient populations that are not described in the drug's approved labeling, or off-label use, limitations on industry-sponsored scientific and educational activities and requirements for promotional activities involving the internet. Although physicians may, in their independent professional medical judgment, prescribe legally available drugs for off-label uses, manufacturers typically may not market or promote such off-label uses. Modifications or enhancements to the product or its labeling or changes of the site of manufacture are often subject to the approval of the FDA and other regulators, who may or may not grant approval or may include a lengthy review process.

Prescription drug advertising is subject to federal, state, and foreign regulations. In the U.S., the FDA regulates prescription drug promotion, including direct-to-consumer advertising. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use. Any distribution of prescription drug products and pharmaceutical samples must comply with the U.S. Prescription Drug Marketing Act, a part of the FDCA.

In the U.S., once a product is approved, its manufacturing is subject to comprehensive and continuing regulation by the FDA. The FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMP. cGMP regulations

require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Additionally, manufacturers and other parties involved in the supply chain for prescription drug products must also comply with product tracking and racing requirements and for notifying the FDA of counterfeit, diverted, stolen and intentionally adulterated products or products that are otherwise unfit for distribution in the U.S. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. These regulations also impose certain organizational, procedural and documentation requirements with respect to manufacturing and quality assurance activities. BLA holders using contract manufacturers, laboratories or packagers are responsible for the selection and monitoring of qualified firms, and, in certain circumstances, qualified suppliers to these firms. These firms and, where applicable, their suppliers are subject to inspections by the FDA at any time, and the discovery of violative conditions, including failure to conform to cGMP, could result in enforcement actions that interrupt the operation of any such product or may result in restrictions on a product, manufacturer, or holder of an approved BLA, including, among other things, recall or withdrawal of the product from the market. In addition, the manufacturer and/or holder of an approved BLA are subject to annual product and establishment fees. These fees are typically increased annually.

The FDA also may require post-marketing testing, also known as Phase 4 testing, to monitor the effects of an approved product or place conditions on an approval via a REMS that could restrict the distribution or use of the product. Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, untitled or warning letters from the FDA, mandated corrective advertising or communications with doctors, withdrawal of approval, and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development.

Coverage and Reimbursement

Sales of any products for which we receive regulatory approval for commercial sale will depend in part on the availability of reimbursement from third-party payors, including government healthcare program administrative authorities, managed care organizations, private health insurers, and other entities. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third-party payors to reimburse all of part of the costs associated with their prescription drugs. Patients are unlikely to use our products unless coverage is provided, and reimbursement is adequate to cover a significant portion of the cost of our products. Therefore, our products, once approved, may not obtain market acceptance unless coverage is provided, and reimbursement is adequate to cover a significant portion of the cost of our products.

The process for determining whether a third-party payor will provide coverage for a drug product typically is separate from the process for setting the price of a drug product or for establishing the reimbursement rate that the payor will pay for the drug product once coverage is approved. Third-party payors may limit coverage to specific drug products on an approved list, also known as a formulary, which might not include all of the FDA-approved drugs for a particular indication. A decision by a third-party payor not to cover our product candidates could reduce physician utilization of our products once approved. Moreover, a third-party payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. Additionally, coverage and reimbursement for drug products can differ significantly from payor to payor. One third-party payor's decision to cover a particular drug product or service does not ensure that other payors will also provide coverage for the medical product or service or will provide coverage at an adequate reimbursement rate. As a result, the coverage determination process will require us to provide scientific and clinical support for the use of our products to each payor separately and will be a time-consuming process.

The containment of healthcare costs has become a priority of federal, state, and foreign governments, and the prices of drugs have been a focus in this effort. Third-party payors are increasingly challenging the prices charged for drug products and medical services, examining the medical necessity, and reviewing the cost effectiveness of drug products and medical services, in addition to questioning safety and efficacy. If these third-party payors do not consider our products to be cost-effective compared to other available therapies, they may not cover our products after FDA approval or, if they do, the level of payment may not be sufficient to allow us to sell our products at a profit.

The American Recovery and Reinvestment Act of 2009 provided funding for the federal government to compare the effectiveness of different treatments for the same illness. The plan for the research was published in 2012 by the Department of Health and Human Services, the Agency for Healthcare Research and Quality and the National Institutes for Health, and periodic reports on the status of

the research and related expenditures will be made to Congress. Although the results of the comparative effectiveness studies are not intended to mandate coverage policies for public or private payors, it is not clear what effect, if any, the research will have on the sales of our product candidates, if any such product or the condition that it is intended to treat is the subject of a study. It is also possible that comparative effectiveness research demonstrating benefits in a competitor's product could adversely affect the sales of our product candidates, once approved. If third-party payors do not consider our products to be cost-effective compared to other available therapies, they may not cover our products after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products on a profitable basis.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the EU provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the EU do not follow price structures of the U.S. and generally tend to be significantly lower.

Anti-Kickback and False Claims Laws and Other Regulatory Matters

In the U.S., among other things, the research, manufacturing, distribution, sale and promotion of drug products and medical devices are potentially subject to regulation and enforcement by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare & Medicaid Services, other divisions of the U.S. Department of Health and Human Services (e.g., the Office of Inspector General), the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency, state Attorneys General and other state and local government agencies. Our current and future business activities, including for example, sales, marketing, and scientific/educational grant programs must comply with healthcare regulatory laws, as applicable, which may include the Federal Anti-Kickback Statute, the Federal False Claims Act, as amended, the privacy and security regulations promulgated under the Health Insurance Portability and Accountability Act ("HIPAA"), as amended, physician payment transparency laws, and similar state laws. Pricing and rebate programs must comply with the Medicaid Drug Rebate Program requirements of the Omnibus Budget Reconciliation Act of 1990, as amended, and the Veterans Health Care Act of 1992, as amended. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage, and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The Federal Anti-Kickback Statute makes it illegal for any person or entity, including a prescription drug manufacturer (or a party acting on its behalf) to knowingly and willfully, directly or indirectly, in cash or in kind, solicit, receive, offer, or pay any remuneration that is intended to induce the referral of business, including the purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of, any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as Medicare or Medicaid. The term "remuneration" has been broadly interpreted to include anything of value. The Federal Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Federal Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Additionally, the intent standard under the Federal Anti-Kickback Statute was amended by the Patient Protection and Affordable Care Act, as amended by the Health Care Education and Reconciliation Act (collectively, the "ACA"), to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the ACA codified case law that a claim including items or services resulting from a violation of the Federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the Federal False Claims Act. Violations of this law are punishable by up to five years in prison, criminal fines, administrative civil money penalties, and exclusion from participation in federal healthcare programs. In addition, many states have adopted laws similar to the Federal Anti-Kickback Statute. Some of these state prohibitions apply to the referral of patients for healthcare services reimbursed by any insurer, not just federal healthcare programs such as Medicare and Medicaid. Due to the breadth of these federal and state anti-kickback laws, and the potential for additional legal or regulatory change in this area, it is possible that our future business activities, including our sales and marketing practices and/or our future relationships with physicians and the medical community might be challenged under anti-kickback laws, which could harm us.

Federal false claims and false statement laws, including the civil False Claims Act, prohibits any person or entity from, among other things, knowingly presenting, or causing to be presented, for payment to federal programs (including Medicare and Medicaid) claims for items or services, including drugs, that are false or fraudulent. Although we would not submit claims directly to payors, manufacturers can be held liable under these laws if they are deemed to "cause" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. In addition, our future activities relating to the reporting of wholesaler or estimated retail prices for our products, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state, and third-party reimbursement for our products, and the sale and marketing of our products, are subject to scrutiny under this law. For example, pharmaceutical companies have been found liable under the Federal Civil False Claims Act in connection with their off-label promotion of drugs. Penalties for a civil False Claims Act violation include three times the actual damages sustained by the government, plus mandatory civil penalties for each separate false claim, the potential for exclusion from participation in federal healthcare programs, and, although the Federal False Claims Act is a civil statute, conduct that results in a False Claims Act violation may also implicate various federal criminal statutes. If the government were to allege that we were, or convict us of, violating these false claims laws, we could be subject to a substantial fine and may suffer a decline in our stock price. In addition, private individuals have the ability to bring actions under the Federal Civil False Claims Act and certain states have enacted laws modeled after the Federal False Claims Act.

Additionally, HIPAA created additional federal criminal statutes that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false, fictitious, or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

There are also an increasing number of state laws that require manufacturers to make reports to states on pricing and marketing information. Many of these laws contain ambiguities as to what is required to comply with the laws. For example, federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs. In addition, as discussed below, a similar federal requirement under the Physician Payments Sunshine Act, requires certain manufacturers to track and report to the federal government certain payments provided to physicians and teaching hospitals made in the previous calendar year, as well as certain ownership and investment interests held by physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors) and their immediate family members. These laws may affect our sales, marketing, and other promotional activities by imposing administrative and compliance burdens on us. In addition, given the lack of clarity with respect to these laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent state and federal authorities. Effective January 1, 2022, these reporting obligations extend to include transfers of value made to certain non-physician providers such as physician assistants and nurse practitioners.

In addition, we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their respective implementing regulations, including the Final Omnibus Rule published on January 25, 2013, imposes specified requirements relating to the privacy, security, and transmission of individually identifiable health information on certain types of individuals and organizations. In addition, certain state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other and from HIPAA in significant ways and may not have the same effect, thus complicating compliance efforts.

The failure to comply with regulatory requirements subjects us to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in significant criminal, civil and/or administrative penalties, damages, fines, disgorgement, exclusion from participation in federal healthcare programs, such as Medicare and Medicaid, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of product approvals, refusal to allow us to enter into supply contracts, including government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

We plan to develop a comprehensive compliance program that establishes internal controls to facilitate adherence to the law and program requirements to which we will or may become subject because we intend to commercialize products that could be reimbursed under a federal healthcare program and other governmental healthcare programs.

Changes in law or the interpretation of existing law could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products;

or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

Healthcare Legislative Reform

In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our products profitably. In particular, in 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the ACA, was enacted, which, among other things, subjected biologic products to potential competition by lower-cost biosimilars; addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations; subjected manufacturers to new annual fees and taxes for certain branded prescription drugs; created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (increased to 70% pursuant to the Bipartisan Budget Act of 2018, effective as of January 1, 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; and provided incentives to programs that increase the federal government's comparative effectiveness research.

Since its enactment, there have been judicial, Congressional, and executive challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how other healthcare reform measures of the Biden administration or other efforts, if any, to challenge, repeal or replace the ACA will impact our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted.

- In August 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals for deficit reduction of at least $1.2 trillion for the years 2013 through 2021. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction, which triggered the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of, up to 2% per fiscal year, and, due to subsequent legislative amendments, will remain in effect through 2030 unless Congress takes additional action. These reductions went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030 unless additional action is taken by Congress. Pursuant to the Coronavirus Aid, Relief, and Economic Security Act, also known as the CARES Act, as well as subsequent legislation, these reductions have been suspended from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic. Then, a 1% payment reduction will occur beginning April 1, 2022 through June 30, 2022, and the 2% payment reduction will resume on July 1, 2022.
- In January 2013, the American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.
- On April 13, 2017, CMS published a final rule that gives states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces.
- On May 30, 2018, the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.
- On May 23, 2019, CMS published a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020.
- On December 20, 2019, former President Trump signed into law the Further Consolidated Appropriations Act (H.R. 1865), which repealed the Cadillac tax, the health insurance provider tax, and the medical device excise tax. It is impossible to determine whether similar taxes could be instated in the future.

There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among

other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At a federal level, President Biden signed an Executive Order on July 9, 2021 affirming the administration's policy to (i) support legislative reforms that would lower the prices of prescription drug and biologics, including by allowing Medicare to negotiate drug prices, by imposing inflation caps, and, by supporting the development and market entry of lower-cost generic drugs and biosimilars; and (ii) support the enactment of a public health insurance option. Among other things, the Executive Order also directs HHS to provide a report on actions to combat excessive pricing of prescription drugs, enhance the domestic drug supply chain, reduce the price that the Federal government pays for drugs, and address price gouging in the industry; and directs the FDA to work with states and Indian Tribes that propose to develop section 804 Importation Programs in accordance with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and the FDA's implementing regulations. FDA released such implementing regulations on September 24, 2020, which went into effect on November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. On September 25, 2020, CMS stated drugs imported by states under this rule will not be eligible for federal rebates under Section 1927 of the Social Security Act and manufacturers would not report these drugs for "best price" or Average Manufacturer Price purposes. Since these drugs are not considered covered outpatient drugs, CMS further stated it will not publish a National Average Drug Acquisition Cost for these drugs. If implemented, importation of drugs from Canada may materially and adversely affect the price we receive for any of our product candidates. Further, on November 20, 2020 CMS issued an Interim Final Rule implementing the Most Favored Nation, or MFN, Model under which Medicare Part B reimbursement rates would have been calculated for certain drugs and biologicals based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita. However, on August 6, 2021 CMS announced a proposed rule to rescind the Most Favored Nations rule. Additionally, on November 30, 2020, HHS published a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. Pursuant to court order, the removal and addition of the aforementioned safe harbors were delayed and recent legislation imposed a moratorium on implementation of the rule until January 1, 2026. 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.

In addition, there have been several changes to the 340B drug pricing program, which imposes ceilings on prices that drug manufacturers can charge for medications sold to certain health care facilities. On December 27, 2018, the District Court for the District of Columbia invalidated a reimbursement formula change under the 340B drug pricing program, and CMS subsequently altered the FYs 2019 and 2018 reimbursement formula on specified covered outpatient drugs ("SCODs"). The court ruled this change was not an "adjustment" which was within the Secretary's discretion to make but was instead a fundamental change in the reimbursement calculation. However, most recently, on July 31, 2020, the U.S. Court of Appeals for the District of Columbia Circuit overturned the district court's decision and found that the changes were within the Secretary's authority. On September 14, 2020, the plaintiffs-appellees filed a Petition for Rehearing En Banc (i.e., before the full court), but was denied on October 16, 2020. Plaintiffs-appellees filed a petition for a writ of certiorari at the Supreme Court on February 10, 2021. On Friday July 2, 2021, the Supreme Court granted the petition. It is unclear how these developments could affect covered hospitals who might purchase our future products and affect the rates we may charge such facilities for our approved products in the future, if any. Although a number of these, and other proposed measures will require authorization through additional legislation to become effective, Congress has indicated that it may continue to seek new legislative and/or administrative measures to control drug costs.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

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

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. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

European Union Drug Review and Approval

Clinical Trial Approval

In the EU, an applicant for authorization of a clinical trial must obtain prior approval from the national competent authority of the EU Member States in which the clinical trial is to be conducted. Furthermore, the applicant may only start a clinical trial at a specific study site after the relevant independent ethics committee has issued a favorable opinion. In April 2014, the EU adopted the new Clinical Trials Regulation (EU) No 536/2014, which replaced the Clinical Trials Directive 2001/20/EC on January 31, 2022. It overhauls the system of approvals for clinical trials in the EU. Specifically, the new legislation, which is directly applicable in all EU Member States (meaning that no national implementing legislation in each EU Member State is required), aims at simplifying and streamlining the approval of clinical trials in the EU. For instance, the new Clinical Trials Regulation provides for a streamlined application procedure via a single-entry point (instead of submitting applications separately to each national competent authority and ethics committee in the Member States in which the trial will be conducted) and strictly defined deadlines for the assessment of clinical trial applications. The Clinical Trials Regulation also makes it more efficient for EU Member States to evaluate and authorize applications together, via the Clinical Trials Information System. The transitory provisions of the new Clinical Trials Regulation offer sponsors the possibility to choose between the requirements of the previous Clinical Trials Directive and the Clinical Trials Regulation if the request for authorization of a clinical trial is submitted in the year after the new Clinical Trials Regulation became applicable. If the sponsor chooses to submit under the Clinical Trials Directive, the clinical trial continues to be governed by the Directive until three years after the new Clinical Trials Regulation became applicable. If a clinical trial continues for more than three years after the Clinical Trials Regulation became applicable, the Clinical Trials Regulation will at that time begin to apply to the clinical trial.

Marketing Authorization

In the European Union, medicinal products can only be commercialized after obtaining a marketing authorization. There are two types of marketing authorizations: (1) the centralized authorization, which is issued by the European Commission through the centralized procedure based on the opinion of the Committee for Medicinal Products for Human Use (“CHMP”), a body of the EMA, and which is valid throughout the entire territory of the European Economic Area, or EEA (comprising the EU Member States plus Norway, Iceland and Liechtenstein); and (2) national marketing authorizations, which is issued by the competent authorities of the Member States of the EU and only authorize marketing in that Member State’s national territory and not the EEA as a whole.

The centralized procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, advanced therapy medicinal products (i.e., gene-therapy, somatic cell-therapy, and tissue-engineered medicines) and medicinal products containing a new active substance indicated for the treatment of HIV / AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune diseases and other immune dysfunctions and viral diseases. The centralized procedure is optional for products containing a new active substance not yet authorized in the EU, or for products that constitute a significant therapeutic, scientific, or technical innovation or which are in the interest of public health. Gene therapy products are a type of advanced therapy medicinal product (“ATMP”) in the EU. The scientific evaluation of marketing authorization applications for ATMPs is primarily performed by a specialized scientific committee called the Committee for Advanced Therapies (“CAT”). The CAT prepares a draft opinion on the quality, safety, and efficacy of the ATMP which is the subject of the marketing authorization application, which is sent for final approval to the CHMP. The CHMP recommendation is then sent to the European Commission, which adopts a decision binding in all EEA Member States. The maximum timeframe for the evaluation of a marketing authorization application for an ATMP is 210 days from receipt of a valid application, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CAT and/or CHMP. Clock stops may extend the timeframe of evaluation of an application considerably beyond 210 days. Where the CHMP gives a positive opinion, the EMA provides the opinion together with supporting documentation to the European Commission, who make the final decision to grant a marketing authorization, which is issued within 67 days of receipt of the EMA’s recommendation. Accelerated assessment may be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from the point of view of public health and, in particular, from the viewpoint of therapeutic innovation. If the CHMP accepts such a request, the timeframe of 210 days for assessment will be reduced to 150 days (excluding clock stops), but it is possible that the CHMP may revert to the standard time limit for the centralized procedure if it determines that the application is no longer appropriate to conduct an accelerated assessment. The development and evaluation of a gene therapy medicinal product must be considered in the context of the relevant EU guidelines, and the EMA may issue new guidelines concerning the development and marketing authorization for gene therapy medicinal products and require that we comply with these new guidelines.

