# **UNITED STATES** SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Amendment No 1 to FORM S-1 **REGISTRATION STATEMENT** 

> Under The Securities Act of 1933

# TSCAN THERAPEUTICS, INC.

(Exact name of Registrant as specified in its charter)

| Delaware                          | 2836  | 82-5282075                          |
|-----------------------------------|---|-------------------------------------|
| (State or other jurisdiction of   | (Primary Standard Industrial                      | (I.R.S. Employer                    |
| incorporation or organization)    | Classification Code Number)                       | Identification Number)              |
|                                   | 830 Winter Street                                 |                                     |
|                                   | Waltham, Massachusetts 02451                      |                                     |
|                                   | (857) 399-9500                                    |                                     |
| (Address, including zin code, and | telephone number, including area code, of Registi | rant's principal executive offices) |
|                                   |   | ,                                   |
|                                   |   |                                     |
|                                   | David Southwell                                   |                                     |
|                                   | President and Chief Executive Officer             |                                     |
|                                   | TScan Therapeutics, Inc.                          |                                     |
|                                   | 830 Winter Street                                 |                                     |
|                                   | Waltham, Massachusetts 02451                      |                                     |
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| Approximate date of commencement of | proposed sale to the | public: As soon a | s practicable after the effec | tive date of this registration statement. |
|-------------------------------------|----------------------|-------------------|-------------------------------|---|
|                                     |                      |                   |                               |   |

| tatement number of the earlier effective registration statement for the same offering. $\Box$   | 3 Securities Act registration      |   |
|---|------------------------------------|---|
| f this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration ffective registration statement for the same offering.   | on statement number of the earlier |   |
| f this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registrati<br>ffective registration statement for the same offering.  | on statement number of the earlier |   |
| ndicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emergi.<br>efinitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act. |                                    |   |
| arge accelerated filer $\square$  | Accelerated filer                  |   |
| Ion-accelerated filer ⊠   | Smaller reporting company          | X |
|   | Emerging growth company            | X |
| f 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 related transition period for complying with any new or related pursuant to Section 7(a)(2)(B) of the Securities Act.  | revised financial accounting       |   |
| CALCIL ATION OF DECISTRATION FEE  |                                    |   |

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.  $\Box$ 

| Title of Each Class of<br>Securities to be Registered | Proposed<br>Maximum<br>Aggregate<br>Offering Price(1)(2) | Amount of<br>Registration Fee(3) |
|---|--|----------------------------------|
| Common Stock, \$0.0001 par value per share            | \$100,000,000.00   | \$10,910.00(4)                   |

- Estimated pursuant to Rule 457(o) under the Securities Act of 1933, as amended.
- Includes the aggregate offering price of additional shares that the underwriters have the option to purchase. Calculated pursuant to Rule 457(o) based on an estimate of the proposed maximum aggregate offering price.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities, and we are not soliciting offers to buy these securities in any jurisdiction where the offer or sale is not permitted.

PROSPECTUS (Subject To Completion)
Issued April 30, 2021



| TScan Therapeutics, Inc. is offering         | shares of its common stock.    | This is our initial public offeri | ng and no publi | c market currently exists for |
|--|--------------------------------|-----------------------------------|-----------------|-------------------------------|
| our shares of common stock. We anticipate th | at the initial public offering | price will be between \$          | and \$          | per share.                    |
| We have applied to list our common stock on  | the Nasdaa Global Market u     | nder the symbol "TCRX."           |                 |                               |

We are an "emerging growth company" and a "smaller reporting company" as defined under the federal securities laws.

We have two classes of common stock: the voting common stock offered hereby and which has one vote per share, and non-voting common stock. For a description of the rights of the voting common stock and non-voting common stock, please see "<u>Description of capital stock</u>" beginning on page 202 of this prospectus. We are offering voting common stock in this offering, and unless otherwise noted or unless the context provides otherwise, all references in this prospectus to our "common stock", "common shares" or "shares" refers to our voting common stock.

A SHARE

Investing in our common stock involves risks. See "Risk Factors" beginning on page 14.

|  | Per Share | <u>Total</u> |
|--|-----------|--------------|
| Initial public offering price              | \$        | \$           |
| Underwriting discounts and commissions (1) | \$        | \$           |
| Proceeds, before expenses, to us           | \$        | \$           |

PRICE \$

We have granted the underwriters an option to purchase up to an additional shares of common stock at the initial public offering price less underwriting discounts and commissions to cover over-allotments. If the underwriters exercise this option in full, the total underwriting discounts and commissions payable by us will be \$ , and the total proceeds, before expenses to us will be \$ .

The Securities and Exchange Commission and state securities regulators have not approved or disapproved of these securities, or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the shares of common stock to purchasers on , 2021.

MORGAN STANLEY

JEFFERIES

COWEN

BARCLAYS

, 2021

<sup>(1)</sup> See "Underwriters" for a description of the compensation payable to the underwriters.

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Through and including , 2021 (the 25th day after the date of this prospectus), all dealers effecting transactions in shares of our common stock, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

We and the underwriters have not authorized anyone to provide you with any information or to make any representations other than those contained in this prospectus or in any free writing prospectuses we have prepared. We and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus or in any applicable free writing prospectus is accurate only as of the date of this prospectus or any such free writing prospectus, as applicable, regardless of its time of delivery or of any sale of our common stock. Our business, financial condition, results of operations and future growth prospects may have changed since that date.

For investors outside the United States: Neither we nor any of the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside of the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of our common stock and the distribution of this prospectus outside of the United States.

TScan, the TScan logo and our other registered or common law trademarks appearing in this prospectus are the property of TScan Therapeutics, Inc. This prospectus contains references to our trademarks and service marks and to those belonging to other entities. Solely for convenience, trademarks and trade names referred to in this prospectus, including logos, artwork and other visual displays, may appear without the ® or TM symbols, but such references are not intended to indicate in any way that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other entities' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other entity.

#### PROSPECTUS SUMMARY

This summary highlights selected information contained elsewhere in this prospectus and is qualified in its entirety by the more detailed information and financial statements included elsewhere in this prospectus. It does not contain all of the information that may be important to you and your investment decision. You should carefully read this entire prospectus, including the sections titled "Risk factors," "Management's discussion and analysis of financial condition and results of operations" and our financial statements and related notes before making an investment decision. In this prospectus, unless context requires otherwise, references to "we," "us," "our," "TScan," or "the Company" refer to TScan Therapeutics, Inc.

#### Overview

We are a preclinical-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 believe this two-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 after 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 plan to submit Investigational New Drug, or IND, applications for each of TSC-100 and TSC-101 with the U.S. Food and Drug Administration, or FDA, in the fourth quarter of 2021. In addition, we are developing multiple TCR-T therapy candidates for the treatment of various 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 are currently advancing four solid tumor programs, TSC-200, TSC-201, TSC-202, and TSC-203, through lead optimization, and expect to submit IND applications for at least three of our four solid tumor TCR-T therapy candidates in the second half of 2022, with the fourth IND 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 has 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.

#### **Our Pipeline**

We are leveraging our proprietary platform technologies to develop a robust pipeline of TCR-T therapies with the goal of building our ImmunoBank of TCRs to treat a wide range of tumor types. 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.



- (1) TSC-200 will only be developed in HPV-positive cancers, which include head & neck, cervical, and anal cancers.
- (2) For additional information regarding the targets for TSC-201 and TSC-202, see "Business Solid Tumor Program TSC-200 Series."

In addition to our proprietary pipeline programs noted above, we also are in the discovery phase for our TSC-102 program. Beyond our proprietary pipeline programs, we have also entered into collaborations with strategic partners for applications of our platform technologies. We have a collaboration and license agreement with Novartis to identify novel cancer antigens from the T cells of patients with one specific type of cancer. Novartis has the option to license and develop therapies for up to three discovered targets. 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.

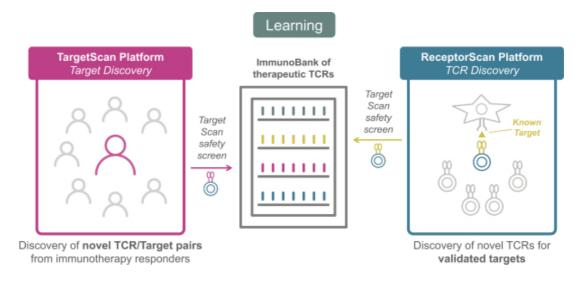
# **Our Approach**

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. We select TCRs that are highly active with no apparent problematic off-target effects to be added to our 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. 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 are added to ImmunoBank.

#### **Our Proprietary Target and TCR Discovery Process**

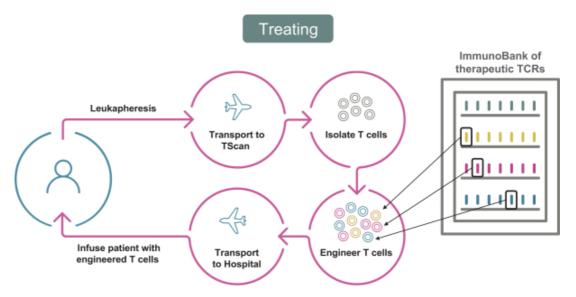


#### Treating

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. Our manufacturing process begins with obtaining white blood cells 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. 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**



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 this will allow us to 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.
- *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; and (v) manufacture TCR-T therapies efficiently and consistently without the use of viral vectors using our T-Integrate technology. The three central elements of our platform that differentiate us from other cell therapy companies are TargetScan, ReceptorScan, and T-Integrate.

TargetScan. 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. TargetScan is also 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.

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 previously identified clinically validated targets. We co-culture hundreds of millions of CD8+ T cells from either healthy donors or cancer patients with dendritic 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.

*T-Integrate.* 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 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 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 Programs**

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 well-recognized cancer targets that have been discovered in patients with exceptional responses to HCT-associated immunotherapy, including HA-1 and HA-2. In addition, to further expand our liquid tumor program, we are developing additional product candidates that target other similarly validated antigens, enabling us to expand the addressable patient population.

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. 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. We plan to incorporate additional product candidates into this trial design as they advance into the clinic, which we believe will allow us to provide a broad array of therapeutic options for the majority of patients with hematologic malignancies receiving HCT. In our clinical trials of TSC-100 and TSC-101, we also plan to evaluate the potential benefit of combining the two therapies as a multiplexed TCR-T therapy for patients who are positive for both HA-1 and HA-2.

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.

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 TCR-T therapy 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 four solid TCR-T therapy candidates include a combination of known targets, such as HPV16 for TSC-200 and PRAME for TSC-203, as well as targets that are novel antigens for TCR-T therapy, such as for TSC-201 and TSC-202. In addition to our four lead solid TCR-T therapy candidates, we have identified over 40 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 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 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 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;
- Advance our lead liquid tumor product candidates, TSC-100 and TSC-101, through clinical development;
- Apply experience from our liquid tumor program to efficiently develop our solid tumor program targeting both novel and previously identified antigens;
- Continue to develop internal manufacturing capabilities based on our non-viral T-Integrate system;
- Develop next generation T-cell engineering capabilities, including allogeneic technologies; and
- Opportunistically pursue strategic partnerships and collaborations to maximize the full potential of our platform in therapeutic areas outside of oncology, such as autoimmune disorders and infectious disease.

# **Our History and Team**

We were founded in early 2018 to discover and develop transformational therapies using a novel T-cell target discovery platform developed by Drs. Stephen Elledge and Tomasz Kula at Brigham and Women's Hospital and Harvard Medical School. Since then, we have made substantial progress building our target and TCR discovery platform technologies, discovering new targets and TCRs, advancing our two lead programs into IND-enabling studies, developing in-house manufacturing capabilities, and, in response to the ongoing COVID-19 pandemic, identifying the targets of T cells from recovering COVID-19 patients. In addition, we have entered into multiple strategic collaborations, including with Novartis Institutes for Biomedical Research, Inc. and QIAGEN Sciences, LLC.

We have assembled a highly qualified team with deep experience in T-cell biology, high throughput screening, engineering and manufacturing of cell therapies, as well as in all phases of research and clinical development, from early-stage discovery and IND-enabling studies through registrational clinical trials. Our team includes industry veterans with prior experience at academic and research institutions such as Harvard University, Harvard Medical School, and Massachusetts General Hospital, and companies such as BlueRock Therapeutics, LLC, CRISPR Therapeutics, Inc., Editas Medicine, Inc., Human Genome Sciences, Inc., Kite Pharma, Inc., KSQ Therapeutics, Inc., Merrimack Pharmaceuticals, Inc., Regeneron Pharmaceuticals, Inc., Repertoire Immune Medicines, Inc., and SQZ Biotechnologies Company. Our research efforts also benefit from the informal advice and guidance provided by our scientific advisory board (SAB) members, including Drs. Elledge and Kula, who receive equity and/or cash compensation. Since our inception, we have raised an aggregate of \$160 million from leading biotechnology investors, including RA Capital Management, Novartis Venture Fund, Novartis Institutes for Biomedical Research, Longwood Fund, Bessemer Venture Partners, GV, 6 Dimensions Capital, Astellas Venture Management, and Pitango HealthTech.

# **Recent Developments**

# Preliminary unaudited cash and cash equivalents as of March 31, 2021

On a preliminary unaudited basis, we expect our cash and cash equivalents as of March 31, 2021 to be approximately \$121.5 million. This estimate of cash and cash equivalents is our preliminary estimate based on currently available information and does not present all necessary information for an understanding of our financial condition as of March 31, 2021 or our results of operations for the three months ended March 31, 2021. This preliminary estimate has been prepared by and is the responsibility of our management. Our independent

registered public accounting firm has not audited, reviewed or performed any procedures with respect to this preliminary estimate or the accounting treatment thereof and does not express an opinion or any other form of assurance with respect thereto. We expect to complete our financial statements for the three months ended March 31, 2021 subsequent to the completion of this offering. It is possible that we or our independent registered public accounting firm may identify items that require us to make adjustments to the preliminary estimated cash and cash equivalents balance set forth above and those changes could be material. Accordingly, you should not place undue reliance on this preliminary estimate. The preliminary estimate is not necessarily indicative of any future period and should be read together with the sections titled "Risk factors" and "Special note regarding forward-looking statements."

#### **Private Placement**

In January 2021, we issued and sold 70,136,064 shares of Series C convertible preferred stock and received net cash proceeds of \$99.7 million.

#### **Risks Associated with Our Business**

Investing in our common stock involves substantial risk. Our ability to execute our business strategy is subject to numerous risks, as more fully described in the section entitled "Risk Factors" immediately following this prospectus summary. Some of the most significant challenges and risks are more fully described in the section entitled "Risk Factors" and are summarized in the section entitled "Risk Factor Summary."

#### **Corporate Information**

We were incorporated in the State of Delaware in April 2018. Our principal executive offices are located at 830 Winter Street, Waltham, Massachusetts 02451. Our telephone number is (857) 399-9500. Our website address is www.tscan.com. Information contained on the website is not incorporated by reference into this prospectus, and you should not consider it part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

# Implications of Being an Emerging Growth Company and a Smaller Reporting Company

As a company with less than \$1.07 billion in revenue during our most recently completed fiscal year, we qualify as an "emerging growth company" as defined in Section 2(a) of the Securities Act of 1933, as amended, or the Securities Act, as modified by the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As an emerging growth company, we may take advantage of certain exemptions from requirements that are otherwise applicable, in general, to public companies. These provisions include:

- being permitted to present only two years of audited financial statements in addition to any required unaudited interim financial statements with correspondingly reduced disclosure in the section titled "Management's discussion and analysis of financial condition and results of operations", in registration statements, including this prospectus, subject to certain exceptions;
- an exemption from compliance with the auditor attestation requirement on the effectiveness of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002;
- an exemption from compliance with any requirement that the Public Company Accounting Oversight Board may adopt regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;

- reduced disclosure about our executive compensation arrangements in our periodic reports, proxy statements, and registration statements, including this prospectus;
- exemptions from the requirements to obtain a non-binding advisory vote on executive compensation or a stockholder approval of any golden parachute arrangements; and
- extended transition periods for complying with new or revised accounting standards.

We will remain an emerging growth company until the earliest to occur of: (i) the last day of the fiscal year in which we have more than \$1.07 billion in annual revenue; (ii) the date we qualify as a "large accelerated filer," with at least \$700 million of equity securities held by non-affiliates; (iii) the date on which we have issued, in any three-year period, more than \$1.0 billion in non-convertible debt securities; and (iv) the last day of the fiscal year ending after the fifth anniversary of the completion of this offering.

We may take advantage of these exemptions until such time that we are no longer an emerging growth company. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock. Further, pursuant to Section 107 of the JOBS Act, as an emerging growth company, we have elected to take advantage of the extended transition period for complying with new or revised accounting standards until those standards would otherwise apply to private companies. As a result, our operating results and consolidated financial statements may not be comparable to the operating results and financial statements of other companies who have adopted the new or revised accounting standards. It is possible that some investors will find our common stock less attractive as a result, which may result in a less active trading market for our common stock and higher volatility in our stock price.

We are also a "smaller reporting company," meaning that the market value of our stock held by non-affiliates plus the proposed aggregate amount of gross proceeds to us as a result of this offering is less than \$700 million and our annual revenue was less than \$100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company after this offering 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 future annual reports on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

For certain risks related to our status as an emerging growth company and a smaller reporting company, see the section titled "Risk Factors—Risks Related to Our Common Stock and this Offering—We are an "emerging growth company" and a "smaller reporting company," and we cannot be certain if the reduced reporting applicable to emerging growth companies and smaller reporting companies will make our common stock less attractive to investors."

# THE OFFERING Common stock offered by us shares Option to purchase additional shares of common stock from us shares Common stock to be outstanding after this offering shares, or shares if the underwriters exercise their option to purchase additional shares of common stock in full Non-voting common stock to be outstanding after this offering shares Total common stock and non-voting common stock to be outstanding after shares if the underwriters exercise their option this offering shares, or to purchase additional shares of common stock in full Directed Share Program At our request, the underwriters have reserved up to shares, or % of the shares offered by this prospectus, for sale at the initial public offering price through a directed share program to certain of our directors, officers, employees and business associates and other parties related to us. If purchased by these persons, these shares will be subject to a 180-day lock-up restriction. The number of shares available for sale to the general public will be reduced to the extent that such persons purchase such reserved shares. Any reserved shares not so purchased will be offered by the underwriters to the general public on the same basis as the other shares offered by this prospectus. Morgan Stanley & Co. LLC will administer our directed share program. See the sections titled "Certain Relationships and Related Party Transactions" and "Underwriters-Directed Share Program."

Use of proceeds

price range set forth on the cover page of this prospectus, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

We intend to use the net proceeds from this offering, together with our existing cash, to conduct clinical trials for TSC-100, TSC-101, and TSC-102, conduct IND-enabling activities and initiate clinical trials for

option to purchase additional shares in full), based upon an assumed

shares of

million if the underwriters exercise their

per share, the midpoint of the

million

We estimate that the net proceeds from the sale of

(or approximately \$

initial public offering price of \$

common stock in this offering will be approximately \$

TSC-200, TSC-201, TSC-202 and TSC-203, continue

Risk factors

Proposed Nasdaq trading symbol

development of our preclinical discovery programs and platform technologies, expand our manufacturing facility, as well as for working capital and other general corporate purposes. See the section titled "Use of Proceeds" for additional information.

See "Risk Factors" and the other information included in this prospectus for a discussion of risks you should carefully consider before investing in our common stock.

"TCRX"

The number of shares of our common stock and non-voting common stock to be outstanding after this offering is based on 140,961,519 shares of our common stock outstanding as of December 31, 2020, after giving effect to the automatic conversion of all outstanding shares of our preferred stock, including 70,136,064 shares of Series C convertible preferred stock issued in January 2021, into an aggregate of 128,053,586 shares of common stock (of which shares will be non-voting common stock) upon the completion of this offering, and excludes the following:

- 11,852,840 shares of common stock issuable upon the exercise of options outstanding under our 2018 Stock Plan, as amended, or the 2018 Plan, as of December 31, 2020, with a weighted-average exercise price of \$0.32 per share;
- 10,436,957 shares of common stock issuable upon the exercise of options outstanding under our 2018 Plan, granted after December 31, 2020, at a weighted-average exercise price of \$0.88 per share;
- 1,191,950 shares of common stock reserved for future issuance under our 2018 Plan, based on the number of shares available for issuance as of December 31, 2020, plus additional shares of common stock added to the plan in January 2021, less the shares of common stock underlying options granted subsequent to December 31, 2020 and set forth above, which shares will be added to the shares to be reserved under our 2021 Plan, at the time our 2021 Plan becomes effective in connection with this offering;
- 26,880,000 shares of common stock that will become available for future issuance under our 2021 Plan, which will become effective upon the effectiveness of the registration statement of which this prospectus forms a part, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the 2021 Plan; and
- 2,086,000 shares of common stock that will become available for future issuance under our 2021 Employee Stock Purchase Plan, or the 2021 ESPP, which will become effective upon the effectiveness of the registration statement of which this prospectus forms a part, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the 2021 ESPP.

Unless otherwise indicated, all information in this prospectus reflects and assumes:

- the automatic conversion of all shares of our preferred stock, including the Series C convertible preferred stock issued in January 2021, into shares of common stock (of which shares will be non-voting common stock) upon the completion of this offering;
- the filing and effectiveness of our amended and restated certificate of incorporation and the adoption of our amended and restated bylaws, each of which will occur immediately prior to the completion of this offering;
- no exercise of the underwriters' option to purchase additional shares of common stock;
- no exercise of the outstanding options described above after December 31, 2020; and
- no purchase of shares through our directed share program described under "Underwriters—Directed Share Program."

# SUMMARY CONSOLIDATED FINANCIAL DATA

The following tables set forth a summary of our historical consolidated financial data as of, and for, the periods ended on the dates indicated. The summary consolidated statements of operations data for the years ended December 31, 2019 and 2020 and the consolidated balance sheet data as of December 31, 2020 are derived from our audited consolidated financial statements and related notes included elsewhere in this prospectus. You should read these summary financial data together with our financial statements and related notes appearing elsewhere in this prospectus and the information in the section titled "Management's discussion and analysis of financial condition and results of operations." The selected consolidated financial data in this section are not intended to replace our consolidated financial statements and the related notes and are qualified in their entirety by the consolidated financial statements and related notes included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results to be expected in the future.

|   | Year ende   | ed December 31, |
|---|-------------|-----------------|
| (in thousands, except share and per share data)               | 2019        | 2020            |
| Statement of operations data:                                 |             |                 |
| Revenue:  |             |                 |
| Collaboration and license revenue                             | \$ —        | \$ 1,085        |
| Operating expenses:   |             |                 |
| Research and development                                      | 9,442       | 20,577          |
| General and administrative                                    | 4,768       | 6,741           |
| Total operating expenses                                      | 14,210      | 27,318          |
| Loss from operations  | (14,210)    | (26,233)        |
| Other income:   |             |                 |
| Interest income   | 552         | 106             |
| Net loss  | \$ (13,658) | \$ (26,127)     |
| Net loss per, basic and diluted                               | \$ (4.33)   | \$ (3.48)       |
| Weighted average common shares outstanding, basic and diluted | 3,157,800   | 7,511,378       |

|                                      |           | As of December 31, 2020         |                |  |
|--------------------------------------|-----------|---------------------------------|----------------|--|
|                                      |           | Pro                             | Pro forma as   |  |
|                                      | Actual    | forma(1)                        | adjusted(2)(3) |  |
|                                      | (in       | (in thousands, except share and |                |  |
| Balance sheet data:                  |           | per share data                  |                |  |
| Cash                                 | \$ 34,791 | \$134,491                       | \$             |  |
| Working capital(4)                   | 18,999    | 118,699                         |                |  |
| Total assets                         | 49,738    | 149,438                         |                |  |
| Total liabilities                    | 32,519    | 32,519                          |                |  |
| Convertible preferred stock          | 59,681    | _                               |                |  |
| Accumulated deficit                  | (43,533)  | (43,533)                        |                |  |
| Total stockholders' (deficit) equity | (42,462)  | 116,919                         |                |  |

Pro forma balance sheet data gives effect to (i) the issuance of 70,136,064 shares of Series C convertible preferred stock issued in January 2021 and (ii) the automatic conversion of all outstanding shares of our convertible preferred stock, including the shares of Series C convertible preferred stock issued in January 2021, into an aggregate of shares of common stock (of which shares will be non-voting common stock) upon completion of this offering, as if such conversion had occurred on December 31, 2020.

of common stock (of which shares will be non-voting common stock) upon completion of this offering, as if such conversion had occurred on December 31, 2020.

The pro forma as adjusted column gives further effect to the sale and issuance of shares of our common stock by us in this offering at the assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

- The pro forma as adjusted information is illustrative only and will depend on the actual public offering price and other terms of this offering determined at pricing. A \$1.00 increase (decrease) in the assumed initial public offering price of \$ per share, the midpoint of the estimated offering price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash, working capital, total assets and total stockholders' equity by \$ million, assuming that the number of shares of common stock offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions payable by us. An increase (decrease) of 1.0 million shares in the number of shares of common stock offered by us, as set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash, working capital, total assets and total stockholders' equity by \$ million, assuming no change in the assumed initial public offering price of \$ per share, the midpoint of the estimated offering price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. (3)
- (4) We define working capital as current assets less current liabilities.

#### 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 prospectus, including "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 prospectus before deciding whether to invest in shares of our common stock. 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. In that event, the market price of our common stock could decline, and you could lose part or all of your investment. See "Special Note Regarding Forward-Looking Statements."

#### RISK FACTOR SUMMARY

Our business operations are subject to numerous risks and uncertainties, including those outside of our control, that could cause our actual results to be harmed, including risks regarding 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.
- Even if this offering is successful, 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.

# 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.

- 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 establish our own 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**

#### 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 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. As of December 31, 2020, we had an accumulated deficit of \$43.5 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
- 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.

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.

Even if this offering is successful, 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. 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, upon the completion of this offering, we expect to incur additional costs associated with operating as a public company.

As of December 31, 2020, we had \$34.8 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 anticipated level of operations through at least the next 12 months without the proceeds from this offering. With the expected net proceeds from this offering, we believe that our cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements through . Accordingly, the expected net proceeds from this offering 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.

# 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 or 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 operate our own 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 our 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 create and operate our proposed 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, TSC-100, TSC-101, TSC-102, TSC-200, TSC-201, TSC-202, and TSC-203, 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. 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-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 quarantee 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.

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 expect to submit an IND for TSC-100 and TSC-101 in the fourth quarter of 2021 and submit IND applications for at least three of our four solid tumor TCR-T therapy candidates in the second half of 2022, with the fourth IND 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

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., 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, Selecta Biosciences, Inc., TCR2 Therapeutics Inc., Adaptive Therapeutics, Inc., Immatics US, 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. For additional information regarding our competition, see "Business—Competition."

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 produ

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 cyberattacks 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 establish our own 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 establish our own 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 establishing manufacturing capacity to support our Phase 1 and Phase 2 clinical trials for TSC-100, TSC-101, TSC-102, 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-201, 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, upon completion of this offering and 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

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.

Effective upon the closing of this offering, we will adopt 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 e

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 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 pr

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. See "Business—License and Collaboration Agreements" for more information regarding our agreement with PHSA. 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 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 mark

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 jurisdi

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 operatio

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 (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. See "Business—License and Collaboration Agreements" for more information regarding our collaboration agreements.

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 December 31, 2020, we had 57 full-time employees and 1 part-time employee. As our development and commercialization plans and strategies develop, and as we transition into 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.

#### 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.

# 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.

## 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.

#### 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 most recent private placements and other transactions that have occurred over the past three years, we may have experienced, and, upon closing of this offering, may experience, 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 to this Offering

There has been no prior public market for our common stock, the stock price of our common stock may be volatile or may decline regardless of our operating performance and stockholders may not be able to resell their shares at or above the initial public offering price.

There has been no public market for our common stock prior to this offering. The initial public offering price for our common stock will be determined through negotiations between the underwriters and us and may vary from the market price of our common stock following this offering. If a purchaser of shares of our common stock in this offering, may not be able to resell those shares at or above the initial public offering price. An active or liquid market in our common stock may not develop upon the completion of this offering or, if it does develop, it may not be sustainable. The market price of our common stock may fluctuate significantly in response to numerous factors, many of which are beyond our control, 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 ECP 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 COVID-19;
- 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
- any other factors discussed in this prospectus.

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.

## Purchasers of shares of our common stock in this offering will experience substantial and immediate dilution.

Purchasers of shares of our common stock in this offering will experience substantial and immediate dilution in the pro forma net tangible book value per share after giving effect to this offering of \$ per share as of December 31, 2020, based on an assumed initial public offering price of our common stock of \$ per share, the midpoint of the price range on the cover page of this prospectus, because the price that a purchaser pays will be substantially greater than the pro forma net tangible book value per share of the common stock that the purchaser acquires. This dilution is due in large part to the fact that our earlier investors paid substantially less than the initial public offering price when they purchased their shares of our capital stock.

Purchasers in this offering will experience additional dilution upon exercise of options to purchase common stock under our equity incentive plans, upon vesting of options to purchase common stock under our equity incentive plans, if we issue restricted stock to our employees under our equity incentive plans or if we otherwise issue additional shares of our common stock.

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. After this offering, we will have outstanding shares of our common stock (including shares of non-voting common stock), based on the number of shares outstanding as of March 31, 2021. All of the shares of common stock sold in this offering will be available for sale in the public market, unless purchased by our affiliates or existing stockholders. Substantially all of our outstanding shares of common stock are currently restricted from resale as a result of "lock-up" agreements (which may be waived by Morgan Stanley & Co. LLC, Jefferies LLC, Cowen and Company, LLC, and Barclays Capital Inc. with or without notice), as more fully described in "Shares Eligible for Future Sale." These shares will become available to be sold 181 days after the date of this prospectus. Shares held by directors, executive officers and other affiliates will be subject to volume limitations under Rule 144 under the Securities Act of 1933, as amended, or the Securities Act, and various vesting agreements.

After our initial public offering, certain of our stockholders will have rights, subject to some conditions and subject to the lock-up agreements described 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, subject to lockup agreements. We also intend to register 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 (including the lock-up agreements described above).

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.

Prior to this offering our executive officers, directors, and 5% or greater stockholders beneficially owned, in the aggregate, approximately 72.5% of our outstanding voting stock as of March 31, 2021, and, upon the closing of this offering, assuming that same group will beneficially own approximately % of our outstanding voting stock (assuming no purchases of shares in this offering by any members of this group (including through our directed share program), no exercise by the underwriters of their option to purchase additional shares, no exercise of outstanding options or warrants and after giving effect to the issuance of shares in this offering, and further assuming that all shares of non-voting common stock are converted into voting common stock in accordance with the terms of our amended and restated certificate of incorporation). See "Description of capital stock—Common Stock and Non-Voting Common Stock". As a result, these stockholders, acting together, will 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, including those who purchase shares in this offering, oppose them. 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 during the period beginning at the closing of our initial public offering and for the three years thereafter, as long as (1) the BBA Funds and their affiliates, collectively, beneficially own at least 75% of the Series C convertible preferred stock purchased by the BBA Funds in such Series C convertible preferred stock financing, or such number of shares of our common stock issued upon conversion of such number of shares of Series C convertible preferred stock (in either case, as adjusted for any stock split, stock dividend, combination, or other recapitalization or reclassification or similar transaction), and (2) the BBA Funds and their affiliates, collectively, beneficially own at least 2% of our then outstanding voting common stock. For more information regarding this nominating agreement, see the section entitled "Management—Board composition." 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.