National marketing authorizations are for products not falling within the mandatory scope of the centralized procedure. Where a product has already been authorized for marketing in a Member State of the EU, this marketing authorization can be recognized in another Member States through the mutual recognition procedure. If the product has not received a national marketing authorization in any Member State at the time of application, it can be approved simultaneously in various Member States through the decentralized procedure. Under the decentralized procedure an identical dossier is submitted to the competent authorities of each of the Member States

in which an authorization is sought, one of which is selected by the applicant as the Reference Member State ("RMS"). If the RMS proposes to authorize the product, and the other Member States do not raise objections, the product is granted a national marketing authorization in all the Member States where the authorization was sought.

Under the above-described procedures, before granting the MAA, the EMA or the competent authorities of the Member States of the EU make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety, and efficacy.

Now that the UK (which comprises Great Britain and Northern Ireland) has left the EU, Great Britain will no longer be covered by centralized marketing authorizations (under the Northern Ireland Protocol, centralized marketing authorizations will continue to be recognized in Northern Ireland). All medicinal products with a current centralized marketing authorization were automatically converted to Great Britain marketing authorizations on January 1, 2021. For a period of two years from January 1, 2021, the Medicines and Healthcare products Regulatory Agency, or MHRA, the UK medicines regulator, may rely on a decision taken by the European Commission on the approval of a new marketing authorization in the centralized procedure, in order to more quickly grant a new Great Britain marketing authorization. A separate application will, however, still be required.

Regulatory exclusivity

In the EU, innovative products authorized for marketing (i.e., reference products) may qualify for eight years of data exclusivity and an additional two years of market exclusivity upon marketing authorization. The data exclusivity period prevents generic or biosimilar applicants from relying on the preclinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar marketing authorization in the EU during a period of eight years from the date on which the reference product was first authorized in the EU. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until ten years have elapsed from the initial authorization of the reference product. The ten-year market exclusivity period can be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. Even if an innovative medicinal product gains the prescribed period of data exclusivity, however, another company may market another version of the product if such company obtained marketing authorization based on a marketing authorization application with a completely independent data package of pharmaceutical tests, preclinical tests, and clinical trials.

Orphan designation and exclusivity

The criteria for designating an orphan medicinal product in the EU, are similar in principle to those in the U.S. Under Article 3 of Regulation (EC) 141/2000, a medicinal product may be designated as orphan if the following criteria are fulfilled: (i) it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (ii) either (a) such condition affects no more than five in 10,000 persons in the EU when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the EU to justify the necessary investment in its development; and (iii) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU, or if such a method exists, the product will be of significant benefit to those affected by the condition, as defined in Regulation (EC) 847/2000. Orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers and are, upon grant of a marketing authorization, entitled to ten years of market exclusivity for the approved therapeutic indication. The application for orphan designation must be submitted before the application for marketing authorization. The applicant will receive a fee reduction for the marketing authorization application if the orphan designation has been granted, but not if the designation is still pending at the time the marketing authorization is submitted. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The ten-year market exclusivity may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation, for example, if the product is sufficiently profitable not to justify maintenance of market exclusivity. Otherwise, orphan medicine marketing exclusivity may be revoked only in very select cases, such as if:

- a second applicant can establish that its product, although similar to the authorized product, is safer, more effective, or otherwise clinically superior;
- the marketing authorization holder for the authorized product consents to a second orphan medicinal product application; or
- the marketing authorization holder for the authorized product cannot supply enough orphan medicinal product.

The aforementioned EU rules are generally applicable in the EEA.

PRIME designation

In March 2016, the EMA launched an initiative to facilitate development of product candidates in indications, often rare, for which few or no therapies currently exist. The PRIority MEdicines (PRIME), scheme is intended to encourage drug development in areas of unmet medical need and provides accelerated assessment of products representing substantial innovation, where the marketing authorization application will be made through the centralized procedure. Eligible products must target conditions for which where is an unmet medical need, i.e., there is no satisfactory method of diagnosis, prevention or treatment in the EU or, if there is, the new medicine will bring a major therapeutic advantage) and they must show potential to benefit patients with unmet medical needs based on early clinical data. Products from small- and medium-sized enterprises may qualify for earlier entry into the PRIME scheme than larger companies. Many benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and accelerated marketing authorization application assessment once a dossier has been submitted. Importantly, a dedicated contact and rapporteur from the EMA's CHMP or Committee for Advanced Therapies are appointed early in PRIME scheme facilitating increased understanding of the product at the EMA's committee level. A kick-off meeting initiates these relationships and includes a team of multidisciplinary experts at the EMA to provide guidance on the overall development and regulatory strategies. Where, during the course of development, a medicine no longer meets the eligibility criteria, support under the PRIME scheme may be withdrawn.

Brexit and the Regulatory Framework in the United Kingdom

In June 2016, the electorate in the UK voted in favor of leaving the EU (commonly referred to as "Brexit"), and the UK formally left the EU on January 31, 2020. There was a transition period during which EU pharmaceutical laws continued to apply to the UK, which expired on December 31, 2020. However, the EU and the UK have concluded a trade and cooperation agreement, or TCA, which was provisionally applicable since January 1, 2021 and has been formally applicable since May 1, 2021. The TCA includes specific provisions concerning pharmaceuticals, which include the mutual recognition of GMP, inspections of manufacturing facilities for medicinal products and GMP documents issued but does not foresee wholesale mutual recognition of UK and EU pharmaceutical regulations. At present, Great Britain has implemented EU legislation on the marketing, promotion and sale of medicinal products through the Human Medicines Regulations 2012 (as amended) (under the Northern Ireland Protocol, the EU regulatory framework will continue to apply in Northern Ireland). The regulatory regime in Great Britain therefore largely aligns with current EU regulations, however it is possible that these regimes will diverge in future now that Great Britain's regulatory system is independent from the EU and the TCA does not provide for mutual recognition of UK and EU pharmaceutical legislation. For example, the UK has implemented the now repealed Clinical Trials Directive 2001/20/EC into national law through the Medicines for Human Use (Clinical Trials) Regulations 2004 (as amended). The extent to which the regulation of clinical trials in the UK will mirror the new Clinical Trials Regulation now that has come into effect is not yet known, however the Medicines and Healthcare products Regulatory Agency ("MHRA"), the UK medicines regulator, has opened a consultation on a set of proposals designed to improve and strengthen the UK clinical trials legislation. Such consultation is open until 14 March 2022.

The Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act, or the FCPA, prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring us to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Additional Regulation

In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern our use, handling and disposal of various biological, chemical and radioactive substances used in, and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. We believe that we are in material compliance with applicable environmental laws and that continued compliance therewith will not have a material adverse effect on our business. We cannot predict, however, how changes in these laws may affect our future operations.

Other Regulations

We are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances. We may incur significant costs to comply with such laws and regulations now or in the future.

Human Capital

As of March 4, 2022, we had 104 full-time employees and 1 part-time employee, 30 of whom have Ph.D. or M.D. degrees. Of these full-time employees, 82 employees are engaged in research and development activities and 23 are engaged in finance, business development and other general and administrative functions. None of our employees are represented by labor unions or covered by collective bargaining agreements, and we have not experienced any work stoppages. We consider our relations with our employees to be good.

We recognize that attracting, motivating and retaining talent at all levels is vital to our continued success. Our employees are a significant asset, and we aim to create an equitable, inclusive and empowering environment in which our employees can grow and advance their careers, with the overall goal of developing, expanding and retaining our workforce to support our current pipeline and future business goals. By focusing on employee retention and engagement, we also improve our ability to support our clinical trials, our pipeline, our platform technologies, business and operations, and also protect the long-term interests of our securityholders.

Our success also depends on our ability to attract, engage and retain a diverse group of employees. Our efforts to recruit and retain a diverse and passionate workforce include providing competitive compensation and benefits packages and ensuring we listen to our employees.

We value innovation, passion, data-driven decision making, persistence and honesty, and are building a diverse environment where our employees can thrive and be inspired to make exceptional contributions to bring novel and more effective therapies to cancer patients.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, motivating and integrating our existing and future employees. The principal purposes of our equity incentive plans are to attract, retain and motivate selected employees, consultants and directors through grants of stock-based compensation awards and payments of cash-based performance bonus awards, in order to increase stockholder value and the success of our company by motivating our employees to perform to the best of their abilities and achieve our objectives. We are committed to providing a competitive and comprehensive benefits package to our employees. Our benefits package provides a balance of protection along with the flexibility to meet the individual health and wellness needs of our employees. We plan to continue to refine our efforts related to optimizing our use of human capital as we grow, including improvements in the way we hire, develop, motivate and retain employees.

Facilities

Our facilities are located at two adjacent leased sites, both located at 830 Winter Street, Waltham, Massachusetts, 02451. The first site consists of 25,472 square feet of office and laboratory space and is primarily used for research, clinical, manufacturing, and corporate activities. Our lease expires September 30, 2024, with an option to extend three years. The second site consists of 14,447 square feet of office and laboratory space and is primarily used for preclinical and clinical research. Our lease on this facility expires on March 31, 2026.

On November 29, 2021, we entered into a lease agreement for an additional approximately 113,487 square feet of office and laboratory space located at 880 Winter Street, Waltham Massachusetts, 02451, which will serve as our headquarters. The term of the lease will commence on the earlier of the date we commence our business operations at the location or when all improvements to the facility are completed and necessary occupancy permits are obtained. The lease will have a term of approximately ten years and two months.

We believe that these facilities are adequate to meet our needs for the immediate future, and that, should it be needed, suitable additional space will be available to accommodate any such expansion of our operations.

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.

Available Information

Our website address is https://www.tscan.com/. The information contained on, or that can be accessed through, our website is not incorporated by reference into this Annual Report on Form 10-K or in any other report or document we have filed or may file with the Securities and Exchange Commission, or SEC, and any reference to our website address is intended to be an inactive textual reference only. We will make available on our website, free of charge, our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and any amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. The SEC maintains an Internet site, http://www.sec.gov, containing reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC.

In addition, we routinely post on the "Investors and Media" page of our website investor and scientific presentations, SEC filings, press releases, public conference calls and webcasts and other statements about our business and results of operations, some of which may contain information that may be deemed material to investors. Accordingly, investors should monitor these portions of our website, in addition to following our press releases, SEC filings, public conference calls and webcasts, as well as our social media channels (our Twitter and LinkedIn). This list of channels may be updated from time to time on our investor relations website and may include other social media channels than the ones described above. The contents of our website or these channels, or any other website that may be accessed from our website or these channels, shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended.

A copy of our Corporate Governance Guidelines, and Code of Conduct are posted on our website, https://www.tscan.com and are available in print to any person who requests copies by contacting us by calling (857) 399-9500 or by writing to TScan Therapeutics, Inc., 830 Winter Street, Waltham, Massachusetts 02451, Attention: Zoran Zdraveski.

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 Annual Report, including the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and the accompanying notes included elsewhere in this Annual Report and in our final prospectus for our IPO. 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.

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 include, but are not limited to, the following:

Risks Related to Our Business and Industry

- 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.
- We have incurred significant losses since inception, and we expect to incur losses over the next several years and may not be able to achieve or sustain revenues or profitability in the future.
- We have never generated, and may never generate, any revenue from sales of cell therapy products.
- We will need to obtain substantial additional funding to complete the development and any commercialization of our product candidates, if approved.
- 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.
- Global economic uncertainty and financial market volatility caused by political instability, changes in international trade relationships and conflicts, such as the conflict between Russia and Ukraine, could make it more difficult for us to access financing and could adversely affect our business and operations.

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.
- 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 no direct experience as a company in conducting clinical trials or 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 the evolving effects of the COVID-19 pandemic and responses thereto.
- 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 stem cell transplantation is a high-risk procedure with curative potential that may result in complications or adverse events for patients in our clinical trials 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 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.
- We plan to expand our existing manufacturing facility and infrastructure in lieu of relying on third parties for the manufacture of our product candidates for certain clinical purposes, which will be costly and time-consuming and 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.
- 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.
- Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval for and commercialize our product candidates and affect the prices we may obtain.

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 may be adversely affected.
- We are currently, and expect in the future to be, party to material license or collaboration agreements.
- 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

- If the third parties we plan to rely on to conduct our clinical trials do not properly and successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates.
- We may not realize the benefits of our current or future collaborations, alliances, or licensing arrangements.

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 not yet initiated our first clinical trial. 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.

We have incurred significant net losses in each period since our inception in April 2018. For the years ended December 31, 2019 and 2020, we reported net losses of $13.7 million and $26.1 million, respectively, and $15.8 million and $48.6 million for the three and twelve months ended December 31, 2021, respectively. As of December 31, 2021, we had an accumulated deficit of $92.2 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 investigational new drug applications, or 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 then expand our manufacturing capabilities;
- 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.

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 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 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 to discover the natural targets of clinically relevant TCRs through our TargetScan technology, to discover highly active TCRs for known targets through our ReceptorScan technology, to genetically engineer patient- or donor-derived T cells safely and reproducibly through our T-Integrate technology, to obtain regulatory approval for product candidates derived from our proprietary platform and related technologies, and to then commercialize our product candidates addressing one or more indications. All of our product candidates will require significant additional clinical and non-clinical development, review and approval by the FDA or other regulatory authorities in one or more jurisdictions, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before they can be successfully commercialized. Our 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 preclinical-stage immunotherapy 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 collaborations, establishing manufacturing for initial quantities of our product candidates, and establishing arrangements for component materials for such manufacturing. All of our product candidates are still in preclinical development. We have not yet demonstrated our ability to successfully initiate, 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. All of our product candidates are in the preclinical stages of development and will require additional preclinical studies, process development, clinical development, regulatory review and approval, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before we can generate any revenue from product sales. None of our product candidates have completed IND-enabling studies. TSC-100, one of our lead product candidates targeting HA-1, an epitope present on leukemia cells, is in the early stages of development and has not yet been evaluated in clinical trials and will require additional regulatory review and approval, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before we can generate any revenue from product sales. Our other product candidates are in early preclinical stages. We have not yet administered any of our product candidates in humans and, as such, we face significant translational risk as our product candidates advance 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 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 complete IND-enabling studies and successfully submit INDs or comparable applications;
- whether we are required by the U.S. Food and Drug Administration (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 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 liquid or solid tumors;

- our ability and the ability of third parties with whom we contract to manufacture adequate clinical and commercial supplies of our product candidates or any future product candidates, remain in good standing with regulatory authorities and develop, validate and maintain commercially viable manufacturing processes that are compliant with 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 commercialize 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 and through our initial public offering. 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 December 31, 2021, we had $161.4 million in cash and cash equivalents. Based on our current operating plan, we believe that our existing cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements into 2024. Accordingly, our existing cash and cash equivalents will not be sufficient for us to fund any of our product candidates through regulatory approval, and we will need to raise substantial additional capital to complete the development and commercialization of our product candidates through equity offerings, debt financings, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements or other sources. We may also need to raise additional funds sooner if we choose to pursue additional indications for our product candidates or otherwise expand more rapidly than we presently anticipate.

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

- the scope, rate of progress, costs and results of our drug discovery, preclinical 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;
- the 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 conflict between Russia and Ukraine, 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 an escalation in conflict between Russia and Ukraine, including any 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.

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 liquid 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 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 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 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 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 and delaying 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 very early in our development efforts. All of our product candidates are still in preclinical development. 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 very early in our development efforts. All of our product candidates are still in preclinical development, with TSC-100, our most advanced product candidate, still in preclinical development and not having completed IND-enabling studies. 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 establishing 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 no direct 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 no direct experience as a company in conducting clinical trials at TScan. 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 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.

We currently intend to further expand our existing cell manufacturing facility for Phase 1 and Phase 2 clinical trials, which will require significant resources, and 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 the 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) 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 in 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 preclinical studies or our planned IND-enabling studies of TSC-100, TSC-101, TSC-102, TSC-200, TSC-201, TSC-202, and TSC-203 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 program 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 collaboration, 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 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, including as a result of actions taken by governments and individuals in response to the COVID-19 pandemic;
- having subjects complete a clinical trial or return for post-treatment follow-up;
- clinical trial sites deviating from 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;
- the effects of the ongoing COVID-19 global 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 (DSMB) 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 the evolving 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. The COVID-19 pandemic has had and may continue have a material effect on our operations as well as the business or operations of our partners or other third parties with whom we or our partners conduct business.