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) following the fifth anniversary of the completion of this offering, (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 this prospectus and 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.

After the completion of this offering, we will be 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.

After the completion of this offering, we will be 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 the year after this offering is completed, 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 this offering, 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 the net proceeds from this offering 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, expanding our 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 the net proceeds, including working capital and other general corporate purposes, and purchasers in this offering and other 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 the net proceeds from our initial public offering in a manner that does not produce income or that loses value. These investments may not yield a favorable return to our investors.

## 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.

## 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.

# 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 COVID-19; 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 that will be in effect at the completion of this offering could make a merger, tender offer or proxy contest difficult, thereby depressing the trading price of our common stack.

Following the completion of this offering, 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 that will be in effect at the completion of this offering will 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.

For information regarding these and other provisions, see the section titled "Description of capital stock."

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 will be 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 will provide 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 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, including claims arising from this offering. 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 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.

#### SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this prospectus, 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," "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 prospectus include, but are not limited to, statements about:

- the beneficial characteristics, safety, efficacy, therapeutic effects and potential advantages of our 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 resources and the proceeds from this offering 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" elsewhere in this prospectus. 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 prospectus 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 prospectus are made as of the date of this prospectus, 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 prospectus to conform these statements to actual results or to changes in our expectations.

You should read this prospectus and the documents that we reference in this prospectus and have filed with the SEC as exhibits to the registration statement of which this prospectus is a part with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

## INDUSTRY AND MARKET DATA

This prospectus 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 prospectus 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.

#### USE OF PROCEEDS

We estimate that the net proceeds from this offering will be approximately \$\frac{million}{million}, or \$\frac{million}{million} if the underwriters exercise their option to purchase additional shares in full, assuming an initial public offering price of \$\frac{per}{per}\$ per share, the midpoint of the estimated price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Each \$1.00 increase (decrease) in the assumed initial public offering price of \$ per share, the midpoint of the estimated price range set forth on the cover page of this prospectus, would increase (decrease) the net proceeds to us from this offering by \$ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of shares we are offering. An increase (decrease) of 1.0 million shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase (decrease) our net proceeds from this offering by \$ million, assuming no change in the assumed initial public offering price per share and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

As of December 31, 2020, we had cash of \$34.8 million. In addition, we issued and sold 70,136,064 shares of our Series C convertible preferred stock in January 2021 for an aggregate of \$99.7 million in net proceeds. We currently intend to use the net proceeds from this offering, together with our existing cash, as follows:

- approximately \$30.0 million to fund the Phase 1/2 clinical development of TSC-100, TSC-101, and TSC-102, through completion of the Phase 1 portion and part of the Phase 2 portion of our planned Phase 1/2 clinical trials;
- approximately \$35.0 million to conduct IND-enabling activities and initiate the Phase 1 clinical trials for TSC-200, TSC-201, TSC-202 and TSC-203;
- approximately \$25.0 million for the continued development of our discovery programs; and
- the remainder for continued development of our TargetScan and ReceptorScan platforms, expansion of our manufacturing facility, working
  capital and other general corporate purposes, which may include the hiring of additional personnel, capital expenditures and the costs of
  operating as a public company.

This expected use of the net proceeds from this offering represents our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering or the amounts that we will actually spend on the uses set forth above. The amounts and timing of our actual expenditures and the extent of our preclinical, clinical and future development activities may vary significantly depending on numerous factors, including the progress of our and our development partner's development efforts, the status of and results from our planned clinical trials, the timing of regulatory submissions and the outcome of regulatory review, the timing and costs associated with the manufacture and supply of product candidates for clinical development or commercialization, as well as any collaborations that we may enter into with third parties for our product candidates, and any unforeseen cash needs. As a result, we will retain broad discretion over the allocation of the net proceeds from this offering.

Based on our planned use of the net proceeds from this offering and our existing cash, we estimate that such funds will be sufficient to enable us to fund our operating expenses and capital expenditure requirements through . We have based these estimates on assumptions that may prove to be wrong and we could use our capital resources sooner than we currently expect.

We may also use a portion of the net proceeds from this offering for the acquisition or in-license of other therapeutic products, businesses or technologies, although we have no current agreements or commitments for

any material acquisitions or licenses of any products, businesses or technologies. Pending our use of the net proceeds from this offering, we plan to invest the net proceeds in a variety of capital preservation investments, including short-term interest-bearing investment-grade securities, certificates of deposit or government securities.

# DIVIDEND POLICY

We have never declared or paid any cash dividends on our capital stock and we do not currently intend to pay any cash dividends on our capital stock for the foreseeable future. We currently intend to retain all available funds and any future earnings to support operations and to finance the growth and development of our business. Our future ability to pay cash dividends on our capital stock may also be limited by the terms of any future debt or preferred securities or any future credit facility.

#### **CAPITALIZATION**

The following table sets forth our cash and our capitalization as of December 31, 2020:

- on an actual basis;
- on a pro forma basis to give effect to (i) the issuance and sale of 70,136,064 shares of Series C convertible preferred stock in January 2021 for net cash proceeds of \$99.7 million; (ii) the automatic conversion of all outstanding shares of our preferred stock, which includes our Series C convertible preferred stock, into an aggregate of 128,053,586 shares of common stock (including shares of non-voting common stock) upon completion of this offering, as if such conversion had occurred on December 31, 2020; and (iii) the filing and effectiveness of our amended and restated certificate of incorporation, which will occur immediately prior to the completion of this offering; and
- on a pro forma as adjusted basis to give further effect to the sale and issuance of shares of our common stock by us in this offering at the assumed initial public offering price of \$ per share of common stock, the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

You should read this information in conjunction with our financial statements and the related notes appearing elsewhere in this prospectus, as well as the section of this prospectus titled "Management's discussion and analysis of financial condition and results of operations."

|  | As of December 31, 2020 |                   |                 |  |
|--|-------------------------|-------------------|-----------------|--|
|  |                         |                   | Pro Forma<br>as |  |
|  | Actual                  | Pro Forma         | Adjusted(1)     |  |
|  | (in thou                | are and per       |                 |  |
| Cash and cash equivalents  | \$ 34,791               | \$134,491         | \$              |  |
| Preferred stock: Convertible preferred stock (Series A Preferred Stock and Series B Preferred Stock), \$0.0001 par value; 57,917,522 shares authorized; 57,917,522 shares issued and outstanding, actual; no shares authorized, issued, and outstanding, pro forma and pro forma as adjusted | \$ 59,681               | <del></del><br>\$ |                 |  |
|  | \$ 55,001               | <u> </u>          |                 |  |
| Stockholders' (deficit) equity:  |                         |                   |                 |  |
| Preferred stock, \$0.0001 par value per share; no shares authorized, issued and outstanding, actual;   |                         |                   |                 |  |
| shares authorized, no shares issued and outstanding, pro forma and pro forma as adjusted   | <del>_</del>            |                   |                 |  |
| Common stock, \$0.0001 par value per share; 86,000,000 shares authorized, 12,907,933 shares issued and 9,314,183 outstanding, actual; shares authorized, shares issued and   |                         |                   |                 |  |
| outstanding, pro forma; 300,000,000 shares authorized, shares issued and shares  |                         |                   |                 |  |
| outstanding, pro forma as adjusted   | 1                       | 14                |                 |  |
| Non-voting common stock, \$0.0001 par value per share; no shares authorized, issued or outstanding,  | 1                       | 17                |                 |  |
| actual; 10,000,000 shares authorized, shares issued and outstanding, pro forma and pro forma as  |                         |                   |                 |  |
| adjusted   |                         | _                 |                 |  |
| Additional paid-in capital   | 1,070                   | 160,438           |                 |  |
| Accumulated deficit  | (43,533)                | (43,533)          |                 |  |
| Total stockholders' (deficit) equity   | (42,462)                | 116,919           |                 |  |
|  |                         |                   | ¢               |  |
| Total capitalization   | \$ 17,219               | \$116,919         | <b>D</b>        |  |

The proforma as adjusted information is illustrative only and will depend on the actual public offering price and other terms of this offering determined at pricing. A \$1.00 increase (decrease) in the assumed initial public offering price of \$ per share of common stock, the midpoint of the estimated offering price range set forth on the cover page of this prospectus, would increase (decrease) the proforma as adjusted amount of each of cash, additional paid-in capital, total stockholders' equity and total capitalization by \$ million, assuming that the number of shares of common stock offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions payable by us. An increase (decrease) of 1.0 million shares in the number of shares of common stock offered by us, as set forth on the cover page of this prospectus, would increase (decrease) the proforma as adjusted amount of each of cash, additional paid-in capital, total stockholders' equity and total capitalization by \$ million, assuming no change in the assumed initial public offering price of \$ per share of common stock, the midpoint of the estimated offering price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The above discussion and table are based on shares of common stock outstanding as of December 31, 2020 and excludes the following:

- 3,593,750 shares of common stock that were issued and outstanding but that were subject to a right of repurchase by us at December 31, 2020 and are not included in stockholders' equity pursuant to U.S. generally accepted accounting principles, or GAAP;
- 11,852,840 shares of common stock issuable upon the exercise of options outstanding under our 2018 Plan, as of December 31, 2020, with a weighted-average exercise price of \$0.32 per share;
- 10, 436,957 shares of common stock issuable upon the exercise of options outstanding under our 2018 Plan, granted after December 31, 2020, at a weighted-average exercise price of \$0.88 per share;
- 1,191,950 shares of common stock reserved for future issuance under our 2018 Plan, based on the number of shares available for issuance as of December 31, 2020, plus additional shares of common stock added to the plan in January 2021, less the shares of common stock underlying options granted subsequent to December 31, 2020 and set forth above, which shares will be added to the shares to be reserved under our 2021 Plan, at the time our 2021 Plan becomes effective in connection with this offering;
- 26,880,000 shares of common stock that will become available for future issuance under our 2021 Plan, which will become effective upon the effectiveness of the registration statement of which this prospectus forms a part, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the 2021 Plan; and
- 2,086,000 shares of common stock that will become available for future issuance under our 2021 ESPP, which will become effective upon the effectiveness of the registration statement of which this prospectus forms a part, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the 2021 ESPP.

#### DILUTION

If you invest in our common stock in this offering, your ownership interest will be immediately diluted to the extent of the difference between the assumed initial public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock immediately after this offering.

As of December 31, 2020, our historical net tangible book value (deficit) was \$(42.5) million, or \$(4.56) per share of common stock. Our historical net tangible book value (deficit) represents our total tangible assets less our liabilities and preferred stock, which is not included in stockholders' (deficit). Our historical net tangible book value (deficit) per share represents historical net tangible book value (deficit) divided by 9,314,183 shares of common stock outstanding as of December 31, 2020.

Our proforma net tangible book value as of December 31, 2020, was \$116.9 million, or \$0.85 per share of common stock, after giving effect to (i) the issuance and sale of 70,136,064 shares of Series C convertible preferred stock for net cash proceeds of \$99.7 million in January 2021; and (ii) the automatic conversion of all outstanding shares of our preferred stock, which includes our Series C convertible preferred stock, into an aggregate of shares of common stock (including shares of non-voting common stock) immediately prior to the completion of this offering.

After giving further effect to our sale of shares of common stock in this offering at an assumed initial public offering price of \$ per share, the midpoint of the estimated price range set forth on the cover page of this prospectus and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of December 31, 2020 would have been \$ million, or \$ per share. This represents an immediate increase in pro forma as adjusted net tangible book value of \$ per share to our existing stockholders and an immediate dilution of \$ per share to investors purchasing common stock in this offering. We determine dilution per share to new investors participating in this offering by subtracting pro forma as adjusted net tangible book value per share after this offering from the assumed initial public offering price per share paid by investors participating in this offering. The following table illustrates this dilution to investors participating in this offering on a per share basis:

| Assumed initial public offering price per share  | \$       |
|--|----------|
| Historical net tangible book value (deficit) per share as of December 31, 2020   | \$(4.56) |
| Increase in historical net tangible book value per share attributable to conversion of our outstanding preferred stock | 5.41     |
| Pro forma net tangible book value per share as of December 31, 2020  | 0.85     |
| Increase in pro forma net tangible book value per share attributable to new investors in this offering                 |          |
| Pro forma as adjusted net tangible book value per share immediately after this offering                                |          |
| Dilution per share to new investors purchasing shares in this offering   | \$       |

The pro forma as adjusted dilution information discussed above is illustrative only and will depend on the actual initial public offering price and other terms of this offering determined at pricing. A \$1.00 increase (decrease) in the assumed initial public offering price of \$ per share, the midpoint of the estimated price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted net tangible book value by \$ per share and the dilution per share to new investors by \$ per share, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. An increase (decrease) of 1.0 million shares of common stock in the number of shares we are offering would increase (decrease) our pro forma as adjusted net tangible book value by \$ million, or \$ per share, and the pro forma dilution per share to investors in this offering by \$ per share, assuming no

change in the assumed initial public offering price, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

If the underwriters' option to purchase additional shares of common stock in this offering is exercised in full, the pro forma as adjusted net tangible book value would be \$\frac{million}{million}\$, representing an immediate increase in pro forma as adjusted net tangible book value per share of \$\frac{to}{million}\$ to existing stockholders and immediate dilution per share to investors participating in this offering of \$\frac{t}{million}\$, assuming an initial public offering price of \$\frac{t}{million}\$ per share of common stock, the midpoint of the price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The table below summarizes, as of December 31, 2020, on the pro forma as adjusted basis described above, the number of shares of our common stock, the total consideration, and the average price per share paid to us by our existing stockholders and to be paid by new investors participating in this offering at an assumed initial public offering price of \$ per share, the midpoint of the estimated price range set forth on the cover page of this prospectus, and before deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

|  | Shares purchased |         | Total consideration |         | Weighted-<br>average<br>price per |
|--|------------------|---------|---------------------|---------|-----------------------------------|
|  | Number           | Percent | Amount              | Percent | share                             |
| Existing stockholders                        |                  | %       | \$                  | %       | \$                                |
| New investors participating in this offering |                  |         |                     |         |                                   |
| Total  |                  | 100%    | \$                  | 100%    |                                   |

The table above assumes no exercise of the underwriters' option to purchase additional shares of common stock in this offering. If the underwriters' option to purchase additional shares of common stock is exercised in full, the number of shares held by existing stockholders will be reduced to % of the total number of shares of common stock to be outstanding upon completion of this offering, and the number of shares of common stock held by new investors participating in this offering will be increased to % of the total number of shares of common stock to be outstanding upon completion of the offering.

Each \$1.00 increase (decrease) in the assumed initial public offering price of \$ per share would increase (decrease) total consideration paid by new investors by \$ million and increase (decrease) the percent of total consideration paid by new investors by \$%, assuming the number of shares we are offering, as set forth on the cover page of this prospectus, remains the same. We may also increase or decrease the number of shares we are offering. An increase (decrease) of 1,000,000 in the number of shares offered by us would increase (decrease) total consideration paid by new investors by \$ million, assuming no change in the assumed initial price to the public.

The tables and discussion above are based on the number of shares of our common stock outstanding as of December 31, 2020 and gives effect to the conversion of all of our outstanding preferred stock into shares of our common stock (including non-voting common stock) upon the completion of this offering and excludes the following:

- 3,593,750 shares of common stock that were issued and outstanding but that were subject to a right of repurchase by us at December 31, 2020 and are not included in stockholders' equity pursuant to GAAP;
- 11,852,840 shares of common stock issuable upon the exercise of options outstanding under our 2018 Plan, as of December 31, 2020, with a weighted-average exercise price of \$0.32 per share;
- 10,436,957 shares of common stock issuable upon the exercise of options outstanding under our 2018 Plan, granted after December 31, 2020, at a weighted-average exercise price of \$0.88 per share;

- 1,191,950 shares of common stock reserved for future issuance under our 2018 Plan, based on the number of shares available for issuance as of December 31, 2020, plus additional shares of common stock added to the plan in January 2021, less the shares of common stock underlying options granted subsequent to December 31, 2020 and set forth above, which shares will be added to the shares to be reserved under our 2021 Plan, at the time our 2021 Plan becomes effective in connection with this offering;
- 26,880,000 shares of common stock that will become available for future issuance under our 2021 Plan, which will become effective upon the effectiveness of the registration statement of which this prospectus forms a part, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the 2021 Plan; and
- 2,086,000 shares of common stock that will become available for future issuance under our 2021 ESPP, which will become effective upon the effectiveness of the registration statement of which this prospectus forms a part, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the 2021 ESPP.

To the extent that any outstanding options are exercised or new awards are granted under our equity compensation plans, new investors will experience further dilution.

#### MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes included elsewhere in this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" and "Special Note Regarding Forward-looking Statements" sections of this prospectus, 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 preclinical-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. We believe this two-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 after 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. In addition, we are developing multiple TCR-T therapy candidates for the treatment of various 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.

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 and revenue received under our collaboration agreement with Novartis Institutes for Biomedical Research, Inc., or Novartis, and licensing agreements with QIAGEN Sciences, LLC, or Qiagen, and other parties. Through December 31, 2020, we have received gross proceeds of \$60.0 million from sales of our convertible preferred stock. 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 term. During January 2021, we received an additional \$99.7 million of net cash proceeds from the sale of our Series C convertible preferred stock.

We have incurred significant operating losses since our inception. We reported net losses of \$13.7 million and \$26.1 million for the years ended December 31, 2019 and 2020, respectively. As of December 31, 2020, we had an accumulated deficit of \$43.5 million. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. We expect that our expenses and capital expenditures will increase substantially in connection with our ongoing activities, particularly if and as we:

- continue our research and development efforts to identify and develop product candidates and submit investigational new drug applications, or INDs, for such product candidates;
- conduct preclinical studies and commence clinical trials for our current and future product candidates based on our proprietary platform;
- develop processes suitable for manufacturing and clinical development
- continue to develop and expand our manufacturing capabilities;
- 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
- operate as a public company.

We will not generate revenue from sales of our therapies unless and until we successfully complete clinical development and obtain regulatory approval for one or more of our product candidates. If we obtain regulatory approval for any of our product candidates, we expect to incur significant expenses related to developing our commercialization capability to support the sales, marketing and distribution of those therapies. Further, following the completion of this offering, we expect to incur additional costs associated with operating as a public company.

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

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

We believe that the expected net proceeds from this offering, together with our existing cash will enable us to fund our operating expenses and capital expenditures into . We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. See "—Liquidity and capital resources" and "Risk factors—Risks related to our financial position and need for additional capital."

## **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.

## **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 and potential milestone payments contingent on clinical, regulatory and sales success that could aggregate in the hundreds of millions of dollars. 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, 2020, we recognized \$0.8 million of revenue associated with the Novartis Agreement. We expect to recognize the remaining arrangement consideration over the expected research term, which is not expected to exceed 3 years. In addition, we have received an aggregate of \$20.0 million of cash representing the one-time, non-refundable, non-contingent and non-creditable upfront payment and have receivables for reimbursement of expenditures under the arrangement of \$0.3 million as of December 31, 2020.

## **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 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 also anticipate that we will incur 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. 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 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, 2020, we had federal and state net operating loss carryforwards of \$17.6 million and \$16.7 million, respectively, which may be used to offset future taxable income, if any. These amounts expire at various dates through 2040. The federal net operating losses generated in and after 2018 can be carried forward indefinitely. As of December 31, 2020, we had federal and state tax credit carryforwards of \$1.5 million and \$0.8 million, respectively. These amounts expire at various dates through 2035. 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**

The following table summarizes our results of operations for the years ended December 31, 2019 and 2020:

|                                   | Year I<br>Decem |                |             |  |
|-----------------------------------|-----------------|----------------|-------------|--|
|                                   | 2019            | 2020           | Change      |  |
|                                   | (in tho         | (in thousands) |             |  |
| Revenue                           |                 |                |             |  |
| Collaboration and license revenue | \$ —            | \$ 1,085       | \$ 1,085    |  |
| Operating expenses:               |                 |                |             |  |
| Research and development          | 9,442           | 20,577         | 11,135      |  |
| General and administrative        | 4,768           | 6,741          | 1,973       |  |
| Total operating expenses          | 14,210          | 27,318         | 13,108      |  |
| Loss from operations              | (14,210)        | (26,233)       | (12,023)    |  |
| Other income:                     |                 |                |             |  |
| Interest income                   | 552             | 106            | (446)       |  |
| Net loss                          | \$(13,658)      | \$(26,127)     | \$ (12,469) |  |

#### Revenue

We had no revenue for the year ended December 31, 2019 compared to \$1.1 million for the year ended December 31, 2020. The increase in revenue was associated with the recognition of the \$1.1 million of revenue primarily associated with the Novartis Agreement. The revenue generated from the Novartis Agreement is expected to increase significantly in 2021.

#### Research and Development Expenses

The following table summarizes our research and development expenses for the years ended December 31, 2019 and 2020:

|   |         | Year Ended<br>December 31, |           |
|---|---------|----------------------------|-----------|
|   | 2019    | 2020                       | Change    |
|   | (in tho | (in thousands)             |           |
| Preclinical studies                                     | 3,328   | 7,922                      | 4,594     |
| Legal and professional fees                             | 345     | 859                        | 514       |
| Personnel expenses (including stock-based compensation) | 3,618   | 7,383                      | 3,765     |
| Facility-related and other                              | 2,151   | 4,413                      | 2,262     |
| Total research and development expenses                 | \$9,442 | \$ 20,577                  | \$ 11,135 |
|   |         |                            |           |

Research and development expenses were \$9.4 million for the year ended December 31, 2019 compared to \$20.6 million for the year ended December 31, 2020. The increase in research and development expenses was primarily attributable to a \$4.6 million increase in laboratory supplies, research material, and preclinical studies. Additionally, there was a \$3.8 million increase in personnel expenses, including an increase of \$0.1 million related to stock-based compensation expense and a \$2.7 million increase in professional fees, facility-related expenses and other expenses due to the expansion of leased facilities.

## General and Administrative Expenses

General and administrative expenses were \$4.8 million for the year ended December 31, 2019 compared to \$6.7 million for the year ended December 31, 2020. The increase in general and administrative expense was primarily due to a \$1.4 million increase in legal and professional fees, as well as a \$0.4 million increase in personnel expenses, which includes an increase of \$0.3 million related to stock-based compensation expense and an increase of \$0.1 million in other expenses.

#### Other Income

Other income for the year ended December 31, 2019 was \$0.6 million, compared to \$0.1 million for the year ended December 31, 2020. The decrease primarily related to the money market interest rates decreasing due to the COVID-19 pandemic and a draw down on cash to fund operations.

#### **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. We have not generated any product revenue 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. As of December 31, 2020, we had cash and restricted cash of \$35.4 million. In January 2021, we issued and sold 70,136,064 shares of Series C convertible preferred stock for net cash proceeds of \$99.7 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;
- 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 operating as a public company.

We believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will enable us to fund our operating expenses and capital expenditure requirements into . 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, following the completion of this offering, we will be a publicly traded company and 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, 2021. However, while we remain an emerging growth company or 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 the section of this prospectus titled "Risk Factors" 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:

|   | Year Ended D | Year Ended December 31, |            |  |
|---|--------------|-------------------------|------------|--|
|   | 2019         | 2020                    | Change     |  |
|   | (in thou     | (in thousands)          |            |  |
| Net cash provided by (used in) operating activities | \$ (12,522)  | \$ (3,023)              | \$ 9,499   |  |
| Net cash used in investing activities               | (1,247)      | (4,238)                 | (2,991)    |  |
| Net cash provided by financing activities           | 34,812       | 288                     | (34,524)   |  |
| Net increase (decrease) in cash and restricted cash | \$ 21,043    | \$ (6,973)              | \$(28,016) |  |

#### **Operating Activities**

During the year ended December 31, 2019, operating activities used \$12.5 million of cash, due to our net loss of \$13.7 million, partially offset by non-cash charges of \$0.7 million and net cash provided by changes in our operating assets and liabilities of \$0.3 million.

During the year ended December 31, 2020, operating activities used \$3.0 million of cash, due to our net loss of \$26.1 million, partially offset by non-cash charges of \$1.8 million and net cash provided by changes in our operating assets and liabilities of \$21.3 million. Net cash provided by changes in our operating assets and liabilities primarily consisted of a \$19.4 million increase in deferred revenue from the upfront payment in the Novartis Agreement.

#### **Investing Activities**

During the year ended December 31, 2019 and 2020, net cash used in investing activities was \$1.2 million and \$4.2 million, respectively, related to the purchases of property and equipment.

# Financing Activities

During the year ended December 31, 2019, net cash provided by financing activities was \$34.8 million, consisting primarily of net proceeds from our issuance of convertible preferred stock.

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.

# **Critical Accounting Policies and Significant Judgments and Estimates**

Our financial statements are prepared in accordance with generally accepted accounting principles in the United States, or GAAP. The preparation of our financial statements and related disclosures requires us to make

estimates and judgments that affect the reported amounts of assets, liabilities, costs and expenses, and the disclosure of contingent assets and liabilities in our financial statements. 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 financial statements included elsewhere in this prospectus, 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 salesbased 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.

## **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 all stock-based awards granted based on the fair value on the date of the grant using the Black-Scholes option-pricing model for options or the difference, if any, between the purchase price per share of the award and the fair value of our common stock for restricted common stock awards. 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 only service-based vesting conditions. The Black-Scholes option-pricing model 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 common stock options, the risk-free

interest rate for a period that approximates the expected term of our common stock options, and our expected dividend yield.

## Determination of Fair Value of Common Stock

As there has been no public market for our common stock to date, the estimated fair value of our common stock has been determined by our board of directors as of the date of each option grant, with input from management, considering our most recently available third party valuations of common stock and our board of directors' assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent valuation through the date of the grant. These third party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation. Our common stock valuations were prepared using either an option pricing method, or OPM, or a hybrid method, both of which used market approaches to estimate our enterprise value. The hybrid method is a probability-weighted expected return method, or PWERM, where the equity value in one or more of the scenarios is calculated using an OPM. The PWERM is a scenario-based methodology that estimates the fair value of common stock based upon an analysis of future values for the company, assuming various outcomes. The common stock value is based on the probability-weighted present value of expected future investment returns considering each of the possible outcomes available as well as the rights of each class of stock. The future value of the common stock under each outcome is discounted back to the valuation date at an appropriate risk-adjusted discount rate and probability weighted to arrive at an indication of value for the common stock. A discount for lack of marketability of the common stock is then applied to arrive at an indication of value for the common stock. The OPM treats common stock and preferred stock as call options on the total equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company's securities changes. Under this method, the common stock has value only if the funds available for distribution to stockholders exceeded the value of the preferred stock liquidation preferences at the time of the liquidity event, such as a strategic sale or a merger. These third party valuations were performed at various dates, which resulted in valuations of our common stock of \$0.30 per share as of July 8, 2019, \$0.64 per share as of June 10, 2020, \$0.71 per share as of January 15, 2021, \$1.41 per share as of March 1, 2021 and \$1.70 per share as of March 19, 2021. In addition to considering the results of these third party valuations, our board of directors considered various objective and subjective factors to determine the fair value of our common stock as of each grant date, including:

- the price at which we sold shares, or expected to sell shares, of our preferred stock and the superior rights and preferences of the preferred stock relative to our common stock at the time of each grant;
- the progress of our research and development programs;
- our stage of development and commercialization and our business strategy;
- external market conditions affecting the biopharmaceutical and biotechnology industries, and trends within those industries;
- our financial position, including cash on hand, and our historical and forecasted performance and operating results;
- the lack of an active public market for our common stock and our preferred stock;
- the likelihood of achieving a liquidity event, such as an initial public offering, or IPO, or a sale of our company in light of prevailing market conditions; and
- the analysis of IPOs and the market performance of similar companies in our industry.

The assumptions underlying these valuations represented management's best estimate, which involved inherent uncertainties and the application of management's judgment. As a result, if we had used significantly different assumptions or estimates, the fair value of our common stock and our stockbased compensation expense could have been materially different.

Once a public trading market for our common stock has been established in connection with the completion of this offering, it will no longer be necessary for our board of directors to estimate the fair value of our common stock in connection with our accounting for granted stock options and other such awards we may grant, as the fair value of our common stock will be determined based on the quoted market price of our common stock.

As of December 31, 2020, based on the assumed initial public offering price per share of \$ cover page of this prospectus, the aggregate intrinsic value of our outstanding stock options, was \$ vested stock options.

, the midpoint of the price range set forth on the million, with \$ million related to

## **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 proposed aggregate amount of gross proceeds to us as a result of this offering is less than \$700 million and our annual revenue was less than \$100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company after this offering 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.

#### **Quantitative and Qualitative Disclosures about Market Risks**

We are exposed to market risk related to changes in interest rates. As of December 31, 2020, we had cash and cash equivalents of \$35.4 million, which included restricted cash of \$0.6 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.

We are not currently exposed to significant market risk related to changes in foreign currency exchange rates. Our operations may be subject to fluctuations in foreign currency exchange rates in the future. We do not believe that inflation has had a material effect on our business, financial condition, or results of operations during the years ended December 31, 2019 and 2020. Our operations may be subject to inflation in the future.

#### BUSINESS

#### Overview

We are a preclinical-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 believe this two-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 after 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 plan to submit 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. In addition, we are developing multiple TCR-T therapy candidates for the treatment of various 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 are currently advancing four solid tumor programs, TSC-200, TSC-201, TSC-202, and TSC-203, through lead optimization, and expect to submit IND applications for at least three of our four solid tumor TCR-T therapy candidates in the second half of 2022, with the fourth IND 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 this will allow us to 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.
- 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 three central elements of our platform that differentiate us from other cell therapy companies are TargetScan, ReceptorScan, and T-Integrate.

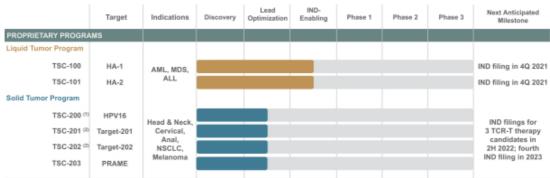
TargetScan. At the core of our proprietary platform is our TargetScan technology that enables us to identify the natural target of a TCR using an unbiased, genome-wide high-throughput screen. We have developed this technology to be extremely versatile and applicable across multiple therapeutic areas, 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. Using TargetScan, we have identified more than 40 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 we have already identified highly active TCRs that recognize these targets. TargetScan is also 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.

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<sup>+</sup> 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.

*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 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 leveraging our proprietary platform technologies to develop a robust pipeline of TCR-T therapies with the goal of building our ImmunoBank of TCRs to treat a wide range of tumor types. 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.



- (1) TSC-200 will only be developed in HPV-positive cancers, which include head & neck, cervical, and anal cancers.
- (2) For additional information regarding the targets for TSC-201 and TSC-202, see "Business Solid Tumor Program TSC-200 Series."

In addition to our proprietary pipeline programs noted above, we also are in the discovery phase for our TSC-102 program, which is targeting an additional MiHA target that is presented on HLA-B\*07:02. Our overall strategy is to progressively build this program to provide a broad array of therapeutic options for the majority of patients with hematologic malignancies receiving HCT. Beyond our proprietary pipeline programs, we have also entered into collaborations with strategic partners for applications of our platform technologies. We have a collaboration and license agreement with Novartis to identify novel cancer antigens from the T cells of patients with one specific type of cancer. Novartis has the option to license and develop therapies for up to three discovered targets. 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 addition, to further

expand our liquid tumor program, we are developing additional product candidates that target other similarly validated antigens, enabling us to expand the addressable patient population.

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. 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. We plan to incorporate additional product candidates into this trial design as they advance into the clinic, which we believe will allow us to provide a broad array of therapeutic options for the majority of patients with hematologic malignancies receiving HCT. In our clinical trials of TSC-100 and TSC-101, we also plan to evaluate the potential benefit of combining the two therapies as a multiplexed TCR-T therapy for patients who are positive for both HA-1 and HA-2.

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.

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 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 four product candidates include a combination of known targets, such as HPV16 for TSC-200 and PRAME for TSC-203, as well as targets that are novel antigens for TCR-T therapy, such as for TSC-201 and TSC-202. In addition to our four lead product candidates, we have identified over 40 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 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 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 History and Team**

We were founded in early 2018 to discover and develop transformational therapies using a novel T-cell target discovery platform developed by Drs. Stephen Elledge and Tomasz Kula at Brigham and Women's Hospital and Harvard Medical School. Since then, we have made substantial progress building our target and TCR discovery platform technologies, discovering new targets and TCRs, advancing our two lead programs into IND-enabling studies, developing in-house manufacturing capabilities, and, in response to the ongoing

COVID-19 pandemic, identifying the targets of T cells from recovering COVID-19 patients. In addition, we have entered into multiple strategic collaborations, including with Novartis Institutes for Biomedical Research, Inc., and QIAGEN Sciences, LLC.

We have assembled a highly qualified team with deep experience in T-cell biology, high throughput screening, engineering and manufacturing of cell therapies, as well as in all phases of research and clinical development, from early-stage discovery and IND-enabling studies through registrational clinical trials. Our team includes industry veterans with prior experience at academic and research institutions such as Harvard University, Harvard Medical School, and Massachusetts General Hospital, and companies such as BlueRock Therapeutics, LLC, CRISPR Therapeutics, Inc., Editas Medicine, Inc., Human Genome Sciences, Inc., Kite Pharma, Inc., KSQ Therapeutics, Inc., Merrimack Pharmaceuticals, Inc., Regeneron Pharmaceuticals, Inc., Repertoire Immune Medicines, Inc., and SQZ Biotechnologies Company. Our research efforts also benefit from the informal advice and guidance provided by our scientific advisory board members, including Drs. Elledge and Kula, who receive equity and/or cash compensation. Since our inception, we have raised an aggregate of \$160 million from leading biotechnology investors, including RA Capital Management, Novartis Venture Fund, Novartis Institutes for Biomedical Research, Longwood Fund, Bessemer Venture Partners, GV, 6 Dimensions Capital, Astellas Venture Management, and Pitango HealthTech.

#### **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 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 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.
- 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 antitumor 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. We plan to submit INDs for each of TSC-100 and TSC-101 in the fourth quarter of 2021. In addition, through our liquid tumor programs, we are building 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 our TargetScan technology, we have identified over 40 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 four selected target antigens that are frequently expressed across multiple solid tumor types. Our first four solid tumor TCR-T therapy candidates include a combination of known targets, such as HPV16 for TSC-200 and PRAME for TSC-203, 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 therapies, 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 good manufacturing practices, or GMP, manufacturing facility that we expect will provide sufficient capacity to support all of our clinical programs through Phase 2 clinical trials.
- **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, or iPSCs. 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 established a partnership for COVID-19 with QIAGEN Sciences, LLC for the development of a T cell-based diagnostic.

#### **Background on T-Cell Therapies**

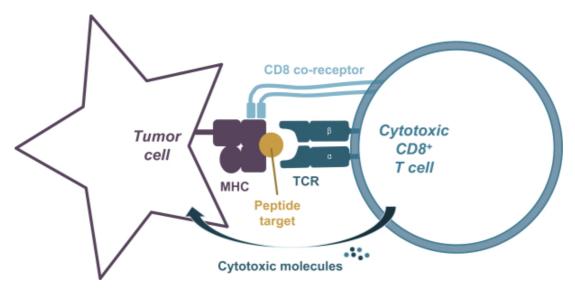
The human immune system constantly provides a natural and highly effective defense against cancer, which only forms when tumor cells find a way to evade the immune system. The treatment of cancer was revolutionized about a decade ago with the advent of immunotherapy – therapeutic approaches designed 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 exquisite specificity of the TCR-peptide-MHC interaction to selectively target tumor cells.

## Current Approaches to T-Cell Therapy

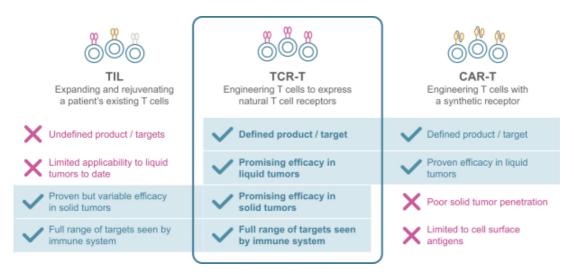
Multiple approaches are being explored to develop effective T cell-based therapies for the treatment of cancer. One approach is to isolate naturally occurring T cells from a patient's tumor, referred to as TILs, expand and activate those cells *ex vivo*, and then return them to the patient via intravenous 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 specific T cells present in the patient. If the patient's TILs do not have appropriate anti-cancer specificities or if their 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 preferentially 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 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.

#### **Comparison of T-Cell Therapy Modalities**



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**

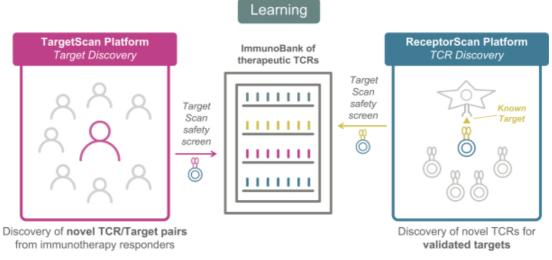
Our approach is based on the central premise that we can *learn* from patients who are winning their fight against cancer in order to *treat* those who are not. Using our proprietary platform technologies, we are analyzing the T cells of cancer patients with exceptional responses to immunotherapy to 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 TargetScan 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 TargetScan 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 are added to ImmunoBank.

## **Our Proprietary Target and TCR Discovery Process**

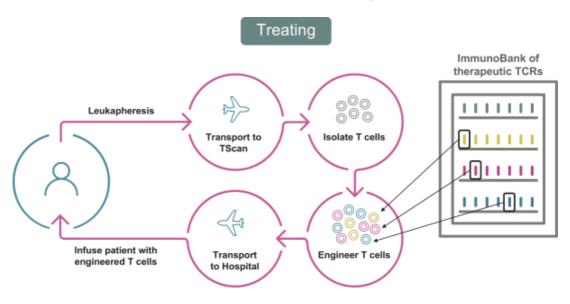


## **Treating**

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. Our manufacturing process begins with obtaining white blood cells 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 cancer target X, their T cells will be reprogrammed with a TCR that recognizes target X.

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 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.
- 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**

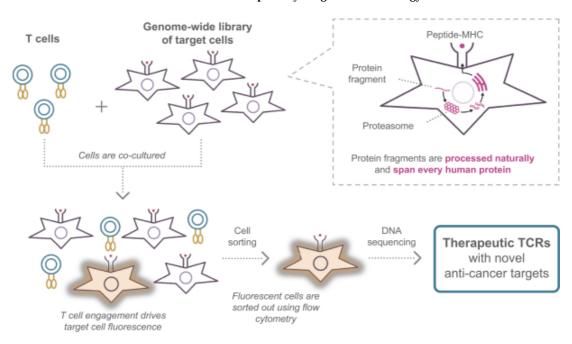
Our proprietary platform is designed to: (i) discover anti-cancer TCRs from patients with exceptional responses to immunotherapy; (ii) determine novel targets of clinically relevant TCRs; (iii) discover novel TCRs that recognize clinically validated targets; (iv) identify off-targets of TCRs to eliminate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

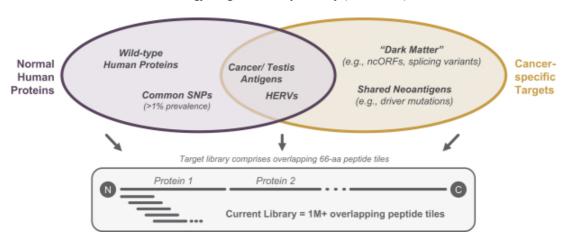
To identify the target of a clinically active TCR found in the T cells of a patient actively responding to immunotherapy, we mix T cells expressing that TCR with a genome-wide library of target cells where every cell in the library expresses a different protein fragment. In each target cell, the protein 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)

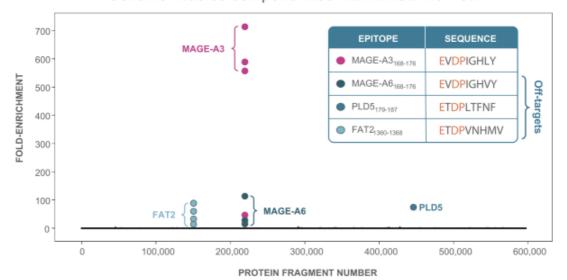


Our Oncology Target Discovery Library allows us to precisely identify the novel targets recognized by TCRs from patients who are actively responding to immunotherapy. In addition, because the library comprehensively covers every non-mutated human protein sequence, we are also able to fully characterize 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.

We have validated our TargetScan technology with a proof-of-concept screen using our Oncology Target Discovery Library (version 2.0), which included approximately 600,000 protein fragments spanning every human protein. Using a TCR known to recognize MAGE-A3, our screen, as shown below, correctly identified MAGE-A3 as its natural target, 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. 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.

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

# Genome-wide screen performed with MAGE-A3 TCR

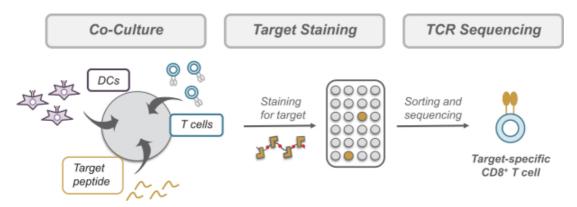


Using TargetScan, we have identified more than 40 shared antigens in patient tumors, and over 90% of these targets have not previously been identified as targets for TCR-T therapy. We believe this provides us with a competitive advantage, because not only are we among the first to identify these targets as tumor-specific antigens, but we have already identified highly active TCRs that recognize these targets.

## ReceptorScan—Discovery of Novel Therapeutic TCRs for Known Targets

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 previously identified, clinically validated targets. As shown in the graphic below, we co-culture hundreds of millions of CD8+ T cells from either healthy donors or cancer patients with dendritic 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

#### Overview of Our Proprietary ReceptorScan Technology



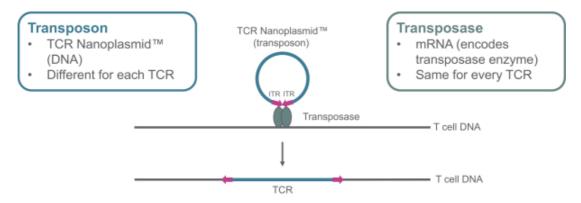
## T-Integrate—Genetic Engineering of T Cells Using Transposons

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.

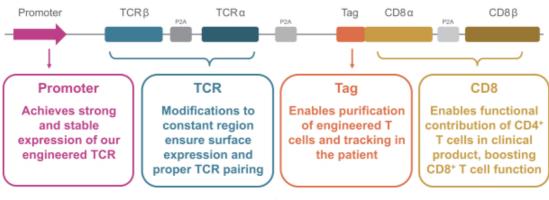
As a more efficient and reproducible alternative to lentivirus, we have developed T-Integrate to genetically engineer T cells using a transposon/transposase system, as shown in the graphic below. In this system, DNA encoding the TCR is manufactured as a Nanoplasmid and enables DNA delivery using a smaller 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**



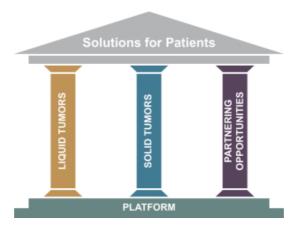
Our transposon vector includes both the beta and alpha chains of the TCR under the control of a strong promoter. This is designed to ensure that high levels of the TCR are produced on the surface of the T cells and that the TCRs that are normally expressed in the patient or donor's T cells, or the 'endogenous' 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. An illustration of the construct of our TCR-T therapies is shown below.

## **Construct of our TCR-T Therapies**



## **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.

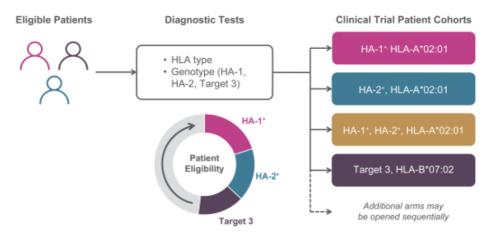


## **Our Liquid Tumor Program**

We are developing our liquid tumor program to treat patients with hematologic malignancies who are undergoing for 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. In addition, to further expand our liquid tumor program, we are developing additional product candidates that target other similarly validated antigens, enabling us to expand the addressable patent population.

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. We also plan to incorporate additional product candidates into this trial design as they advance into the clinic, which we believe has the potential to allow us to provide a broad array of therapeutic options for the majority of patients with hematologic malignancies receiving HCT. In our clinical trials of TSC-100 and TSC-101, we also plan to evaluate the potential benefit of combining the two therapies as a multiplexed TCR-T therapy for patients who are positive for both HA-1 and HA-2.

## **Our Clinical Development Strategy for Multiple TCR-T Therapies**

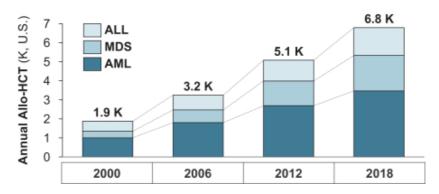


#### **Background on Hematologic Malignancies**

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 MHC-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 41%.

Approximately 7,000 allogeneic HCT procedures are performed yearly in the United States, primarily in patients with AML or acute lymphocytic leukemia, 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 availability, an increase in disease prevalence due to aging populations, and improved conditioning regimens permitting broader use in older patient segments. 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. In addition, adoption of safer and more effective conditioning regimens is anticipated to continue to drive an increasing use of HCT in patient segments previously deemed too old or unfit for transplant or those who failed to achieve proper remission prior to transplant.

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



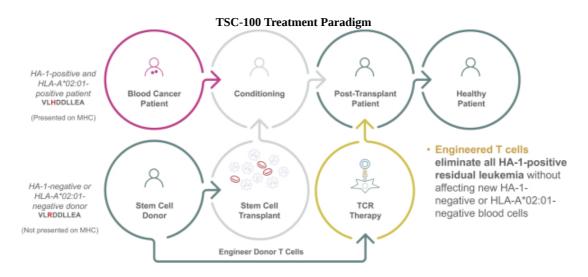
However, despite the increasing use of HCT and the resulting clinical benefits or cures, up to half of the patients who receive HCT relapse, at which point there are limited treatment options and the prognosis is very poor. Clinical observations have shown that if the T cells of the donor recognize certain 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. We plan to file an IND for TSC-100 with the FDA in the fourth quarter of 2021.

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 VLHDDLLEA, 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.

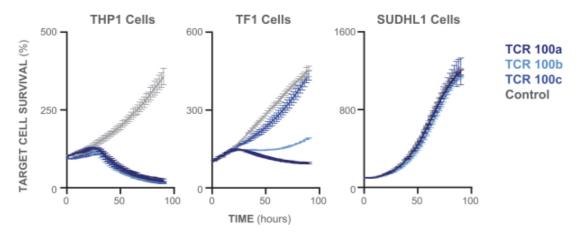


#### Preclinical Data

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

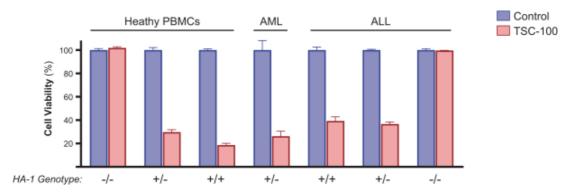
HA-1-specific TCRs, including TCRs reported in the literature. Our preclinical studies also demonstrated that SUDHL1 cells, which lack HA-1 expression, were resistant to all tested HA-1-specific TCRs, as expected, highlighting the high selectivity and potential safety of TCR-T therapies.

# 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 (VLHDLLEA), 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 healthy blood cells and leukemia cells.

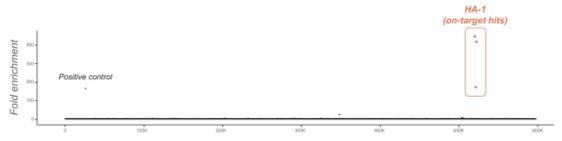
TSC-100 Displays Specific Cytotoxic Activity Towards HA-1-positive Cells



Previous clinical studies by others with TCRs that exhibited unexpected off-target effects led to significant toxicities. In order to reduce the potential for TCR-100a to exhibit problematic off-target effects, we used

TargetScan 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 genome 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.

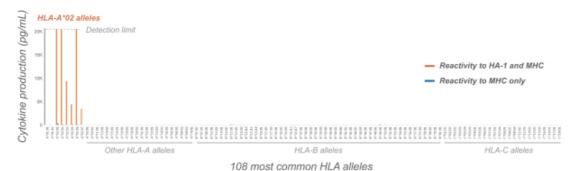
## TargetScan Screen Reveals No Significant Off-Targets for TCR-100a



Genome-wide library covering every protein encoded by the human genome

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. We intend to file an IND for TSC-101 in the fourth quarter of 2021.

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.

Similar to TCR-100a, we used ReceptorScan to identify TCR-101a amongst a screen of 240 million T cells. We tested TCR-101a *in vitro* using cell lines and found superior antigen binding and cytotoxicity compared with more than 300 other TCRs assessed. As shown in the figure below, TCR-101a had superior activity against DEL cells, which have high levels of HA-2, and THP-1 cells, which have low levels of HA-2. In addition, TCR-101a had no effect against NB4 cells, which do not express HLA-A\*02:01, indicating that TCR-101a should not affect donor blood cells that are HLA-A\*02:01-negative. We are currently conducting preclinical studies using TargetScan to assess potential off-target effects and performing alloreactivity studies to ensure that other HLA types are not misrecognized.

#### **DEL Cells NB4 Cells** THP1 Cells 1200 500 2000 TARGET CELL SURVIVAL (%) **TCR 101a** 250 TCR 101b 200 200 **TCR 101c** Control 1000 50 100 50 50 TIME (hours)

TCR-101a Demonstrates Superior Cytotoxicity in vitro Compared to Other TCRs

## TSC-102 and Additional Liquid Tumor Programs

To broaden the eligible HCT patient population beyond those who have the HLA type A\*02:01, we have identified a third miHA that requires a different HLA type, B\*07:02, to be displayed on the surface of blood cells. Like HA-1 and HA-2, this target was identified in HCT patients who achieved durable complete remissions from their hematologic cancers with little to no GvHD. This antigen is highly expressed in normal and malignant hematopoietic cells and is not expressed in normal tissues, based on publicly available databases. We are developing TSC-102 as an allogeneic TCR-T therapy candidate directed at eliminating residual cancer cells in patients with hematologic malignancies who are positive for both this antigen and HLA-B\*07:02 and undergo HCT using a donor who is negative for either the target or this specific HLA type.

Approximately 25% of the population has the HLA type B\*07:02, and the antigen we have chosen is present in about 71% of these individuals. Therefore, approximately 18% of patients undergoing HCT would be eligible for treatment with TSC-102. Using ReceptorScan, we have identified over 1,000 potential TCRs that recognize this target and studies are underway to identify the most potent TCR candidate. We are continuing to conduct target validation studies and to assess our TCR candidates using TargetScan.

In addition to TSC-102, we are continuing to explore additional miHA targets to provide a broad array of therapeutic options for the majority of patients with hematologic malignancies receiving HCT.

#### 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 8 out of 8 HLA alleles are considered the highest priority donor type for patients undergoing allogeneic HCT, but these types of donor 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 8 out of 8 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 3 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.

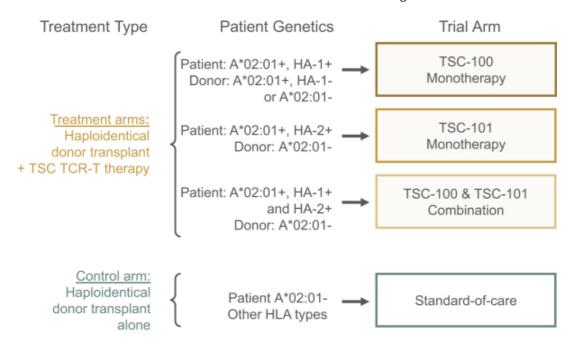
The use of haplos greatly expands the donor pool for patients undergoing HCT and provides patients with the optionality to choose donors who are mismatched on specific HLA types, such as A\*02:01, as opposed to being mismatched on certain minor antigens, such as HA-1 or HA-2. We are developing TSC-100 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 safety studies for TSC-100 and TSC-101 within a single, multi-arm Phase 1 clinical trial. Once safety results are available for the individual therapies, we plan to open a third arm to evaluate the safety of multiplexed therapy, combining TSC-100 and TSC-101 in patients who are positive for both HA-1 and HA-2.

Our Phase 1 clinical trial is designed to include the measurement 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, TSC-101, or the combination to be included as part of the efficacy analysis in a future biologics license application, or BLA, filing.

## Planned Multi-Arm Phase 1 Clinical Trial Design

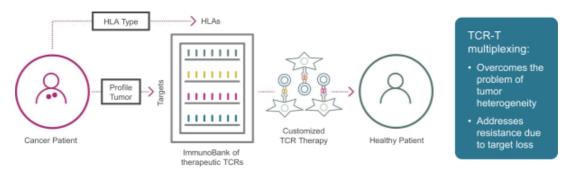


#### **Solid Tumor Program**

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 four solid tumor TCR-T therapy candidates include a combination of known targets, such as HPV16 for TSC-200 and PRAME for TSC-203, 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 four solid tumor TCR-T therapy candidates through lead optimization, and we expect to submit IND applications for at least three of our four candidates in the second half of 2022, with the fourth IND expected to be filed in 2023. In addition to our four lead solid tumor TCR-T therapy candidates, we have identified over 40 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 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 each patient 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 respond to checkpoint inhibitors, highlighting the need for T cell-based therapies that can treat the majority of patients who do not respond. Despite their efficacy in only a subset of patients, checkpoint inhibitors generated 2019 sales of approximately \$22 billion.

One reason why many 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 we can expand the dramatic responses observed with checkpoint inhibitor therapy to the many patients for whom these therapies are ineffective.

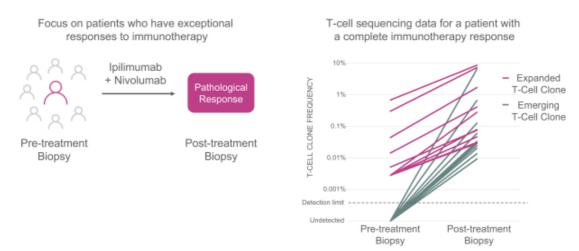
#### **Our Solution**

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 & 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.

Novel Targets Identified from Patients with Head & Neck Cancer

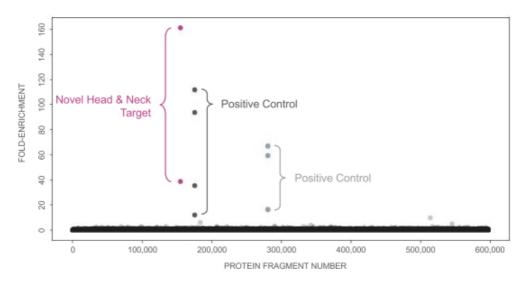
One of the ways we identify anti-cancer TCRs is by focusing on T cells that clonally expand in a tumor when the patient responds to checkpoint inhibitor therapy. Some of this work is being performed under collaborative research agreements with various academic institutions. Using single cell sequencing, our collaborators determined the TCR sequences of thousands of T cells in the tumors of patients with head & 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 & neck cancer who had a complete response to immunoterapy.

## 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 & neck cancer who are responding to immune checkpoint inhibitors, which has resulted in our discovery of over 20 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 TargetScan technology in identifying TCRs with clean specificity profiles.

## Identification of a Novel Target from a Patient with Head & Neck Cancer



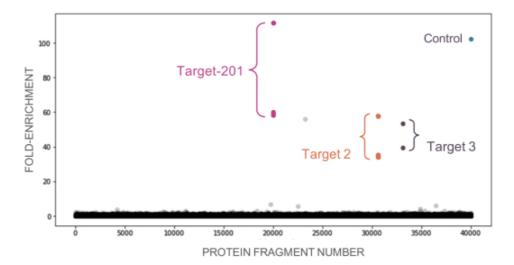
## Novel Targets Identified from Patients with Melanoma

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 tiles across 1,600 CTA genes. Because this library is substantially less complex than our genome-wide Oncology Target Discovery Library, we can screen the 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.

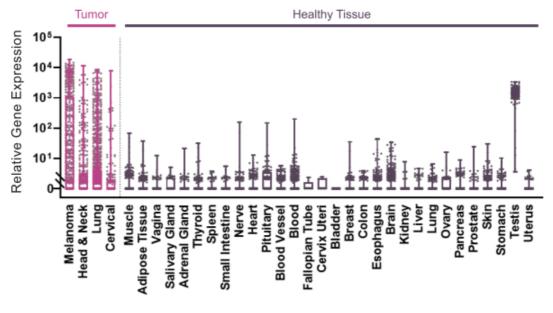
# Three Novel Cancer/Testis Antigen Targets Identified from TIL-Responsive Patients



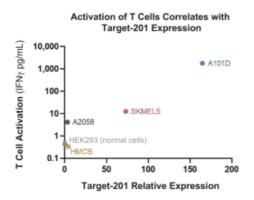
## TCR and Target Validation Process

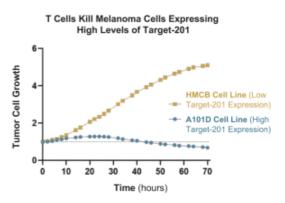
When we discover novel TCR/target pairs, we first determine if the gene that encodes the target is expressed at high levels in normal tissue. As shown below, Target-201 is exclusively expressed in testis, which is an immune privileged tissue and, as a result, should not pose a significant safety concern. 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 & neck cancer, and cervical cancer.

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



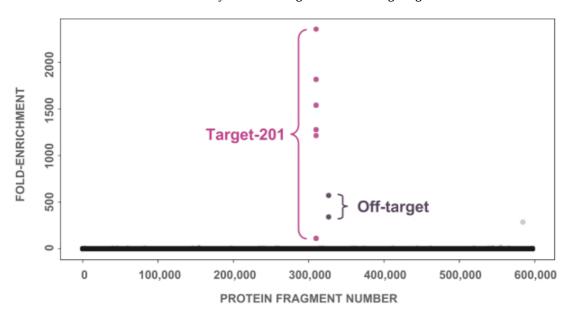
Next, as part of our discovery process, we test if the TCRs discovered with our approach are able to kill cancer cells that naturally express the relevant target and specific HLA type. As shown below on the left, when T cells expressing the TCR that recognizes Target-201 are cultured with melanoma cell lines that naturally express different levels of Target-201, such as A101D and SKMEL5, the degree to which the T cells gets 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 TargetScan 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 TargetScan



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 four solid tumor TCR-T therapy candidates include a combination of known targets, such as HPV16 for TSC-200 and PRAME for TSC-203, 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 & neck cancer, NSCLC, and 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 & 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 & 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 & 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 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 immuneprivileged 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 & 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 & neck cancers. Target-202 is also expressed in HPV-negative tumors, including approximately 40% of lung cancers and up to 80% of primary breast cancers. Using ReceptorScan, we have identified hundreds 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. In addition, we are using TargetScan to discover additional novel epitopes derived from Target-202 presented on other HLA types.

## TSC-203

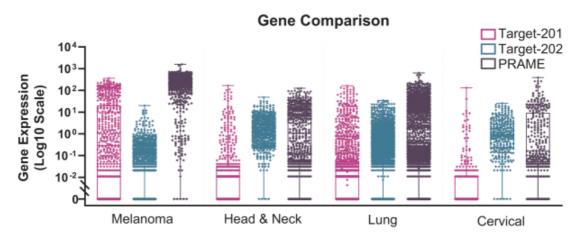
We are developing TSC-203 as a TCR-T therapy candidate targeting a known cancer antigen, Preferentially Expressed Antigen in Melanoma, or PRAME. Similar to Target-201, PRAME contributes to tumorigenesis by suppressing cellular signals that control cell division, and higher expression levels of PRAME 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 and approximately 90% of melanomas and head & neck cancers express PRAME. Moreover, PRAME expression is very 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 four lead solid tumor TCR-T therapy candidates, we have identified more than 40 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 to enable customized multiplexed TCR-T therapy for a wide range of solid tumor patients.

## Clinical Development Plan for Our Solid Tumor Program

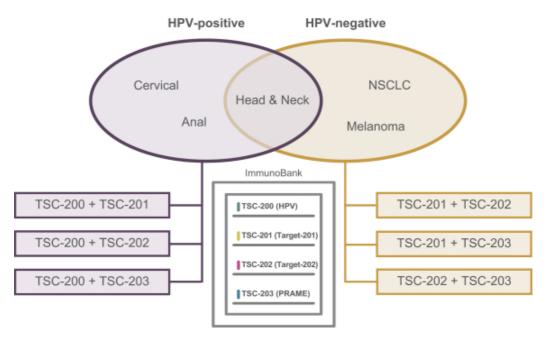
For the initial first-in-human studies for our TSC-200 series of TCR-T therapy candidates, we plan to evaluate at least three TCRs in parallel to determine the safety and preliminary efficacy of multiplexed TCR-T therapy. We envision using TSC-200 as the backbone therapy for patients with HPV-positive malignancies, including head & neck, cervical, and anal cancers. According to the Center for Disease Control, the incidence of HPV-positive cancers in the U.S. is approximately 35,000 cases per year, with five-year survival rates ranging from approximately 50% to 70%. The targets of TSC-201, TSC-202, and TSC-203 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, and TSC-203 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 & neck cancer, melanoma, and NSCLC. A summary of our planned Phase 1 clinical strategy is shown below. We plan to submit IND applications for at least three of our four solid tumor TCR-T therapy candidates in the second half of 2022, with the fourth IND expected to be filed 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.

## TSC-200 Series Phase 1 Clinical Strategy



## **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

Location of immunodominant T cell targets in the SARS-CoV-2 genome 100 Patients positive for epitope (%) 60 40 20 0 ORF1ab Spike 3a E М 6 7a 7b A\*02:01 A\*01:01 A\*03:01

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.

## **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 \$0.3 million as of December 31, 2020. 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

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 platform 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 (10th) anniversary of the first commercial sale of such product or process. The royalty rates are also subject to reduction upon certain other events.

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 is required to pay 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. To date, we have not received any payments from Qiagen under the Qiagen Agreement other than the Option Fee and we are not owed any payment from Qiagen under the Qiagen Agreement other than the option exercise fee.