Health epidemics in regions where we have concentrations of potential clinical trial sites or other business operations could adversely affect our business, including by causing significant disruption in the operations of third parties upon whom we rely. For example, the COVID-19 pandemic has presented a substantial public health and economic challenge around the world and is affecting employees, patients, communities and business operations, as well as the U.S. economy and financial markets. Our headquarters is located in the Greater Boston Area. In addition, several of our third party suppliers and contractors are located in countries and regions that have been negatively impacted by the COVID-19 global pandemic. In March 2020, the U.S. government imposed bans and restrictions on travel between the United States, Asia and certain other continents and countries and other countries have restricted travel to and from the United States. Although, the Commonwealth of Massachusetts has permitted businesses to re-open on a limited basis, we have implemented work-from-home policies for a vast majority of our employees. While we have implemented what we believe to be a reasonable protocol to ensure the safety and wellbeing of employees returning to the office, these measures may not be sufficient to mitigate the risks posed by the virus or otherwise be satisfactory to government authorities. The effects of our work-from-home policies may negatively impact productivity, disrupt our business and delay our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of any current or future restrictions and other limitations on our ability to conduct our business in the ordinary course. 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, including any determinations that we may make to continue to operate or to re-open our facilities where permitted by applicable law. These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, financial condition, results of operations and growth prospects.

In addition, our planned clinical trials may be affected by the COVID-19 outbreak. Site initiation and patient enrollment may be delayed due to prioritization of hospital resources toward the COVID-19 outbreak. Some patients may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 and adversely impact our planned clinical trial operations.

Furthermore, while the potential economic impact brought by, and the duration of, the COVID-19 pandemic may be difficult to assess or predict, the pandemic could result in significant and prolonged disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. 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 we expect the COVID-19 pandemic to continue to adversely affect our business operations, 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, such as the ultimate duration of the pandemic, travel restrictions, quarantines, social distancing and business closure requirements in the U.S. and in other countries, and the effectiveness of actions taken globally to contain and treat COVID-19. In addition, to the extent the evolving effects of 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 currently intend to establish facilities to manufacture our clinical scale product candidates for our Phase 1 and Phase 2 clinical trials for TSC-100, TSC-101, TSC-102, TSC-200, TSC-201, TSC-202, and TSC-203. 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 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 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 contract manufacturers, we may not control the manufacturing process of, and may be completely dependent on, such 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 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 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 ongoing COVID-19 pandemic, the U.S.-China trade war or unstable political environments. If we or any 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 TSC-200, 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 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 hematopoietic cell transplantation are very sick and may pass away from complications of their standard clinical transplantation 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 hematopoietic stem cell transplantation is a high-risk procedure with curative potential that may result in complications or adverse events for patients in our clinical trials 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 hematopoietic stem cell transplantation, 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 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 submitted INDs for TSC-100 and TSC-101 in the fourth quarter of 2021 and expect to submit IND applications for at least two of our four solid tumor TCR-T therapy candidates in the second half of 2022, with the remaining expected to be filed in 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). We cannot guarantee, however, that the FDA will permit us to combine our product candidates with each other in a multiplexed TCR-T therapy before more extensive safety data are available 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 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 the TCR-T treatment. GvHD is a common toxicity in patients undergoing allogeneic hematopoietic stem cell transplantation, the focus of our liquid tumor 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 a 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 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 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 or lentiviral vectors 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 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 liquid tumor 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 liquid tumor 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;
- the 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 patients 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 hematopoietic stem cell transplantation, 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 it 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 hematopoietic stem cell transplantation 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 hematopoietic stem cell transplantation. 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, or 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 weathering the effects of the ongoing COVID-19 global pandemic. 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 multiple companies, including Kite Pharma Inc., a subsidiary of Gilead, Inc., Adaptimmune Therapeutics, Plc., Juno Therapeutics, Inc., a subsidiary of Bristol-Myers Squibb, Inc. (including Yescarta, which is approved for the treatment for your large B-cell lymphoma or follicular lymphoma, two types of non-Hodgkin lymphoma), Iovance Biotherapeutics, Inc., Achilles Therapeutics plc, Geneos Therapeutics, Inc., PACT Pharma, Inc., Celyad, S.A., Fate Therapeutics, Inc., Nkarta, Inc., Medigene AG, Ziopharm Oncology, Inc., Bayer AG, Novartis AG (including Kymriah, which is approved for the treatment of B-cell acute lymphoblastic leukemia), Selecta Biosciences, Inc., TCR2 Therapeutics Inc., Adaptive Therapeutics, Inc., Immatics US, Inc., Lyell Immunopharma, Inc., Allogene Therapeutics, Inc., Sana Biotechnology, Inc., 3T Biosciences, Inc. and Regeneron Pharmaceuticals, Inc. 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. 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.

Although we plan to further expand our existing manufacturing facility, 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.

We plan to further expand our existing manufacturing facility and infrastructure in lieu of relying on third parties for the manufacture of our product candidates for certain clinical purposes and the use of third party manufacturing suites, which will be costly, time-consuming, and which may not be successful.

We are in the process of expanding our existing manufacturing capacity to support our Phase 1 and Phase 2 clinical trials for TSC-100, TSC-101, TSC-102, TSC-200, TSC-201, TSC-202, and TSC-203. We have no 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. Even if we are successful in establishing a manufacturing suite or 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.

We have limited process development experience and have not yet established lot to lot or donor consistency with healthy or unhealthy donors. 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 contract manufacturing organizations (CMOs). In addition, if we make manufacturing changes to our product candidates in the future, we may need to conduct additional preclinical or clinical studies 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 TSC-100, TSC-101, TSC-102, TSC-200, TSC-201, TSC-202, and TSC-203 and some of our other 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 TSC-100, TSC-101, TSC-102, TSC-200, TSC-201, TSC-202, and TSC-203 and some or all of our other 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. 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 TSC-100, TSC-101, TSC-102, TSC-200, TSC-201 and TSC-202 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 TSC-100 and 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 TSC-102, TSC-200, TSC-201, TSC-202, and TSC-203 or any other 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 TSC-100, TSC-101, TSC- 200, TSC-201, TSC 202, and TSC-203 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.

Accelerated approval by the FDA, even if granted for TSC-100, TSC-101, TSC-102, TSC-200, TSC-201, TSC-202, and TSC-203 or any other 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 TSC-100, TSC-101, TSC-102, TSC-200, TSC-201, TSC-202, and TSC-203, 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 as a condition for accelerated approval pre-approval of promotional materials, 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 or regulatory review or approval process, and receiving accelerated approval does not provide assurance of ultimate FDA approval.

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, the United Kingdom left the European Union on January 31, 2020, an event commonly referred to as "Brexit," and following the "transition period," on December 30, 2020, the European Union, the European Atomic Energy Community and the United Kingdom signed a Trade and Cooperation Agreement. Brexit imposes new regulatory costs and challenges that may have a material adverse effect on us and our operations. We may face decreased chances to obtain market approval for our product candidates in the European Union, including the possibility that the European Medicines Agency will not accept data from our clinical trials conducted in the United Kingdom or will only do so if we comply with certain conditions. Conversely, since a significant proportion of the United Kingdom's regulatory framework affecting the pharmaceutical and biotechnological industry is derived from European Union directives and regulations, Brexit could materially alter the regulatory regime with respect to our product candidates in the United Kingdom, which may increase the time and costs associated with obtaining regulatory approval from the relevant authorities. It may also be time-consuming and expensive for us to alter our internal operations in order to comply with new regulations. Altered regulations could also add time and expense to the process by which our product candidates receive regulatory approval in the United Kingdom and the European Union.

Furthermore, following the Brexit vote, the European Union moved the European Medicines Agency's headquarters from the United Kingdom 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 European Union and/or the United Kingdom.

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. 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;
- 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.

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 gene 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 CMS, an agency within 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.

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. Our inability to promptly obtain coverage and profitable reimbursement rates third party 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.

Increasingly, third party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement. 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.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval for and commercialize our product candidates and affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

In the United States, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (Affordable Care Act or ACA), was signed into law, intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

Among the provisions of the Affordable Care Act that are of importance to our potential product candidates are the following:

- an annual, nondeductible fee payable by any entity that manufactures, or imports specified branded prescription drugs and biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- an increase in the discount rate for the federal 340B program to eligible hospitals;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% point-of-sale discounts off negotiated prices;
- extension of manufacturers' Medicaid rebate liability;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, and we expect there will be additional challenges and amendments to the Affordable Care Act in the future. For example, legislation informally titled the Tax Cuts and Jobs Acts (TCJA) was enacted, which, among other things, removed penalties for not complying with the individual mandate to carry health insurance. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, ruled that the individual mandate is a critical and inseverable feature of the Affordable Care Act, and therefore, because it was repealed as part of the TCJA, the remaining provisions of the Affordable Care Act are invalid as well. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court's decision that the individual mandate was unconstitutional but remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The U.S. Supreme Court is currently reviewing the case, although it is unclear when the Supreme Court will make a decision. It is also unclear how other efforts to challenge, repeal or replace the Affordable Care Act will affect the law or our business.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. In August 2011, the Budget Control Act of 2011, among other things, included aggregate reductions of Medicare payments to providers of 2% per fiscal

year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2021, unless additional Congressional action is taken. In addition, on January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers, including hospitals, and an increase in the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain.

We expect that other healthcare reform measures that may be adopted in the future may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates, if approved.

Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. Individual states in the United States have become increasingly aggressive in implementing regulations designed to contain pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. Legally mandated price controls on payment amounts by third party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidates, if approved, or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

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.

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 the Office of Tissues and Advanced Therapies within its Center for Biologics Evaluation and Research to consolidate the review of gene therapy and related products, and has established the Cellular, Tissue and Gene Therapies Advisory Committee, among others, to advise this review. Recently, the National Institutes of Health proposed to revise its guidelines for overseeing gene therapy research, including deleting the protocol registration and reporting requirements for certain therapies and eliminating Recombinant DNA Advisory Committee review and reporting requirements for human gene transfer research.

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.

Separately, in response to the global COVID-19 pandemic, on March 10, 2020, the FDA announced its intention to postpone most foreign inspections of manufacturing facilities and products through April 2020, and subsequently, on March 18, 2020, the FDA announced its intention to temporarily postpone routine surveillance inspections of domestic manufacturing facilities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

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. The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in

cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs;

- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other third party payors that are false or fraudulent or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (for example, public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization;
- the federal Physician Payment Sunshine Act, created under the Affordable Care Act and its implementing regulations, which require manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to HHS information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

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, or the 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 of 2018, or CCPA, which increases privacy rights for California residents and imposes obligations on companies that process their personal information and meet certain revenue or volume processing thresholds, came into effect on January 1, 2020, and was further amended by the California Privacy Rights Act (CPRA) on November 3, 2020. 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 CPRA significantly modifies the CCPA by expanding residents' rights with respect to certain personal information and creates a new state agency to oversee implementation and enforcement efforts. Many of the CPRA's provisions will become effective on January 1, 2023. 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. 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. 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 EU General Data Protection Regulation (GDPR), which became effective on May 25, 2018, is wide-ranging in scope and imposes numerous requirements on companies that process personal data. Specifically, the GDPR greatly increased the European's Commission's jurisdictional reach of its data privacy and security laws and introduced a broad array of requirements for handling personal data, including, for example, requirements to establish a legal basis for processing, higher standards for obtaining consent from individuals to process their personal data, more robust disclosures to individuals, a strengthened individual data rights regime, requirements to implement safeguards to protect the security and confidentiality of personal data that requires the adoption of administrative, physical and technical safeguards, shortened timelines for data breach notifications to appropriate data protection authorities or data subjects, limitations on retention and secondary use of information, increased requirements pertaining to health data and obligations to take certain measures when engaging third party processors in connection with the processing of personal data. EU member states are tasked under the GDPR to enact, and have enacted, certain implementing legislation that adds to and/or further interprets the GDPR requirements and potentially extends our obligations and potential liability for failing to meet such obligations. The GDPR, together with national legislation, regulations and guidelines of the EU member states governing the processing of personal data, impose strict obligations and restrictions on the ability to collect, use, retain, disclose, transfer and otherwise process personal data. In particular, the GDPR also imposes strict obligations, restrictions and rules concerning the rights of individuals to whom the personal data relates, the transfer of personal data to countries outside the

European Economic Area, including the United States, security breach notifications and the security and confidentiality of personal data. 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, and other administrative penalties. 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. 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. Following the withdrawal of the United Kingdom from the European Union, data privacy and security laws that are substantially similar to the GDPR are in effect in the United Kingdom, which carry similar risks and authorize similar fines for certain violations.

Certain legal regimes outside of the United States, including in the United Kingdom and under the GDPR, prohibit the transfer of personal data to the United States unless certain measures are in place, including, for example, executing Standard Contractual Clauses, or historically, relying on the receiving entity's certification under the EU-US and/or Swiss-US Privacy Shield Frameworks, or the Privacy Shield Frameworks. The Privacy Shield Frameworks were invalidated, and the adequacy of Standard Contractual Clauses is now in question, following the Court of Justice of the European Union's July 2020 decision in the so-called Schrems II case (Data Protection Commissioner v. Facebook Ireland Limited, Maximillian Schrems (Case C-311/18)). There is no guarantee that any transfer mechanism upon which we rely will be deemed to be valid by the relevant legal authorities, or that mechanisms that are currently deemed to be valid will remain valid in the future. This uncertainty, and its eventual resolution, may increase our costs of compliance, impede our ability to transfer data and conduct our business and harm our business or results of operations.

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.

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 a very early stage. In particular, we do not own or exclusively license any issued patents and all of the patent applications we own are provisional applications. In addition, although we plan to file patent applications with respect to TSC-102, TSC-200, TSC-202, and TSC-203, we currently have not filed any patent applications with respect to these product candidates. Accordingly, our current patent rights do not provide us any legal right to prevent third parties from competing with us in any way. 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 in the United States 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. (or 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 (or "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.

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 agreement, including:

- the scope of rights granted under the license 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 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 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 do not have any issued patents, but our pending owned U.S. provisional patent applications include claims that cover compositions of matter of our TSC-100 and TSC-101 TCR-T therapy 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. As of April 16, 2021, our patent portfolio consisted of one patent family exclusively licensed

from BWH, which family includes one pending U.S. non-provisional patent application and six pending foreign non-provisional patent applications directed to a granzyme B (GzB)-based antigen screening technology platform compositions of matter and certain screening methods thereof, and seven patent families encompassing an aggregate of 16 U.S. provisional patent applications. The claims of these patent applications are drawn to subject matter in the following main technology areas: certain compositions of matter directed to SARS-CoV-2 immunodominant antigens, anti-SARS-CoV-2 TCRs, anti-SARS-CoV-2 vaccines, anti-HA-1 TCRs (including the TSC-100 TCR-T therapy candidate), anti-HA-2 TCRs (including the TSC-101 TCR-T therapy candidate), TCRs targeting the antigen of TSC-201, and certain therapeutic and diagnostic uses thereof, as well as a phospholipid scrambling reporter-based T cell antigen screening platform and certain screening methods thereof. 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 2042, 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, or the 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 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.

In the United States, we have filed only provisional patent applications, and outside the United States we have made no filings; our only rights outside the United States consist of seven pending patent applications that we exclusively license from BWH. 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, or the 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 European Union. 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. For example, our existing Collaboration and License Agreement with Novartis Institutes for BioMedical Research, Inc. (Novartis) grants Novartis options to obtain exclusive, worldwide licenses to certain target antigens identified in performance of such agreement and corresponding T-cell receptors for such target antigens. In addition, our collaboration agreements may place restrictions or additional obligations on our ability to license additional compounds in different indications, targets, diseases or geographical locations. If we fail to comply with or breach any provision of a collaboration agreement, a collaborator may have the right to terminate, in whole or in part, such agreement or to seek damages. Many of our collaborators also have the right to terminate the collaboration agreement for convenience. For example, Novartis may terminate its Collaboration and License Agreement with us at any time for any or no reason upon 90 days' notice. 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 are in the process of adding manufacturing capacity at our facilities in Waltham, which we expect to be operational in the second fiscal quarter of 2021, but the build-out and staffing of the manufacturing suite may be delayed and the suite may never become operational. 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 ongoing 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, including our Chief Executive Officer, our Chief Business Officer, and our Chief Scientific Officer. 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 March 4, 2022, we had 104 full-time employees and 1 part-time employee. 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 a greater than 50% change (by value) in its equity ownership 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 IPO, our most recent private placements and other transactions that have occurred over the past three years, we may have experienced, 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, 2020, we had U.S. federal net operating loss carryforwards of $17.6 million and U.S. federal research and development tax credit carryforwards of $1.5 million that expire through 2040 and which could be limited if we experience an "ownership change." The reduction of the corporate tax rate under the TCJA may cause a reduction in the economic benefit of our net operating loss carryforwards and other deferred tax assets available to us. Under the TCJA, federal net operating losses generated after December 31, 2017 will not be subject to expiration.

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 on July 19, 2021. Prior to July 19, 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;
- 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 majority of our outstanding common stock;
- the expiration of market standoff or contractual lock-up agreements;
- 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. Securities and industry analysts do not currently, and may never, publish research on our company. 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 when lock-up periods end. 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. 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, subject to existing market standoff or lock-up agreements.

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 March 4, 2021 our executive officers, directors, and entities affiliated with such persons beneficially owned, in the aggregate, approximately 15% of our outstanding voting stock and approximately 29% 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 $1.07 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 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.

We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, or the other rules and regulations of the Securities and Exchange Commission, or the SEC, or any securities exchange relating to public companies. Compliance with the various reporting and other requirements applicable to public companies requires considerable time and attention of management and we will incur significant legal, accounting and other expenses that we did not incur as a private company. We cannot provide assurance that we will satisfy our obligations as a public company on a timely basis.

In addition, as a public company, it may be more difficult or more costly for us to obtain certain types of insurance, including directors' and officers' liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified personnel to serve on our board of directors, our board committees 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.