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. 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 are building 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 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 200 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. and 3T Biosciences Inc. In addition, we may face competition from other TCR companies such as Adaptimmune Therapeutics, Plc., Medigene AG, and Ziopharm Oncology, Inc., as well as TCR<sup>2</sup> Therapeutics Inc. We may also face competition from companies focused on CAR-T, TIL and other cell therapies, such as Kite Pharma, Inc., a subsidiary of Gilead, Inc., Juno Therapeutics, Inc., a subsidiary of Bristol-Myers Squibb, Inc., Iovance Biotherapeutics, Inc., Instil Bio, Inc., Achilles Therapeutics plc, Geneos Therapeutics, Inc., and PACT Pharma, Inc. There are also companies utilizing other cell-based approaches that may be competitive to our product candidates. For example, companies such as Celyad, S.A., 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. and Kiadis Pharma U.S. Corporation, who are also developing cell therapies in the post-HCT setting.

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. Insurers and other third party payors may also encourage the use of generic products or specific branded products. As a result, obtaining market acceptance of, and gaining significant share of the market 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, 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 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 April 16, 2021, we do not own or exclusively in-license any issued patents and all of our owned patent applications are provisional patent applications. In addition, although we plan to file patent applications with respect to TSC-102, TSC-200, TSC-202 and TSC-203, as of April 16, 2021, we have not filed any patent applications with respect to these product candidates. As of April 16, 2021, we have filed sixteen U.S. provisional patent applications, nine of which are jointly owned by us and AHS Hospital Corporation ("AHS"). AHS has exclusively licensed their interest to us in such patent applications. Conversion of such patent applications to utility patent applications is expected to occur between June 2021 and April 2022.

As set forth in detail below, our provisional 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.

## SARS-CoV-2 technology

We filed four U.S. provisional patent applications (U.S. patent application serial number 63/040,267, filed June 17, 2020; U.S. patent application serial number 63/050,930, filed July 13, 2020; U.S. patent application serial number 63/056,462, filed July 24, 2020; and U.S. patent application serial number 63/056,849, filed July 27, 2020) drawn to SARS-CoV-2 immunodominant peptide compositions of matter and certain therapeutic and diagnostic uses thereof. Any patents issuing from any non-provisional patent applications claiming priority to these provisional patent applications would be expected to expire in 2041 (absent any adjustments or extensions of term).

We also filed four U.S. provisional patent applications (U.S. patent application serial number 63/056,511, filed July 24, 2020; U.S. patent application serial number 63/056,945, filed July 27, 2020; U.S. patent application serial number 63/069,926, filed August 25, 2020; and U.S. patent application serial number 63/111,448, filed November 9, 2020) drawn to anti-SARS-CoV-2 TCR compositions of matter and certain therapeutic and diagnostic uses thereof. Any patents issuing from any non-provisional patent applications claiming priority to these provisional patent applications would be expected to expire in 2041 (absent any adjustments or extensions of term).

We also filed a U.S. provisional patent application (U.S. patent application serial number 63/113,024, filed November 12, 2020) drawn to anti-SARS-CoV-2 vaccine compositions of matter and certain therapeutic and diagnostic uses thereof. Any patents issuing from any non-provisional patent applications claiming priority to this provisional patent application would be expected to expire in 2041 (absent any adjustments or extensions of term).

Each of these nine U.S. provisional patent applications is jointly owned by us and AHS. AHS has exclusively licensed their interest to us in such patent applications.

#### HA-1 technology

We filed four U.S. provisional patent applications (U.S. patent application serial number 63/110,851, filed November 6, 2020; U.S. patent application serial number 63/111,462, filed November 9, 2020; U.S. patent application serial number 63/129,804, filed December 23, 2020; and U.S. patent application serial number 63/175,350, filed April 15, 2021) drawn to anti-HA-1 TCR compositions of matter (including the TSC-100 TCR-T therapy candidate) and certain therapeutic and diagnostic uses thereof. Any patents issuing from any non-provisional patent applications claiming priority to these provisional patent applications would be expected to expire in 2041 (absent any adjustments or extensions of term).

## HA-2 technology

We filed a U.S. provisional patent application (U.S. patent application serial number 63/174,818, filed April 14, 2021) drawn to anti-HA-2 TCR compositions of matter (including the TSC-101 TCR-T therapy candidate) and certain therapeutic and diagnostic uses thereof. Any patents issuing from any non-provisional patent applications claiming priority to this provisional patent application would be expected to expire in 2042 (absent any adjustments or extensions of term).

## TSC-201 technology

We filed a U.S. provisional patent application (U.S. patent application serial number 63/174,808, filed April 14, 2021) drawn to anti-TSC-201 TCR compositions of matter and certain therapeutic and diagnostic uses thereof. Any patents issuing from any non-provisional patent applications claiming priority to these provisional patent applications would be expected to expire on 2042 (absent any adjustments or extensions of term).

## Screening technology

We filed a U.S. provisional patent application (U.S. patent application serial number 63/055,766, filed July 22, 2020) drawn to a phospholipid scrambling reporter-based T cell antigen screening platform

compositions of matter and certain screening methods thereof. Any patents issuing from any non-provisional patent applications claiming priority to these provisional patent applications would be expected to expire in 2041 (absent any adjustments or extensions of term).

Our provisional 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.

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 technologyplatform compositions of matter and certain screening methods thereof (consisting of one pending U.S. patent application (U.S. patent application serial number 16/619,859, filed December 5, 2019) and six pending foreign patent applications in Australia (patent application serial number 2018279728, filed December 5, 2019), Canada (patent application serial number 3,066,645, filed December 6, 2019), China (patent application serial number 201880051295.1, filed February 6, 2020), Europe (patent application serial number 18812782.3, filed January 7, 2020), Hong Kong (patent application serial number 62020017383.4, filed October 9, 2020), and Japan (patent application serial number 2019-567577, filed December 6, 2019)). Any patents issuing from the U.S. and foreign patent applications are expected to expire in 2038 (absent any adjustments or extensions of term). 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 one issued U.S. patent (patent number 10,627,411, granted on April 21, 2020 and expected to expire August 4, 2035), one pending U.S. patent application (U.S. patent application serial number 16/841,943, filed April 7, 2020), and one issued foreign patent in Canada (patent number 2,943,569, granted on February 23, 2021 and expected to expire March 25, 2035)). Any patent issuing from the U.S. patent application is expected to expire in 2035 (absent any adjustments or extensions of term). We do not have any additional material licenses to any technology or intellectual property rights.

As of April 16, 2021, we own or have rights to two pending U.S. trademark applications, 14 foreign trademark registrations, and three pending foreign trademark applications.

## **Government Regulation**

The FDA and other regulatory authorities at federal, state, and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring, and post-approval reporting of biologics such as those we are developing. We, along with third party contractors, will be required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our product candidates.

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

 completion of preclinical laboratory tests and animal studies performed in accordance with the FDA's current Good Laboratory Practices regulation;

- submission to the FDA of an IND, which must become effective before clinical trials may begin and must be updated annually or when significant changes are made;
- approval by an independent Institutional Review Board, or IRB, or ethics committee at each treatment site before the trial is commenced;
- performance of adequate and well-controlled human clinical trials to establish the safety, purity and potency of the proposed biologic product candidate for its intended purpose;
- preparation of and submission to the FDA of a BLA after completion of all pivotal clinical trials;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is
  produced to assess compliance with cGMP and to assure that the facilities, methods and controls are adequate to preserve the biological
  product's continued safety, purity and potency, and of selected clinical investigation sites to assess compliance with Good Clinical Practices,
  or GCP; and
- FDA review and approval of the BLA to permit commercial marketing of the product for particular indications for use in the United States.

#### **Preclinical and Clinical Development**

Prior to beginning the first clinical trial with a product candidate, we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical studies. The IND also includes results of animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial. 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 had historically been subject to review by the Recombinant DNA Advisory Committee, or RAC, of the NIH Office of Biotechnology Activities, or OBA, pursuant to the NIH Guidelines for Research Involving Recombinant DNA Molecules, or NIH Guidelines. On August 17, 2018, the NIH issued a notice in the Federal Register and issued a public statement proposing changes to the oversight framework for gene therapy trials, including changes to the applicable NIH Guidelines to modify the roles and responsibilities of the RAC with respect to human clinical trials of gene therapy products, and requesting public comment on its proposed modifications. During the public comment period, which closed October 16, 2018, the NIH announced that it would no longer accept new human gene transfer protocols for review as part of the protocol registration process or convene the RAC to review individual clinical protocols. These trials will remain subject to the FDA's oversight and other clinical trial regulations, and oversight at the local level will continue as set forth in the NIH Guidelines. 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.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under 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. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site and must monitor the study until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

For purposes of BLA approval, human clinical trials are typically conducted in three sequential phases that may overlap.

- Phase 1—The investigational product is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.
- Phase 2—The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- Phase 3—The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so-called Phase 4 studies may be made a condition to approval of the BLA. Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the biological characteristics of the product candidate and must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product, or for biologics, the safety, purity and potency. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

## **BLA Submission and Review**

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. The BLA must include all relevant data available from pertinent preclinical and clinical studies, 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. The submission of a BLA requires payment of a substantial application user fee to FDA, unless a waiver or exemption applies, and the sponsor of an approved BLA is also subject to an annual program fee.

Once a BLA has been submitted, the FDA's goal is to review standard applications within ten months after it accepts the application for filing, or, if the application qualifies for priority review, six months after the FDA accepts the application for filing. In both standard and priority reviews, the review process is often significantly extended by FDA requests for additional information or clarification. The FDA reviews a BLA to determine, among other things, whether a product is safe, pure and potent and the facility in which it is manufactured, processed, packed, or held meets standards designed to assure the product's continued safety, purity and potency. The FDA may convene an advisory committee to provide clinical insight on application review questions. Before approving a BLA, the FDA will typically inspect the facilities where the product is manufactured. The FDA will not approve an application 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 will typically inspect one or more treatment sites to assure compliance with GCP. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response letter will describe all of the deficiencies that the FDA has identified in the BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the Complete Response letter without first conducting required inspections, testing submitted product lots, and/or reviewing proposed labeling. In issuing the Complete Response letter, the FDA may recommend actions that the applicant might take to place the BLA in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the BLA with a Risk Evaluation and Mitigation Strategy, or REMS, to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more Phase 4 post market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization and may limit further marketing of the product based on the results of these post-marketing studies.

## **Expedited Development and Review Programs**

The FDA offers a number of expedited development and review programs for qualifying product candidates. The fast track program is intended to expedite or facilitate the process for reviewing new products that meet

certain criteria. Specifically, new products are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a fast track product has opportunities for frequent interactions with the review team during product development and, once a BLA is submitted, the product may be eligible for priority review. A fast track product may also be eligible for rolling review, where the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA.

A product intended to treat a serious or life-threatening disease or condition may also be eligible for breakthrough therapy designation to expedite its development and review. A product can receive breakthrough therapy designation if preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the fast track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product, including involvement of senior managers.

Any marketing application for a biologic submitted to the FDA for approval, including a product with a fast track designation and/or breakthrough therapy designation, may be eligible for other types of FDA programs intended to expedite the FDA review and approval process, such as priority review and accelerated approval. A product is eligible for priority review if it has the potential to provide a significant improvement in the treatment, diagnosis or prevention of a serious disease or condition compared to marketed products. For products containing new molecular entities, priority review designation means the FDA's goal is to take action on the marketing application within six months of the 60-day filing date (compared with ten months under standard review).

Additionally, products studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may receive accelerated approval upon a determination that the product has 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, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled post-marketing clinical studies to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. 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.

In 2017, FDA established a new regenerative medicine advanced therapy, or RMAT, designation as part of its implementation of the 21st Century Cures Act. The RMAT designation is intended to fulfill the 21st Century Cures Act requirement that FDA facilitate an efficient development program for, and expedite review of, any drug that meets the following criteria: (1) it qualifies as a RMAT, 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, with limited exceptions; (2) it is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and (3) preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such a disease or condition. Like breakthrough therapy designation, RMAT designation provides potential benefits that include more frequent meetings with FDA to discuss the development plan for the product candidate and eligibility for rolling review and priority review. Products granted RMAT designation may also be eligible for accelerated approval on the basis of a surrogate or intermediate endpoint reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of sites, including through expansion to additional sites. Once approved, when appropriate, the FDA can permit fulfillment of post-

approval requirements under accelerated approval through the submission of clinical evidence, clinical studies, patient registries, or other sources of real world evidence such as electronic health records; through the collection of larger confirmatory datasets; or through post-approval monitoring of all patients treated with the therapy prior to approval.

Fast track designation, breakthrough therapy designation, priority review, accelerated approval, and RMAT designation do not change the standards for approval but may expedite the development or approval process.

## **Orphan Drug Designation**

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

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusive approval (or exclusivity), which means that the FDA may not approve any other applications, including a full 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. Orphan drug exclusivity does not prevent FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the BLA application fee.

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

#### **Post-Approval Requirements**

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing user fee requirements, under which FDA assesses an annual program fee for each product identified in an approved BLA. Biologic manufacturers and their subcontractors 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, which impose certain procedural and documentation requirements upon us and our third party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market.

Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of a product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;
- product seizure or detention, or refusal of the FDA to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of biologics. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

## Biosimilars and Reference Product Exclusivity

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA, signed into law in 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-approved reference biological product. To date, a number of biosimilars have been licensed under the BPCIA, and numerous biosimilars have been approved in Europe. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars.

Biosimilarity, 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 study or studies. 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 in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. Complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

A biological product can also obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

The BPCIA is complex and continues to be interpreted and implemented by the FDA. In addition, recent government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate impact, implementation, and impact of the BPCIA is subject to significant uncertainty.

## Other U.S. Healthcare Laws and Compliance Requirements

In the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including but not limited to, the Centers for Medicare and Medicaid Services, or CMS, other divisions of the U.S. Department of Health and Human Services (such as the Office of Inspector General and the Health Resources and Service Administration), the Department of Justice, or the DOJ, and individual U.S. Attorney offices within the DOJ, and state and local governments. For example, sales, marketing and scientific/educational grant programs may have to comply with the anti-fraud and abuse provisions of the Social Security Act, the false claims laws, the privacy and security provisions of the Health Insurance Portability and Accountability Act, or HIPAA, and similar state laws, each as amended, as applicable.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. The federal Anti-Kickback Statute has been interpreted to apply to arrangements between therapeutic product manufacturers on one hand and prescribers and purchasers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the federal Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all

of its facts and circumstances. Our practices, including our arrangements with physicians, may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor.

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 and Education Reconciliation Act of 2010, or collectively, 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, or FCA.

The federal false claims and civil monetary penalty laws, including the FCA, which can be enforced by private citizens through civil qui tam actions, prohibit any person or entity from, among other things, knowingly presenting, or causing to be presented, a false or fraudulent claim for payment to, or approval by, the federal healthcare programs, including Medicare and Medicaid, or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. For instance, historically, pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of the product for unapproved, off-label, and thus generally non-reimbursable, uses.

HIPAA created additional federal criminal statutes that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third party payors, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, 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. Like the federal Anti-Kickback Statute, the ACA amended the intent standard for certain healthcare fraud statutes under HIPAA 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.

Also, many states have similar, and typically more prohibitive, fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Additionally, to the extent that our product is sold in a foreign country, we may be subject to similar foreign laws.

We may be subject to data privacy and security regulations 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, or HITECH, and their implementing regulations, impose requirements relating to the privacy, security and transmission of individually identifiable health information on certain healthcare providers, healthcare clearinghouses, and health plans, known as covered entities, as well as independent contractors, or agents of covered entities that receive or obtain individually identifiable health information in connection with providing a service on behalf of a covered entity, known as a business associates. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to business associates. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, many state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways, are often not pre-empted by HIPAA, and may have a more prohibitive effect than HIPAA, thus complicating compliance efforts.

In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price and best price. Further, these 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. It is difficult to predict how Medicare coverage and reimbursement policies will be applied to our products in the future and coverage and reimbursement under different federal healthcare programs are not always consistent. Medicare reimbursement rates may also reflect budgetary constraints placed on the Medicare program.

Additionally, the federal Physician Payments Sunshine Act, or the Sunshine Act, within the ACA, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) report annually to CMS information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members. In addition, many states also govern the reporting of payments or other transfers of value, many of which differ from each other in significant ways, are often not pre-empted, and may have a more prohibitive effect than the Sunshine Act, thus further complicating compliance efforts.

In order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of drug and biological products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical and biotechnology companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical and biotechnology companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

Ensuring business arrangements with third parties comply with applicable healthcare laws and regulations is a costly endeavor. If our operations are found to be in violation of any of the federal and state healthcare laws described above or any other current or future governmental regulations that apply to us, we may be subject to penalties, including without limitation, civil, criminal and/or administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, private "qui tam" actions brought by individual whistleblowers in the name of the government, or refusal to allow us to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

## Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we may obtain regulatory approval. In the United States and in foreign markets, sales of any products for which we receive regulatory approval for commercial sale will depend, in part, on the extent to which third party payors provide coverage and establish adequate reimbursement levels for such products. In the United States,

third party payors include federal and state healthcare programs, private managed care providers, health insurers and other organizations. Coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid in the United States, and commercial payors are critical to new product acceptance.

Third party payors decide which therapeutics they will pay for and establish reimbursement levels. Coverage and reimbursement by a third party payor may depend upon a number of factors, including the third party payor's determination that use of a therapeutic 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.

We cannot be sure that reimbursement will be available for any product that we commercialize and, if coverage and reimbursement are available, we cannot be sure that the level of reimbursement will be adequate. Coverage may also be more limited than the purposes for which the product is approved by the FDA or comparable foreign regulatory authorities. Limited coverage and less than adequate reimbursement may reduce the demand for, or the price of, any product for which we obtain regulatory approval.

Third party payors are increasingly challenging the price, examining the medical necessity, and reviewing the cost-effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy. Obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with branded drugs and drugs administered under the supervision of a physician. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. Obtaining coverage and reimbursement approval of a product from a third party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our product on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. A third party payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Additionally, in the United States there is no uniform policy among third party payors for coverage or reimbursement. Third party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies, but also have their own methods and approval processes. Therefore, one third party payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Adequate third party payor reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. If reimbursement is not available only at limited levels, we may not be able to successfully commercialize any product candidate that we successfully develop.

Certain of our products, once approved, may be administered by a physician. Under currently applicable U.S. law, certain products not usually self-administered (including injectable drugs) may be eligible for coverage under Medicare through Medicare Part B. Medicare Part B is part of original Medicare, the federal health care program that provides health care benefits to the aged and disabled, and covers outpatient services and supplies, including certain pharmaceutical products, that are medically necessary to treat a beneficiary's health condition. As a condition of receiving Medicare Part B reimbursement for a manufacturer's eligible drugs or biologicals, the manufacturer is required to participate in other government healthcare programs, including the Medicaid Drug Rebate Program and the 340B Drug Pricing Program. The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of the Department of Health and Human Services as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. Under the 340B Drug Pricing Program, the manufacturer must extend discounts to entities that participate in the program.

Different pricing and reimbursement schemes exist in other countries. In the European Union, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines but monitor and control company profits. The downward pressure on health care costs has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any product candidates for which we receive regulatory approval for commercial sale may suffer if the government and third party payors fail to provide coverage and adequate reimbursement. In addition, emphasis on managed care, the increasing influence of health maintenance organizations, and additional legislative changes in the United States has increased, and we expect will continue to increase, the pressure on healthcare pricing. The downward pressure on the rise in healthcare costs in general, particularly prescription medicines, medical devices and surgical procedures and other treatments, has become very intense. Coverage policies and third party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

# **Healthcare Reform**

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect the ability to profitably sell product candidates for which marketing approval is obtained. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

For example, the ACA has substantially changed healthcare financing and delivery by both governmental and private insurers. Among the ACA provisions of importance to the pharmaceutical and biotechnology industries, in addition to those otherwise described above, are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs and biologic agents apportioned among these entities according to their market share in some government healthcare programs that began in 2011;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, retroactive to January 1, 2010, to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively, and capped the total rebate amount for innovator drugs at 100% of the average manufacturer price;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (and 70% starting on 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 manufacturers' outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for

individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability;

- expansion of the entities eligible for discounts under the 340B Drug Discount Program;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- expansion of healthcare fraud and abuse laws, including the FCA and the federal Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- 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;
- requirements to report certain financial arrangements with physicians and teaching hospitals;
- a requirement to annually report certain information regarding drug samples that manufacturers and distributors provide to physicians;
- establishment of a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending; and
- a licensure framework for follow on biologic products.

Some of the provisions of the ACA have yet to be implemented, and there have been legal and political challenges to certain aspects of the ACA. Since January 2017, President Trump has signed two executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. In December 2017, the Tax Cuts and Jobs Act of 2017 was enacted which repeals, effective January 1, 2019, the tax penalty for an individual's failure to maintain ACA-mandated health insurance, commonly referred to as the "individual mandate." Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amends the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." More recently, in July 2018, CMS published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment.

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, included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect beginning on April 1, 2013 and, due to subsequent legislative amendments to the statute, including the BBA, will stay in effect through 2027 unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Further, 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 and enacted 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 the federal level, the Trump administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Additionally, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. The U.S. Department of Health and Human Services has already started the process of soliciting feedback on some of these measures and, at the same, is immediately implementing others under its existing authority. For example, in September 2018, CMS announced that it will allow Medicare Advantage Plans the option to use step therapy for Part B drugs beginning January 1, 2019, and in October 2018, CMS proposed a new rule that would require direct-to-consumer television advertisements of prescription drugs and biological products, for which payment is available through or under Medicare or Medicaid, to include in the advertisement the Wholesale Acquisition Cost, or list price, of that drug or biological product. Although a number of these, and other proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the states 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.

Additionally, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017, or 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 I 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 drug manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

## 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.

## **Employees and Human Capital**

As of March 11, 2021, we had 60 full-time employees and 1 part-time employees, 25 of whom have Ph.D. or M.D. degrees. Of these full-time employees, 50 employees are engaged in research and development activities and 10 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 employeeetention 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 in March 31, 2026. We believe that our 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.

#### MANAGEMENT

## **Executive Officers, Directors and Key Employees**

#### **Executive Officers**

The following table sets forth the names and positions of our executive officers, including their ages, as of March 1, 2021:

| <u>Name</u>                    | Age | <u>Position</u>                                 |
|--------------------------------|-----|---|
| David Southwell                | 60  | President, Chief Executive Officer and Director |
| Gavin MacBeath, Ph.D.          | 51  | Chief Scientific Officer                        |
| William Desmarais, Ph.D., MBA. | 51  | Chief Business Officer                          |

The following is a biographical summary of the experience of our executive officers.

David Southwell has served as our President, Chief Executive Officer and as a member of our board of directors since October 2018. Prior to joining us, Mr. Southwell was President, Chief Executive Officer and a member of the board of directors of Inotek Pharmaceuticals Corporation from June 2014 until Inotek's merger with Rocket Pharmaceuticals, Inc. in January 2018. Previously, Mr. Southwell served as Executive Vice President, Chief Financial Officer of Human Genome Sciences, Inc. from 2010 until its merger with GlaxoSmithKline plc. in 2012. Prior to Human Genome Sciences, Mr. Southwell served as Executive Vice President and Chief Financial Officer of Sepracor, Inc from 1994 to 2008. Mr. Southwell is a member of the Board of Directors of PTC Therapeutics, Inc., and Rocket Pharmaceuticals. He previously has served on the boards of Spero Therapeutics from 2017 to 2019; Inventiv Health, Inc. in 2016; THL Credit Inc. from 2007 to 2015; Human Genome Sciences Inc. from 2008 until his appointment as Chief Financial Officer in 2010; and Biosphere Medical Inc. as Chairman from 2005 to 2010. Mr. Southwell received a B.A. from Rice University and an M.B.A. from the Tuck School at Dartmouth College, where he has served as head of the M.B.A. Advisory Board from 2008 to 2011, and served on the Board of Advisors from 2011 until 2020. We believe that Mr. Southwell is qualified to serve on our board of directors because of the perspective and experience he provides as our President and Chief Executive Officer as well as his broad experience within the life sciences industry, together with his historical perspective on our operations.

Gavin MacBeath, Ph.D. has served as our Chief Scientific Officer since December 2018. He has two decades of experience in academia and industry, founding companies and driving research from early-stage discovery through drug approval. Prior to joining us, Dr. MacBeath served as the Chief Scientific Officer at Abpro Corporation from March 2017 to July 2018, where he advanced T cell-engaging bispecific antibodies through pre-clinical development. Previously, Dr. MacBeath served as Co-founder and SVP of Discovery at Merrimack Pharmaceuticals, Inc. from February 2014 to October 2016. Dr. MacBeath began his career in academia, where he served as the first fellow at Harvard's Bauer Center for Genomics Research, as an Assistant Professor and later Associate Professor in the Department of Chemistry & Chemical Biology at Harvard University, and as Lecturer and Principal Investigator at Harvard Medical School. Dr. MacBeath received his undergraduate degree from the University of Manitoba, his Ph.D. from The Scripps Research Institute, and postdoctoral training with Dr. Stuart Schreiber at Harvard University.

William Desmarais, Ph.D., MBA has served as our Chief Business Officer since March 2021. Prior to joining TScan, Dr. Desmarais served as Vice President of Business Development of Momenta Pharmaceuticals, Inc. from September 2017 until Momenta's acquisition by Johnson & Johnson in February 2021. Before Momenta, Dr. Desmarais spent 11 years in roles of increasing responsibility within business development and research and development at Eli Lilly & Co. Dr. Desmarais received his Ph.D. in Biophysics and Structural Biology from Brandeis University, an MBA from Massachusetts Institute of Technology and a B.S. in Cell and Developmental Biology from Purdue University.

# Non-Employee Directors

The following table sets forth the names and positions of our non-employee directors, including their ages, as of March 1, 2021:

| Name                               | Age | Position                 |
|------------------------------------|-----|--------------------------|
| Timothy Barberich(1),(2),(3)       | 73  | Chairperson of the Board |
| Stephen Biggar, M.D., Ph.D.(2),(3) | 50  | Director                 |
| Katina Dorton(1),(2)               | 63  | Director                 |
| Ittai Harel(1),(3)                 | 53  | Director                 |
| Andrew Hedin <sup>(4)</sup>        | 35  | Director                 |
| Nandita Shangari, Ph.D.(4)         | 40  | Director                 |
| Brian Silver <sup>(5)</sup>        | 52  | Director                 |
| Christoph Westphal, M.D., Ph.D.(6) | 52  | Director                 |

(1) Member of the audit committee

Member of the compensation committee

Member of the nominating and corporate governance

(4) Resigning as a director immediately prior to the effectiveness of the registration statement of which this prospectus forms a part.

(5) As of May 3, 2021, Mr. Silver plans to resign as a member of our board of directors and become our Chief Financial Officer.

(6) Resigning as a director immediately after the pricing of this offering.

The following is a biographical summary of the experience of our non-employee directors.

Timothy Barberich has served as a member of our board of directors since March 2019 and as the Chair of our board of directors since March 2021. Mr. Barberich is founder and former Chairman and Chief Executive Officer of Sepracor Inc., a publicly traded, research-based, pharmaceutical company based in Marlborough, Massachusetts, which was acquired by Dainippon Sumitomo Pharma Co., Ltd. in 2009. He founded Sepracor in 1984 and served as Chief Executive Officer from 1984 to May 2007 and as Chairman of the Board from 1990 to 2009. Mr. Barberich has been Chairman of BioNevia Pharmaceuticals since June 2008 and Chief Executive Officer since 2014. He currently serves on the board of directors of Frequency Therapeutics, Inc. and Verastem, Inc. He also previously served on the boards of directors of Neurovance Inc, Inotek Pharmaceuticals, Inc., HeartWare, International, Inc., Tokai Pharmaceuticals, BioSphere Medical, Inc. and GeminX Pharmaceuticals until each company was acquired. Mr. Barberich has also served on the board of trustees of Boston Medical Centre and the board of the Pharmaceutical Research and Manufacturers' Association (PhRMA). Prior to founding Sepracor, Mr. Barberich spent 10 years as a senior executive at Bedford, Massachusetts-based Millipore Corporation. Mr. Barberich is a graduate of Kings College and holds a Bachelor's of Science degree in Chemistry. The Board of Directors believes that Mr. Barberich's qualifications to sit on the Board include his significant experience in the development and commercialization of pharmaceutical products, his leadership experience at other pharmaceutical companies and his service on other boards of directors.

Stephen Biggar, M.D., Ph.D. has served as a member of our board of directors since March 2021. Dr. Biggar is a partner at Baker Bros. Advisors LP, a biotechnology-focused investment advisor to fund partnerships whose investors are primarily endowments and foundations, Dr. Biggar joined in April 2000. Dr. Biggar serves on the boards of Kiniksa Pharmaceuticals, Ltd., and Acadia Pharmaceuticals Inc. Dr. Biggar received an M.D. and a Ph.D. in Immunology from Stanford University and received a B.S. in Genetics from the University of Rochester. We believe that Dr. Biggar is qualified to serve as a member of our board of directors due to his extensive experience in the life sciences industry.

Katina Dorton, J.D., M.B.A. has served on our board of directors since March 2021. She currently serves as Chief Financial Officer of Nodthera Limited, a company developing medicines to inhibit the NLRP3 inflammasome. She also serves on the board of directors for Fulcrum Therapeutics, Inc., Pandion Therapeutics, Inc., and US Ecology, Inc.. Previously Ms. Dorton has held CFO positions at several biotechnology companies, including Repare Therapeutics Inc., a synthetic lethality and DNA repair-focused oncology company from 2019 through 2020, and AVROBIO, Inc., a lentiviral gene therapy company from 2017 through 2018 and Immatics GmbH, a biotechnology company from 2015 through 2017. Earlier in her career, Ms. Dorton served as a Managing Director in investment banking for Morgan Stanley and Needham & Company and as an attorney at Sullivan & Cromwell. Ms. Dorton received her J.D. from the University of Virginia School of Law, her M.B.A. from George Washington University and her B.A. from Duke University. We believe that Ms. Dorton is qualified to serve on our board of directors due to her extensive leadership experience in multiple publicly-traded and privately-held pharmaceutical and biotechnology companies, and expertise in developing, financing and providing executive leadership in numerous biopharmaceutical companies.

Ittai Harel has served as a member of our board of directors since August 2019. Mr. Harel has served as the Managing General Partner of Pitango Venture Capital since 2006 and has extensive investment experience in the biotechnology and healthcare industry, including digital health, medical devices, diagnostics, and specialty pharma. Before joining Pitango, Mr. Harel headed up Corporate Development at Nektar Therapeutics (Nasdaq: NKTR) and served as Executive Vice President at IDGene Pharmaceuticals, Inc. He also served as head of business development at IDEXX Laboratories, Inc. Mr. Harel currently serves on the board of directors of DouxMatok, Intensix Ltd., LifeBond Ltd., EarlySense, Medisafe, Vertos Medical Inc., and Click Therapeutics, Inc. and serves as Chairman of the Board at LifeBond Ltd. and EarlySense. Mr. Harel holds a B.Sc. in Chemical Engineering and Biotechnology from Ben Gurion University, and an M.B.A. from the Sloan School of Management. We believe that Mr. Harel is qualified to serve as a member of our board of directors due to his extensive experience in the life sciences industry as a venture capitalist.

Andrew Hedin has served as a member of our board of directors since July 2020. Mr. Hedin has served as an investment professional at Bessemer Venture Partners, a venture capital firm, since 2015 and has been a partner since 2021. Mr. Hedin serves as a director or observer of the board of directors of several privately held life sciences and healthcare companies. Mr. Hedin holds an M.B.A. with Honors from The Wharton School and a B.A. from the University of Pennsylvania.

Nandita Shangari, Ph.D. has served as a member of our board of directors since September 2020. Dr. Shangari has served as a Principal at the Novartis Venture Fund since 2018. Prior to joining NVF, she was part of the Novartis Oncology Business Development and Licensing team from 2017 to 2018 where she managed key alliances for the Oncology Portfolio. Before that, Dr. Shangari held the Global Program Team Director position as part of the Kymriah® Global Program Team from 2015 to 2017 where she helped bring this novel cell therapy to market, for two indications, in the US and EU. Dr. Shangari has also held strategic and group head roles in the Novartis Preclinical Investigative Toxicology organization. Dr. Shangari received her B.Sc. in Biochemistry and Ph.D. in Pharmaceutical Sciences from the University of Toronto, Canada.

*Brian Silver* has served as a member of our board of directors since December 2020. Mr. Silver has served as the Chief Financial Officer and Head of Corporate Development of Freeline Therapeutics Holdings plc (Freeline), a systemic gene therapy company focused on inherited rare disorders, since November 2018. Before joining Freeline, Mr. Silver was a partner in the healthcare group of Perella Weinberg Partners, a leading independent global advisory firm, from August 2013 to November 2018. Prior to that, Mr. Silver held a variety of positions in Morgan Stanley's investment banking division, most recently as a managing director in the healthcare group, from March 1998 to July 2013. Before that Mr. Silver was an investment banking associate at Salomon Brothers from August 1997 to March 1998 and a corporate associate at Sullivan & Cromwell LLP from

August 1994 through July 1997. Mr. Silver received an A.B. with honors from Harvard College and a J.D. with honors from the University of Chicago Law School. We believe that Mr. Silver is qualified to serve as a member of our board of directors due to his extensive experience in the pharmaceutical and biotechnology industry, combined with his deep expertise in finance, accounting, business development, and legal affairs. Freeline has announced Mr. Silver's resignation as CFO effective April 30, 2021, and as of May 3, 2021, Mr. Silver plans to step down as a member of our board of directors and become our Chief Financial Officer.

Christoph Westphal, M.D., Ph.D. has served as a member of our board of directors since our founding. Dr. Westphal is one of our co-founders and served as our Chief Executive Officer from our founding through October 2018, at which point Dr. Westphal transitioned to our Chair. Dr. Westphal has been a partner of Longwood Fund, LP, a venture capital investment fund, since 2010. Dr. Westphal co-founded Verastem, Inc. in August 2010, served as Verastem's Chairman since March 2011, and Executive Chairman since July 2013, and was Verastem's Chief Executive Officer from September 2011 to July 2013 and its President from September 2011 until January 2013. Dr. Westphal served as the President of SR One, the corporate venture capital arm of GlaxoSmithKline plc, from 2010 until 2011. Dr. Westphal co-founded Sirtris Pharmaceuticals, Inc., which was acquired by GlaxoSmithKline plc in 2008, and served as its Chief Executive Officer from 2004 to 2010. He also co-founded Alnara Pharmaceuticals, Inc., Concert Pharmaceuticals, Inc., Acceleron Pharma, Inc., serving as its Chief Executive Officer in 2003, Alnylam Pharmaceuticals, Inc., serving as its Chief Executive Officer in 2001. Dr. Westphal is also co-founder of Longwood portfolio companies, including Immunitas Therapeutics, Inc. serving as its Chief Executive Officer and also as Chairman of the board, ImmuneID serving as executive chair and Pyxis Oncology, Inc. Dr. Westphal has served or currently serves as a member or director of the Boston Commercial Club, the Biotechnology Industry organization's (BIO) Emerging Companies Section Governing Board, the Board of Fellows of Harvard Medical School, and the Board of Trustees of the Boston Symphony Orchestra. He earned his M.D. from Harvard Medical School, his Ph.D. in Genetics from Harvard University and his B.A. from Columbia University.

## **Board Composition**

Our board of directors currently consists of nine members, who were elected pursuant to the amended and restated voting agreement that we entered into with certain holders of our common stock and certain holders of our preferred stock and the related provisions of our amended and restated certificate of incorporation, as currently in effect.

The provisions of this voting agreement will terminate upon the completion of this offering, after which there will be no further contractual obligations regarding the election of our directors, except as described below. Our directors hold office until their successors have been elected and qualified or appointed, or the earlier of their death, resignation or removal.

In connection with our Series C convertible preferred stock financing described in the "Certain relationships and related party transactions" section of this prospectus, 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 during the period beginning at the closing of our initial public offering and for the three years thereafter, as long as (1) the BBA Funds and their affiliates, collectively, beneficially own at least 75% of the Series C convertible preferred stock purchased by the BBA Funds in such Series C convertible preferred stock financing, or such number of shares of our common stock issued upon conversion of such number of shares of Series C convertible preferred stock (in either case, as adjusted for any stock split, stock dividend, combination, or other

recapitalization or reclassification or similar transaction), and (2) the BBA Funds and their affiliates, collectively, beneficially own at least 2% of our then outstanding voting common stock.

In accordance with the terms of our amended and restated certificate of incorporation and amended and restated bylaws that will be in effect upon the completion of this offering, our board of directors will be divided into three classes with staggered three-year terms. At each annual meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election. Our directors will be divided among the three classes as follows:

- the Class I directors will be Timothy Barberich and Stephen Biggar, M.D., Ph.D. and their terms will expire at the first annual meeting of stockholders to be held after the closing of this offering;
- the Class II directors will be Ittai Harel and Katina Dorton and their terms will expire at the second annual meeting of stockholders to be held after the closing of this offering; and
- the Class III director will be David Southwell and his term will expire at the third annual meeting of stockholders to be held after the closing
  of this offering.

Directors in a particular class will be elected for three-year terms at the annual meeting of stockholders in the year in which their terms expire. As a result, 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. Each director's term continues until the election and qualification of his or her successor, or the earlier of his or her death, resignation or removal.

Our amended and restated certificate of incorporation and amended and restated bylaws that will be in effect upon the completion of this offering provide that only our board of directors can fill vacant directorships, including newly-created seats. Any additional directorships resulting from an increase in the authorized number of directors would be distributed pro rata among the three classes so that, as nearly as possible, each class would consist of one-third of the authorized number of directors.

The classification of our board of directors may have the effect of delaying or preventing changes in our control or management. See the section titled "Description of capital stock—Anti-takeover provisions—Certificate of incorporation and bylaw provisions" elsewhere in this prospectus.

#### **Director Independence**

Upon the completion of this offering, we anticipate that our common stock will be listed on Nasdaq. Under the rules of Nasdaq, independent directors must comprise a majority of a listed company's board of directors. In addition, the rules of Nasdaq require that, subject to specified exceptions, each member of a listed company's audit, compensation and nominating and corporate governance committees be independent. Audit committee members and compensation committee members must also satisfy the independence criteria set forth in Rule 10A-3 and Rule 10C-1, respectively, under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Under the rules of Nasdaq, a director will only qualify as an "independent director" if, in the opinion of that company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

To be considered to be independent for purposes of Rule 10A-3 under the Exchange Act and under the rules of Nasdaq, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors or any other board committee: (1) accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries or (2) be an affiliated person of the listed company or any of its subsidiaries.

To be considered independent for purposes of Rule 10C-1 under the Exchange Act and under the rules of Nasdaq, the board of directors must affirmatively determine that each member of the compensation committee is independent, including a consideration of all factors specifically relevant to determining whether the director has

a relationship to the company which is material to that director's ability to be independent from management in connection with the duties of a compensation committee member, including, but not limited to: (i) the source of compensation of such director, including any consulting, advisory or other compensatory fee paid by the company to such director and (ii) whether such director is affiliated with the company, a subsidiary of the company or an affiliate of a subsidiary of the company.

Our board of directors undertook a review of its composition, the composition of its committees and the independence of our directors and considered whether any director has a material relationship with us that could compromise his or her ability to exercise independent judgment in carrying out his or her responsibilities. Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, our board of directors has determined that, other than Mr. Southwell, our Chief Executive Officer, all of our directors, do not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" as that term is defined under the rules of Nasdaq, including in the case of all the members of our audit committee, the independence criteria set forth in Rule 10A-3 under the Exchange Act, and in the case of all the members of our compensation committee, the independence criteria set forth in Rule 10C-1 under the Exchange Act.

In making these determinations, our board of directors considered the current and prior relationships that each non-employee director has with our company and all other facts and circumstances our board of directors deemed relevant in determining his or her independence, including the beneficial ownership of our capital stock by each non-employee director, and the transactions involving them described in the section titled "Certain relationships and related party transactions" elsewhere in this prospectus. There are no family relationships among any of our directors or executive officers.

## **Board Leadership Structure**

Our board of directors is currently chaired by Mr. Barberich. As a general policy, our board of directors believes that separation of the positions of chairperson of our board of directors and Chief Executive Officer reinforces the independence of our board of directors from management, creates an environment that encourages objective oversight of management's performance and enhances the effectiveness of our board of directors as a whole. As such, Mr. Southwell serves as our President and Chief Executive Officer while Mr. Barberich serves as the chairperson of our board of directors but is not one of our executive officers. We currently expect and intend the positions of chairperson of our board of directors and Chief Executive Officer to continue to be held by two individuals in the future.

#### Role of the Board in Risk Oversight

One of the key functions of our board of directors is informed oversight of our risk management process. In particular, our board of directors is responsible for monitoring and assessing strategic risk exposure. Our executive officers are responsible for the day-to-day management of the material risks we face. Our board of directors administers its oversight function directly as a whole. Our board of directors will also administer its oversight through various standing committees, which will be constituted prior to the completion of this offering, that address risks inherent in their respective areas of oversight. For example, our audit committee will be responsible for overseeing the management of risks associated with our financial reporting, accounting and auditing matters; our compensation committee will oversee the management of risks associated with our compensation policies and programs; and our nominating and corporate governance committee will oversee the management of risks associated with director independence, conflicts of interest, composition and organization of our board of directors and director succession planning.

## **Board Committees**

Our board of directors has previously established an audit committee, a compensation committee and a nominating and corporate governance committee. Prior to the completion of this offering, our board of directors

may establish other committees to facilitate the management of our business. Our board of directors and its committees will set schedules for meeting throughout the year and can also hold special meetings and act by written consent from time to time, as appropriate. Our board of directors expects to delegate various responsibilities and authority to committees as generally described below. The committees will regularly report on their activities and actions to the full board of directors. Each member of each committee of our board of directors will qualify as an independent director in accordance with the listing standards of Nasdaq. We plan to amend and restate the existing charters for each committee of our board of directors prior to the completion of this offering. Upon the completion of this offering, copies of each charter will be posted on the investor relations portion of our website, www.tscan.com. The inclusion of our website address in this prospectus does not include or incorporate by reference the information on our website into this prospectus. Members will serve on these committees until their resignation or until otherwise determined by our board of directors.

### **Audit Committee**

The members of our audit committee are Katina Dorton, Ittai Harel and Timothy Barberich. Ms. Dorton is the chair of the audit committee. Each member of our audit committee can read and understand fundamental financial statements. Each member of our audit committee is independent under the rules and regulations of the SEC and the listing standards of Nasdaq applicable to audit committee members. Our board of directors has determined that Ms. Dorton qualifies as an audit committee financial expert within the meaning of SEC regulations and meets the financial sophistication requirements of Nasdaq.

Effective at the time of the offering, our audit committee will assist our board of directors with its oversight of the integrity of our financial statements; our compliance with legal and regulatory requirements; the qualifications, independence and performance of the independent registered public accounting firm; the design and implementation of our risk assessment and risk management. Among other things, our audit committee is responsible for reviewing and discussing with our management the adequacy and effectiveness of our disclosure controls and procedures. The audit committee also will discuss with our management and independent registered public accounting firm the annual audit plan and scope of audit activities, scope and timing of the annual audit of our financial statements, and the results of the audit, quarterly reviews of our financial statements and, as appropriate, initiates inquiries into certain aspects of our financial affairs. Our audit committee is responsible for establishing and overseeing procedures for the receipt, retention and treatment of any complaints regarding accounting, internal accounting controls or auditing matters, as well as for the confidential and anonymous submissions by our employees of concerns regarding questionable accounting or auditing matters. In addition, our audit committee has direct responsibility for the appointment, compensation, retention and oversight of the work of our independent registered public accounting firm. Our audit committee has sole authority to approve the hiring and discharging of our independent registered public accounting firm, all audit engagement terms and fees and all permissible non-audit engagements with the independent auditor. Our audit committee will review and oversee all related person transactions in accordance with our policies and procedures.

Our audit committee operates under a written charter that satisfies the applicable rules of the SEC and the listing standards of Nasdaq. We believe that the composition of our audit committee will meet the requirements for independence under current Nasdaq and SEC rules and regulations.

## **Compensation Committee**

The members of our compensation committee are Stephen Biggar, Timothy Barberich and Katina Dorton. Dr. Biggar is the chair of the compensation committee. Each member of our compensation committee is independent under the rules and regulations of the SEC and the listing standards of Nasdaq applicable to compensation committee members. Effective at the time of the offering, our compensation committee will assist our board of directors with its oversight of the forms and amount of compensation for our executive officers (including officers reporting under Section 16 of the Exchange Act), the administration of our equity and non-equity incentive plans for employees and other service providers and certain other matters related to our compensation programs. Our compensation committee, among other responsibilities, evaluates the performance

of our chief executive officer and, in consultation with him, evaluates the performance of our other executive officers (including officers reporting under Section 16 of the Exchange Act).

Effective at the time of the offering, our compensation committee will operate under a written charter that satisfies the applicable rules of the SEC and the listing standards of Nasdaq. We believe that the composition of our compensation committee will meet the requirements for independence under current Nasdaq and SEC rules and regulations.

## Nominating and Corporate Governance Committee

The members of our nominating and corporate governance committee are Timothy Barberich, Stephen Biggar and Ittai Harel. Each member of our nominating and corporate governance committee is independent under the rules and regulations of the SEC and the listing standards of Nasdaq applicable to nominating and corporate governance committee. Effective at the time of the offering, our nominating and corporate governance committee will assist our board of directors with its oversight of and identification of individuals qualified to become members of our board of directors, consistent with criteria approved by our board of directors, and selects, or recommends that our board of directors selects, director nominees; develops and recommends to our board of directors a set of corporate governance guidelines and oversees the evaluation of our board of directors.

## **Compensation Committee Interlocks and Insider Participation**

No member of our compensation committee is currently or has at any time during the past year been an officer or employee of our company. None of our executive officers currently serves, or in the past fiscal year has served, as a member of the board of directors or compensation committee (or other board committee performing equivalent functions or, in the absence of any such committee, the entire board of directors) of any entity that has one or more executive officers serving on our board of directors or compensation committee.

#### **Code of Conduct**

Our board of directors will adopt a Code of Conduct prior to the completion of this offering. The Code of Conduct will apply to all of our employees, officers, directors, contractors, consultants, suppliers and agents. Upon the completion of this offering, the full text of the Code of Conduct will be posted on the investor relation portion of our website, www.tscan.com. We intend to disclose future amendments to, or waivers of, the Code of Conduct, as and to the extent required by SEC regulations, at the same location on our website identified above or in public filings. Information contained on our website is not incorporated by reference into this prospectus, and you should not consider information contained on our website to be part of this prospectus or in deciding whether to purchase shares of our common stock. We have included our website address in this prospectus solely as an inactive textual reference.

## **Director Compensation**

# Director Compensation Table for the Year Ended December 31, 2020

The following table sets forth information regarding the compensation of our non-employee directors who served as a director during our year ended December 31, 2020. Other than as set forth in the table and described more fully below, during our year ended December 31, 2020, we did not pay any fees to, make any equity awards or non-equity awards to or pay any other compensation to the non-employee members of our board of directors. David Southwell, our President and Chief Executive Officer, receives no compensation for his service as a director, and is not included in the table below. The compensation of Mr. Southwell as a named executive officer is set forth below in the subsection above entitled "—Executive compensation—Summary Compensation Table."

Katina Dorton and Stephen Biggar, M.D., Ph.D. are not included in the table below since these directors were appointed to our board of directors in 2021.

| Name<br>Christoph Westphal, M.D., Ph.D. | Fees<br>earned or<br>paid in<br>cash (\$) | Stock<br>awards<br>(\$) | Option<br>awards<br>(\$)(1)(2) | All other compensation (\$) | Total<br>(\$) |
|---|---|-------------------------|--------------------------------|-----------------------------|---------------|
| -                                       | _   | _                       | _                              | _                           | _             |
| Andrew Hedin                            | _   | _                       | _                              | _                           | _             |
| Nandita Shangari, Ph.D.                 | _   | _                       | _                              | _                           | _             |
| Ittai Harel                             |   | _                       | _                              | _                           | _             |
| Timothy Barberich                       | _   | _                       | _                              | _                           | _             |
| Douglas Fambrough, Ph.D.(3)             | _   | _                       | 117,810(6)                     | _                           | 117,810       |
| Brian Silver                            | _   | _                       | _                              | _                           | _             |
| Hannes Smarason <sup>(4)</sup>          | _   | _                       | _                              | _                           |               |
| Lea Hachigian, Ph.D.(5)                 | _   | _                       | _                              | _                           |               |
|   |   |                         |                                |                             |               |

The amounts in this column represent the aggregate grant date fair value of option awards granted to the non-employee director in the applicable fiscal year computed in accordance with FASB ASC Topic 718. See Note 7 of the notes to our audited financial statements included elsewhere in this prospectus for a discussion of our assumptions made in determining the grant date fair value of our equity awards.

On January 27, 2021, Mr. Silver was granted an option to purchase 400,000 shares of our common stock, with an exercise price of \$0.71 per share. Such option vests over four years, with 25% of the shares vesting on December 14, 2021, and 1/48th of the shares vesting upon the completion of each month of continuous service with us thereafter.

On March 16, 2021, in connection with her appointment to our board of directors, Ms. Dorton was granted an option to purchase 400,000 shares of our common stock, with an exercise price of \$1.41 per share. Such option vests over four years, with 25% of the shares vesting on March 1, 2021, and 1/48th of the shares vesting upon the completion of each month of continuous service with us thereafter.

We entered into a services agreement with Dr. Westphal on October 9, 2018, which was amended in June 2019. Pursuant to the terms of the services agreement, as amended, Dr. Westphal received cash compensation at a monthly rate of \$15,000 per month from October 2018 through October 2019. Following October 31, 2019, Dr. Westphal's service to us has been provided for no cash compensation. Dr. Westphal currently directly owns 7,500,000 shares of our common stock.

Prior to this offering, other than as discussed below, we had not implemented a formal policy or agreements with respect to compensation payable to our non-employee directors.

We reimburse our directors for expenses associated with attending meetings of our board of directors and its committees.

## **Director Compensation**

Our board of directors adopted the following compensation program in March 2021 for our non-employee directors following competion of this offering.

As of December 31, 2020, our non-employee directors held outstanding stock options as follows: Mr. Barberich (options to purchase 392,700 shares) and Dr. Fambrough (options to purchase 392,700 shares)

Dr. Fambrough resigned from our board of directors on March 1, 2021.

Mr. Smarason resigned from our board of directors on January 15, 2021.

Dr. Hachigian resigned from our board of directors on January 21, 2021.

On February 26, 2020, Dr. Fambrough was granted an option to purchase 392,700 shares of our common stock, with an exercise price of \$0.30 per share. Such option vested over four years, with 25% of the shares vesting on the first anniversary of February 26, 2020, and 1/48th of the shares vesting upon the completion of each month of continuous service with us thereafter. At the time of Dr. Fambrough's resignation, he was vested in 98,175 shares subject to this stock option. The 294,525 unvested shares subject to this option were forfeited in connection with Dr. Fambrough's resignation. On March 3, 2021, Dr. Fambrough exercised the vested portion of this option for 98,175 shares of our common stock.

Each non-employee director will be paid an annual cash retainer of \$40,000. The chair of the audit committee will be paid an additional \$7,500 annually, the chair of the compensation committee will be paid an additional \$6,000 annually and the chair of the nominating and corporate governance committee will be paid an additional \$4,000 annually. In addition to any fees received as chair of our committees, members of the audit committee will be paid an additional \$7,500 annually, members of the compensation committee will be paid an additional \$6,000 annually and members of the nominating and corporate governance committee will be paid an additional \$4,000 annually. All retainers will be paid in quarterly installments.

In addition, the compensation program for our non-employee directors will include both an initial equity award upon joining our board of directors and an annual equity award in connection with each annual meeting of our stockholders.

- Annual Equity Award—Following the conclusion of each regular annual meeting of stockholders, each continuing non-employee director will receive an option to purchase 75,000 shares of our common stock under our 2021 Equity Incentive Plan. The option will vest in twelve equal monthly installments following the date of grant, subject to the non-employee director's continuous service. All non-employee directors as of the offering will be granted this annual equity award.
- Initial Equity Award—Our board of directors intends to provide for an initial option grant to purchase our common stock for any new employee directors following this offering. It is expected that such initial equity award will vest in three equal annual installments on each anniversary of the date of grant, subject to the non-employee director's continuous service.
- Any non-employee director equity awards will also vest in full in the event of our "change in control" (as defined in our 2021 Equity Incentive Plan) or a director's death or disability.

#### **EXECUTIVE COMPENSATION**

The following discussion relates to the compensation of our Chief Executive Officer, David Southwell, our Chief Scientific Officer, Gavin MacBeath, Ph.D., and our former Chief Business Officer, Henry Rath for the fiscal year ended December 31, 2020. Mr. Southwell, Dr. MacBeath and Mr. Rath are collectively referred to in this prospectus as our named executive officers.

## **Summary compensation table**

The following table shows information regarding the compensation of our named executive officers for the fiscal year ended December 31, 2020.

| Name and principal position                     | Year | Salary<br>(\$) | Bonus<br>(\$) | Option<br>Awards<br>(\$) | All Other<br>Compensation<br>(\$) | Total<br>(\$) |
|---|------|----------------|---------------|--------------------------|-----------------------------------|---------------|
| David Southwell                                 |      |                |               |                          |                                   |               |
| Chief Executive Officer                         | 2020 | 466,700        | 275,353(2)    | _                        | 8,185(3)                          | 750,238       |
| Gavin MacBeath, Ph.D.  Chief Scientific Officer | 2020 | 350,200        | 171,598(2)    | _                        | 11,170(3)                         | 532,968       |
| Henry Rath former Chief Business Officer(1)     | 2020 | 355,350        | _             | _                        | 12,166(3)                         | 367,516       |

<sup>(1)</sup> Mr. Rath's employment with us terminated as of January 31, 2021.

## Narrative explanation of compensation arrangements with our named executive officers

## Base salaries and annual incentive opportunities.

The base salaries of all of our named executive officers are reviewed from time to time and adjusted when our board of directors or its compensation committee determines an adjustment is appropriate. For our 2020 fiscal year, the base salary for Mr. Southwell was \$466,700, Dr. MacBeath was \$350,200 and Mr. Rath was \$355,350. For our 2021 fiscal year, Mr. Southwell's base salary is \$550,000 and Dr. MacBeath's base salary is \$400,000.

Each of our named executive officers is eligible to earn an incentive bonus each fiscal year, with such bonus awarded based on individual performance goals, as well as achievement of corporate goals related to our product development and advancement of pre-clinical studies established by our chief executive officer and approved by our board of directors. During our fiscal year ended December 31, 2020, our named executive officers were eligible to earn cash incentive bonuses based on a combination of corporate and individual goals. We require that participants continue to be employed through the payment date to receive a bonus. For our 2021 fiscal year, Mr. Southwell's annual bonus target is 55% of his base salary and Dr. MacBeath's annual bonus target is 40% of his base salary.

Pursuant to agreements with us, Mr. Southwell and Dr. MacBeath are each eligible to receive certain acceleration benefits in the event of our change in control, as described in the footnotes to the "Outstanding equity awards at the year ended December 31, 2020" table and under the "Agreements with Our Named Executive Officers and Potential Payments upon Termination or Change of Control" section below.

<sup>(2)</sup> Represents bonuses earned in 2020 and paid in 2021.

<sup>(2)</sup> Represents boliuses earlied in 2020 and paid in 2021.

(3) This amount represents certain benefits paid to the named executive officers, including reimbursement for long term disability insurance, payment of domestic partner medical benefits, and Company matching contributions to 401(k) plan in the amounts of \$10,404 and \$11,400 to Dr. MacBeath and Mr. Rath, respectively.

### Equity compensation.

We offer stock options to our employees, including our named executive officers, as the long-term incentive component of our compensation program. Our stock options allow our employees to purchase shares of our common stock at a price equal to the fair market value of our common stock on the date of grant. In the past, our board of directors or compensation committee has determined the fair market value of our common stock based on inputs including valuation reports prepared by third party valuation firms. Generally, our stock options granted to new hires have vested as to 25% of the total number of option shares on the first anniversary of the award and in equal monthly installments over the following 36 months.

## Employee benefits and perquisites.

Our named executive officers are eligible to participate in our health and welfare plans to the same extent as are full-time employees generally. We generally do not provide our named executive officers with perquisites or other personal benefits.

## Retirement benefits.

We have established a 401(k) tax-deferred savings plan, which permits participants, including our named executive officers, to make contributions by salary deduction pursuant to Section 401(k) of the Internal Revenue Code. We are responsible for administrative costs of the 401(k) plan. We match 100% of every dollar contributed up to 4% of salary, subject to certain limitations under the Internal Revenue Code. In fiscal year 2020, Dr. MacBeath and Mr. Rath received a Company matching contribution of \$10,404 and \$11,400, respectively.

## Outstanding equity awards at the year ended December 31, 2020

The following table sets forth information regarding each unexercised option and all unvested stock held by each of our named executive officers as of December 31, 2020.

The vesting schedule applicable to each outstanding award is described in the footnotes to the table below.

|                       | Number of<br>securities<br>underlying<br>unexercised<br>options<br>exercisable | Number of<br>securities<br>underlying<br>unexercised<br>options<br>unexercisable | Option<br>exercise<br>price | Option<br>expiration |
|-----------------------|--|--|-----------------------------|----------------------|
| Name                  | (#)  | (#)  | (\$)                        | date                 |
| David Southwell       | 331,689(1),(2),(3)   | 663,377  | \$ 0.24                     | 10/8/2028            |
| David Southwell       | 190,872(1),(2),(3)   | 381,744  | \$ 0.24                     | 2/4/2029             |
| David Southwell       | 411,686(1),(4)   | 1,235,058  | \$ 0.30                     | 12/17/2029           |
| Gavin MacBeath, Ph.D. | 155,789(1),(2),(5)   | 315,790  | \$ 0.24                     | 1/23/2029            |
| Gavin MacBeath, Ph.D. | 114,027(1),(4)   | 342,082  | \$ 0.30                     | 12/17/2029           |
| Henry Rath            | 228,026(1),(2),(6)   | 319,237(7)   | \$ 0.24                     | 5/7/2029             |
| Henry Rath            | 60,380(1),(4)  | 181,142(8)   | \$ 0.30                     | 12/17/2029           |

<sup>25%</sup> of the shares vest on the first anniversary of the vesting commencement date, and 1/48th of the shares vest upon the completion of each month of continuous service thereafter. If we are subject to a change of control, then 100% of any unvested shares subject to this option shall immediately vest.

The vesting commencement date is October 9, 2018. The vesting commencement date is December 5, 2019.

The vesting commencement date is December 3, 2018.

The vesting commencement date is April 22, 2019.

Mr. Rath's employment with us terminated as of January 31, 2021. As a result of this termination, 307,836 of such unexercisable options expired as of such date.

(8) Mr. Rath's employment with us terminated as of January 31, 2021. As a result of this termination, 176,110 of such unexercisable options expired as of such date.

On January 27, 2021, Mr. Southwell was granted an option to purchase 4,251,733 shares of our common stock, and Dr. MacBeath was granted an option to purchase 1,365,934 shares of our common stock, each with an exercise price of \$0.71 per share. The option shares vest over four years, with 25% of the shares vesting on the first anniversary of January 25, 2021, and 1/48th of the shares vesting upon the completion of each month of continuous service thereafter.

### **Employment agreements**

### Agreements with Our Named Executive Officers and Potential Payments upon Termination or Change of Control

We currently maintain employment agreements with each of Mr. Southwell and Dr. MacBeath, as summarized below. The employment agreements provide for at-will employment and, other than in the context of a termination without cause or a resignation for good reason (as such terms are defined in the employment agreements), may be terminated at any time. The severance benefits that Messrs. Southwell and Rath and Dr. MacBeath are entitled to and the acceleration benefits that Mr. Southwell and Dr. MacBeath are entitled to, each pursuant to their offer letters and award agreements, are summarized below.

#### Agreements with David Southwell

We entered into an employment agreement with Mr. Southwell on October 9, 2018, which was amended in December 2019 and then replaced with a new employment agreement effective as of April 23, 2021. Pursuant to the terms of the new employment agreement, Mr. Southwell receives a base salary at annual rate of \$581,532 per year. He is also eligible to receive an annual performance bonus of up to 55% of his annual base salary, subject to his achievement of certain performance metrics to be approved and updated by our board of directors on an annual basis.

The employment agreement also provides Mr. Southwell with severance benefits if the Company terminates his employment without cause or if Mr. Southwell resigns for good reason, equal to (i) salary continuation at his then current base salary for eighteen months following the separation and (ii) payment of the employer share of COBRA premiums for up to eighteen months. If such separation without cause or for good reason occurs within the 3 months prior or 12 months following a change of control, then Mr. Southwell will be entitled to a lump sum payment equal to 1.5 times his base salary plus annual target bonus, plus his pro-rata target bonus and payment COBRA premiums for up to eighteen months. Such severance payments are conditioned upon Mr. Southwell executing a general release of all claims that he may have against the Company. The Company's obligation to make severance payments during the applicable severance period will cease immediately upon Mr. Southwell's (i) breach of his restrictive covenants (described below) or (ii) acceptance of any paid employment or consulting engagement during any period in which the Company is obligated to make such payments. Mr. Southwell is obligated to inform the Company in the event that he has accepted any such paid employment or consulting engagement. If the Company is subject to a change of control and in the three months prior to or twelve months following Mr. Southwell is terminated without cause or resigns for good reason, then 100% of any unvested shares or equity awards shall immediately vest and be non-forfeitable.

"Cause" is defined in the offer letter as (a) any material breach by Mr. Southwell of any agreement to which he and the Company are both parties to and that is injurious to the Company; (b) substantial negligence in the performance of, or substantial failure to perform, his services to the Company, which breach, negligence or failure, as applicable, is not cured within 30 days following written notice by the Company; (c) commission by Mr. Southwell of a felony or other crime involving moral turpitude; or (d) willful misconduct by Mr. Southwell which has, or could reasonably be expected to have, a material adverse effect upon the business, interests or reputation of the Company,

"Resignation for Good Reason" is defined in the offer letter as a separation as a result of Mr. Southwell's resignation after one of the following conditions has come into existence without Mr. Southwell's consent: (a) a material diminution in his compensation (except for across-the-board reductions affecting the Company's similarly situated employees generally), (b) a material diminution in Mr. Southwell's title (it being understood that the removal of the President title shall not in and of itself constitute "Good Reason"), duties, authority and responsibilities within the Company, or (c) a material breach of the Company's obligations under any agreement between the Company and Mr. Southwell; provided in each case that "Good Reason" shall not exist unless Mr. Southwell has given written notice to the Company within 60 days of the initial existence of the event(s) giving rise to such Good Reason, including specific details regarding such event(s), and unless the Company has thereafter failed to cure such event(s) within 30 days after delivery of such written notice.