We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the rules and regulations of the Nasdaq Global Market, or Nasdaq. The Sarbanes Oxley Act requires, among other things, that we maintain effective disclosure controls

and procedures and internal controls over financial reporting. Commencing with our fiscal year ending December 31, 2022, we must perform system and process design evaluation and testing of the effectiveness of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our Form 10-K filing for that year, as required by Section 404 of the Sarbanes-Oxley Act. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, including through hiring additional financial and accounting personnel, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. This will require that we incur substantial additional professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts. Prior to becoming a public company, we have never been required to test our internal controls within a specified period and, as a result, we may experience difficulty in meeting these reporting requirements in a timely manner.

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

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls over financial reporting, we may not be able to produce timely and accurate financial statements. If that were to happen, our investors could lose confidence in our reported financial information, the market price of our stock could decline and we could be subject to sanctions or investigations by the SEC or other regulatory authorities including equivalent foreign authorities.

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

We cannot specify with any certainty the particular uses of the net proceeds that we will receive from this offering, but we currently expect such uses will include conducting clinical trials for TSC-100, TSC-101, and TSC-102, conducting IND-enabling activities and initiate clinical trials for TSC-200, TSC-201, TSC-202, and TSC-203, continuing development of our pre-clinical discovery programs and platform technologies, further expanding our existing manufacturing facility, and other general corporate purposes, which may include the hiring of additional personnel, capital expenditures and the costs of operating as a public company. 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. 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, including impact of the COVID-19 pandemic; 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

U.S. federal income tax reform could adversely affect us.

On December 22, 2017, the United States enacted the "Tax Cuts and Jobs Act", or TCJA, that significantly reformed the Code. The TCJA, among other things, contained significant changes to corporate taxation, including a reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, the limitation of the tax deduction for net interest expense to 30% of adjusted earnings (except for certain small businesses), the limitation of the deduction for net operating loss carryforwards (NOLs) arising in taxable years beginning after December 31, 2017 to 80% of current year taxable income and elimination of NOL carrybacks for losses arising in taxable years ending after December 31, 2017 (though any such NOLs may be carried forward indefinitely), the imposition of a one-time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, the elimination of U.S. tax on foreign earnings (subject to certain important exceptions), the allowance of immediate deductions for certain new investments instead of deductions for depreciation expense over time, and the modification or repeal of many business deductions and credits. The financial statements contained herein reflect the effects of the TCJA based on current guidance. However, there remain uncertainties and ambiguities in the application of certain provisions of the TCJA, and, as a result, we made certain judgments and assumptions in the interpretation thereof.

As part of Congress's response to the COVID-19 pandemic, the Families First Coronavirus Response Act (FFCR Act) was enacted on March 18, 2020, and the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) was enacted on March 27, 2020. Both contain numerous tax provisions. In particular, the CARES Act retroactively and temporarily (for taxable years beginning before January 1, 2021) suspends application of the 80%-of-income limitation on the use of NOLs, which was enacted as part of the TCJA. It also provides that NOLs arising in any taxable year beginning after December 31, 2017 and before January 1, 2021 are generally eligible to be carried back up to five years. The CARES Act also temporarily (for taxable years beginning in 2019 or 2020) relaxes the limitation of the tax deductibility for net interest expense by increasing the limitation from 30% to 50% of adjusted taxable income.

Regulatory guidance under the TCJA, the FFCR Act and the CARES Act is and continues to be forthcoming and such guidance could ultimately increase or lessen impact of these laws on our business and financial condition. It is also likely that Congress will enact

additional tax legislation in connection with the COVID-19 pandemic, some of which could have an impact on our company. In addition, it is uncertain if and to what extent various states will conform to the TCJA, the FFCR Act or the CARES Act.

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 1B. Unresolved Staff Comments.

Not Applicable

Item 2. Properties

We occupy approximately 25,472 square feet of office and laboratory space in Waltham, Massachusetts under a lease that expires in September 2024 and another 14,447 square feet of space under a sublease that will expire in March 2026. In addition, the Company has entered a lease agreement for 113,487 square feet of space, of which the commencement date is anticipated in November 2022 with an expiration date in December 2032.

Item 3. 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 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Market Information
Our common stock has been publicly traded on The Nasdaq Global Market under the symbol “TCRX” since July 16, 2021. Prior to that time, there was no public market for our common stock.

Holders
As of March 4, 2022, there were over 100 holders of record of our common stock. This number does not include beneficial owners whose shares are held by nominees in street name.

Dividends

We have not declared or paid any cash dividends on our capital stock since our inception. We intend to retain future earnings, if any, to finance the operation and expansion of our business and do not anticipate paying any cash dividends to holders of common stock in the foreseeable future.

Securities authorized for issuance under equity compensation plans

Information about our equity compensation plans is incorporated herein by reference to Item 12, *Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters*, of this Annual Report on Form 10-K

Recent Sale of Unregistered Equity Securities

Not Applicable

Use of Proceeds

In July 2021, our Registration Statement on Form S-1 (No. 333-225491) 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 from that described in the Prospectus.

Item 6. [Reserved]

Item 7. 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 consolidated financial statements and related notes appearing at the end of this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, 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" section of this Annual Report on Form 10-K, 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, or 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. Using one of our proprietary platform technologies, 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 T cell receptors, or 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 believe this three-pronged approach will enable us to discover and develop a wide array of potential treatment options for patients with cancer.

We are advancing a robust pipeline of TCR-T therapy candidates for the treatment of patients with hematologic and solid tumor malignancies. Our lead liquid tumor 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 stem cell transplantation, or 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 submitted Investigational New Drug, or IND, applications with the U.S. Food and Drug Administration, or FDA, for each of TSC-100 and TSC-101 in the fourth quarter of 2021. The FDA has cleared the IND for TSC-100 while the IND for TSC-101 remains on clinical hold pending additional assessment of the potential for off-tumor reactivity in certain tissues. We plan to initiate the Phase 1 clinical study of TSC-100 in the first half of 2022. Pending clearance of the IND for TSC-101, we will initiate the TSC-101 arm of the trial. 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 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 the key solid tumor resistance mechanisms of target loss as well as HLA loss. We are currently advancing five solid tumor programs, with TSC-200 in IND-enabling activities, TSC-204 advancing to IND-enabling studies, and TSC-201, TSC-202, and TSC-203, in lead optimization, and expect to submit two IND applications for our solid tumor TCR-T therapy candidates in the second half of 2022, with additional IND applications expected to be submitted in 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 convertible preferred stock, proceeds from the initial public offering ("IPO") completed in July 2021 and revenue received under our collaboration agreement with Novartis Institutes for BioMedical Research, Inc., or Novartis. Through December 31, 2021, we have received net proceeds of $159.4 million from sales of our convertible preferred stock. We received $89.6 million in net proceeds (after deducting underwriting discounts, commissions and offering costs), from our IPO. Under the terms of our Collaboration and License Agreement with Novartis, we received a $20.0 million upfront payment and agreed to invest an estimated $10.0 million in research costs that will be reimbursed by Novartis over the research period of the agreement.

Impact of COVID-19

In March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic. The ongoing COVID-19 global and national health emergency has caused significant disruption in the international and United States economies and financial markets. The spread of COVID-19 has caused illness, quarantines, cancellation of events and travel, business and school shutdowns, reduction in business activity and financial transactions, labor shortages, supply chain interruptions and overall economic and financial market instability and business disruptions for us and many of our vendors.

In response to public health directives and orders and to help minimize the risk of the virus to employees, we have taken a series of actions aimed at safeguarding our employees and business associates, including implementing a flexible work-at-home policy. These disruptions could result in increased costs of execution of development plans or may negatively impact the quality, quantity, timing and regulatory usability of data that we would otherwise be able to collect. While these disruptions are currently expected to be temporary, there is considerable uncertainty around the duration of these disruptions. Therefore, the related financial impact and duration cannot be reasonably estimated at this time.

Initial Public Offering

On July 16, 2021, we completed our IPO in which we issued and sold 6,666,667 shares of our voting common stock at an initial public offering price of $15.00 per share, for aggregate gross proceeds of $100 million. Our shares are traded on The Nasdaq Global Market under the ticker symbol "TCRX." We received $89.6 million in net proceeds from the IPO after deducting underwriting discounts and commissions, and offering costs borne by us. Upon closing of the IPO, all of our outstanding shares of convertible preferred stock automatically converted into 15,616,272 shares of common stock (of which 5,143,134 shares are non-voting common stock).

Components of Results of Operations

Revenue

To date, our revenue has been derived from our one collaboration and two licensing agreements. We have not generated any revenue from the sale of therapies to date, nor do we expect to originate revenues therefrom in the near future, if at all. If our development efforts for our product candidates are successful and result in regulatory approval or if we enter into additional license or collaboration agreements with third parties, we may generate additional revenue in the future from sales of our therapies, payments from license or collaboration agreements that we may enter into with third parties, or any combination thereof. However, there can be no assurance as to when we will generate such revenue, if at all. We expect that our revenue for at least the next several years will be derived primarily from collaborations and licenses that we may enter into in the future, if any.

Collaboration Revenue

In March 2020, we entered into a Collaboration and License Agreement, or the Novartis Agreement, with Novartis Institutes for BioMedical Research, Inc., or Novartis, to collaborate on their research efforts to discover and develop novel TCR-T therapies. Under the Novartis Agreement, we will identify and characterize TCRs in accordance with a research plan, transfer data arising from the research plan, and Novartis will have the option to license and develop TCRs for up to three novel targets identified in performance of the collaboration during the collaboration period of the Novartis Agreement. Novartis will also have rights of first negotiation for certain additional targets and TCRs identified in performance of the collaboration during a defined period. We are free to develop TCRs against targets not licensed by Novartis.

The collaboration includes an upfront fee and research funding together totaling $30.0 million. We have the potential to receive up to $10.0 million per target, of which Novartis may select up to three, and potential milestone payments, contingent on clinical, regulatory and sales success. In addition to the milestones, Novartis will pay us royalties equal to a percentage in the mid-single-digits to low-teens on net sales for each therapy.

The Novartis Agreement is within the scope of ASC 606 under which we have identified a single performance obligation consisting of the research services, data reporting and participation in a joint steering committee. During the year ended December 31, 2021, we recognized $9.8 million of revenue associated with the Novartis Agreement, which includes recognition of the upfront payment and research funding. We expect to recognize the remaining arrangement consideration over the expected research term, which is not expected to exceed 3 years from the execution of the agreement.

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred in connection with our research activities, including our therapeutic discovery efforts, preclinical trials and the development of our proprietary platform technologies and product candidates. We expense research and development costs as incurred, which include:

- employee-related expenses, including salaries, bonuses, benefits, stock-based compensation, and other related costs for those employees involved in research and development efforts;
- expenses incurred in connection with our research programs, including under agreements with third parties, such as consultants and contract research organizations, or CROs;
- the cost of raw materials, developing and scaling our manufacturing process, and manufacturing our product candidates for use in our research and preclinical studies, including under agreements with third parties, such as consultants, contractors, and contract manufacturing organizations, or CMOs;
- laboratory supplies and research materials;
- facilities, depreciation, and other expenses, which include direct and allocated expenses for rent and maintenance of facilities and insurance; and
- payments made under third party licensing agreements.

We expense research and development costs as incurred. Non-refundable advance payments that we make for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed, or when it is no longer expected that the goods will be delivered or the services rendered. Upfront payments under license agreements are expensed upon receipt of the license, and annual maintenance fees under license agreements are expensed in the period in which they are incurred. Milestone payments under license agreements are accrued, with a corresponding expense being recognized, in the period in which the milestone is determined to be probable of achievement and the related amount is reasonably estimable.

Our direct external research and development expenses consist of costs that include fees, reimbursed materials, direct material costs, and other costs paid to consultants, contractors, CMOs and CROs in connection with our development and manufacturing activities. We do not allocate employee costs, general laboratory supplies, and facilities expenses, including depreciation or other indirect costs, to specific product development programs because these costs are deployed across multiple programs and our platform technology and, as such, are not separately classified. When our TCR-T therapy candidates enter clinical development, we will begin to segregate related research and development expenses by product candidate.

Product candidates in later stages of clinical development generally have higher development costs than those in preclinical and earlier stages of clinical development, primarily due increased size and duration of later stage clinical trials. We expect that our research and development expenses will increase substantially in connection with our planned preclinical and clinical development activities in the near term and in the future. At this time, we cannot accurately estimate or know the nature, timing and costs of the efforts that will be necessary to complete the preclinical and clinical development of any of our product candidates. The successful development and commercialization of our product candidates is highly uncertain. This is due to the numerous risks and uncertainties associated with therapeutic development and commercialization, including the following:

- the number and scope of preclinical and clinical programs we decide to pursue;
- the timing and progress of preclinical and clinical development activities for each program;
- our ability to raise additional funds necessary to complete preclinical and clinical development of and commercialize our product candidates;
- the progress of the development efforts of parties with whom we may enter into collaboration arrangements;
- our ability to maintain our current research and development programs and to establish new ones;
- our ability to establish new licensing or collaboration arrangements;
- the successful initiation and completion of clinical trials with safety, tolerability and efficacy profiles that are satisfactory to the U.S. Food and Drug Administration, or the FDA, or any comparable foreign regulatory authority;
- the receipt and related terms of regulatory approvals from applicable regulatory authorities;

- the availability of raw materials for use in the manufacture of our product candidates;
- our ability to consistently manufacture our product candidates for use in clinical trials;
- our ability to establish and operate a manufacturing facility, or secure manufacturing supply through relationships with third parties;
- our ability to obtain and maintain patents, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- our ability to protect our rights in our intellectual property portfolio;
- the commercialization of our product candidates, if and when approved;
- obtaining and maintaining third party insurance coverage and adequate reimbursement;
- the acceptance of our product candidates, if approved, by patients, the medical community and third party payors;
- competition with other products and therapies; and
- a continued acceptable safety profile of our therapies following approval.

A change in the outcome of any of these variables with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of these product candidates. We may never succeed in obtaining regulatory approval for any of our product candidates or in establishing market acceptance for any product candidates that may be approved.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and personnel expenses, including stock-based compensation, for our personnel in executive, legal, finance and accounting, human resources, and other administrative functions. General and administrative expenses also include legal fees relating to corporate matters; professional fees paid for accounting, auditing, consulting, and tax services; insurance costs; travel expenses; and facility costs not otherwise included in research and development expenses.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research activities and development of our product candidates. We have incurred significantly increased accounting, audit, legal, regulatory, compliance and director and officer insurance costs as well as investor and public relations expenses associated with operating as a public company and anticipate this expenses to increase in 2022 as we complete a full year as a public company. In addition, if we obtain regulatory approval for a product candidate and do not enter into a third-party commercialization collaboration, we expect to incur significant expenses related to building a sales and marketing team to support sales, marketing and distribution activities.

Other Income

Other income consists primarily of interest earned on our cash and cash equivalents balances held in financial institutions.

Income Taxes

Since our inception, we have not recorded any U.S. federal or state income tax benefits for the net losses we have incurred in any year or for our earned research and development tax credits, due to the uncertainty of realizing a benefit from those items. As of December 31, 2021, we had federal and state net operating loss carryforwards of $69.1 million and $66.9 million, respectively, which may be used to offset future taxable income, if any. These amounts expire at various dates through 2041. The federal net operating losses generated in and after 2018 can be carried forward indefinitely. As of December 31, 2021, we had federal and state tax credit carryforwards of $3.5 million and $2.3 million, respectively. These amounts expire at various dates through 2036. Due to the degree of uncertainty related to the ultimate use of the deferred tax assets, we have fully reserved these tax benefits, as the determination of the realization of the deferred tax benefits was not determined to be more likely than not.

Results of Operations

Years ended December 31, 2021 and 2020

The following table summarizes our results of operations for the years ended December 31, 2021 and 2020 (in thousands):

	Year Ended December 31,		
	2021	2020	Change
Revenue			
Collaboration and license revenue	$ 10,141	$ 1,085	$ 9,056
Operating expenses:			
Research and development	44,954	20,577	24,377
General and administrative	13,828	6,741	7,087
Total operating expenses	58,782	27,318	31,464
Loss from operations	(48,641)	(26,233)	(22,408)
Other income:			
Interest income	16	106	(90)
Net loss	$ (48,625)	$ (26,127)	$ (22,498)

Revenue

We had $10.1 million revenue for the year ended December 31, 2021 and $1.1 million revenue for the year ended December 31, 2020. The increase was related to the recognition of revenue associated with the Novartis Agreement, which has an expected term that ends no later than March 2023. The revenue generated from the Novartis Agreement has increased for the year ended December 31, 2021 as compared to December 31, 2020 as a result of the timing of research activities, which commenced in September 2020. As of December 31, 2021, the Company had current and long-term deferred revenue of $11.4 million and $1.5 million, respectively. Revenue is anticipated to slightly increase through 2022.

Research and Development Expenses

The following table summarizes our research and development expenses for the years ended December 31, 2021 and 2020 (in thousands):

	Year Ended December 31,		
	2021	2020	Change
Preclinical studies	$ 23,915	$ 7,922	$ 15,993
Legal and professional fees	787	859	(72)
Personnel expenses (including stock-based compensation)	12,690	7,383	5,307
Facility-related and other	7,562	4,413	3,149
Total research and development expenses	$ 44,954	$ 20,577	$ 24,377

The increase in research and development expenses was primarily attributable to a $16.0 million increase in laboratory supplies, research material, and preclinical studies in order to support the IND submissions for TSC-100 and TSC-101. There was a $5.3 million increase in personnel expenses, including an increase of $0.6 million related to stock-based compensation expense, due to an increase in headcount from 45 to 77. Finally, there was a $3.1 million increase in facility-related expenses and other expenses due to the expansion of leased facilities as well as the increased depreciation related to purchases of laboratory equipment.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the years ended December 31, 2021 and 2020 (in thousands):

	Year Ended December 31,		
	2021	2020	Change
Personnel expenses (including stock-based compensation)	$ 6,795	$ 2,525	$ 4,270
Legal and professional fees	2,814	2,827	(13)
Other expenses	4,219	1,389	2,830
Total general and administrative expenses	13,828	6,741	7,087

The increase in general and administrative expense was primarily due to a $4.3 million increase in personnel expenses, which includes an increase of $1.4 million related to stock-based compensation expense due to an increase in headcount from 12 to 21. In addition, there was an increase of $2.8 million in other expenses primarily related to increased costs due to public company D&O insurance, depreciation expense, recruiting, and market research.