Mr. Southwell also entered into our standard Non-Disclosure, Non-Competition and Assignment of Intellectual Property Agreement, which contains 12-month post-termination non-solicitation and non-competition provisions, provided that such 12-month period will automatically be extended for the amount of time, if any, during which Mr. Southwell engages in any activity in violation of such provisions. In the event of Mr. Southwell's termination without cause or resignation for good reason in the 3 months prior to or 12 months following a change in control, then the restrictive covenants are no longer enforceable.

### Agreements with Gavin MacBeath, Ph.D.

We entered into an offer letter with Dr. MacBeath on November 28, 2018 that was replaced with a new employment agreement effective as of April 23, 2021. Pursuant to the terms of the offer letter, Dr. MacBeath joined the Company as its Chief Scientific Officer. Dr. MacBeath received a one-time signing bonus equal to \$10,000. The Company entered a new employment agreement with Dr. MacBeath in April 2021 that provides for current base salary of \$400,000 per year. He is also eligible to receive an incentive performance bonus of up to 40% of his annual base salary, which bonus amount shall be determined by our board of directors and dependent on the achievement of specific company, team and individual performance objectives.

The employment agreement also provides Dr. MacBeath with severance benefits if the Company terminates his employment without cause or resigns for good reason, equal to (i) salary continuation at his then current base salary for twelve months following the separation and (ii) payment of the employer share of COBRA premiums for up to twelve months, subject to Dr. MacBeath executing a general release of claims against the Company. If such separation without cause or for good reason occurs within the 3 months prior or 12 months following a change of control, then Mr. Southwell will be entitled to a lump sum payment equal to one (1) times his base salary plus annual target bonus, plus pro-rata target bonus and payment COBRA premiums for up to twelve months. If the Company is subject to a change of control and in the three months prior or twelve months following Dr. MacBeath is terminated without cause or resigns for good reason, then 100% of any unvested shares or equity awards shall immediately vest and be non- forfeitable. The Company's obligation to make severance payments during the applicable severance period will cease immediately upon Dr. MacBeath's (i) breach of his restrictive covenants (described below) or (ii) acceptance of any paid employment or consulting engagement during any period in which the Company is obligated to make such payments.

"Cause" is defined in the offer letter as (a) any material breach by Dr. MacBeath of any agreement to which he and the Company are both parties to and that is injurious to the Company; (b) substantial negligence in the performance of, or substantial failure to perform, his services to the Company, which breach, negligence or failure, as applicable, is not cured within 30 days following written notice by the Company; (c) commission by Dr. MacBeath of a felony or other crime involving moral turpitude; or (d) willful misconduct by Dr. MacBeath which has, or could reasonably be expected to have, a material adverse effect upon the business, interests or reputation of the Company.

"Resignation for Good Reason" is defined in the offer letter as a separation as a result of Dr. MacBeath's resignation after one of the following conditions has come into existence without Dr. MacBeath's consent: (a) a

material diminution in his compensation (except for across-the-board reductions affecting the Company's similarly situated employees generally), (b) a material diminution in Dr. MacBeath's title, duties, authority and responsibilities within the Company, or (c) a material breach of the Company's obligations under any agreement between the Company and Dr. MacBeath; provided in each case that "Good Reason" shall not exist unless Dr. MacBeath has given written notice to the Company within 60 days of the initial existence of the event(s) giving rise to such Good Reason, including specific details regarding such event(s), and unless the Company has thereafter failed to cure such event(s) within 30 days after delivery of such written notice.

In addition, on December 31, 2018, Dr. MacBeath entered into our standard Proprietary Information and Inventions Agreement, which contains one-year post-termination non-solicitation and non-competition provisions, provided that such one-year period will automatically be extended for an additional year following the separation date if Dr. MacBeath breaches a fiduciary duty to the Company or unlawfully takes, physically or electronically, any property belonging to the Company. In the event of Dr. MacBeath's termination without cause or resignation for good reason in the 3 months prior to or 12 months following a change in control, then the restrictive covenants are no longer enforceable.

## Agreements with William Desmarais

We entered into an offer letter with Mr. Desmarais on March 16, 2021 that was replaced with a new employment agreement effective as of April 23, 2021. Pursuant to the terms of the offer letter, Mr. Desmarais joined the Company as its Chief Business Officer on March 2, 2021. Mr. Desmarais' current base salary is \$360,000 per year. He is also eligible to receive an incentive performance bonus of up to 40% of his annual base salary, which bonus amount shall be determined by our board of directors and dependent on the achievement of specific company, team and individual performance objectives.

The employment agreement also provides Mr. Desmarais with severance benefits if the Company terminates his employment without cause or resigns for good reason, equal to (i) salary continuation at his then current base salary for twelve months following the separation and (ii) payment of the employer share COBRA premiums for up to twelve months, subject to Mr. Desmarais executing a general release of claims against the Company. If such separation without cause or for good reason occurs within the 3 months prior or 12 months following a change of control, then Mr. Southwell will be entitled to a lump sum payment equal to one (1) times his base salary plus annual target bonus, plus pro-rata target bonus and payment COBRA premiums for up to twelve months. If the Company is subject to a change of control and in the three months prior or twelve months following Mr. Desmarais is terminated without cause or resigns for good reason, then 100% of any unvested shares or equity awards shall immediately vest and be non-forfeitable. The Company's obligation to make severance payments during the applicable severance period will cease immediately upon Mr. Desmarais' (i) breach of his restrictive covenants (described below) or (ii) acceptance of any paid employment or consulting engagement during any period in which the Company is obligated to make such payments.

Mr. Desmaarais was granted an option to purchase 981,448 shares of our common stock with an exercise price of \$1.70. The option shares vest over four years, with 25% of the shares vesting on the first anniversary of March 22, 2021, and 1/48th of the shares vesting upon the completion of each month of continuous service thereafter.

"Cause" is defined in the offer letter as (a) any material breach by Mr. Desmarais of any agreement to which he and the Company are both parties to and that is injurious to the Company; (b) substantial negligence in the performance of, or substantial failure to perform, his services to the Company, which breach, negligence or failure, as applicable, is not cured within 30 days following written notice by the Company; (c) commission by Mr. Desmarais of a felony or other crime involving moral turpitude; or (d) willful misconduct by Mr. Desmarais which has, or could reasonably be expected to have, a material adverse effect upon the business, interests or reputation of the Company.

"Resignation for Good Reason" is defined in the offer letter as a separation as a result of Mr. Desmarais' resignation after one of the following conditions has come into existence without Mr. Desmarais' consent: (a) a material diminution in his compensation (except for across-the-board reductions affecting the Company's similarly situated employees generally), (b) a material diminution in Mr. Desmarais' title, duties, authority and responsibilities within the Company, or (c) a material breach of the Company's obligations under any agreement between the Company and Mr. Desmarais; provided in each case that "Good Reason" shall not exist unless Mr. Desmarais has given written notice to the Company within 60 days of the initial existence of the event(s) giving rise to such Good Reason, including specific details regarding such event(s), and unless the Company has thereafter failed to cure such event(s) within 30 days after delivery of such written notice.

In addition, Mr. Desmarais entered into our standard Proprietary Information and Inventions Agreement, which contains one-year post-termination non-solicitation and non-competition provisions, provided that such one-year period will automatically be extended for an additional year following the separation date if Mr. Desmarais breaches a fiduciary duty to the Company or unlawfully takes, physically or electronically, any property belonging to the Company. In the event of Mr. Desmarais' termination without cause or resignation for good reason in the 3 months prior to or 12 months following a change in control, then the restrictive covenants are no longer enforceable.

### Agreements with Henry Rath

We entered into an offer letter with Mr. Rath on April 8, 2019. Pursuant to the terms of the offer letter, Mr. Rath joined the Company as its Chief Business Officer on April 23, 2019. Mr. Rath received a base salary at an initial annual rate of \$345,000 per year. He was also eligible to receive an incentive performance bonus of up to 35% of his annual base salary, which bonus amount shall be determined by our board of directors and dependent on the achievement of specific company, team and individual performance objectives.

The offer letter also provides Mr. Rath with severance benefits if the Company terminates his employment without cause, equal to salary continuation at his then current base salary for six months following the separation, subject to Mr. Rath executing a general release of claims against the Company. "Cause" is defined in the offer letter as (a) a material breach by Mr. Rath of any agreement to which he and the Company are both parties to and that is injurious to the Company; (b) negligence in the performance of, or substantial failure to perform, his services to the Company, which breach, negligence or failure, as applicable, is not cured within 30 days following written notice by the Company; (c) commission by Mr. Rath of a felony or other crime involving moral turpitude; or (d) willful misconduct by Mr. Rath which has, or could reasonably be expected to have, a material adverse effect upon the business, interests or reputation of the Company

In addition, on April 23, 2019, Mr. Rath entered into our standard Proprietary Information and Inventions Agreement, which contains one-year post-termination non-solicitation and non-competition provisions, provided that such one-year period will automatically be extended for an additional year following the separation date if Mr. Rath breaches a fiduciary duty to the Company or unlawfully takes, physically or electronically, any property belonging to the Company. As noted above, however, the non-competition restrictions were waived by the Company upon Mr. Rath's execution and non-revocation of his separation agreement.

On January 26, 2021, we entered into a separation agreement with Mr. Rath. Such agreement was amended on February 3, 2021, and, subject to the terms and conditions thereof, provides for (i) the continuation of his base salary for six months, equal to an aggregate amount of \$172,500 and (ii) a transition bonus in the amount of \$32,000, to be paid in two installments, each subject to Mr. Rath's full cooperation and support of his transition and compliance with the separation agreement. The first installment of the transition bonus in the amount of \$15,000 was paid on February 28, 2021, and the second in the amount of \$17,000 shall be paid on March 31, 2021. Further, the Company waived the post-termination non-compete restrictions contained in Mr. Rath's Proprietary Information and Inventions Agreement with the Company. The separation agreement contains a one-year non-solicitation covenant. In addition, the Company agreed to use its best efforts to seek the approval of

the Company's board of directors to allow Mr. Rath to exercise the options that were vested as of his termination date to be exercised on a cashless net exercise basis at any time before the expiration date of the applicable option.

# **Equity plans**

## 2021 Equity Incentive Plan

Our board of directors intends to adopt our 2021 Equity Incentive Plan, or the 2021 Plan, prior to the offering, and it will be submitted to our stockholders for approval. We expect that our 2021 Plan will become effective upon the effectiveness of the registration statement of which this prospectus is a part. Our 2021 Plan is intended to replace our 2018 Stock Plan, or the 2018 Plan. However, awards outstanding under our 2018 Plan will continue to be governed by their existing terms. Although not yet adopted, we expect that our 2021 Plan will have the features described below.

Share Reserve. The number of shares of our common stock available for issuance under our 2021 Plan will equal the sum of 26,880,000 shares plus up to 23,802,549 shares remaining available for issuance under, or issued pursuant to or subject to awards granted under, our 2018 Plan. The number of shares reserved for issuance under our 2021 Plan will be increased automatically on the first business day of each of our fiscal years, commencing in 2021 and ending in 2031, by a number equal to the smallest of:

- 4% of the shares of common stock outstanding on the last business day of the prior fiscal year; or
- the number of shares determined by our board of directors.

In general, to the extent that any awards under our 2021 Plan or our 2018 Plan are forfeited, terminate, expire or lapse without the issuance of shares, or if we repurchase the shares subject to awards granted under our 2021 Plan, those shares will again become available for issuance under our 2021 Plan or our 2018 Plan, as will shares applied to pay the exercise or purchase price of an award or to satisfy tax withholding obligations related to any award.

Administration. The compensation committee of our board of directors will administer our 2021 Plan. The compensation committee will have complete discretion to make all decisions relating to our 2021 Plan and outstanding awards, including repricing outstanding options and modifying outstanding awards in other ways.

Eliqibility. Employees, non-employee directors, consultants and advisors will be eligible to participate in our 2021 Plan.

Under our 2021 Plan, the aggregate grant date fair value of awards granted to our non-employee directors may not exceed \$750,000 in any one fiscal year, except that the grant date fair value of awards granted to newly appointed non-employee directors may not exceed \$1,500,000 in the fiscal year in which such non-employee director is initially appointed to our board of directors.

*Types of awards*. Our 2021 Plan will provide for the following types of awards:

- incentive and nonstatutory stock options;
- stock appreciation rights;
- restricted shares; and
- · stock units.

Options and Stock Appreciation Rights. The exercise price for options granted under our 2021 Plan may not be less than 100% of the fair market value of our common stock on the grant date. Optionees will be permitted to pay the exercise price in cash or, with the consent of the compensation committee:

with shares of common stock that the optionee already owns;

- by an immediate sale of shares through a broker approved by us;
- by instructing us to withhold a number of shares having an aggregate fair market value that does not exceed the exercise price; or
- by other methods permitted by applicable law.

An optionee who exercises a stock appreciation right receives the increase in value of our common stock over the base price. The base price for stock appreciation rights may not be less than 100% of the fair market value of our common stock on the grant date. The settlement value of a stock appreciation right may be paid in cash, shares of our common stock or a combination.

Options and stock appreciation rights vest as determined by the compensation committee. In general, they will vest over a four-year period following the date of grant. Options and stock appreciation rights expire at the time determined by the compensation committee but in no event more than ten years after they are granted. These awards generally expire earlier if the participant's service terminates earlier.

Restricted Shares and Stock Units. Restricted shares and stock units may be awarded under our 2021 Plan in return for any lawful consideration, and participants who receive restricted shares or stock units generally are not required to pay cash for their awards. In general, these awards will be subject to vesting. Vesting may be based on length of service, the attainment of performance-based milestones or a combination of both, as determined by the compensation committee.

Corporate Transactions. In the event we are a party to a merger, consolidation or certain change in control transactions, outstanding awards granted under our 2021 Plan, and all shares acquired under our 2021 Plan, will be subject to the terms of the definitive transaction agreement (or, if there is no such agreement, as determined by our compensation committee). Unless an award agreement provides otherwise, such treatment may include any of the following with respect to each outstanding award:

- the continuation, assumption or substitution of an award by a surviving entity or its parent;
- the cancellation of an award without payment of any consideration;
- the cancellation of the vested portion of an award (and any portion that becomes vested as of the effective time of the transaction) in exchange for a payment equal to the excess, if any, of the value that the holder of each share of our common stock receives in the transaction over (if applicable) the exercise price otherwise payable in connection with the award; or
- the assignment of any reacquisition or repurchase rights held by us in respect of an award of restricted shares to the surviving entity or its parent (with proportionate adjustments made to the price per share to be paid upon exercise of such rights).

The compensation committee is not required to treat all awards, or portions thereof, in the same manner.

The vesting of an outstanding award may be accelerated by the administrator upon the occurrence of a change in control, whether or not the award is to be assumed or replaced in the transaction, or in connection with a termination of service following a change in control transaction.

A change in control includes:

- any person acquiring beneficial ownership of more than 50% of our total voting power;
- the sale or other disposition of all or substantially all of our assets; or
- our merger or consolidation after which our voting securities represent 50% or less of the total voting power of the surviving or acquiring entity.

Changes in Capitalization. In the event of certain changes in our capital structure without our receipt of consideration, such as a stock split, reverse stock split or dividend paid in common stock, proportionate adjustments will automatically be made to:

- the maximum number and kind of shares available for issuance under our 2021 Plan, including the maximum number and kind of shares that may be issued upon the exercise of incentive stock options;
- the maximum number and kind of shares covered by, and exercise price, base price or purchase price, if any, applicable to each outstanding stock award; and
- the maximum number and kind of shares by which the share reserve may increase automatically each year.

In the event that there is a declaration of an extraordinary dividend payable in a form other than our common stock in an amount that has a material effect on the price of our common stock, a recapitalization, a spin-off or a similar occurrence, the compensation committee may make such adjustments to any of the foregoing as it deems appropriate, in its sole discretion.

Amendments or Termination. Our board of directors may amend, suspend or terminate our 2021 Plan at any time. If our board of directors amends our 2021 Plan, it does not need stockholder approval of the amendment unless required by applicable law, regulation or rules. Our 2021 Plan will terminate automatically 10 years after the later of the date when our board of directors adopted our 2021 Plan or approved the latest share increase that was also approved by our stockholders.

### 2018 Stock Plan

Our board of directors adopted and our stockholder approved our 2018 Stock Plan, or the 2018 Plan, in April 2018. No further awards will be made under our 2018 Plan after this offering; however, awards outstanding under our 2018 Plan will continue to be governed by their existing terms.

Share Reserve. As of December 31, 2020, we have reserved 13,282,049 shares of our common stock for issuance under our 2018 Plan, all of which may be issued as incentive stock options. As of December 31, 2020, options to purchase 11,852,840 shares of our common stock, at exercise prices ranging from \$0.24 to \$0.64 per share, or a weighted-average exercise price of \$0.32 per share were outstanding under our 2018 Plan, and 240,026 shares of our common stock remained available for future issuance. Unissued shares subject to awards that expire, are forfeited, or are cancelled, shares reacquired by us and shares withheld in payment of the purchase price or exercise price of an award or in satisfaction of withholding taxes will again become available for issuance under our 2018 Plan or, following consummation of this offering, under our 2021 Plan.

Administration. Our board of directors, or a committee thereof, has administered our 2018 Plan since its adoption; however, following this offering, the compensation committee of our board of directors will generally administer our 2018 Plan. The administrator has complete discretion to make all decisions relating to our 2018 Plan and outstanding awards.

*Eligibility*. Employees, non-employee members of our board of directors and consultants are eligible to participate in our 2018 Plan. However, only employees are eligible to receive incentive stock options.

Types of Awards. Our 2018 Plan provides for the following types of awards granted with respect to shares of our common stock:

- incentive and nonstatutory stock options to purchase shares of our common stock;
- direct award or sale of shares of our common stock, including restricted shares; and
- restricted stock units.

*Options*. The exercise price for options granted under our 2018 Plan is determined by our board of directors, but may not be less than 100% of the fair market value of our common stock on the grant date. Optionees may pay the exercise price in cash or cash equivalents or by one, or any combination of, the following forms of payment, as permitted by the administrator in its sole discretion:

- Surrender of shares of common stock that the optionee already owns;
- Delivery of a full-recourse promissory note, with the option shares pledged as security against the principal and accrued interest on the note;
- An immediate sale of the option shares through a company-approved broker, if the shares of our common stock are publicly traded;
- Surrendering a number of vested shares subject to the option having an aggregate fair market value no greater than the aggregate exercise price, or the sum of such exercise price plus all or a portion of the minimum amount required to be withheld under applicable law; or
- Other methods permitted by the Delaware General Corporation Law, as amended.

Options vest as determined by the administrator. In general, we have granted options that vest over a four-year period. Options expire at the time determined by the administrator, but in no event more than ten years after they are granted, and generally expire earlier if the optionee's service terminates.

*Restricted Shares*. Restricted shares may be awarded or sold under our 2018 Plan in return for cash or cash equivalents or, as permitted by the administrator in its sole discretion, in exchange for services rendered to us, by delivery of a full-recourse promissory note or through any other means permitted by applicable law. Restricted shares vest as determined by the administrator.

Restricted Stock Units. Restricted stock units may be awarded or sold under our 2018 Plan. No cash consideration shall be required of the recipient in connection with the grant of restricted stock units. Settlement of vested restricted stock units may be made in the form of (i) cash, (ii) shares of our common stock, or (iii) any combination of both, as determined by the administrator. Restricted stock units vest as determined by the administrator.

Corporate Transactions. In the event that we are a party to a merger or consolidation or in the event of a sale of all or substantially all of our stock or assets, awards granted under our 2018 Plan will be subject to the agreement governing such transaction or, in the absence of such agreement, in the manner determined by the administrator. Such treatment may include, without limitation, one or more of the following with respect to outstanding awards:

- The continuation, assumption or substitution of an award by the surviving entity or its parent;
- Cancellation of the vested portion of the award in exchange for a payment equal to the excess, if any, of the value of the shares subject to the award over any exercise price per share applicable to the award;
- Cancellation of the award without payment of any consideration;
- Suspension of the optionee's right to exercise the option during a limited period of time preceding the completion of the transaction; or
- Termination of any right the optionee has to exercise the option prior to vesting in the shares subject to the option.

The administrator is not obligated to treat all awards in the same manner. The administrator has the discretion, at any time, to provide that an award under our 2018 Plan will vest on an accelerated basis in connection with a corporate transaction or to amend or modify an award so long as such amendment or modification is not inconsistent with the terms of the 2018 Plan or would not result in the impairment of a participant's rights without the participant's consent.

Changes in Capitalization. In the event of certain specified changes in the capital structure of our common stock, such as a stock split, reverse stock split, stock dividend, reclassification or any other increase or decrease in the number of issued shares of stock effective without receipt of consideration by us, proportionate adjustments will automatically be made in (i) each of the number and kind of shares available for future grants under our 2018 Plan, (ii) the number and kind of shares covered by each outstanding option and all restricted shares, (iii) the exercise price per share subject to each outstanding option and (iv) any repurchase price applicable to shares granted under our 2018 Plan. In the event of an extraordinary cash divided that has a material effect on the fair market value of our common stock, a recapitalization, spin-off or other similar occurrence, the administrator at its sole discretion may make appropriate adjustments to one or more of the items described above.

Amendments or Termination. The administrator may at any time amend, suspect or terminate our 2018 Plan, subject to stockholder approval in the case of an amendment if the amendment increases the number of shares available for issuance or materially changes the class of persons eligible to receive incentive stock options. Our 2018 Plan will terminate automatically ten years after the later of the date when our board of directors adopted the plan or the date when our board of directors most recently approved an increase in the number of shares reserved thereunder which was also approved by our stockholders, provided, however, that in any event, it will terminate upon the completion of this offering, but as noted above, awards outstanding under our 2018 Plan will remain outstanding and will continue to be governed by their existing terms.

### 2021 Employee Stock Purchase Plan

*General*. Our board of directors intends to adopt our 2021 Employee Stock Purchase Plan, or 2021 ESPP. Our 2021 ESPP will become effective as of the effective date of the registration statement of which this prospectus is a part. Our 2021 ESPP is intended to qualify under Section 423 of the Internal Revenue Code. Our 2021 ESPP has the features described below.

*Share Reserve.* 2,086,000 shares of our common stock have been reserved for issuance under our 2021 ESPP. The number of shares reserved for issuance under our 2021 ESPP will automatically be increased on the first business day of each of our fiscal years, commencing in 2022 and ending in 2041, by a number equal to the least of:

- 2.000.000 shares:
- 1% of the shares of common stock issued and outstanding on the last business day of the prior fiscal year; or
- the number of shares determined by our board of directors.

The number of shares reserved under our 2021 ESPP will automatically be adjusted in the event of a stock split, stock dividend or a reverse stock split (including an adjustment to the per-purchase period share limit).

Administration. The compensation committee of our board of directors will administer our 2021 ESPP.

*Eligibility.* All of our employees will be eligible to participate in our ESPP, although the administrator may exclude certain categories of employees from an offering period, as permitted by applicable law, including employees employed for less than two years, working less than 20 hours per week, who are employed less than five months per year, or are highly compensated employees. Eligible employees may begin participating in our 2021 ESPP at the start of any offering period.

*Offering Periods.* Each offering period will last a number of months determined by the compensation committee, not to exceed 27 months. A new offering period will begin periodically, as determined by the compensation committee. Offering periods may overlap or may be consecutive.

Amount of Contributions. Our 2021 ESPP will permit each eligible employee to purchase common stock through payroll deductions. Each employee's payroll deductions may not exceed 15% of the employee's cash compensation. Each participant may purchase up to the number of shares determined by our board of directors on any purchase date, not to exceed 7,500 shares. The value of the shares purchased in any calendar year may not exceed \$25,000. Participants may withdraw their contributions at any time before stock is purchased.

*Purchase Price*. The price of each share of common stock purchased under our 2021 ESPP will not be less than 85% of the lower of the fair market value per share of common stock on the first day of the applicable offering period or the fair market value per share of common stock on the purchase date.

Other Provisions. Employees may end their participation in our 2021 ESPP at any time. Participation ends automatically upon termination of employment with us. If we experience a change in control, our 2021 ESPP will end and shares will be purchased with the payroll deductions accumulated to date by participating employees, unless the rights to purchase our common stock under the 2021 ESPP for an offering period then in progress are continued, assumed or substituted by the surviving entity. Our board of directors or our compensation committee may amend or terminate our 2021 ESPP at any time.

### CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following is a description of transactions since our incorporation on April 17, 2018 to which we have been a party in which the amount involved exceeded the lesser of (i) \$120,000 or (ii) one percent of the average of our total assets at year end for the last two completed fiscal years; and in which any of our executive officers, directors or beneficial holders of more than 5% of our capital stock (or any immediate family member of, or person sharing the household with, any of these individuals or entities), which we collectively refer to as a related person, had or will have a direct or indirect material interest, other than compensation arrangements which are described in "Management—Director compensation" and "Executive compensation." We believe that all of these transactions were on terms as favorable as could have been obtained from unrelated third parties.

### **Sales of Securities**

### Series A Convertible Preferred Stock Financing

In June 2018 and December 2018, we issued and sold an aggregate of 26,315,790 shares of our Series A convertible preferred stock at a cash purchase price of \$0.95 per share for an aggregate purchase price of approximately \$25 million. Each share of Series A convertible preferred stock will convert into one share of common stock upon the completion of this offering The table below sets forth the number of shares of Series A convertible preferred stock sold to our directors, executive officers and holders of more than 5% of our capital stock:

| Investor(1)  | Shares of Series A<br>convertible<br>preferred stock | Total purchase price |
|--|--|----------------------|
| Entities affiliated with 6 Dimensions Capital      | 5,263,158  | \$ 5,000,000         |
| Entities affiliated with Bessemer Venture Partners | 5,263,158  | 5,000,000            |
| Entities affiliated with GV                        | 5,263,158  | 5,000,000            |
| Longwood Fund IV, L.P.                             | 5,263,158  | 5,000,000            |
| Novartis Bioventures Ltd.                          | 5,263,158  | 5,000,000            |

<sup>(1)</sup> See "Principal stockholders" for additional information about shares held by these entities and individuals.

## Series B Convertible Preferred Stock Financing

In July and August 2019, we issued and sold an aggregate of 27,272,728 shares of our Series B convertible preferred stock at a cash purchase price of \$1.10 per share for an aggregate purchase price of approximately \$30 million. Then, in November 2019, we issued and sold an aggregate of 4,329,004 shares of our Series B convertible preferred stock at a cash purchase price of \$1.155 per share for an aggregate purchase price of approximately \$5 million. Each share of Series B convertible preferred stock will convert into one share of common stock upon the completion of this offering. The table below sets forth the number of shares of Series B convertible preferred stock sold to our directors, executive officers and holders of more than 5% of our capital stock:

| Investor(1)  | Shares of Series B<br>convertible<br>preferred stock | Total purchase price |
|--|--|----------------------|
| Entities affiliated with 6 Dimensions Capital      | 5,454,545  | \$ 6,000,000         |
| Entities affiliated with Bessemer Venture Partners | 2,727,273  | 3,000,000            |
| Entities affiliated with GV                        | 2,727,273  | 3,000,000            |
| Longwood Fund IV, L.P.                             | 2,727,273  | 3,000,000            |
| Novartis Bioventures Ltd.                          | 2,727,273  | 3,000,000            |
| Novartis Institutes for Biomedical Research, Inc.  | 4,545,455  | 5,000,000            |
| Astellas Venture Management LLC                    | 4,329,004  | 5,000,000            |
| Entities affiliated with Pitango Healthtech        | 5,931,819  | 6,525,001            |

 $<sup>(1) \</sup>qquad \hbox{See "Principal stockholders" for additional information about shares held by these entities.}$ 

# Series C Convertible Preferred Stock Financing

In January 2021, we issued and sold an aggregate of 70,136,064 shares of our Series C convertible preferred stock at a cash purchase price of \$1.4258 per share for an aggregate purchase price of approximately \$100 million. Each share of Series C convertible preferred stock will convert into one share of common stock upon the completion of this offering The table below sets forth the number of shares of Series C convertible preferred stock sold to our directors, executive officers and holders of more than 5% of our capital stock:

| Investor(1)  | Shares of Series C<br>convertible<br>preferred stock | Total purchase price |
|--|--|----------------------|
| Entities affiliated with 6 Dimensions Capital      | 2,104,082  | \$ 3,000,000         |
| Entities affiliated with Bessemer Venture Partners | 1,402,721  | 2,000,000            |
| Entities affiliated with GV                        | 841,633  | 1,200,000            |
| Longwood Fund IV, L.P.                             | 1,402,721  | 2,000,000            |
| Novartis Bioventures Ltd.                          | 2,244,354  | 3,200,000            |
| Entities affiliated with Pitango Healthtech        | 2,104,082  | 3,000,000            |
| Entities affiliated with Baker Bros. Advisors LP   | 32,478,654   | 46,308,065           |
| JMD III Holdings Limited                           | 10,520,410   | 15,000,000           |

<sup>(1)</sup> See "Principal Stockholders" for additional information about shares held by these entities.

### **Agreements With Stockholders**

### **Investors' Rights Agreement**

In connection with the sale of our Series C convertible preferred stock, we entered into an amended and restated investors' rights agreement with certain investors, including entities affiliated with 6 Dimensions Capital, Bessemer Venture Partners, entities affiliated with GV, Longwood Fund IV, L.P., Novartis Bioventures Ltd., Pitango Healthtech, entities affiliated with Baker Bros. Advisors LP, and JMD III Holdings Limited and including entities with which certain of our directors are affiliated. Under our investors' rights agreement, certain holders of our capital stock have the right to demand that we file a registration statement or request that their shares of our capital stock be covered by a registration statement that we are otherwise filing. See the section titled "Description of capital stock—Registration rights" elsewhere in this prospectus for additional information regarding these registration rights. Other customary investor rights under this agreement, including rights of information, observation and first refusal, will terminate immediately before the consummation of this offering.

## **Voting Agreement**

In connection with the sale of our Series C convertible preferred stock, we entered into an amended and restated voting agreement with certain investors, including entities affiliated with 6 Dimensions Capital, Bessemer Venture Partners, entities affiliated with GV, Longwood Fund IV, L.P., Novartis Bioventures Ltd., Pitango Healthtech, entities affiliated with Baker Bros Advisors LP, and JMD III Holdings Limited and including entities with which certain of our directors are affiliated. Under our voting agreement, certain holders of our capital stock have agreed as to the manner in which they will vote their shares of our capital stock on certain matters, including with respect to the election of directors. The voting agreement will terminate upon the completion of this offering, at which time there will be no further contractual obligations regarding the manner in which shares are voted with respect to the election of our directors.

# Right of First Refusal and Co-Sale Agreement

In connection with the sale of our Series C convertible preferred stock, we entered into an amended and restated first refusal and co-sale agreement with certain investors, including entities affiliated with 6 Dimensions Capital, Bessemer Venture Partners, entities affiliated with GV, Longwood Fund IV, L.P., Novartis Bioventures Ltd., Pitango Healthtech, entities affiliated with Baker Bros Advisors LP, and JMD III Holdings Limited and including entities with which certain of our directors are affiliated. Under our first refusal and co-sale agreement, certain holders of our capital stock have the right of first refusal and co-sale relating to the shares of our common

stock held by the parties to the agreement. Upon the consummation of this offering our first refusal and co-sale agreement will terminate.

### License Agreements

### Collaboration and License Agreement with Novartis

On March 27, 2020, we entered into a Collaboration and License Agreement, or the Novartis Agreement, with Novartis Institutes for BioMedical Research, Inc., or Novartis. Pursuant to the Novartis Agreement, we have received an aggregate of \$20.0 million of cash representing the one-time, non-refundable, non-contingent and non-creditable upfront payment and have receivables for reimbursement of expenditures under the arrangement of \$0.3 million as of December 31, 2020. We granted Novartis options to obtain exclusive, worldwide licenses to certain target antigens identified in performance of the Novartis Agreement and corresponding T-cell receptors for such target antigens. 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, or the Optioned Program.

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. Novartis may terminate the Novartis Agreement entirely or on a program-by-program basis at any time for convenience upon 90 days' notice, but Novartis will be required to pay any payment obligations incurred prior to termination.

## **Royalty Agreement**

In connection with our incorporation in April 2018 we entered into a royalty agreement with Christoph Westphal, M.D., Ph.D. who is 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. At the time the original royalty agreement and the amended and restated version were executed, Dr. Westphal was our chief executive officer and the chairman of our board of directors. Pursuant to the royalty agreement, we are required to pay the aforementioned affiliated entity 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 for a defined period of time set forth in the royalty agreement. 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.

#### Nominating Rights and Registration Rights Agreements with BBA Funds

In connection with our Series C convertible preferred stock financing, 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 during the period beginning at the closing of our initial public offering and for the three years thereafter, as long as (1) the BBA Funds and their affiliates, collectively, beneficially own at least 75% of the Series C convertible preferred stock financing, or such number of shares of our common stock issued upon conversion of such number of shares of Series C convertible preferred stock (in either case, as adjusted for any stock split, stock dividend, combination, or other recapitalization or reclassification or similar transaction), and (2) the BBA Funds and their affiliates, collectively, beneficially own at least 2% of our then outstanding voting common stock.

Also in connection with our Series C convertible preferred stock financing, we entered into a Registration Rights Agreement with the BBA Funds, pursuant to which, among other things, we agreed to provide the BBA Funds with certain "resale" registration rights and related "piggy-back" rights.

Additionally, we agreed to use commercially reasonable efforts to cause the underwriters of this offering to provide the BBA Funds the opportunity to participate in this offering in an amount equal to such the BBA Funds' pro rata share of an aggregate of at least 25% of the total number shares of common stock being offered by us, excluding in such calculation any shares offered for sale pursuant to the underwriters' option to purchase additional shares in connection with this offering. Despite our commercially reasonable efforts, the underwriters may, in their sole discretion, determine that the BBA Funds' participation in such proportion is not advisable and designate a reduced number of, or no, shares for purchase by the BBA Funds.

### **Equity Grants to Executive Officers and Directors**

We have agreements with and have granted stock options to certain of our executive officers and non-employee directors, as more fully described in "Executive compensation."

## **Indemnification Agreements**

We have entered, and intend to continue to enter, into separate indemnification agreements with each of our directors and executive officers, in addition to the indemnification provided for in our restated certificate of incorporation and amended and restated bylaws. The indemnification agreements and our restated certificate of incorporation and amended and restated bylaws that will be in effect upon the completion of this offering require us to indemnify our directors, executive officers and certain controlling persons to the fullest extent permitted by Delaware law.

# **Employment Agreements**

We have entered into employment agreements with our executive officers. For more information regarding these agreements, see the section entitled "Executive compensation—Employment agreements."

# **Consulting and Other Agreements With Our Directors**

We have entered into consulting and other agreements with certain of our directors. For more information regarding these agreements, see the section entitled "Management—Director compensation."

# **Directed Share Program**

At our request, the underwriters have reserved up to shares, or up to % of the shares offered by this prospectus, for sale at the initial public offering price through a directed share program to certain of our directors, officers, employees and business associates and other parties related to us. If purchased by these persons, these shares will be subject to a 180-day lock-up restriction. Morgan Stanley & Co. LLC will administer our directed share program. See the section titled "Underwriters—Directed Share Program."

## **Related Party Transaction Policy**

Effective upon the completion of this offering, we intend to adopt a formal written policy providing that we are not permitted to enter into any transaction that exceeds \$120,000 and in which any related person has a direct or indirect material interest without the consent of our audit committee. Our audit committee will have the primary responsibility for reviewing and approving or disapproving such "related party transactions." The charter of our audit committee will provide that our audit committee shall review and approve in advance any related party transaction. In approving or rejecting any such transaction, our audit committee is to consider the relevant facts and circumstances available and deemed relevant to our audit committee, including whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances and the extent of the related person's interest in the transaction.

All of the transactions described in this section were entered into prior to the adoption of this policy. Although we have not had a written policy for the review and approval of transactions with related persons, our board of directors has historically reviewed and approved any transaction where a director or officer had a financial interest, including the transactions described above. Prior to approving such a transaction, the material facts as to relationship or interest of the relevant director, officer or holder of 5% or more of any class of our voting securities in the agreement or transaction was disclosed to our board of directors. Our board of directors took this information into account when evaluating the transaction and in determining whether such transaction was fair to us and in the best interest of all our stockholders.

### PRINCIPAL STOCKHOLDERS

The following table sets forth information with respect to the beneficial ownership of our capital stock as of April 15, 2021 and as adjusted to reflect the sale of common stock offered by us in this offering, for:

- each of the named executive officers;
- each of our directors;
- all of current our executive officers and directors as a group; and
- each person, or group of affiliated persons, who is known by us to beneficially own more than 5% of our common stock.

We have determined beneficial ownership in accordance with the rules of the SEC. Except as indicated in the footnotes below, we believe, based on the information furnished to us, that the persons and entities named in the table below have sole voting and investment power with respect to all shares of common stock that they beneficially own, subject to applicable community property laws.

Applicable percentage ownership is based on 141,792,162 shares of common stock outstanding as of April 15, 2021, after giving effect to the conversion of all outstanding shares of preferred stock as of that date into an aggregate of 128,053,586 shares of our common stock (including shares of our non-voting common stock). For purposes of computing percentage ownership after this offering, we have assumed that (i) shares of common stock will be issued by us in this offering (including shares of non-voting common stock); (ii) the underwriters will not exercise their option to purchase up to additional shares of common stock and (iii) none of our executive officers, directors or stockholders who beneficially own more than five percent of our common stock will participate in this offering. In computing the number of shares of common stock beneficially owned by a person or entity and the percentage ownership of that person or entity, we deemed to be outstanding all shares of common stock subject to options held by that person or entity that are currently exercisable or that will become exercisable within 60 days of April 15, 2021. We did not deem these shares outstanding, however, such shares were included for the purpose of computing the percentage ownership of any other person or entity.

The following table does not reflect any shares of common stock that may be purchased in this offering pursuant to our directed share program described under "Underwriters—Directed Share Program." If any shares are purchased by our existing principal shareholders, directors, executive officers or their affiliated entities, the number and percentage of shares beneficially owned by them after this offering will differ from those set forth in the following table.

Upon the closing of this offering, each outstanding share of our Series A convertible preferred stock Series B convertible preferred stock and Series C convertible preferred stock, will automatically convert into shares of voting common stock in accordance with the provisions of our amended and restated certificate of incorporation, or our current charter, with the exception of certain outstanding shares of our preferred stock owned by entities affiliated with or managed by Baker Brothers Life Sciences, L.P., 667, L.P., and , which shares will automatically convert into an aggregate of shares of non-voting common stock.

Unless otherwise indicated, the address of each beneficial owner listed in the table below is c/o TScan Therapeutics, Inc., 830 Winter Street, Waltham, Massachusetts 02451.

Shares Peneficially Owned Dries To This

|   | Shares Beneficially Owned Prior To This<br>Offering |          |                        |     | Beneficial Ownership After The<br>Offering      |                       |     |                        |             |  |
|---|---|----------|------------------------|-----|---|-----------------------|-----|------------------------|-------------|--|
|   | Voting<br>Common<br>Stock                           |          | Non-Vo<br>Comm<br>Stoc | ion | % of Total Outstanding Capital Stock before the | Votin<br>Comm<br>Stoc | ion | Non-Vo<br>Comn<br>Stoc | ting<br>ion | % of Total Outstanding Capital Stock after the |
| Name of Beneficial Owner                              | Shares  | <u>%</u> | Shares                 | %   | Offering  | Shares                | %   | Shares                 | %           | Offering                                       |
| 5% or Greater Stockholders                            |   |          |                        |     |   |                       |     |                        |             |  |
| Entities affiliated with Baker Bros. Advisors LP(1)   | 35,068,032  | 24.7%    | _                      | _   | 24.7%   |                       | %   |                        |             |  |
| Entities affiliated with 6 Dimensions Capital(2)      | 12,821,785  | 9.0%     | _                      | _   | 9.0%  |                       | %   | _                      | _           |  |
| Entities affiliated with Bessemer Venture Partners(3) | 9,393,152   | 6.6%     | _                      | _   | 6.6%  |                       | %   | _                      | _           |  |
| Longwood Fund IV, L.P.(4)                             | 9,393,152   | 6.6%     | _                      | _   | 6.6%  |                       | %   | _                      | _           |  |
| Novartis Bioventures Ltd.(5)                          | 14,780,240  | 10.4%    | _                      | _   | 10.4%   |                       | %   | _                      | _           |  |
| JMD III Holdings Limited(6)                           | 10,520,410  | 7.4%     | _                      | _   | 7.4%  |                       | %   | _                      | _           |  |
| Entities affiliated with $GV(7)$                      | 8,832,064   | 6.2%     | _                      | _   | 6.2%  |                       | %   | _                      | _           |  |
| Entities affiliated with Pitango Healthtech Fund(8)   | 8,035,901   | 5.7%     |                        |     | 5.7%  |                       | %   |                        |             |  |
| Named Executive Officers, Other Officers, and         |   |          |                        |     |   |                       |     |                        |             |  |
| Directors:  |   |          |                        |     |   |                       |     |                        |             |  |
| David Southwell <sup>(9)</sup>                        | 2,288,335   | 1.6%     | _                      | _   | 1.6%  |                       | %   | _                      | _           |  |
| Gavin MacBeath, Ph.D.(10)                             | 565,776   | *        | _                      | _   | *   |                       |     | _                      | _           |  |
| William Desmarais Ph.D., MBA                          | _   | *        | _                      | _   | *   |                       |     | _                      | _           |  |
| Henry Rath  | 259,495   | *        | _                      | _   | *   |                       |     | _                      | _           |  |
| Timothy Barberich(11)                                 | 467,494   | *        | _                      | _   | *   |                       |     | _                      | _           |  |
| Andrew Hedin  | _   | *        | _                      | _   | *   |                       |     | _                      | _           |  |
| Nandita Shangari, Ph.D.                               | _   | *        | _                      | _   | *   |                       |     | _                      | _           |  |
| Ittai Harel   | _   | *        | _                      | _   | *   |                       |     | _                      | _           |  |
| Christoph Westphal, M.D., Ph.D.(12)                   | 17,893,152  | 12.6%    | _                      | _   | 12.6%   |                       | %   | _                      | _           |  |
| Brian Silver  | _   | *        | _                      | _   | *   |                       | *   | _                      | _           |  |
| Katina Dorton   | _   | *        | _                      |     | *   |                       | *   |                        |             |  |
| Stephen Biggar, M.D., Ph.D.                           | _   | *        | _                      |     | *   |                       | *   |                        |             |  |
| All executive officers and directors as a group       |   |          |                        |     |   |                       |     |                        |             |  |
| (11 persons) <sup>(13)</sup>                          | 21,214,757  | 14.8%    | _                      | _   | 14.8%   |                       | %   | _                      | _           |  |

Panaficial Ownership After The

Represents beneficial ownership of less than one percent.

Consists of (i) shares of common stock held by 667, L.P. (667) and (ii) shares of common stock held by Baker Brothers Life Sciences, L.P. (Baker Life Sciences and together with 667, the BBA Funds). Baker Bros. Advisors LP, or BBA, is the management company and investment adviser to the BBA Funds and has complete and unlimited discretion (1) and authority with respect to the BBA Funds investments and voting power over investments. Baker Bros. Advisors (GP) LLC, or BBA-GP, is the sole general partner of BBA. The managing members of BBA-GP are Julian C. Baker and Felix J. Baker. BBA-GP, Felix J. Baker, Julian C. Baker and BBA may be deemed to be beneficial owners of the securities directly held by the BBA Funds. The address for the above referenced entities is 860 Washington Street, 3rd Floor, New York, NY 10014.

directly held by the BBA Funds. The address for the above referenced entities is 860 Washington Street, 3rd Floor, New York, NY 10014.

Consists of (i) shares of common stock held by 6 Dimensions Capital, L.P. and (ii) shares of common stock held by 6 Dimensions Affiliates Fund, L.P. The general partner of each of 6 Dimensions Capital, L.P. and 6 Dimensions Affiliates Fund, L.P. is 6 Dimensions Capital, L.L.C, which is in turn ultimately controlled by Dr. Chen Lian Yong (Leon). Wei Li, Ph.D., is an affiliate of 6 Dimensions Capital GP, LLC and a member of our board of directors. The address of 6 Dimensions Capital, L.P. and 6 Dimensions Affiliates Fund, L.P., is Unit 6706, 67/F, The Center, 99 Queen's Road Central, Central, Hong Kong.

Consists of (i) shares of common stock held by Bessemer Venture Partners IX L.P. (BVP IX) and (ii) shares of common stock held by Bessemer Venture Partners IX Institutional L.P. (BVP IX Institutional, and together with BVP IX, the BVP

<sup>(3)</sup> 

- Entities). Deer IX & Co. L.P. (Deer IX L.P.) is the general partner of the BVP Entities. Deer IX & Co. Ltd. (Deer IX Ltd.) is the general partner of Deer IX L.P. Robert P. Goodman, David J. Cowan, Byron B. Deeter, Jeremy S. Levine, Robert M. Stavis and Adam Fisher are the directors of Deer IX Ltd. and hold the voting and dispositive power for the BVP Entities. Investment and voting decisions with respect to the shares held by the BVP Entities are made by the directors of Deer IX Ltd. acting as an investment committee. Andrew Hedin disclaims beneficial ownership of the securities held by the BVP Entities, except to the extent of his pecuniary interest, if any, in such securities by virtue of his interest in the BVP Entities. The address of each of these entities is c/o Bessemer Venture Partners, 1865 Palmer Ave., Suite 104, Larchmont, NY 10538.
- address of each of these entities is c/o Bessemer Venture Partners, 1865 Palmer Ave., Suite 104, Larchmont, NY 10538.

  (4) These shares of common stock are held by Longwood Fund IV, L.P. (Longwood). The general partner of Longwood is Longwood Fund IV GP, LLC (Longwood GP). Longwood GP may be deemed to have sole voting and dispositive power over the shares held by Longwood. Each of Richard Aldrich and Christoph Westphal, M.D., Ph.D. are managers of Longwood GP and may be deemed to share voting and dispositive power over of the shares held by Longwood. The address of Longwood and Longwood GP is 800 Boylston St., Suite 1555, Boston, MA 02199.
- (5) Consists of shares of common stock held by Novartis Bioventures Ltd. and shares of common stock held by Novartis Institutes for BioMedical Research, Inc. (referred to as "NIBR") (collectively referred to as the "Novartis Entities"). Novartis Bioventures Ltd. is a Swiss corporation and an indirect wholly owned subsidiary of Novartis AG. NIBR is an indirect wholly owned subsidiary of, and controlled by, Novartis AG. As a result, Novartis Bioventures Ltd. and Novartis AG may be deemed to have shared voting and investment power over the securities held by Novartis Bioventures Ltd. and Novartis AG may be deemed to have shared voting and investment power over the securities held by NIBR. The address for each of Novartis Bioventures Ltd. and Novartis AG is Lichtstrasse 35, CH-4056 Basel, Switzerland. The address for NIBR is 250 Massachusetts Avenue, Cambridge, MA 02139.
- (6) These shares of common stock are held by JMD III Holdings Limited. JMD III Holdings Limited is incorporated in the Cayman Islands and is wholly owned by Hillhouse Venture Fund V, L.P. Hillhouse Capital Management, Ltd. ("HCM") acts as the sole management company of Hillhouse Venture Fund V, L.P. Mr. Lei Zhang may be deemed to have controlling power over HCM. Mr. Lei Zhang disclaims beneficial ownership of all of the shares held by JMD III Holdings Limited, except to the extent of his pecuniary interest therein. The registered address of JMD III Holdings Limited is 89 Nexus Way, Camana Bay, P.O. Box 31106, Grand Cayman KY1-1205, Cayman Islands.
- address of JMD III Holdings Limited is 89 Nexus Way, Camana Bay, P.O. Box 31106, Grand Cayman KY1-1205, Cayman Islands.

  (7) Consists of (i) shares of common stock held by GV 2017, L.P. and (ii) shares of common stock held by GV 2019, L.P. GV 2017 GP, L.L.C. (the general partner of GV 2017, L.P.), GV 2017 GP, L.L.C.) (the general partner of GV 2017 GP, L.P.), Alphabet Holdings LLC (the managing member of GV 2017 GP, L.L.C.), XXVI Holdings Inc. (the controlling stockholder of XXVI Holdings Inc.) may each be deemed to have sole power to vote or dispose of the shares held directly by GV 2017, L.P. GV 2019 GP, L.P.). (the general partner of GV 2019, L.P.), GV 2019 GP, L.L.C.), XXVI Holdings Inc. (the managing member of GV 2019 GP, L.P.). Alphabet Holdings LLC (the managing member of GV 2019 GP, L.P.), Alphabet Holdings LLC (the managing member of GV 2019 GP, L.P.), Alphabet Holdings LLC (the managing member of GV 2019 GP, L.P.), Alphabet Holdings LLC (the managing member of GV 2019 GP, L.P.), Alphabet Holdings LLC (the managing member of GV 2019 GP, L.P.), Alphabet Holdings LLC (the managing member of GV 2019 GP, L.P.), GV 2017 GP, L.P., GV 2019 GP,
- (8) Consists of (i) shares are held of record by Pitango HealthTech Fund I, L.P., and (ii) shares held of record by Pitango HealthTech Principals Fund I, L.P; and (iii) shares held of record by Pitango HealthTech Fund I Israel, L.P. (collectively, the Pitango Entities). The Pitango Principals (as defined below) possess shared voting and dispositive power with respect to all shares of common stock held by all Pitango Entities. The general partner of the Pitango Entities is Pitango HT Fund I, L.P. (the GP). The general partner of the GP is Pitango GP Health Holdings Ltd. (the GP of The GP). The partners in the GP are, either directly or via holding companies and intermediary entities formed for tax purposes, the following individuals: Guy Ezekiel, Ittai Harel, Aaron Mankovski, Zeev Binman, Isaac Hillel, Eyal Nic, Nechemia (Chemi) Peres, Ayal Itzkovits and Rami Kalish (the Pitango Principals). The shareholder of the GP of the GP is the Pitango Principal sare the shareholders of the Management Company. The Pitango Principals are the shareholders of the Management Company. The Pitango Principals are the shareholders of the Management Company. The Pitango Principals are the shareholders of the Amangement Company. The Pitango Principals are the shareholders of the address for the above listed entities is 11 HaMenofim Street, Building B, Herzeliya 4672562, Israel.
- (9) Consists of (i) 712,581 shares of common stock held by Mr. Southwell and (ii) 1,575,754 shares of common stock issuable upon exercise of outstanding stock options held by Mr. Southwell, which are exercisable within 60 days of April 15, 2021.
- (10) Consists of (i) 367,105 shares of common stock held by Dr. MacBeath and (ii) 198,671 shares of common stock issuable upon exercise of outstanding stock options held by Dr. MacBeath, which are exercisable within 60 days of April 15, 2021.
- which are exercisable within 60 days of April 15, 2021.

  (11) Consists of (i) 272,727 shares of common stock held by Mr. Barberich and (ii) 194,767 shares of common stock issuable upon exercise of outstanding stock options held by Mr. Barberich, which are exercisable within 60 days of April 15, 2021.
- which are exercisable within 60 days of April 15, 2021.

  (12) Consists of (i) 7,500,000 shares of common stock held by Dr. Westphal, (ii) 1,000,000 shares of common stock held by Dr. Sylvia Westphal and (iii) the securities held by Longwood as set forth in footnote 4 above, for which Dr. Westphal may be deemed to share voting and investment power.
- (13) Consists of (i) 19,245,565 shares of common stock and (ii) 1,969,192 shares of common stock issuable upon exercise of outstanding stock options held by our current directors and executive officers, which are exercisable within 60 days of April 15, 2021.

### DESCRIPTION OF CAPITAL STOCK

The following descriptions of our capital stock and certain provisions of our amended and restated certificate of incorporation and amended and restated bylaws are summaries and are qualified by reference to the amended and restated certificate of incorporation and the amended and restated bylaws that will be in effect upon completion of this offering. A description of our capital stock and the material terms and provisions of our amended and restated certificate of incorporation and amended and restated bylaws that will be in effect upon the completion of this offering and affecting the rights of holders of our capital stock is set forth below. The forms of our amended and restated certificate of incorporation and our amended and restated bylaws to be adopted in connection with this offering will be filed as exhibits to the registration statement relating to this prospectus.

Upon the completion of this offering, our amended and restated certificate of incorporation will authorize shares of undesignated preferred stock, the rights, preferences and privileges of which may be designated from time to time by our board of directors.

Upon the completion of this offering, our authorized capital stock will consist of which:

shares, all with a par value of \$0.0001 per share, of

- 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.

As of December 31, 2020, after giving effect to (i) the issuance of 70,136,064 shares of Series C convertible preferred stock issued in January 2021 and (ii) the conversion of all outstanding shares of preferred stock, including the shares of Series C convertible preferred stock into an aggregate of 128,053,586 shares of our common stock (including shares of our non-voting common stock), there were outstanding:

- 140,961,519 shares of our common stock held of record by 45 stockholders; and
- 11,852,840 shares of our common stock issuable upon exercise of outstanding stock options.

## **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. See "Dividend policy" for more information.

## 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 that will be in effect upon the completion of this offering will 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**

Upon the completion of this offering, no shares of preferred stock will be outstanding, but we will be 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.

## **Options**

As of December 31, 2020, there were options to purchase 11,852,840 shares of our common stock outstanding, at a weighted average exercise price of \$0.32 per share, of which 2,973,359 were vested and exercisable as of that date. All of such options were granted under our 2018 Plan.

# **Registration Rights**

Following the completion of this offering, the holders of shares of our common stock (including shares of non-voting common stock) issued upon the conversion of our preferred stock will be entitled to contractual rights to require us to register those shares under the Securities Act. These registration rights are provided under the terms of our amended and restated investors' rights agreement between us and the holders of these shares, which we entered into on January 15, 2021.

We will pay all expenses relating to any demand or piggyback registration described below, other than underwriting discounts and commissions. The registration rights terminate upon the earliest to occur of: (i) the

fifth anniversary of the completion of this offering; (ii) a liquidation event; or (iii) with respect to the registration rights of an individual holder, such time after consummation of this offering 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.

## **Demand Registration Rights**

The holders of the registrable securities will be entitled to certain demand registration rights. At any time beginning 180 days following the effectiveness of this offering, the holders of 35% or more of the registrable securities then outstanding may make a written request that we register at least 35% of the registrable securities (or a lesser percent if the anticipated aggregate offering price, net of selling expenses, would exceed \$10 million) some or all of their registrable securities, subject to certain specified conditions and exceptions. We are required to use commercially reasonable efforts to effect the registration and will pay all registration expenses, other than underwriting discounts and commissions, related to any demand registration. We are not obligated to effect more than two of these registrations.

### **Piggyback Registration Rights**

In connection with this offering, holders of our registrable securities were entitled to, and the necessary percentage of holders waived, their rights to notice of this offering and to include their registrable securities in this offering. If we propose to register any of our securities under the Securities Act either for our own account or for the account of other stockholders in another offering, the holders of shares having registration rights will, subject to certain exceptions, be entitled to include their shares in our registration statement, provided that the underwriters of any such offering have the right to limit the number of shares included in the registration. These registration rights are subject to specified other conditions and limitations as set forth in our amended and restated investors' rights agreement.

## Form S-3 Registration Rights

At any time after we are qualified to file a registration statement on Form S-3, and subject to limitations and conditions specified in the amended and restated investors' rights agreement, the holders of registrable securities then outstanding may make a written request that we prepare and file a registration statement on Form S-3 under the Securities Act covering their shares, so long as the aggregate price to the public is at least \$3,000,000. We are not obligated to effect more than two of these Form S-3 registrations in any 12-month period. Such holders will pay pro rata all expenses related to filing a registration statement on Form S-3.

#### **Anti-Takeover Provisions**

### **Delaware Law**

Upon the completion of this offering, we will be 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 amended and restated 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

Upon the completion of this offering, our amended and restated certificate of incorporation and our amended and restated bylaws will 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 will 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 will 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 will provide that our board of directors will be 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 will provide 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 will further provide 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 will provide 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 will also specify 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 will 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**

Upon the completion of this offering, our amended and restated certificate of incorporation will provide 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 a

### **Transfer Agent and Registrar**

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

### Listing

We have applied to list our common stock on The Nasdaq Global Market under the symbol "TCRX."

### SHARES ELIGIBLE FOR FUTURE SALE

Before this offering, there has not been a public market for shares of our common stock and a liquid trading market for our common stock may not develop or be sustained after this offering. Future sales of substantial amounts of shares of our common stock, including shares issued upon the exercise of outstanding options, in the public market following this offering or the possibility of these sales occurring, could cause the prevailing market price for our common stock to fall or impair our ability to raise equity capital through sales of equity securities in the future.

Following this offering, we will have outstanding shares of our common stock, based on the number of shares outstanding as of December 31, 2020, after giving effect to the automatic conversion of all outstanding shares of our preferred stock, including 70,136,064 shares of Series C convertible preferred stock issued in January 2021, into an aggregate of shares of common stock (including shares of our non-voting common stock) upon the completion of this offering. This includes shares of common stock that we are selling in this offering, which shares may be resold in the public market immediately unless purchased by our affiliates and assuming no additional exercise of outstanding options other than as described elsewhere in this prospectus and the conversion of all outstanding shares of our preferred stock into an aggregate of shares of our common stock upon the closing of this offering.

Of these shares, all shares sold in this offering will be freely tradable without restriction under the Securities Act, unless purchased by our "affiliates," as that term is defined in Rule 144 under the Securities Act. The remaining shares of common stock that are not sold in this offering, will be "restricted securities," as that term is defined in Rule 144 under the Securities Act, and we expect that substantially all of these restricted securities will be subject to the 180-day lock-up period under the lock-up agreements as described below. These restricted securities are eligible for public sale only if they are registered under the Securities Act or if they qualify for an exemption from registration under Rule 144 or Rule 701 under the Securities Act, which are summarized below.

In addition, we, our executive officers and directors, and substantially all of our security holders have entered into market standoff agreements with us or lock-up agreements with the underwriters under which they have agreed, subject to specific exceptions, not to sell any of our capital stock until at least 180 days after the date of this prospectus, as described below. As a result of these agreements and the provisions of our investors' rights agreement disclosed in "Description of capital stock—Registration rights," subject to the provisions of Rule 144 or Rule 701, shares will be available for sale in the public market as follows:

- beginning on the date of this prospectus, the unless purchased by our affiliates; shares sold in this offering will be immediately available for sale in the public market,
- beginning 181 days after the date of this prospectus, additional shares will become eligible for sale in the public market, of which shares will be held by affiliates and subject to the volume and other restrictions of Rule 144, as described below; and
- the remainder of the shares will be eligible for sale in the public market from time to time thereafter, subject in some cases to the volume and other restrictions of Rule 144, as described below.

We cannot estimate the number of shares of our common stock that our existing stockholders will elect to sell under Rule 144.

## **Rule 144**

In general, under Rule 144 as currently in effect, a person who has beneficially owned shares of our restricted common stock for at least six months would be entitled to sell their securities provided that such person is not deemed to have been one of our affiliates at the time of, or at any time during the 90 days preceding, a sale, and we are subject to the periodic reporting requirements of the Exchange Act, for at least 90 days before the

sale. In addition, under Rule 144, any person who is not an affiliate of ours and has held their shares for at least one year, including the holding period of any prior owner other than one of our affiliates, would be entitled to sell an unlimited number of shares immediately upon the completion of this offering without regard to whether current public information about us is available. Persons who have beneficially owned shares of our restricted common stock for at least six months but who are our affiliates at the time of, or any time during the 90 days preceding, a sale, would be subject to additional restrictions, by which such person would be entitled to sell within any three-month period only a number of securities that does not exceed the greater of either of the following:

- 1% of the number of shares of our capital stock then outstanding, which will equal shares immediately after the completion of this offering, assuming no exercise by the underwriters of their option to purchase additional shares; or
- the average weekly trading volume of our common stock on Nasdaq during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

provided, in each case, that we have been subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale. Such sales both by affiliates and by non-affiliates must also comply with the manner of sale, current public information and notice provisions of Rule 144.

## **Rule 701**

Any of our employees, directors, officers, consultants, advisors or service providers, other than a person who is deemed to have been one of our affiliates during the immediately preceding 90 days, who purchased shares under a written compensatory plan or contract prior to this offering may be entitled to rely on the resale provisions of Rule 701. Rule 701, as currently in effect, permits resales of shares, in reliance upon Rule 144 but without compliance with certain restrictions, including the holding period requirement, of Rule 144. Rule 701 further provides that non-affiliates may sell such shares in reliance on Rule 144 without having to comply with the public information, volume limitation or notice provisions of Rule 144. All holders of Rule 701 shares are required to wait until 90 days after the date of this prospectus before selling such shares if such resale is pursuant to Rule 701. All Rule 701 shares are, however, subject to lock-up agreements and will only become eligible for sale upon the expiration of these lock-up agreements.

## **Lock-Up Agreements**

In connection with this offering, we and all directors and officers and the holders of substantially all of our outstanding stock and stock options have agreed with the underwriters, subject to certain exceptions, not to offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, shares of our common stock or any securities convertible into or exchangeable for shares of our common stock or enter into any swap or other arrangement that transfers to another any of the economic consequences of ownership of our common stock during the period from the date of this prospectus continuing through the date 180 days after the date of this prospectus, except with the prior written consent of Morgan Stanley & Co. LLC, Jefferies LLC, Cowen and Company, LLC, and Barclays Capital Inc. These agreements are subject to certain exceptions, as set forth in "Underwriters."

Certain of our employees, including our executive officers, and directors may enter into written trading plans that are intended to comply with Rule 10b5-1 under the Exchange Act. Sales under these trading plans would not be permitted until the expiration of the lock-up agreements relating to our initial public offering described above.

## **Registration Rights**

Under our amended and restated investors' rights agreement, after the completion of this offering, the holders of up to shares of our common stock (including shares of non-voting common stock) will, subject to the lock-up agreements referred to above, be entitled to certain rights, subject to certain conditions, 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 other stockholders. The registration of these shares of our common stock under the Securities Act would result in these shares becoming eligible for sale in the public market without restriction under the Securities Act immediately upon the effectiveness of such registration, subject to the Rule 144 limitations applicable to affiliates. See the section titled "Description of capital stock—Registration rights" for a description of these registration rights.