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 Novartis Agreement, we received an upfront payment of $20 million. Additionally, Novartis is obligated to reimburse us for costs incurred to perform the research and development activities of up to $10 million. To date, we have funded our operations primarily with proceeds from sales of equity securities, most recently, with proceeds from the sale of common stock in our IPO in July 2021. As of December 31, 2021, we had cash and cash equivalents of $161.4 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 and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements into 2024. 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. 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.

Moreover, as a public company, we will incur significant legal, accounting and other expenses that we were not required to incur as a private company. In addition, the Sarbanes-Oxley Act of 2002, as well as rules adopted by the SEC and Nasdaq, requires public companies to implement specified corporate governance practices that are currently not applicable to us as a private company. Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we will first be required to furnish a report by our management on our internal control over financial reporting for the year ending December 31, 2022. However, while we remain an emerging growth company and a smaller reporting company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. We expect these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly.

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

- the scope, timing, rate of progress and costs of our drug discovery efforts, preclinical development activities, laboratory testing and clinical trials for our product candidates;
- the number and scope of clinical programs we decide to pursue;
- the cost, timing and outcome of preparing for and undergoing regulatory review of our product candidates;
- the scope and costs of development and manufacturing activities;
- the cost and timing associated with commercializing our product candidates, if they receive marketing approval;
- the amount of revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval;

- the achievement of milestones or occurrence of other developments that trigger payments under any collaboration agreements we might have at such time;
- the extent to which we acquire or in-license other product candidates and technologies;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- our efforts to enhance operational systems and our ability to attract, hire and retain qualified personnel, including personnel to support the development of our product candidates and, ultimately, the sale of our products, following FDA approval;
- our implementation of various computerized information systems;
- impact of COVID-19 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 2, Item 1A. “Risk Factors” of this Annual 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):

	Year Ended December 31,		
	2021	2020	Change
Net cash used in operating activities	$ (48,677)	$ (3,023)	$ (45,654)
Net cash used in investing activities	(9,941)	(4,238)	(5,703)
Net cash provided by financing activities	189,668	288	189,380
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 131,050	$ (6,973)	$ 138,023

Operating Activities

During the year ended December 31, 2021, net cash used in operating activities of $48.7 million was primarily driven by:

- our net loss of $48.6 million;
- an increase in prepaid and other current assets of $2.6 million, and;
- a decrease in deferred revenue of $6.5 million

These were partially offset by:

- non-cash charges of $5.8 million related to depreciation expense and stock-based compensation, and;
- an increase in accrued expenses and other current liabilities of $3.2 million.

During the year ended December 31, 2020, net cash used in operating activities of $3.0 million was primarily driven by:

- our net loss of $26.1 million, and;
- an increase in prepaid expenses and other current assets of $1.2 million

These were partially offset by:

- non-cash charges of $1.7 million related to depreciation expense and stock-based compensation;
- an increase in deferred revenue of $19.4 million, due the receipt of upfront payments related to the Novartis Collaboration;
- an increase in accrued expenses of $1.5 million, and;
- an increase in accounts payable and other current liabilities of $1.1 million

Investing Activities

During the years ended December 31, 2021 and 2020, net cash used in investing activities was $9.9 million and $4.2 million, respectively, primarily related to the purchases of laboratory equipment, leasehold improvements, and construction in progress.

Financing Activities

During the year ended December 31, 2021, net cash provided by financing activities was $189.7 million, consisting primarily of net proceeds of $99.7 million from our issuance of convertible preferred stock, $89.6 million from our IPO, and $0.3 million in net proceeds from the exercise of common stock options.

During the year ended December 31, 2020, net cash provided by financing activities was $0.3 million, consisting primarily of net proceeds from the exercise of common stock options.

Contractual Obligations

The following is a summary of our significant contractual obligations as of December 31, 2021 (in thousands):

	Total	Less than 1 year	1 to 3 years	4 to 5 years	More than 5 years
Contractual Obligations:					
Operating lease commitments (1)	$ 94,099	$ 2,075	$ 19,378	$ 17,289	$ 55,356
Total Contractual Obligations	$ 94,099	$ 2,075	$ 19,378	$ 17,289	$ 55,356

(1) Represents future minimum lease payments under our operating lease for 840 Winter Street in Waltham, Massachusetts and an additional space at 880 Winter Street Waltham, Massachusetts of which rent is anticipated to commence January 2023. The term is expected to expire December 2032.

We enter into contracts in the normal course of business with third-party CROs for clinical trials, preclinical studies, and other services and products for operating purposes. These contracts generally provide for termination following a certain period after notice and therefore we believe that our non-cancelable obligations under these agreements are not material, and they are not included in the table above.

Critical Accounting Policies and Estimates

Our consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States, or GAAP. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, costs and expenses. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We

evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2 to our consolidated financial statements, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our financial statements.

Revenue recognition

To date, our revenues have consisted of consideration related to the Novartis Agreement. We adopted the provisions of Accounting Standards Update 2014-09, Revenue from Contracts with Customers (Topic 606), or ASC 606, on January 1, 2018. In accordance with ASC 606, we recognize revenue when our customers obtain control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services.

To determine the appropriate amount of revenue to be recognized for arrangements determined to be within the scope of ASC 606, we perform the following five steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the assessment of the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when, or as we satisfy each performance obligation.

As part of the accounting for arrangements under ASC 606, we must use significant judgment to determine the performance obligations based on the determination under step (ii) above. We also use judgment to determine whether milestones or other variable consideration, except for royalties and sales-based milestones, should be included in the transaction price as described below. We recognize revenue based on those amounts when, or as, the performance obligations under the contract are satisfied.

We utilize judgment to assess the nature of the performance obligation to determine whether the performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition. The measure of progress, and the resulting periods over which revenue should be recognized, are subject to estimates by management and may change over the course of the arrangement, which are subject to review by the joint steering committee, or JSC. Such a change could have a material impact on the amount of revenue we record in future periods. We concluded that the transfer of control to the customer for the performance obligation occurs over the time period that the research and development services are provided by us. We recognize revenue for the performance obligation as those services are provided using an input method, based on the cumulative costs incurred compared to the total estimated costs expected to be incurred to satisfy the performance obligation. The cost-to-cost method is, in management's judgment, the best measure of progress towards satisfying the performance condition.

At the inception of each arrangement that includes research, development or regulatory milestone payments, we evaluate whether the milestones are considered likely to be met and estimate the amount to be considered for inclusion in the transaction price using the most-likely-amount method. If it is probable that a significant reversal in the amount of cumulative revenue recognized would not occur, the associated milestone value is included in the transaction price. For milestone payments due upon events that are not within our control, such as regulatory approvals, we are not able to assert that it is likely that the regulatory approval will be granted and that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur until those approvals are received. In making this assessment, we evaluate factors such as the scientific, clinical, regulatory, commercial, and other risks that must be overcome to achieve the particular milestone. There is considerable judgment involved in determining whether it is probable that a significant reversal in the amount of cumulative revenue recognized would not occur.

We reevaluate the transaction price and our total estimated costs expected to be incurred at the end of each reporting period and as uncertain events, such as changes to the expected timing and cost of certain research, development and manufacturing activities that we are responsible for, are resolved or other changes in circumstances occur. If necessary, we will adjust our estimate of the transaction price or our estimates of the total costs expected to be incurred. To date, we have not had any significant changes in our estimates.

Accrued research and development expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued research and development expenses. This process involves estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs. The majority of our service providers invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some require advance payments. We make estimates of our accrued expenses as of each balance sheet date in the financial statements based on facts and circumstances known to us at that time. At each period end, we corroborate the accuracy of these estimates with the service providers and make adjustments, if necessary. Examples of estimated accrued research and development expenses include those related to fees paid to:

- Vendors in connection with discovery and preclinical development activities;

- CROs in connection with preclinical and clinical studies and testing; and
- CMOs in connection with the process development and scale up activities and the production of materials.

We record the expense and accrual related to contract research and manufacturing based on our estimates of the services received and efforts expended considering a number of factors, including our knowledge of the progress towards completion of the research, development, and manufacturing activities; invoicing to date under contracts; communication from the contract research organizations, contract manufacturing organizations and other companies of any actual costs incurred during the period that have not yet been invoiced; and the costs included in the contracts and purchase orders. The financial terms of these agreements are subject to negotiation, vary from contract to contract, and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust the accrual or the amount of prepaid expense accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. To date, there have not been any material adjustments to our prior estimates of accrued research and development expenses.

Stock-based compensation

We measure stock-based awards granted to employees and directors based on fair value on the date of the grant using the Black-Scholes option-pricing model for options. Compensation expense for those awards is recognized over the requisite service period, which is generally the vesting period of the respective award. We use the straight-line method to record the expense of awards with service-based vesting conditions. We use the graded-vesting method to record the expense of awards with both service-based and performance-based vesting conditions, commencing when achievement of the performance condition becomes probable.

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model, which uses as inputs the fair value of our common stock and assumptions we make for the volatility of our common stock, the expected term of our stock options, the risk-free interest rate for a period that approximates the expected term of our stock options and our expected dividend yield.

Prior to our IPO, there was no public market for our common stock, and consequently, the estimated fair value of our common stock was determined by our board of directors as of the date of each option grant, with input from management, considering third-party valuations of our common stock as well as our board of directors' assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent third-party valuation through the date of the grant. Since our IPO, we have determined the fair market value of our common stock using the closing price of our common stock as reported on the Nasdaq Global Select Market.

Recently Issued Accounting Pronouncements

We do not believe that any recently issued accounting pronouncements will materially impact our financial position and results of operations.

Emerging Growth Company and Smaller Reporting Company Status

The Jumpstart Our Business Startups Act of 2012 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 until those standards would otherwise apply to private companies. We have elected not to "opt out" of such extended transition period, 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 IPO is less than $700 million and our annual revenue was less than $100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our 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 7A. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risk related to changes in interest rates. As of December 31, 2021, we had cash, cash equivalents, and restricted cash of $166.4 million which were held in savings accounts at banking institutions and money market funds that invest in U.S. Government securities. Interest income is sensitive to changes in the general level of interest rates; however, due to the nature of these investments, an immediate 10% change in market interest rates would not have a material effect on the fair market value of our cash balance or on our financial position or results of operations.

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation had a material effect on our business, financial condition or results of operations during the years and three months ended December 31, 2021 and 2020.

Item 8. Financial Statements and Supplementary Data

The financial statements required to be filed pursuant to this Item 8 are appended to this Annual Report on Form 10-K. An index of those financial statements is found in Item 15, *Exhibits and Financial Statement Schedules*, of this Annual Report on Form 10-K.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, under the supervision and with the participation of our Principal Executive Officer (our Chief Executive Officer) and Principal Financial Officer (our Chief Financial Officer), has evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2021. 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 December 31, 2021, 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 three months ended December 31, 2021 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not Applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this Item 10 will be included in our definitive proxy statement to be filed with the Securities and Exchange Commission, or SEC, with respect to our 2022 Annual Meeting of Stockholders and is incorporated by reference.

We have adopted a Code of Business Conduct and Ethics for all of our directors, officers and employees as required by Nasdaq governance rules and as defined by applicable SEC rules. Stockholders may locate a copy of our Code of Business Conduct and Ethics on our website at www.tscan.com.

Item 11. Executive Compensation.

The information required by this Item 11 will be included in our definitive proxy statement to be filed with the SEC, with respect to our 2022 Annual Meeting of Stockholders and is incorporated by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this Item 12 will be included in our definitive proxy statement to be filed with the SEC, with respect to our 2022 Annual Meeting of Stockholders and is incorporated by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this Item 13 will be included in our definitive proxy statement to be filed with the SEC, with respect to our 2022 Annual Meeting of Stockholders and is incorporated by reference.

Item 14. Principal Accounting Fees and Services.

The information required by this Item 14 will be included in our definitive proxy statement to be filed with the SEC, with respect to our 2022 Annual Meeting of Stockholders and is incorporated by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

- For a list of the financial statements included herein, see Index to the Consolidated Financial Statements on page F-1 of this Annual Report on Form 10-K, incorporated into this Item by reference.
- Financial statement schedules have been omitted because they are either not required or not applicable or the information is included in the consolidated financial statements or the notes thereto.
- 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).
4.1	Fourth Amended and Restated Investors' Rights Agreement, dated January 15, 2021, by and among the Registrant and the other parties thereto (incorporated by reference to Exhibit 4.2 to the Registrant's Registration Statement on S-1 filed with the Securities and Exchange Commission on April 23, 2021).
4.2	Registration Rights Agreement made as of January 15, 2021 by and between the Registrant and the other parties thereto (incorporated by reference to Exhibit 4.3 to the Registrant's Registration Statement on S-1 filed with the Securities and Exchange Commission on April 23, 2021).
4.3	Amended and Restated Nominating Agreement, dated April 22, 2021, by and among the Registrant, Baker Brothers Life Sciences, L.P. and 667, L.P. (incorporated by reference to Exhibit 4.4 to the Registrant's Registration Statement on S-1 filed with the Securities and Exchange Commission on April 23, 2021).
4.4*	Description of the Registrant's securities registered pursuant to Section 12 of the Securities and Exchange Act of 1934, as amended.
10.1	Lease, by and between TScan Therapeutics, Inc. and BXP Waltham Woods LLC, dated November 29, 2021 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on December 2, 2021).
10.2	2018 Stock Option Plan, as amended and forms of agreements thereunder (incorporated by reference to Exhibit 10.2 to the Registrant's Registration Statement on S-1 filed with the Securities and Exchange Commission on April 23, 2021).
10.3	2021 Equity Incentive Plan and form of agreements thereunder (incorporated by reference to Exhibit 10.3 to the Registrant's Registration Statement on S-1/A filed with the Securities and Exchange Commission on May 5, 2021).
10.4	2021 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.4 to the Registrant's Registration Statement on S-1/A filed with the Securities and Exchange Commission on April 30, 2021).
10.5	Amended and Restated Exclusive Patent License Agreement by and between the Registrant and The Brigham and Women's Hospital, Inc. dated April 20, 2021 (incorporated by reference to Exhibit 10.5 to the Registrant's Registration Statement on S-1 filed with the Securities and Exchange Commission on April 23, 2021).
10.6	Lease by and between PPF OFF 828-830 Winter Street LLC and the Registrant, dated August 13, 2019 (incorporated by reference to Exhibit 10.6 to the Registrant's Registration Statement on S-1 filed with the Securities and Exchange Commission on April 23, 2021).
10.7	Option & Exclusive License Agreement by and between the Registrant and QIAGEN Sciences LLC, dated as of November 5, 2020 (incorporated by reference to Exhibit 10.7 to the Registrant's Registration Statement on S-1 filed with the Securities and Exchange Commission on April 23, 2021).
10.8	Collaboration and License Agreement by and between the Registrant and Novartis Institutes for Biomedical Research, dated as of March 27, 2020 (incorporated by reference to Exhibit 10.8 to the Registrant's Registration Statement on S-1 filed with the Securities and Exchange Commission on April 23, 2021).

10.9	Non-Exclusive License Agreement by and between the Registrant and Provincial Health Services Authority, dated as of October 15, 2020 (incorporated by reference to Exhibit 10.9 to the Registrant's Registration Statement on S-1 filed with the Securities and Exchange Commission on April 23, 2021).
10.10	Amended and Restated Royalty Agreement, dated as of June 12, 2018 (incorporated by reference to Exhibit 10.10 to the Registrant's Registration Statement on S-1 filed with the Securities and Exchange Commission on April 23, 2021).
10.11	Employment Agreement, dated April 23, 2021, by and between the Registrant and David Southwell (incorporated by reference to Exhibit 10.13 to the Registrant's Registration Statement on S-1 filed with the Securities and Exchange Commission on April 23, 2021).
10.12	Employment Agreement, dated April 23, 2021, by and between the Registrant and Gavin MacBeath, Ph.D. incorporated by reference to Exhibit 10.14 to the Registrant's Registration Statement on S-1 filed with the Securities and Exchange Commission on April 23, 2021).
10.13	Employment Agreement, dated April 23, 2021, by and between the Registrant and William Desmarais (incorporated by reference to Exhibit 10.17 to the Registrant's Registration Statement on S-1 filed with the Securities and Exchange Commission on April 23, 2021).
10.14	Form of Management Cash Incentive Plan (incorporated by reference to Exhibit 10.18 to the Registrant's Registration Statement on S-1 filed with the Securities and Exchange Commission on April 23, 2021).
10.15	Employment Agreement, dated May 4, 2021, by and between the Registrant and Brian Silver (incorporated by reference to Exhibit 10.19 to the Registrant's Registration Statement on S-1/A filed with the Securities and Exchange Commission on May 5, 2021).
10.16	Employment Agreement, dated July 28, 2021, by and between the Registrant and Zoran Zdraveski (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 10, 2021).
10.17	Form of Indemnification Agreement between the Registrant and each of its directors and executive officers (incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-1, filed with the Securities and Exchange Commission on April 23, 2021).
23.1*	Consent of Independent Registered Public Accounting Firm.
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 Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of 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

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized**.**

TScan Therapeutics, Inc.

Date: March 9, 2022 By: /s/ David Southwell
David Southwell
President and Chief Executive Officer

Each person whose individual signature appears below hereby authorizes and appoints David Southwell and Brian Silver, and each of them, with full power of substitution and resubstitution and full power to act without the other, as his or her true and lawful attorney-in-fact and agent to act in his or her name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file any and all amendments to this Annual Report on Form 10-K and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorneys-in-fact and agents or any of them or their or his substitute or substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the Registrant in the capacities and on March 9, 2022.

Signature	Title	Date
/s/ David Southwell David Southwell	President, Chief Executive Officer and Director (Principal Executive Officer)	March 9, 2022
/s/ Brian Silver Brian Silver, J.D.	Chief Financial Officer (Principal Financial and Accounting Officer)	March 9, 2022
/s/ Stephen Biggar Stephen Biggar, M.D., Ph.D.	Director	March 9, 2022
/s/ Ittai Harel Ittai Harel	Director	March 9, 2022
/s/ Timothy Barberich Timothy Barberich	Director	March 9, 2022
/s/ Gabriela Gruia Gabriela Gruia, M.D.	Director	March 9, 2022
/s/ Katina Dorton Katina Dorton, J.D., M.B.A.	Director	March 9, 2022

INDEX TO THE CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the stockholders and Board of Directors of TScan Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of TScan Therapeutics, Inc. and its subsidiary (the Company) as of December 31, 2021 and 2020, the related consolidated statements of operations, convertible preferred stock and stockholders' equity (deficit), and cash flows, for the years then ended, and the related notes (collectively referred to as the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2021 and 2020, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulation of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
March 9, 2022

We have served as the Company's auditor since 2020.

TScan Therapeutics, Inc.

Consolidated Balance Sheets

(in thousands, except share and per share data)

	December 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 161,405	$ 34,791
Prepaid expenses and other current assets	4,249	1,654
Total current assets	165,654	36,445
Property and equipment, net	11,765	5,659
Right-of-use assets	5,491	6,873
Restricted cash	5,031	595
Long-term deposit	166	166
Total assets	$ 188,107	$ 49,738
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 1,765	$ 2,910
Accrued expenses and other current liabilities	6,517	2,494
Operating lease liability, current portion	1,651	1,415
Deferred revenue, current portion	11,410	10,627
Total current liabilities	21,343	17,446
Deferred revenue, net of current portion	1,497	8,816
Operating lease liability, net of current portion	4,392	6,019
Other long term liabilities	97	238
Total liabilities	27,329	32,519
Commitments and contingencies (Note 10)		
Convertible preferred stock (Note 6)	-	59,681
Stockholders' equity (deficit):		
Preferred stock, $0.0001 par value; 10,000,000 and 7,063,112 shares authorized; no shares issued and outstanding at December 31, 2021 and 2020, respectively	-	-
Voting common stock, $0.0001 par value; 300,000,000 and 165,210,543 shares authorized; 18,881,333 and 1,574,138 shares issued; and 18,764,463 and 1,135,858 shares outstanding at December 31, 2021 and 2020, respectively	2	1
Non-voting common stock, $0.0001 par value; 10,000,000 and 0 shares authorized; 5,143,134 and 0 shares issued; and 5,143,134 and 0 shares outstanding at December 31, 2021 and 2020, respectively	1	-
Additional paid-in capital	252,933	1,070
Accumulated deficit	(92,158)	(43,533)
Total stockholders' equity (deficit)	160,778	(42,462)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 188,107	$ 49,738

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

TScan Therapeutics, Inc.

Consolidated Statements of Operations

(in thousands, except share and per share data)

	Year Ended December 31,	
	2021	**2020**
Revenue		
Collaboration and license revenue	$ 10,141	$ 1,085
Operating expenses:		
Research and development	44,954	20,577
General and administrative	13,828	6,741
Total operating expenses	58,782	27,318
Loss from operations	(48,641)	(26,233)
Other income:		
Interest and other income (loss), net	16	106
Net loss	$ (48,625)	$ (26,127)
Net loss per share, basic and diluted	$ (4.17)	$ (28.52)
Weighted average common shares outstanding—basic and diluted	11,662,672	916,014

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

TScan Therapeutics, Inc.

Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)

(in thousands, except share data and issuance costs)

	Convertible Preferred Stock		Voting Common Stock		Non-voting Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount			
Balances at January 1, 2020	7,063,104	$ 59,681	642,903	$ -	-	$ -	$ 268	$ (17,406)	$ (17,138)
Exercise of stock options	-	-	142,349	1	-	-	287	-	288
Vesting of restricted common stock	-	-	350,606	-	-	-	-	-	-
Stock-based compensation expense	-	-	-	-	-	-	515	-	515
Net loss	-	-	-	-	-	-	-	(26,127)	(26,127)
Balances at December 31, 2020	7,063,104	59,681	1,135,858	1	-	-	1,070	(43,533)	(42,462)
Issuance of Series C convertible preferred stock (net of issuance costs of $270 thousand)	8,553,168	99,730	-	-	-	-	-	-	-
Issuance of common stock (net of issuance costs of $10.4 million)	-	-	6,666,667	1	-	-	89,645	-	89,646
Conversion of convertible preferred stock to common stock and non-voting common stock upon closing of initial public offering	(15,616,272)	(159,411)	10,473,138	-	5,143,134	1	159,411	-	159,412
Exercise of stock options	-	-	167,390	-	-	-	291	-	291
Vesting of restricted common stock	-	-	321,410	-	-	-	-	-	-
Stock-based compensation expense	-	-	-	-	-	-	2,516	-	2,516
Net loss	-	-	-	-	-	-	-	(48,625)	(48,625)
Balances at December 31, 2021	-	$ -	18,764,463	$ 2	5,143,134	$ 1	$ 252,933	$ (92,158)	$ 160,778

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

TScan Therapeutics, Inc.

Consolidated Statements of Cash Flows

(in thousands)

	Year Ended December 31,	
	2021	**2020**
Cash flows from operating activities:		
Net loss	$ (48,625)	$ (26,127)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	3,328	1,230
Stock-based compensation	2,516	515
Loss of sale of property and equipment	-	2
Changes in current assets and liabilities:		
Prepaid expenses and other assets	(2,595)	(1,205)
Right-of-use assets and lease liabilities, net	(9)	442
Accounts payable	10	1,127
Accrued expense and other liabilities	3,234	1,550
Deferred revenue	(6,536)	19,443
Net cash used in operating activities	(48,677)	(3,023)
Cash flows from investing activities:		
Purchases of property and equipment	(9,941)	(4,238)
Net cash used in investing activities	(9,941)	(4,238)
Cash flows from financing activities:		
Proceeds from issuance of convertible preferred stock, net of issuance costs	99,730	-
Proceeds from exercise of stock options	291	288
Proceeds from initial public offering, net of issuance costs	89,647	-
Net cash provided by financing activities	189,668	288
Net increase (decrease) in cash, cash equivalents and restricted cash	131,050	(6,973)
Cash, cash equivalents, and restricted cash - beginning of year	35,386	42,359
Cash, cash equivalents, and restricted cash - end of year	$ 166,436	$ 35,386
Summary of cash, cash equivalents and restricted cash reported within the consolidated balance sheets:		
Cash and cash equivalents	161,405	34,791
Restricted cash	5,031	595
Total cash, cash equivalents, and restricted cash shown in the consolidated statements of cash flows	$ 166,436	$ 35,386
Supplemental cash flow information:		
Purchase of property and equipment in accounts payable and accrued liabilities	$ 828	$ 1,335
Conversion of convertible preferred stock to common stock upon closing of initial public offering	$ 159,411	$ -
Right-of-use-assets obtained in exchange for operating lease liabilities	$ -	$ 3,199

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

1. Nature of Business and Basis of Presentation

Nature of Business

TScan Therapeutics, Inc. (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.

Initial Public Offering

In July 2021, the Company completed an initial public offering ("IPO") in which the Company issued and sold 6,666,667 shares of its voting common stock at a public offering price of $15.00 per share, for aggregate gross proceeds of $100 million and its shares started trading on the Nasdaq Global Market under the ticker symbol “TCRX.” The Company received $89.6 million in net proceeds after deducting $7.0 million in underwriting discounts and commissions, and $3.4 million in offering costs borne by the Company. Upon closing of the IPO, all of the Company's outstanding shares of convertible preferred stock automatically converted into 15,616,272 shares of common stock (of which 5,143,134 shares are non-voting common stock).

In connection with the closing of IPO, the Company amended and restated in its entirety its certificate of incorporation to, among other things: (i) authorize 300,000,000 shares of voting common stock; (ii) authorize 10,000,000 shares of non-voting common stock; (iii) eliminate all references to the previously existing series of preferred stock; and (iv) authorize 10,000,000 shares of preferred stock that may be issued from time to time by the Board in one or more series.

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, clinical studies and clinical trials, the need to obtain marketing approval for its product candidates and the ability to successfully market its therapies 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-reporting capabilities. Even if the Company’s development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from therapy sales.

The accompanying 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 convertible preferred stock, the IPO completed in July 2021 and with payments received under its license and collaboration agreements. Since its inception, the Company has incurred recurring losses, including net losses of $48.6 million and $26.1 million for the years ended December 31, 2021 and 2020, respectively. As of December 31, 2021, the Company had an accumulated deficit of $92.2 million. The Company expects to continue to generate operating losses in the foreseeable future. The Company expects that its cash and cash equivalents as of December 31, 2021 will be sufficient to fund the Company’s operations for at least the next twelve months from the date of the issuance of the financial statements.

Impact of COVID-19

In December 2019, a novel strain of coronavirus, which causes the disease known as COVID-19, was reported to have surfaced in Wuhan, China. Since then, COVID-19 coronavirus has spread globally. In March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic. The ongoing COVID-19 global and national health emergency has caused significant disruption in the international and United States economies and financial markets. The spread of COVID-19 has caused illness, quarantines, cancellation of events and travel, business and school shutdowns, reduction in business activity and financial transactions, labor shortages, supply chain interruptions and overall economic and financial market instability and business disruptions for the Company and many of the Company’s vendors.

In response to public health directives and orders and to help minimize the risk of the virus to employees, the Company has taken a series of actions aimed at safeguarding the Company’s employees and business associates, including implementing a flexible

work-at-home policy. These disruptions could result in increased costs of execution of development plans or may negatively impact the quality, quantity, timing and regulatory usability of data that the Company would otherwise be able to collect. While these disruptions are currently expected to be temporary, there is considerable uncertainty around the duration of these disruptions. Therefore, the related financial impact and duration cannot be reasonably estimated at this time. To date, the Company has not experienced material business disruptions, including with its vendors, as a result of the COVID-19 pandemic.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements reflect the operations of the Company and the Company's wholly owned subsidiary, TScan Securities Corporation. The accompanying consolidated financial statements have been prepared in conformity with generally accepted accounting principles in the United States of America ("US GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative US GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB").

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiary. All intercompany accounts and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of the consolidated financial statements in accordance with US GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of expenses during the reporting period. The Company bases its estimates on historical experience, known trends and other market-specific or relevant factors that it believes to be reasonable under the circumstances. On an ongoing basis, management evaluates its estimates as there are changes in circumstances, facts and experience. Actual results may differ from those estimates or assumptions.

Cash and Cash Equivalents

Cash includes cash in readily available checking and money market accounts. Cash equivalents include all highly liquid investments maturing within 90 days from the date of purchase. The cash equivalents consisted of money market funds.

Restricted Cash

In connection with the Company's facility lease agreements, the Company is required to provide a letter of credit of $0.6 million and $4.4 million for the benefit of the landlords to serve as security deposits. As of December 31, 2021 and 2020, the cash securing the letter of credit was classified as restricted cash (non-current) on the consolidated balance sheets.

Concentrations of Credit Risk

Financial instruments that subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents. The Company's cash deposits on hand at any one financial institution often exceed federally insured limits. The Company places its cash in financial institutions that management believes to be of high credit quality. The Company does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

Property and Equipment

Property and equipment are stated at cost and depreciated using the straight-line method over the estimated useful lives of the respective assets as follows:

	Estimated useful life
Laboratory equipment	3 — 5 years
Furniture and fixtures	3 — 5 years
Office and computer equipment	3 — 5 years
Leasehold improvements	Shorter of the asset's estimated useful life or the remaining lease term

Major additions and betterments are capitalized; expenditures for repairs and maintenance, which do not improve or extend the life of the respective assets, are charged to operating expense as incurred. Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation and amortization are removed from the accounts and any resulting gain or loss is included in loss from operations.

Impairment of Long-Lived Assets

Long-lived assets to be held and used, including property and equipment, are tested for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset may not be fully recoverable. Evaluation of the recoverability of the asset or asset group is based on an estimate of undiscounted future cash flows resulting from the use of the asset or asset group and its eventual disposition. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the asset or asset group, an impairment loss would be based on the excess of the carrying value of the impaired asset over its fair value. The Company did not record any impairment losses on long-lived assets during the periods presented.

Fair Value Measurements

Certain assets and liabilities are carried at fair value under US GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the user of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- **Level 1**—Unadjusted quoted prices in active markets that are accessible to the reporting entity at the measurement date for identical assets and liabilities.
- **Level 2**—Inputs other than quoted prices in active markets for identical assets and liabilities that are observable either directly or indirectly for substantially the full term of the asset or liability. Level 2 inputs include the following:
  - quoted prices for similar assets and liabilities in active markets
  - quoted prices for identical or similar assets or liabilities in markets that are not active
  - observable inputs other than quoted prices that are used in the valuation of the asset or liabilities (e.g., interest rate and yield curve quotes at commonly quoted intervals)
  - inputs that are derived principally from or corroborated by observable market data by correlation or other means
- **Level 3**—Unobservable inputs for the assets or liability (i.e., supported by little or no market activity). Level 3 inputs include management's own assumptions about the assumptions that market participants would use in pricing the asset or liability (including assumptions about risk).

Lease Agreements

The Company records leases under ASU No. 2016-02 Leases (Topic 842) whereby the Company determines if an arrangement is or contains a lease at inception. For leases with a term of 12 months or less, the Company has elected to not recognize a right-of-use asset or lease liability. The Company's operating leases are recognized on the consolidated balance sheets as other noncurrent assets, other current liabilities, and other noncurrent liabilities. The Company does not have any finance leases.

Right-of-use assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating lease right-of-use assets and lease liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. As the rate implicit on the Company's leases are not readily determination, the Company uses an estimate of its incremental borrowing rate for secured borrowings with terms similar to the lease term based on the information available at the lease commencement date in determining the present value of lease payments. Operating lease right-of-use assets also include the effect of any lease payments made and excludes

lease incentives. The lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Lease expense is recognized on a straight-line basis over the lease term.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development costs that are paid in advance of performance (if any) are capitalized as a prepaid expense and amortized over the service period as the services are provided.

Accrued Research and Manufacturing Contract Costs

The Company has entered into various research and development and manufacturing contracts. These agreements are generally cancelable, and related payments are recorded as the corresponding expenses are incurred. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the research studies or clinical trials and manufacturing activities, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates. The Company's historical accrual estimates have not been materially different from the actual costs.

Patent Costs

All patent-related costs incurred in connection with filing and prosecuting patent applications are expensed as incurred due to the uncertainty about the recovery of the expenditure. Amounts incurred are classified as general and administrative expenses.

Revenue Recognition

The Company accounts for revenue under ASU No. 2014-19, *Revenue from Contracts with Customers* (ASC 606). ASC 606 applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, certain collaboration arrangements and financial instruments. ASC 606 provides a five-step framework whereby revenue is recognized when control of promised goods or services is transferred to a customer at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. To determine revenue recognition for arrangements that the Company determines are within the scope of ASC 606, the Company performs the following five steps:

(i) identify the contract(s) with a customer;

(ii) identify the performance obligations in the contract;

(iii) determine the transaction price;

(iv) allocate the transaction price to the performance obligations in the contract; and

(v) recognize revenue when (or as) the performance obligations are satisfied.

The Company only applies the five-step model to contracts when it is probable that the Company will collect the consideration that it is entitled to in exchange for the goods or services the Company transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses whether the goods or services promised within each contract are distinct and, therefore, represent a separate performance obligation. Goods and services that are determined not to be distinct are combined with other promised goods and services until a distinct combined performance obligation is identified.

The Company then allocates the transaction price (that is, the amount of consideration the Company expects to be entitled to from a customer in exchange for the promised goods or services) to each performance obligation and recognizes the associated revenue when (or as) each performance obligation is satisfied. The allocation is based upon standalone selling price. The standalone selling price is the price at which an entity would sell a promised good or service separately to a customer. Because the Company have not sold the same goods or services in our contracts separately to any customers on a standalone basis, the Company estimated the standalone selling price of each combined performance obligation by taking into consideration internal estimates of research and development personnel needed to perform the research and development services, estimates of expected cash outflows to third parties for services and supplies and typical gross profit margins.

The Company enters into collaboration and licensing arrangements that are within the scope of ASC 606, under which the Company may exclusively license to third parties' rights to develop, manufacture and commercialize its product candidates as well as options to acquire additional rights. The terms of these arrangements typically include payment to the Company of one or more of the

following: nonrefundable, upfront license fees; development, regulatory and sales milestone payments; and royalties on net sales of licensed products.

Revenue is typically recognized using a cost-to-cost input model as the measure of progress. Significant management judgment is required in determining the level of effort required under an arrangement and the period over which the Company is expected to complete the Company's performance obligations under an arrangement. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition. The measure of progress, and thereby periods over which revenue should be recognized, are subject to estimates by management and may change over the course of the research and development and licensing agreement. Such a change could have a material impact on the amount of revenue the Company records in future periods.

Amounts received prior to revenue recognition are recorded as deferred revenue in the balance sheets. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified as the current portion of deferred revenue in the balance sheets. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as deferred revenue, net of current portion in the balance sheets.

Customer Options

If an arrangement is determined to contain customer options that allow the customer to acquire additional goods or services, the goods and services underlying the customer options that are not determined to be material rights are not considered to be performance obligations at the outset of the arrangement, as they are contingent upon option exercise. The Company evaluates the customer options for material rights, or options to acquire additional goods or services for free or at a discount. If the customer options are determined to represent a material right, the material right is recognized as a separate performance obligation at the outset of the arrangement. To date, none of our arrangements have included any material rights. The transaction price is allocated to each performance obligation on a relative standalone selling price basis. The observable price of a good or service sold separately provides the best evidence of standalone selling price. However, when standalone selling prices are not readily available, the Company is required to estimate the standalone selling price of each performance obligation. Key assumptions to determine the standalone selling price. Amounts allocated to a material right are not recognized as revenue until the option is exercised or terminates.

Milestone Payments

For each arrangement that includes milestone payments upon the achievement of performance-based milestones, such as development and regulatory milestones, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant reversal of revenue would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company's control, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. Upfront and ongoing development milestones per the Company's collaboration and license agreement are not subject to refund if the development activities are not successful. The Company reevaluates the probability of achievement of such milestones and any related constraint at each reporting period, and any adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment. To date, the Company has not recognized any milestone revenues.

Royalties

For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license to the Company's intellectual property is deemed to be the predominant item to which the royalties relate as it is the primary driver of value, the Company recognizes revenue when the related sales occur in accordance with the sales-based royalty exception under ASC 606-10-55-65. To date, the Company has not recognized any royalty revenue resulting from the Company's collaboration and licensing agreements.

The estimate of deferred revenue also reflects management's estimate of the periods of the Company's involvement in its collaboration and license agreements. The Company's performance obligations generally consist of the performance of research and development services and sharing know-how through participation on steering committees. If these estimates and judgments change over the course of these agreements, it may affect the timing and amount of revenue that the Company recognizes and records in future periods.

Income Taxes

Deferred tax assets and liabilities are recognized for the expected future tax consequences of events that have been included in the consolidated financial statements or tax returns. Under this method, deferred tax assets and liabilities are determined based on the

difference between the consolidated financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. A valuation allowance is provided to reduce the deferred tax asset to an amount, which, more likely than not, will be realized.

The Company recognizes the tax benefit from any uncertain tax positions only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. The tax benefits recognized in the consolidated financial statements from such a position are measured based on the largest benefit that has a greater than fifty percent likelihood of being realized upon ultimate settlement. Interest and penalties associated with uncertain tax positions are recorded as a component of income tax expense. As of December 31, 2021 and 2020, the Company has not identified any uncertain tax positions for which reserves would be required.

Segment Information

Operating segments are defined as components of an entity for which discrete information is available for evaluation by the chief operating decision maker, who is the CEO, in deciding how to allocate resources and in assessing performance. The Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions. All of the Company's assets are held in the United States.

Convertible Preferred Stock

The Company's convertible preferred stock was classified outside of stockholders' deficit because the holders of such shares have liquidation rights in the event of a deemed liquidation that, in certain situations, are not solely within the control of the Company.

Stock-Based Compensation

The Company accounts for stock option awards at fair value, which is measured using the Black-Scholes option-pricing model. The measurement date is generally the date of grant.

The Company recognizes stock-based compensation expense over the requisite service period, which is generally the vesting period of the respective award. For awards that include performance-based vesting conditions, stock-based compensation expense is recognized using the accelerated attribution method when the performance condition is deemed to be probable. The Company accounts for forfeitures as they occur. The Company determines the fair value of restricted stock awards in reference to the fair value of its common stock less any applicable purchase price

The Company classifies stock-based compensation expense in its consolidated statements of operations in the same manner in which the award recipient's salary and related costs are classified or in which the award recipient's service payments are classified.

Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in stockholders' equity (deficit) that result from transactions and economic events other than those with stockholders. There was no difference between net loss and comprehensive loss in the accompanying consolidated financial statements.

Net Loss Per Share

Basic net loss per share is calculated by dividing net loss by the weighted average common shares outstanding during the period. During periods of income, the Company allocates to participating securities a proportional share of income (the two class method). The Company's convertible preferred stock participates in any dividends declared by the Company and are therefore considered to be participating securities. Participating securities have the effect of diluting both basic and diluted earnings per share during periods of income. During periods of loss, the Company allocates no loss to participating securities because they have no contractual obligation to share in the losses of the Company.

Diluted net loss per share is calculated by adjusting weighted average common shares outstanding for the dilutive effect of common stock equivalents outstanding for the period, determined using the treasury-stock and if-converted methods. For purposes of the diluted net income (loss) per share calculation, convertible preferred stock and stock options are considered to be common stock equivalents. All common stock equivalents have been excluded from the calculation of diluted net loss per share as their effect would be anti-dilutive for all periods presented. Therefore, basic and diluted net loss per share were the same for all periods presented.

3. Property and Equipment

Property and equipment consist of the following (in thousands):

	December 31,	
	2021	2020
Laboratory equipment	$ 11,359	$ 5,615
Leasehold improvements	3,433	493
Office and computer equipment	370	202
Furniture and fixtures	412	326
Capitalized software	11	-
Construction-in-progress	1,263	778
Property and equipment	$ 16,848	$ 7,414
Less: accumulated depreciation and amortization	(5,083)	(1,755)
Property and equipment, net	$ 11,765	$ 5,659

Depreciation and amortization expense for the years ended December 31, 2021 and 2020 was $3.3 million and $1.2 million, respectively.

4. Fair Value Measurements

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

	Fair value measurements at December 31, 2021 using:			
	Level 1	Level 2	Level 3	Total
Assets				
Cash equivalents – money market funds	$ 159,668	$ -	$ -	$ 159,668
Total financial assets	$ 159,668	$ -	$ -	$ 159,668

	Fair value measurements at December 31, 2020 using:			
	Level 1	Level 2	Level 3	Total
Assets				
Cash equivalents – money market funds	$ 33,748	$ -	$ -	$ 33,748
Total financial assets	$ 33,748	$ -	$ -	$ 33,748

The cash equivalents are comprised of funds held in an exchange traded money market fund and the fair value of the cash equivalents is determined based upon quoted market price for that fund. There were no transfers among Level 1, Level 2, or Level 3 categories in the periods presented.

The carrying value of accounts payable and accrued expenses that are reported on the consolidated balance sheets approximate their fair value due to the short-term nature of these liabilities.

5. Accrued Expenses and Other Current Liabilities

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

	December 31,	
	2021	2020
Accrued employee compensation and benefits	$ 2,600	$ 1,535
Accrued research and development	1,902	60
Accrued consulting and professional services	949	189
Accrued legal services and license fee	54	578
Other	1,012	132
Total accrued expenses and other current liabilities	$ 6,517	$ 2,494

6. Stockholders' Equity

As of December 31, 2020, the preferred stock consisted of the following (in thousands, except for share data):

	December 31, 2020				
	Preferred Stock Authorized	Preferred Stock Issued and Outstanding	Carrying Value	Liquidation Preference	Common Stock Issuable Upon Conversion
Series A Preferred Stock	26,315,790	3,209,240	$ 24,874	$ 29,838	3,209,240
Series B Preferred Stock	31,601,732	3,853,864	34,807	39,037	3,853,864
Total	57,917,522	7,063,104	$ 59,681	$ 68,875	7,063,104

The preferred stock has the following rights and privileges:

Dividends

Holders of the preferred stock were entitled to receive non-cumulative dividends when, as and if declared by the Board. The Company did not declare dividends on any classes of preferred or common stock

Liquidation

In the event of any liquidation, dissolution, or winding-up of the Company, which would include the sale of the Company, the preferred stock was senior to common stock.

Voting

The holders of preferred stock were entitled to the number of votes equal to the number of shares of common stock into which the shares of preferred stock held by each were then convertible.

Conversion

The holders of preferred stock were able to convert, at any time, each share of preferred stock into shares of common stock at the stated conversion price.

In July 2021, the Company completed the initial public offering ("IPO") in which the Company issued and sold 6,666,667 shares of its voting common stock at a public offering price of $15.00 per share, for aggregate gross proceeds of $100 million and its shares started trading on the Nasdaq Global Market under the ticker symbol “TCRX.” The Company received $89.6 million in net proceeds after deducting $7.0 million in underwriting discounts and commissions, and $3.4 million in offering costs borne by the Company. Upon the completion of the Company’s IPO in July 2021, all outstanding shares of the Company’s preferred stock were converted into 15,616,272 shares of common stock (of which 5,143,134 shares are non-voting common stock). As a result, as of December 31, 2021, no shares of preferred stock are outstanding.

7. Stock Based Compensation

2018 Equity Incentive Plan

On April 20, 2018, the Company adopted the 2018 Stock Plan (the 2018 Plan). The 2018 Plan, as amended, provided for the issuance of up to 2,902,738 shares of common stock to employees, officers, directors, consultants, and advisors in the form of nonqualified and incentive stock options, unvested stock awards, and other stock-based awards.

2021 Equity Incentive Plan

The 2021 Equity Incentive Plan (the 2021 Plan) was approved by the Company’s Board on April 22, 2021 and became effective immediately, although no awards were permitted to be granted under the 2021 Plan until July 15, 2021. The 2021 Plan replaced the 2018 Plan. However, awards outstanding under the 2018 Plan continue to be governed by their existing terms. There were 3,278,048 shares of common stock initially reserved for issuance under the 2021 Plan, plus up to 268,397 shares reserved for issuance under, or issued pursuant to or subject to awards granted under, the 2018 Plan. As of December 31, 2021, there were 2,848,904 shares of common stock available for issuance under the 2021 Plan. The number of shares reserved for issuance under the 2021 Plan will be increased automatically on the first business day of each fiscal year, commencing in 2022 and ending in 2031. The aggregate number of common shares that may be issued under the 2021 Plan shall automatically increase by a number equal to the lesser of (a) 4% of the total number

of shares of common stock actually issued and outstanding on the last day of the preceding fiscal year or (b) a number of shares common stock determined by the Company's Board.

2021 Employee Stock Purchase Plan

The 2021 Employee Stock Purchase Plan (the "2021 ESPP") was approved by the Company's Board on April 22, 2021 and became effective immediately, although no awards were permitted to be granted under the 2021 Plan until July 15, 2021. A total of 254,390 shares of common stock were initially reserved for issuance under the 2021 ESPP. As of December 31, 2021, there were 254,390 shares of common stock available for issuance under the 2021 ESPP. The number of shares reserved for issuance will automatically be increased on the first business day of each fiscal year, commencing on January 1, 2022 and ending on January 1, 2041. The aggregate number of shares of common stock that may be issued under the 2021 ESPP shall automatically increase by a number equal to the least of (i) one percent (1%) of the total number of shares of common stock actually issued and outstanding on the last day of the preceding fiscal year, or (ii) a number of shares of common stock determined by the Company's Board. Shares issued under the 2021 ESPP will be compensatory.

Stock Options

In general, stock options typically vest over four years and have a maximum term of 10 years. Also, the Company typically grants stock options to employees and non-employees at exercise prices deemed by the Board to be equal to the fair value of the common stock at the time of grant. The fair value of the common stock has been determined by the Board at each measurement date based on a variety of different factors, including the results obtained from third party appraisals, the Company's financial position and historical financial performance, the status of development of the Company's services, the current climate in the marketplace, the illiquid nature of the common stock, the effect of the rights and preferences of the preferred stockholders, and the prospects of a liquidity event, among others.

Stock-based compensation expense for the year ended December 31, 2021 and 2020 was classified in the consolidated statement of operations as follows (in thousands):

	Year Ended December 31,	
	2021	**2020**
Research and development	$ 878	$ 248
General and administrative	1,638	267
Total stock-based compensation expense	$ 2,516	$ 515

The Company utilized the Black-Scholes option-pricing model to estimate the fair value of stock options awarded to employees. The Black-Scholes option-pricing model requires several key assumptions. The key assumptions used to apply this pricing model were as follows:

	Year Ended December 31,	
	2021	**2020**
Risk free interest rate	0.79%	0.85%
Expected term (in years)	6.05	6.05
Expected dividend yield	0%	0%
Expected volatility of underlying common stock	75%	73%

The risk-free interest rate was based on rates associated with U.S. Treasury issues approximating the expected life of the stock options. The expected term of stock options granted to employees was determined using the simplified method, which represents the midpoint of the contractual term of the stock option and the weighted-average vesting period of the option. The Company uses the simplified method because it does not have sufficient historical stock option exercise data to provide a reasonable basis upon which to estimate the expected term. The expected dividend-yield assumption was based on the Company's expectation of no future dividend payments. The expected volatility of the underlying stock was based on the average historical volatility of comparable publicly traded companies based on weekly price returns as reported by a pricing service, as the Company does not have a trading history for its common stock.

The following table summarizes the stock option activity under the 2018 Plan and 2021 Plan:

	Stock Options	Weighted Average Exercise Price	Weighted Average Remaining Life (in Years)	Intrinsic Value (in thousands)
Outstanding January 1, 2021	1,445,426	$ 2.62	8.74	$ 3,799
Granted	1,981,311	8.70		
Exercised	(167,390)	2.13		
Canceled	(239,871)	3.73		
Outstanding December 31, 2021	3,019,476	$ 6.55	8.61	$ 2,120
Options vested or expected to vest as of December 31, 2021	3,019,476	$ 6.55	8.61	$ 2,120
Stock options exercisable as of December 31, 2021	610,182	$ 2.63	7.08	$ 2,120

Other information related to the option activity for the years ended December 31, 2021 and 2020:

	Year Ended December 31,	
	2021	2020
Weighted-average fair value of options granted	$ 5.74	$ 2.38
Intrinsic value of options exercised (in thousands)	$ 1,174	$ 148

As of December 31, 2021, the unrecognized compensation cost related to outstanding options was $10.0 million, which is expected to be recognized over a weighted-average period of 2.94 years.

Restricted Common Stock

The Company has granted restricted common stock with service based vesting conditions. Unvested shares of restricted common stock may not be sold or transferred by the holder, except for transfers for estate planning purposes in which the transferee agrees to remain bound by all restrictions set forth in the original common stock purchase agreement. They are legally issued and outstanding but only accounted for as outstanding when vested. These restrictions lapse over the four year vesting term of each award. The purchase price of each share of restricted common stock was $0.001 per share. A summary of the activity for the year ended December 31, 2021 is as follows:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested restricted stock as of January 1, 2021	438,280	-
Vested	(321,410)	-
Unvested restricted stock as of December 31, 2021	116,870	-

The aggregate fair value of restricted stock awards that vested during the year ended December 31, 2021 was nominal.

8. Income Taxes

During the years ended December 31, 2021 and 2020, the Company did not record an income tax provision due to the losses incurred and a full valuation allowance provided on the net deferred tax assets.

A reconciliation of the federal statutory income tax rate to the effective tax rate is as follows:

	Year Ended December 31,	
	2021	2020
Taxes at U.S. statutory rate	21.0%	21.0%
Changes from statutory rate:		
State taxes, net of federal benefit	8.3%	7.8%
Tax credits	4.1%	3.8%
Share-based compensation	-1.0%	-0.3%
Change in valuation allowance	-32.4%	-32.3%
Effective income tax rate	0.0%	0.0%

Deferred tax assets and liabilities reflect the net tax effects of net operating loss carryovers and temporary differences between the carrying amount of assets and liabilities for financial reporting and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets and liabilities were as follows (in thousands):

	Year Ended December 31,	
	2021	2020
Deferred tax assets:		
Net operating loss carryforwards	$ 18,742	$ 4,755
Tax credits	5,319	2,087
Deferred revenue	3,526	5,312
Depreciation and amortization	411	105
Amortization	571	617
Stock-based compensation	99	40
Leasehold liability	1,651	2,031
Other	688	664
Total deferred tax assets	31,007	15,611
Deferred tax liabilities:		
Right of use Asset	(1,500)	(1,878)
Valuation allowance	(29,507)	(13,733)
Net deferred tax assets and liabilities	$ -	$ -

In determining the need for a valuation allowance, the Company has given consideration to its cumulative losses. The Company has assessed the available means of recovering deferred tax assets, including the ability to carryback net operating losses, the existence of reversing taxable temporary differences, the availability of tax planning strategies and forecasted future taxable income. The Company maintains a full valuation allowance against its net deferred tax assets. The valuation allowance increased by $15.8 and $8.4 million during the years ended December 31, 2021 and 2020, respectively.

As of December 31, 2021, the Company had U.S. federal net operating loss carryforwards of approximately $69.1 million. The U.S. federal net operating losses have an indefinite life carryforward. As of December 31, 2021, the Company had Massachusetts net operating loss carryforwards of approximately $66.9 million that expire at various dates through 2041. As of December 31, 2021, the Company had U.S. R&D federal credit carryforwards of approximately $3.5 million that expire at various dates through 2040. As of December 31, 2021, the Company had U.S. state R&D tax credit carryforwards of approximately $2.3 million that expire at various dates through 2036.

Under Sections 382 and 383 of the U.S. Internal Revenue Code, if a corporation undergoes an ownership change, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change attributes, such as net operating losses and research tax credits, to offset its post-change income and taxes may be limited. In general, an ownership change generally occurs if there is a cumulative change in ownership by 5% stockholders that exceeds 50 percentage points over a rolling three-year period. Similar rules may apply under U.S. state tax laws. The Company may have experienced an ownership change in the past and may experience ownership changes in the future as a result of future transactions in its share capital, some of which may be outside the control of the Company. As a result, if the Company earns net taxable income, its ability to use its pre-change net operating loss carryforwards, or other pre-change tax attributes, to offset U.S. federal and state taxable income and taxes may be subject to significant limitations.

The Company accounted for uncertain tax positions using a more likely than not threshold for recognizing and resolving uncertain tax positions. The evaluation of uncertain tax positions is based on factors that include, but are not limited to, changes in tax law, the

measurement of tax positions taken or expected to be taken in tax returns, the effective settlement of matters subject to audit, new audit activity and changes in facts or circumstances related to a tax position. The Company evaluates uncertain tax positions on an annual basis and adjusts the level of the liability to reflect any subsequent changes in the relevant facts surrounding the uncertain positions. The Company accounts for interest and penalties related to uncertain tax positions as part of its provision for income taxes. For the years ended December 31, 2021 and 2020, there were no accrued interest or penalties in the consolidated statements of operations.

The Company is subject to taxation for federal and Massachusetts purposes. As of December 31, 2021, the Company is subject to examination by these taxing authorities for all years since inception.

9. 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. Under the Novartis Agreement, the Company will identify and characterize TCRs in accordance with a research plan, transfer data arising from the research plan. Novartis will have the option to license and develop TCRs for up to three novel targets identified in performance of the collaboration during the collaboration period of the Novartis Agreement. Novartis will also have rights of first negotiation for certain additional targets and TCRs identified in performance of the collaboration during a defined collaboration period of the Novartis Agreement and for 180 days after such collaboration period ends (which collaboration period will end no later than March 2023). If during such 180-day right of first negotiation period, the Company notifies Novartis of the Company's intent to grant a third party a license to a target or TCR identified in the collaboration, then Novartis may obtain the exclusive right to negotiate a license to such target or TCR for an additional 270 days by providing the Company with a term sheet to license such target or TCR within 90 days of the Company's notice of such intent. The Novartis Agreement provides for payments of an upfront fee of $20.0 million, research funding totaling $10.0 million and potential milestone payments contingent on clinical, regulatory and sales success. In addition to payments upon achievement of certain clinical and regulatory milestones, Novartis will pay the Company mid-single to low double-digit royalties on net sales for each product directed to a target licensed by Novartis. After the end of the collaboration period and the expiration of Novartis' first right of negotiation, the Company is free to develop TCRs against targets not licensed by Novartis.

The Company concluded that Novartis meets the definition of a customer, as the Company is delivering research and development activities and know-how rights. The Company identified performance obligations for research and development activities, data reporting and participation in joint steering and research committees. The Company determined there is a single performance obligation due to the services being highly interrelated and are therefore not distinct in the context of the contract. The Company combined the pre-option research services and data reporting into a single performance obligation Novartis has an exclusive option to obtain a commercial license for up to three Targets (as defined in the Novartis Agreement) to pursue further development and commercialization of the respective Target. Pursuant to the Novartis Agreement, the option for Novartis to license, develop, and commercialize Targets is not a performance obligation at the outset of the Novartis Agreement as it is a customer option that does not represent a material right.

The Company looked to the promises in the arrangement to determine the method of recognition that best coincides with the pattern of delivery. 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 is recognizing the revenue associated with the performance obligation using the input method, according to the actual costs incurred as a percentage of total expected costs to complete the research services. As costs are incurred, the Company will recognize revenue over time. Any change in the estimated percentage complete due to a revised cost forecast will be adjusted in the period in which the change in estimate occurs and the revenue recognition will be updated accordingly. The Company expects the research term to last approximately three years, which is inclusive of the option to extend the arrangement.

The Company determined that the $20.0 million upfront payment, together with the $10.0 million of estimated research costs to be reimbursed by Novartis to be the entirety of the consideration to be included in the transaction price as of the outset of the arrangement. The potential milestone payments that the Company is eligible to receive were excluded from the transaction price, as all milestone amounts were fully constrained based on the assessed probability of achievement. The Company will re-evaluate the transaction price at the end of each reporting period and as uncertain events are resolved or other changes in circumstances occur, and, if necessary, adjust the estimate of the transaction price.

During the years ended December 31, 2021 and 2020, the Company recognized $9.8 million and $0.8 million, respectively of revenue associated with the Novartis Agreement based on performance completed during that period. Additionally, during the years ended December 31, 2021 and 2020, the Company incurred $3.3 million and $0.2 million, respectively of costs associated with the Novartis Agreement that were recorded within research and development expenses in the statements of operations. Additionally, as of December 31, 2021, the Company had current and long-term deferred revenue of $11.4 million and $1.5 million, respectively due to

Novartis Agreement. As of December 31, 2020, the Company had current and long-term deferred revenue of $10.6 million and $8.8 million, respectively due to Novartis Agreement.

10. Commitments and Contingencies

Leases

In August 2019, the Company entered a lease for laboratory and office space with a term that expires on September 30, 2024, subject to certain renewal options, which are not deemed highly probable of renewal. The Company provided a letter of credit in the amount of $0.6 million as security for the lease which expires January 31, 2025. The cash securing the letter of credit is classified as restricted cash on the consolidated balance sheet.

In April 2020, laboratory and office space were secured through a sublease that commenced in June 2020 and will continue through March 2026. The Company provided a cash deposit of $0.2 million in conjunction with the execution of the lease which is classified as a long-term asset on the consolidated balance sheet.

On November 1, 2021, the Company entered a new lease for laboratory and office space. This lease will commence when the Company obtains possession of the underlying asset, which is expected to be November 1, 2022. The Company provided a letter of credit in the amount of $4.4 million as a security for the lease, which expires on November 30, 2022, at which point the letter will automatically renew each calendar year up to but not beyond April 1, 2033. The cash securing the letter of credit is classified as restricted cash on the consolidated balance sheet. Annual fixed rent will start at $7.6 million increasing 3% annually to $9.9 million through the original term of the lease, which is ten years and two months following the lease commencement date.

Summary of lease cost

The Company lease cost was $1.3 million and $1.3 million for the years ended December 31, 2021 and 2020, respectively. These amounts include short-term and variable lease costs, which were not significant in any period presented.

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

	Year ended December 31,	
	2021	2020
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows for operating leases	$ 1,948	$ 1,478

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

	Year ended December 31,	
	2021	2020
Weighted-average remaining lease term (in years)	3.4	4.4
Weighted-average discount rate	8%	8%

The following table represents the maturity of the Company's operating lease liabilities as of December 31, 2021 (in thousands):

Year Ending December 31,	Operating
2022	$ 2,075
2023	2,131
2024	1,812
2025	730
2026	184
Thereafter	-
Total future minimum lease payments (1)	6,932
Less: imputed interest	889
Present value of operating lease liability	$ 6,043

(1) As of December 31, 2021, the Company entered into an additional operating lease which had not yet commenced and is therefore not part of the table above nor included in the lease right-of-use asset and liability. This lease will commence when the Company obtains possession of the underlying asset, which is expected to be November 1, 2022.

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. (or 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.

11. Retirement Plan

The Company initiated a defined contribution plan under Section 401(k) of the IRC (the Plan) covering all qualified employees effective January 1, 2019. Employee contributions are voluntary and are determined on an individual basis subject to the maximum allowable under federal tax regulations. The Company made contributions to the Plan of $0.4 million and $0.2 million for the years ended December 31, 2021 and 2020, respectively.

12. 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):

	Year Ended December 31,	
	2021	2020
Numerator:		
Net loss	$ (48,625)	$ (26,127)
Denominator:		
Weighted-average common shares outstanding, basic and diluted	11,662,672	916,014
Net loss per share, basic and diluted	$ (4.17)	$ (28.52)

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:

	December 31,	
	2021	2020
Series A Preferred Stock (as converted to common stock)	-	3,209,240
Series B Preferred Stock (as converted to common stock)	-	3,853,864
Unvested restricted common stock	116,870	438,280
Options to purchase common stock	3,019,476	1,445,427
Total	3,136,346	8,946,811

13. Related-Party Transactions

Novartis and its affiliates hold shares of voting and non-voting common stock and is the customer in the Novartis Agreement discussed in Note 9.

Exhibit 4.4

DESCRIPTION OF SECURITIES REGISTERED UNDER SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

The following description of the securities of TScan Therapeutics, Inc. ("us," "our," "we" or the "Company") registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), is intended as a summary of the material terms of our amended and restated certificate of incorporation and amended and restated bylaws and therefore is not a complete description. This description is based upon, and is qualified by reference to, our amended and restated certificate of incorporation, our amended and restated bylaws, and applicable provisions of the Delaware General Corporation Law. You should read our amended and restated certificate of incorporation and amended and restated bylaws, which are filed as Exhibit 3.1 and Exhibit 3.2, respectively, to the Annual Report on Form 10-K of which this Exhibit 4.4 is a part, for the provisions that are important to you.

Our authorized capital stock consists of 320,000,000 shares, all with a par value of $0.0001 per share, of which:

- 300,000,000 shares are designated common stock;
- 10,000,000 shares are designated non-voting common stock; and
- 10,000,000 shares are designated preferred stock.

Common Stock and Non-Voting Common Stock

The holders of our common stock and non-voting common stock have identical rights, provided that, (i) except as otherwise expressly provided in our amended and restated certificate of incorporation or as required by applicable law, on any matter that is submitted to a vote by our stockholders, holders of our common stock are entitled to one vote per share of common stock, and holders of our non-voting common stock are not entitled to any votes per share of non-voting common stock, including for the election of directors, and (ii) holders of our common stock have no conversion rights, while holders of our non-voting common stock shall have the right to convert each share of our non-voting common stock into one share of common stock at such holder's election, provided that as a result of such conversion, such holder, together with its affiliates and any members of a Schedule 13(d) group with such holder, would not beneficially own in excess of 4.99% of our common stock immediately prior to and following such conversion, unless otherwise as expressly provided for in our amended and restated certificate of incorporation. However, this ownership limitation may be increased or decreased to any other percentage designated by such holder of non-voting common stock upon 61 days' notice to us.

Dividend Rights

Subject to preferences that may apply to shares of preferred stock outstanding at the time, the holders of outstanding shares of our common stock and non-voting common stock are entitled to receive dividends out of funds legally available if our board of directors, in its discretion, determines to issue dividends and only then at the times and in the amounts that our board of directors may determine.

Voting Rights

The holders of our common stock are entitled to one vote per share. Stockholders do not have the ability to cumulate votes for the election of directors. Our amended and restated certificate of incorporation and amended and restated bylaws provide for a classified board of directors consisting of three classes of approximately equal size, each serving staggered three-year terms. Only one class of directors will be elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms.

No Preemptive or Similar Rights

Our common stock and non-voting common stock are not entitled to preemptive rights and are not subject to conversion, redemption or sinking fund provisions.

Right to Receive Liquidation Distributions

Upon our dissolution, liquidation or winding-up, the assets legally available for distribution to our stockholders are distributable ratably among the holders of our common stock and non-voting common stock, subject to prior satisfaction of all outstanding debt and liabilities and the preferential rights and payment of liquidation preferences, if any, on any outstanding shares of preferred stock.

Preferred Stock

No shares of preferred stock are outstanding, but we are authorized, subject to limitations prescribed by Delaware law, to issue preferred stock in one or more series, to establish from time to time the number of shares to be included in each series and to fix the designation, powers, preferences and rights of the shares of each series and any associated qualifications, limitations or restrictions. Our board of directors also can increase or decrease the number of shares of any series, but not below the number of shares of that series then outstanding, without any further vote or action by our stockholders. Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of the common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in control of our Company and may adversely affect the market price of our common stock and the voting and other rights of the holders of common stock. We have no current plan to issue any shares of preferred stock.

Registration Rights

Pursuant to the terms of our amended and restated investors' rights agreement, dated January 15, 2021, with certain of our stockholders, certain of our stockholders are entitled to rights with respect to the registration of their shares (which we refer to herein as "registrable securities") under the Securities Act of 1933, as amended (the "Securities Act"), including demand registration rights, piggyback registration rights, and short-form registration rights..

We will pay all expenses relating to any registration described above, other than underwriting discounts and commissions. The registration rights terminate upon the earliest to occur of: (i) July 15, 2024; (ii) a liquidation event; or (iii) with respect to the registration rights of an individual holder, such time as Rule 144 or another similar exemption under the Securities Act is available for the sale of all of such holder's shares without limitation during a three-month period.

Anti-Takeover Provisions

Delaware Law

We are governed by the provisions of Section 203 of the Delaware General Corporation Law regulating corporate takeovers. This section prevents some Delaware corporations from engaging, under some circumstances, in a business combination, which includes a merger or sale of at least 10% of the corporation's assets with any interested stockholder, meaning a stockholder who, together with affiliates and associates, owns or, within three years prior to the determination of interested stockholder status, did own 15% or more of the corporation's outstanding voting stock, unless:

- the transaction is approved by the board of directors prior to the time that the interested stockholder became an interested stockholder;

- upon closing of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding those shares owned (i) by persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

- subsequent to such time that the stockholder became an interested stockholder the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders by at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

A Delaware corporation may "opt out" of these provisions with an express provision in its original certificate of incorporation or an express provision in its certificate of incorporation or bylaws resulting from a stockholders' amendment approved by at least a majority of the outstanding voting shares. We have not opted out of these provisions. As a result, mergers or other takeover or change in control attempts of us may be discouraged or prevented.

Certificate of Incorporation and Bylaw Provisions

Our amended and restated certificate of incorporation and our amended and restated bylaws include a number of provisions that may have the effect of deterring hostile takeovers or delaying or preventing changes in control of our management team, including the following:

- *Board of Directors Vacancies*. Our amended and restated certificate of incorporation and amended and restated bylaws authorize our board of directors to fill vacant directorships, including newly-created seats. In addition, the number of directors constituting our board of directors will be set only by resolution adopted by a majority vote of our entire board of directors. These provisions would prevent a stockholder from increasing the size of our board of directors and gaining control of our board of directors by filling the resulting vacancies with its own nominees.

- *Classified Board*. Our amended and restated certificate of incorporation and amended and restated bylaws provide that our board of directors are classified into three classes of directors, each of which will hold office for a three-year term. In addition, directors may only be removed from the board of directors for cause and only by the approval of 66 2/3% of our then-outstanding shares of our common stock. A third party may be discouraged from making a tender offer or otherwise attempting to obtain control of us as it is more difficult and time consuming for stockholders to replace a majority of the directors on a classified board of directors.

- *Stockholder Action; Special Meeting of Stockholders*. Our amended and restated certificate of incorporation provides that stockholders will not be able to take action by written consent, and will only be able to take action at annual or special meetings of our stockholders. Stockholders will not be permitted to cumulate their votes for the election of directors. Our amended and restated bylaws further provides that special meetings of our 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.

- *Advance Notice Requirements for Stockholder Proposals and Director Nominations.* Our amended and restated bylaws provides advance notice procedures for stockholders seeking to bring business before our annual meeting of stockholders, or to nominate candidates for election as directors at any meeting of stockholders. Our amended and restated bylaws also specifies certain requirements regarding the form and content of a stockholder's notice. These provisions may preclude our stockholders from bringing matters before our annual meeting of stockholders or from making nominations for directors at our meetings of stockholders.

- *Issuance of Undesignated Preferred Stock*. Our board of directors have the authority, without further action by the holders of common stock, to issue up to 10,000,000 shares of undesignated preferred stock with rights and preferences, including voting rights, designated from time to time by the board of directors. The existence of authorized but unissued shares of preferred stock will enable our board of directors to render more difficult or discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise.

Choice of Forum

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 amended and restated certificate of incorporation or our amended and restated bylaws or any action asserting a claim against us that is governed by the internal affairs doctrine. This provision would 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 will be 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.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Computershare Inc. The transfer agent's address is 150 Royall Street, Canton, Massachusetts 02021, and its telephone number is (800) 942-5909.

Listing

Our common stock is listed on The Nasdaq Global Market under the symbol "TCRX."

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement No. 333-257941 on Form S-8 of our report dated March 9, 2022, relating to the financial statements of TScan Therapeutics, Inc. appearing in this Annual Report on Form 10-K for the year ended December 31, 2021.

/s/ Deloitte & Touche LLP

Boston, Massachusetts March 9, 2022

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, David Southwell, certify that:

1. I have reviewed this Annual Report on Form 10-K 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. (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

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

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

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

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

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

Date: March 9, 2022

By: /s/ David Southwell

Name: David Southwell

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, Brian Silver, certify that:

1. I have reviewed this Annual Report on Form 10-K 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. (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

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

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

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

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

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

Date: March 9, 2022

By: /s/ Brian Silver

Name: Brian Silver

Title: Chief Financial Officer

(Principal Financial and Accounting Officer)

Exhibit 32.1

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

In connection with the Annual Report of TScan Therapeutics, Inc. (the "Company") on Form 10-K for the period ending December 31, 2021 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: March 9, 2022

By: /s/ David Southwell
David Southwell
(Principal Executive Officer)

ACTIVE/115677509.1

Exhibit 32.2

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 Annual Report of TScan Therapeutics, Inc. (the "Company") on Form 10-K for the period ending December 31, 2021 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: March 9, 2022

By: /s/ Brian Silver
Brian Silver
(Principal Financial and Accounting Officer)

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