## **Equity Plans**

As of December 31, 2020, we had outstanding options to purchase an aggregate of 11,852,840 shares of our common stock under the 2018 Plan. Following this offering, we intend to file a registration statement on Form S-8 under the Securities Act to register all of the shares of our common stock subject to options outstanding or reserved for issuance under our equity plans. We expect to file this registration statement as soon as practicable after the completion of this offering. This registration statement will become effective immediately upon filing, and shares covered by this registration statement will thereupon be eligible for sale in the public markets, subject to vesting restrictions, the lock-up agreements described above and Rule 144 limitations applicable to affiliates. For a more complete discussion of our stock plans, see "Executive compensation—Equity plans."

## MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES FOR NON-U.S. HOLDERS OF OUR COMMON STOCK

The following is a general discussion of the material U.S. federal income tax considerations applicable to non-U.S. holders (as defined below) with respect to their ownership and disposition of shares of our common stock issued pursuant to this offering. For purposes of this discussion, a non-U.S. holder means a beneficial owner of our common stock (other than an entity or arrangement that is treated as a partnership for U.S. federal income tax purposes) that is not, for U.S. federal income tax purposes, any of the following:

- an individual citizen or resident of the United States;
- a corporation (or other entity treated as a corporation for U.S. federal income tax purposes) created or organized in the United States or under the laws of the United States, any state thereof or the District of Columbia;
- · an estate, the income of which is includable in gross income for U.S. federal income tax purposes regardless of its source; or
- a trust if (i) a court within the United States is able to exercise primary supervision over the administration of the trust and one or more "U.S. persons," as defined under the Code, have the authority to control all substantial decisions of the trust or (ii) such trust has made a valid election to be treated as a U.S. person for U.S. federal income tax purposes.

This discussion is based on current provisions of the Internal Revenue Code of 1986, as amended, or "Code", existing, temporary and proposed Treasury Regulations promulgated thereunder, judicial opinions, published positions of the Internal Revenue Service, or "IRS", and other applicable authorities, all of which are subject to change or to differing interpretation, possibly with retroactive effect. This discussion assumes that a non-U.S. holder holds shares of our common stock as a capital asset (generally, property held for investment) for U.S. federal income tax purposes. This discussion does not address all aspects of U.S. federal income taxation that may be important to a particular non-U.S. holder in light of that non-U.S. holder's individual circumstances, nor does it address any aspects of the unearned income Medicare contribution tax pursuant to the Health Care and Education Reconciliation Act of 2010, any U.S. gift taxes, any U.S. alternative minimum taxes or any state, local or non-U.S. taxes. This discussion may not apply, in whole or in part, to particular non-U.S. holders in light of their individual circumstances or to holders subject to special treatment under the U.S. federal income tax laws (such as insurance companies, tax-exempt organizations, financial institutions, brokers or dealers in securities, "controlled foreign corporations," "passive foreign investment companies," non-U.S. holders that hold our common stock as part of a straddle, conversion transaction or other integrated investment, holders who own, actually or constructively, more than 5% of our common stock, and certain U.S. expatriates).

If a partnership (or other entity or arrangement treated as a partnership for U.S. federal income tax purposes) holds our common stock, the tax treatment of a partner therein will generally depend on the status of the partner and the activities of the partnership. Partners of a partnership holding our common stock should consult their tax advisor as to the particular U.S. federal income tax consequences applicable to them.

INVESTORS CONSIDERING THE PURCHASE OF OUR COMMON STOCK SHOULD CONSULT THEIR OWN TAX ADVISORS REGARDING THE APPLICATION OF THE U.S. FEDERAL INCOME AND ESTATE TAX LAWS TO THEIR PARTICULAR SITUATIONS AND THE CONSEQUENCES OF NON-U.S., STATE, OR LOCAL LAWS AND TAX TREATIES.

## **Dividends**

We do not expect to declare or make any distributions on our common stock in the foreseeable future. If we do pay dividends on shares of our common stock, however, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as

determined under U.S. federal income tax principles. Distributions in excess of our current and accumulated earnings and profits will constitute a return of capital that is applied against and reduces, but not below zero, a non-U.S. holder's adjusted tax basis in shares of our common stock. Any excess will be treated as capital gain and such gain will be subject to the treatment described below under "—Gain on sale or other disposition of common stock." Any such distributions will also be subject to the discussion below under "—Backup withholding and information reporting" and "—Foreign account tax compliance act."

Any dividend paid to a non-U.S. holder on our common stock that is not effectively connected with a non-U.S. holder's conduct of a trade or business in the United States will generally be subject to U.S. withholding tax at a 30% rate. The withholding tax might apply at a reduced rate, however, under the terms of an applicable income tax treaty between the United States and the non-U.S. holder's country of residence. You should consult your own tax advisors regarding your entitlement to benefits under a relevant income tax treaty. Generally, in order for the applicable withholding agent to withhold tax at a lower treaty rate, a non-U.S. holder must certify its entitlement to treaty benefits. A non-U.S. holder generally can meet this certification requirement by providing an IRS Form W-8BEN, W-8BEN-E or other appropriate form (or any successor or substitute form thereof) to the applicable withholding agent. If the non-U.S. holder holds the stock through a financial institution or other agent acting on the holder's behalf, the holder will be required to provide appropriate documentation to the holder's agent. The holder's agent will then be required to provide certification to the applicable withholding agent, either directly or through other intermediaries. If you are eligible for a reduced rate of U.S. federal withholding tax under an income tax treaty, you may generally obtain a refund or credit of any excess amounts withheld by filing an appropriate claim for a refund with the IRS in a timely manner.

Dividends received by a non-U.S. holder that are effectively connected with a U.S. trade or business conducted by the non-U.S. holder, and if required by an applicable income tax treaty between the United States and the non-U.S. holder's country of residence, are attributable to a permanent establishment maintained by the non-U.S. holder in the United States, are not subject to U.S. withholding tax. To obtain this exemption, a non-U.S. holder must provide the applicable withholding agent with an IRS Form W-8ECI properly certifying such exemption. Such effectively connected dividends, although not subject to withholding tax, are taxed at the same U.S. federal income tax rates applicable to U.S. persons, net of certain deductions and credits. In addition to being taxed at U.S. federal income tax rates, dividends received by a corporate non-U.S. holder that are effectively connected with a U.S. trade or business of the corporate non-U.S. holder may also be subject to a branch profits tax at a rate of 30% or such lower rate as may be specified by an applicable tax treaty.

### Gain on Sale or Other Disposition of Common Stock

Subject to the discussion below under "—Backup withholding and information reporting" and "—Foreign account tax compliance act," non-U.S. holders will generally not be subject to U.S. federal income tax on any gains realized on the sale, exchange or other disposition of our common stock unless:

- the gain (i) is effectively connected with the conduct by the non-U.S. holder of a U.S. trade or business and (ii) if required by an applicable income tax treaty between the United States and the non-U.S. holder's country of residence, is attributable to a permanent establishment maintained by the non-U.S. holder in the United States (in which case the special rules described below apply);
- the non-U.S. holder is an individual who is present in the United States for 183 days or more in the taxable year of the sale, exchange or other disposition of our common stock, and certain other requirements are met (in which case the gain would be subject to a flat 30% tax, or such reduced rate as may be specified by an applicable income tax treaty, which may be offset by U.S. source capital losses, even though the individual is not considered a resident of the United States); or
- the rules of the Foreign Investment in Real Property Tax Act, or FIRPTA, treat the gain as effectively connected with a U.S. trade or business.

The FIRPTA rules may apply to a sale, exchange or other disposition of our common stock if we are, or were within the shorter of the five-year period preceding the disposition and the non-U.S. holder's holding period, a U.S. real property holding corporation, or USRPHC. In general, we would be a USRPHC if interests in U.S. real property comprised at least half of the value of our worldwide real property and our other assets held for use in a trade or business. We do not believe that we are a USRPHC and we do not anticipate becoming one in the future. Even if we are or were to become a USRPHC, gain arising from the sale or other taxable disposition by a non-U.S. holder will not be subject to U.S. federal income tax if our common stock is "regularly traded," as defined by applicable Treasury Regulations, on an established securities market, and such non-U.S. holder owned, actually and constructively, 5% or less of our common stock throughout the shorter of the five-year period ending on the date of the sale or other taxable disposition or the non-U.S. holder's holding period. If any gain from the sale, exchange or other disposition of our common stock, (i) is effectively connected with a U.S. trade or business conducted by a non-U.S. holder and (ii) if required by an applicable income tax treaty between the United States and the non-U.S. holder's country of residence, is attributable to a permanent establishment maintained by such non-U.S. holder in the United States, then the gain generally will be subject to U.S. federal income tax at the same rates applicable to U.S. persons, net of certain deductions and credits. If the non-U.S. holder is a corporation, under certain circumstances, that portion of its earnings and profits that is effectively connected with its U.S. trade or business, subject to certain adjustments, generally would be subject also to a "branch profits tax" at a rate of 30% or such lower rate as may be specified by an applicable income tax treaty.

## **Backup Withholding and Information Reporting**

The applicable withholding agent must report annually to the IRS and to each non-U.S. holder the amount of dividends paid to, and the tax withheld with respect to, each non-U.S. holder. These reporting requirements apply regardless of whether withholding was reduced or eliminated by an applicable tax treaty. Copies of this information reporting may also be made available under the provisions of a specific tax treaty or agreement with the tax authorities in the country in which the non-U.S. holder resides or is established.

A non-U.S. holder will generally be subject to backup withholding for dividends on our common stock paid to such holder unless such holder certifies under penalties of perjury that, among other things, it is a non-U.S. holder (and the payer does not have actual knowledge or reason to know that such holder is a U.S. person) or otherwise establishes an exemption.

Information reporting and backup withholding generally are not required with respect to the amount of any proceeds from the sale or other disposition of our common stock by a non-U.S. holder outside the United States through a foreign office of a foreign broker that does not have certain specified connections to the United States. However, if a non-U.S. holder sells or otherwise disposes of its shares of common stock through a U.S. broker or the U.S. offices of a foreign broker, the broker will generally be required to report the amount of proceeds paid to the non-U.S. holder to the IRS and impose backup withholding on that amount unless such non-U.S. holder provides appropriate certification to the broker of its status as a non-U.S. holder (and the payer does not have actual knowledge or reason to know that such holder is a U.S. person) or otherwise establishes an exemption.

Backup withholding is not an additional income tax. Any amounts withheld under the backup withholding rules from a payment to a non-U.S. holder generally can be credited against the non-U.S. holder's U.S. federal income tax liability, if any, or refunded, provided that the required information is furnished to the IRS in a timely manner. Non-U.S. holders should consult their tax advisors regarding the application of the information reporting and backup withholding rules to them.

### **Foreign Account Tax Compliance Act**

Under the Foreign Account Tax Compliance Act, or FATCA, withholding tax of 30% applies to certain payments to foreign financial institutions, investment funds and certain other non-U.S. persons that fail to comply with certain information reporting and certification requirements pertaining to their direct and indirect

U.S. securityholders and/or U.S. accountholders and do not otherwise qualify for an exemption. Under applicable Treasury Regulations and IRS guidance, this withholding currently applies to payments of dividends, if any, on, and, subject to the proposed Treasury Regulations discussed below, gross proceeds from the sale or other disposition of, our common stock. An intergovernmental agreement between the United States and a foreign country may modify the requirements described in this paragraph.

While, beginning on January 1, 2019, withholding under FATCA would have applied also to payments of gross proceeds from the sale or other disposition of our common stock, proposed Treasury Regulations eliminate FATCA withholding on payments of gross proceeds entirely. Taxpayers generally may rely on these proposed Treasury Regulations until final Treasury Regulations are issued.

Prospective investors are encouraged to consult with their own tax advisors regarding the possible implications of FATCA on their investment in our common stock.

### **Federal Estate Tax**

Common stock we have issued that is owned (or treated as owned) by an individual who is not a citizen or a resident of the United States (as defined for U.S. federal estate tax purposes) at the time of death will be included in the individual's gross estate for U.S. federal estate tax purposes unless an applicable estate or other tax treaty provides otherwise, and therefore may be subject to U.S. federal estate tax.

PROSPECTIVE INVESTORS SHOULD CONSULT THEIR OWN TAX ADVISORS REGARDING THE POTENTIAL APPLICATION OF WITHHOLDING UNDER FATCA TO THEIR INVESTMENT IN OUR COMMON STOCK. THE PRECEDING DISCUSSION OF U.S. FEDERAL TAX CONSIDERATIONS IS FOR GENERAL INFORMATION PURPOSES ONLY. EACH PROSPECTIVE INVESTOR SHOULD CONSULT ITS OWN TAX ADVISOR REGARDING THE PARTICULAR U.S. FEDERAL, GIFT, ESTATE, STATE, LOCAL, AND NON-U.S. TAX CONSEQUENCES OF PURCHASING, HOLDING, AND DISPOSING OF OUR COMMON STOCK, INCLUDING THE CONSEQUENCES OF ANY PROPOSED CHANGE IN APPLICABLE LAWS.

#### UNDERWRITERS

Under the terms and subject to the conditions in an underwriting agreement dated the date of this prospectus, the underwriters named below, for whom Morgan Stanley & Co. LLC, Jefferies LLC, Cowen and Company, LLC and Barclays Capital Inc. are acting as representatives, have severally agreed to purchase, and we have agreed to sell to them the number of shares indicated below:

|                          | <u>Name</u> | Number of<br><u>Shares</u> |
|--------------------------|-------------|----------------------------|
| Morgan Stanley & Co. LLC |             |                            |
| Jefferies LLC            |             |                            |
| Cowen and Company, LLC   |             |                            |
| Barclays Capital Inc.    |             |                            |
| Total:                   |             |                            |
|                          |             |                            |

The underwriters and the representatives are collectively referred to as the "underwriters" and the "representatives," respectively. The underwriters are offering the shares of common stock subject to their acceptance of the shares from us and subject to prior sale. The underwriting agreement provides that the obligations of the several underwriters to pay for and accept delivery of the shares of common stock offered by this prospectus are subject to the approval of certain legal matters by their counsel and to certain other conditions. The underwriters are obligated to take and pay for all of the shares of common stock offered by this prospectus if any such shares are taken. However, the underwriters are not required to take or pay for the shares covered by the underwriters' over-allotment option described below.

The underwriters initially propose to offer part of the shares of common stock directly to the public at the offering price listed on the cover page of this prospectus and part to certain dealers at a price that represents a concession not in excess of \$ per share under the public offering price. After the initial offering of the shares of common stock, the offering price and other selling terms may from time to time be varied by the representatives.

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase up to additional shares of common stock at the public offering price listed on the cover page of this prospectus, less underwriting discounts and commissions. The underwriters may exercise this option solely for the purpose of covering over-allotments, if any, made in connection with the offering of the shares of common stock offered by this prospectus. To the extent the option is exercised, each underwriter will become obligated, subject to certain conditions, to purchase about the same percentage of the additional shares of common stock as the number listed next to the underwriter's name in the preceding table bears to the total number of shares of common stock listed next to the names of all underwriters in the preceding table.

The following table shows the per share and total public offering price, underwriting discounts and commissions, and proceeds before expenses to us. These amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase up to an additional shares of common stock.

|   |       | Tota        | al       |
|---|-------|-------------|----------|
|   | Per   | <u> </u>    | Full     |
|   | Share | No Exercise | Exercise |
| Public offering price                                   | \$    | \$          | \$       |
| Underwriting discounts and commissions to be paid by us | \$    | \$          | \$       |
| Proceeds, before expenses, to us                        | \$    | \$          | \$       |

The estimated offering expenses payable by us, exclusive of the underwriting discounts and commissions, are approximately \$ . We have agreed to reimburse the underwriters for expense relating to clearance of this offering with the Financial Industry Regulatory Authority up to \$ .

The underwriters have informed us that they do not intend sales to discretionary accounts to exceed 5% of the total number of shares of common stock offered by them.

We have applied to list our common stock on The Nasdaq Global Market under the trading symbol "TCRX".

We, our directors and our executive officers and the holders of substantially all of our outstanding stock and stock options have agreed that, without the prior written consent of the representatives on behalf of the underwriters, we and they will not, and will not publicly disclose an intention to, during the period ending 180 days after the date of this prospectus (the restricted period):

- offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of, directly or indirectly, any shares of common stock or any securities convertible into or exercisable or exchangeable for shares of common stock; or
- enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the common stock, whether any such transaction described above is to be settled by delivery of common stock or such other securities, in cash or otherwise. In addition, we and each such person agrees that, without the prior written consent of the representatives on behalf of the underwriters, we or such other person will not, during the restricted period, make any demand for, or exercise any right with respect to, the registration of any shares of common stock or any security convertible into or exercisable or exchangeable for common stock.

In relation to the Company, the restrictions described above do not apply to:

- (a) the shares to be sold under the underwriting agreement:
- (b) the issuance by us of shares of common stock upon the exercise of an option or warrant, the settlement of restricted stock units or share value award, or the conversion of a convertible loan, note or other security outstanding on the date hereof as described herein;
- (c) the grant of options, restricted stock units, share value awards or any other type of equity award described herein pursuant to employee benefit plans in effect on the date hereof and described herein, or the issuance of shares of common stock by us to employees, officers, directors, advisors or consultants of us pursuant to employee benefit plans in effect on the date hereof and described herein; provided that each recipient shall execute and deliver to the representatives a lock-up letter in the form of this section;
- (d) the filing by us of a registration statement on Form S-8 relating to issuance, vesting, exercise or settlement of equity awards granted or to be granted pursuant to any employee benefit plan in effect on the date hereof and described herein;
- (e) the issuance of or entry into an agreement to issue shares of common stock or any securities convertible into or exercisable or exchangeable for common stock in connection with one or more mergers, acquisitions or securities, businesses, property or other assets, products or technologies, joint ventures, commercial relationships or other strategic corporate transactions or alliances; provided that the aggregate amount of common stock that we may issue or agree to issue pursuant to this paragraph shall not exceed 5% of the total number of shares of our common stock issued and outstanding immediately following the completion of the transactions contemplated by the underwriting agreement determined on a fully diluted basis, and provided further, that each recipient shall execute and deliver to the representatives a lock-up letter in the form of this section; or
- (f) facilitating the establishment of a trading plan on behalf of a shareholder, officer or director of ours pursuant to Rule 10b5-1 under the Exchange Act for the transfer of shares of common stock, provided that (i) such plan does not provide for the transfer of shares of common stock during the restricted

period and (ii) to the extent a public announcement or filing under the Exchange Act, if any, is required of or voluntarily made by us regarding the establishment of such plan, such announcement or filing shall include a statement to the effect that no transfer of shares of common stock may be made under such plan during the restricted period.

In relation to our directors and our executive officers and the holders of substantially all of our outstanding stock and stock options, the restrictions described above do not apply to:

- (a) transactions relating to shares of common stock or other such securities acquired in the offering, if the holder is not an officer or director, or in open market transactions after the completion of the offering;
- (b) transfers as a bona fide gift:
- (c) transfers or distributions to (1) direct or indirect limited partners, members, stockholders, or holders of similar equity interests, (2) to affiliates (as defined in Rule 405 under the Securities Act), or (3) to any investment fund or other entity controlled or managed by certain holders and their affiliates:
- (d) transfers to any immediate family member ("immediate family" shall mean any relationship by blood, marriage or adoption, not more remote than first cousin);
- (e) transfers or dispositions by will or intestacy;
- (f) transfers or dispositions pursuant to a court order or a settlement agreement related to the distribution of assets in connection with the dissolution of a marriage or civil union;
- (g) transfers or dispositions to the Company in connection with the exercise or settlement of options, warrants or other rights to acquire shares of common stock or any security convertible into or exercisable for shares of common stock in accordance with their terms (including the vesting or settlement of restricted stock units and including, in each case, by way of net exercise and/or to cover withholding tax obligations in connection with such exercise, vesting or settlement) pursuant to an employee benefit plan, option, warrant or other right disclosed herein, provided that (i) any such shares issued upon exercise of such option, warrant, restricted stock unit or other right shall be subject to the restrictions set forth in the lock-up agreement, and (ii) any filing under the Exchange Act reporting a reduction in beneficial ownership shall indicate in the footnotes thereto that the filing relates to the applicable circumstances described in this clause, and no other public announcement shall be required or shall be made voluntarily in connection with such transfer;
- (h) the establishment of a trading plan pursuant to Rule 10b5-1 under the Exchange Act; provided that no sales or other transfers occur under such plan, provided that (i) such plan does not provide for the transfer of common stock during the restricted period and (ii) to the extent a public announcement or filing under the Exchange Act, if any, is required of or voluntarily made by or on behalf of the undersigned or the Company regarding the establishment of such plan, such announcement or filing shall include a statement to the effect that no transfer of common stock may be made under such plan during the restricted period;
- (i) any sale, disposal or transfer of shares of common stock to a bona fide third party pursuant to a tender offer for securities of the Company or any merger, consolidation or other business combination involving a Change of Control (as defined below) of the Company occurring after the settlement of the offering, that, in each case, has been approved by the board of directors of the Company; provided that (i) all of the shares of common stock subject to the lock-up agreement that are not so transferred, sold, tendered or otherwise disposed of remain subject to the agreement; and (ii) that it shall be a condition of transfer, sale, tender or other disposition that if such tender offer or other transaction is not completed, any of the shares of common stock subject to the lock-up agreement shall remain subject to the agreement. For the purposes of this paragraph, "Change of Control" means the consummation of any bona fide third party tender offer, merger, consolidation or other similar transaction, the result of which is that any "person" (as defined in Section 13(d)(3) of the Exchange Act), or group of persons, other than the Company or its subsidiaries, becomes the beneficial owner (as defined in Rules 13d-3

and 13d-5 of the Exchange Act) of at least 75% of the total voting power of the voting share capital of the Company; or

(j) in the case of each of our major investors, the placement of any charge, mortgage, lien, pledge, restriction, security interest or other encumbrance in respect of any shares of common stock or any securities convertible into or exercisable or exchangeable for shares of common stock in connection with bona fide margin loans entered into by the major investors or their affiliates in the ordinary course of business; provided, that (i) any beneficiary of such transaction that forecloses or enforces following a default shall sign and deliver a lock up letter substantially in the form of this section, and (ii) no filing under the Exchange Act or other public announcement shall be required or made voluntarily in connection with such pledge or subsequent foreclosure, enforcement or transfer of such shares or securities, subject to certain exceptions;

provided that in the case of any transfer or distribution pursuant to clauses (b), (c), (d), (e), or (f), each donee, transferee, heir, beneficiary or distributee shall execute and deliver to the representatives a lock-up letter in the form of this section; provided further that in the case of any transfer or distribution pursuant to clauses (a), (b), (c) or (d), no filing under the Exchange Act shall be required or shall be voluntarily made in connection with subsequent sales of shares of common stock or other securities acquired in such transactions; and provided further that in the case of any transfer or distribution pursuant to clauses (e) or (f), any filing required under the Exchange Act shall indicate in the footnotes thereto that the filing relates to the circumstances described in the relevant clause and no other public announcement shall be required or shall be made voluntarily in connection with such transfer, disposition or distribution.

The representatives, in their sole discretion, may release the common stock and other securities subject to the lock-up agreements described above in whole or in part at any time.

In order to facilitate the offering of the common stock, the underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of the common stock. Specifically, the underwriters may sell more shares than they are obligated to purchase under the underwriting agreement, creating a short position. A short sale is covered if the short position is no greater than the number of shares available for purchase by the underwriters under the over-allotment option. The underwriters can close out a covered short sale by exercising the over-allotment option or purchasing shares in the open market. In determining the source of shares to close out a covered short sale, the underwriters will consider, among other things, the open market price of shares compared to the price available under the over-allotment option. The underwriters may also sell shares in excess of the over-allotment option, creating a naked short position. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market after pricing that could adversely affect investors who purchase in this offering. As an additional means of facilitating this offering, the underwriters may bid for, and purchase, shares of common stock in the open market to stabilize the price of the common stock. These activities may raise or maintain the market price of the common stock above independent market levels or prevent or retard a decline in the market price of the common stock. The underwriters are not required to engage in these activities and may end any of these activities at any time.

We and the underwriters have agreed to indemnify each other against certain liabilities, including liabilities under the Securities Act.

A prospectus in electronic format may be made available on websites maintained by one or more underwriters, or selling group members, if any, participating in this offering. The representatives may agree to allocate a number of shares of common stock to underwriters for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives to underwriters that may make Internet distributions on the same basis as other allocations.

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory,

investment management, investment research, principal investment, hedging, financing and brokerage activities. Certain of the underwriters and their respective affiliates have, from time to time, performed, and may in the future perform, various financial advisory and investment banking services for us, for which they received or will receive customary fees and expenses.

In addition, in the ordinary course of their various business activities, the underwriters and their respective affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers and may at any time hold long and short positions in such securities and instruments. Such investment and securities activities may involve our securities and instruments. The underwriters and their respective affiliates may also make investment recommendations or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long or short positions in such securities and instruments.

#### **Pricing of the Offering**

Prior to this offering, there has been no public market for our common stock. The initial public offering price will be determined by negotiations between us and the representatives. Among the factors to be considered in determining the initial public offering price will be our future prospects and those of our industry in general, our sales, earnings and certain other financial and operating information in recent periods, and the price-earnings ratios, price-sales ratios, market prices of securities, and certain financial and operating information of companies engaged in activities similar to ours.

### **Directed Share Program**

At our request, the underwriters have reserved up to shares, or up to % of the shares offered by this prospectus, for sale at the initial public offering price through a directed share program to certain of our directors, officers, employees and business associates and other parties related to us. If purchased by these persons, these shares will be subject to a 180-day lock-up restriction.

The number of shares available for sale to the general public will be reduced to the extent that such persons purchase such reserved shares. Any reserved shares not so purchased will be offered by the underwriters to the general public on the same basis as the other shares offered by this prospectus. Other than the underwriting discount described on the front cover of this prospectus, the underwriters will not be entitled to any commission with respect to shares sold pursuant to the directed share program. We will agree to indemnify Morgan Stanley & Co. LLC against certain liabilities and expenses, including liabilities under the Securities Act, in connection with sales of the shares reserved for the directed share program. Morgan Stanley & Co. LLC will administer our directed share program.

#### **Selling Restrictions**

#### Canada

The shares of our common stock may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the shares of our common stock must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable restrictions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 (or, in the case of securities issued or guaranteed by the government of a non-Canadian jurisdiction, section 3A.4) of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

#### European Economic Area

In relation to each Member State of the European Economic Area, each a Member State, no shares have been offered or will be offered pursuant to the offering to the public in that Member State prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Member State or, where appropriate, approved in another Member State and notified to the competent authority in that Member State, all in accordance with the Prospectus Regulation, except that offers of shares may be made to the public in that Member State at any time under the following exemptions under the Prospectus Regulation:

- a. to any legal entity which is a qualified investor as defined under the Prospectus Regulation;
- b. to fewer than 150 natural or legal persons (other than qualified investors as defined under the Prospectus Regulation), subject to obtaining the prior consent of the representatives; or
- c. in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of shares shall require us or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation and each person who initially acquires any shares or to whom any offer is made will be deemed to have represented, acknowledged and agreed to and with each of the underwriters and us that it is a "qualified investor" within the meaning of Article 2(e) of the Prospectus Regulation.

In the case of any shares being offered to a financial intermediary as that term is used in the Prospectus Regulation, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the shares acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer of any shares to the public other than their offer or resale in a Member State to qualified investors as so defined or in circumstances in which the prior consent of the representatives has been obtained to each such proposed offer or resale.

For the purposes of this provision, the expression an "offer to the public" in relation to shares in any Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares, and the expression "Prospectus Regulation" means Regulation (EU) 2017/1129 (as amended).

## **United Kingdom**

In relation to the United Kingdom, no shares of common stock have been offered or will be offered pursuant to this offering to the public in the United Kingdom prior to the publication of a prospectus in relation to the shares that has been approved by the Financial Conduct Authority in the UK in accordance with the UK Prospectus Regulation and the Financial Services and Markets Act 2000 (FSMA), except that offers of shares may be made to the public in the United Kingdom at any time under the following exemptions under the UK Prospectus Regulation and the FSMA:

- a. to any legal entity which is a qualified investor as defined in Article 2 of the UK Prospectus Regulation;
- b. to fewer than 150 natural or legal persons (other than qualified investors as defined in Article 2 of the UK Prospectus Regulation), subject to obtaining the prior consent of the representatives; or
- c. in any other circumstances falling within Section 86 of the FSMA,

provided that no such offer of shares shall require us or any of the underwriters to publish a prospectus pursuant to Section 85 of the FSMA or supplement a prospectus pursuant to Article 23 of the UK Prospectus Regulation. Each person in the United Kingdom who acquires any shares in the offering or to whom any offer is made will be deemed to have represented, acknowledged and agreed to and with us and the underwriters that it is a qualified investor within the meaning of the UK Prospectus Regulation.

For the purposes of this provision, the expression an "offer to the public" in relation to any shares in any relevant state means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares, and the expression "UK Prospectus Regulation" means Regulation (EU) 2017/1129 as it forms part of domestic law by virtue of the European Union (Withdrawal) Act 2018.

We have not authorized and do not authorize the making of any offer of shares through any financial intermediary on their behalf, other than offers made by the underwriters with a view to the final placement of the shares as contemplated in this prospectus. Accordingly, no purchaser of the shares, other than the underwriters, is authorized to make any further offer of the shares on behalf of us or the underwriters.

Any person in the United Kingdom that is not a relevant person should not act or rely on the information included in this document or use it as basis for taking any action. In the United Kingdom, any investment or investment activity that this document relates to may be made or taken exclusively by relevant persons.

### Japan

No registration pursuant to Article 4, paragraph 1 of the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948, as amended) (the FIEL) has been made or will be made with respect to the solicitation of the application for the acquisition of the shares of common stock.

Accordingly, the shares of common stock have not been, directly or indirectly, offered or sold and will not be, directly or indirectly, offered or sold in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan) or to others for re-offering or re-sale, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan except pursuant to an exemption from the registration requirements, and otherwise in compliance with, the FIEL and the other applicable laws and regulations of Japan.

#### For Qualified Institutional Investors (QII)

Please note that the solicitation for newly-issued or secondary securities (each as described in Paragraph 2, Article 4 of the FIEL) in relation to the shares of common stock constitutes either a "QII only private placement" or a "QII only secondary distribution" (each as described in Paragraph 1, Article 23-13 of the FIEL). Disclosure regarding any such solicitation, as is otherwise prescribed in Paragraph 1, Article 4 of the FIEL, has not been made in relation to the shares of common stock. The shares of common stock may only be transferred to QIIs.

## For Non-QII Investors

Please note that the solicitation for newly-issued or secondary securities (each as described in Paragraph 2, Article 4 of the FIEL) in relation to the shares of common stock constitutes either a "small number private placement" or a "small number private secondary distribution" (each as is described in Paragraph 4, Article 23-13 of the FIEL). Disclosure regarding any such solicitation, as is otherwise prescribed in Paragraph 1, Article 4 of the FIEL, has not been made in relation to the shares of common stock. The shares of common stock may only be transferred en bloc without subdivision to a single investor.

## Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or

invitation for subscription or purchase, of the shares of common stock may not be circulated or distributed, nor may the shares of common stock be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore (the SFA), (ii) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), and in accordance with the conditions specified in Section 275, of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares of common stock are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- (a) a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or
- (b) a trust (where the trustee is not an accredited investor) the sole purpose of which is to hold investments and each beneficiary of the trust is an individual who is an accredited investor, securities (as defined in Section 239(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares of common stock pursuant to an offer made under Section 275 of the SFA except:
  - i. to an institutional investor or to a relevant person defined in Section 275(2) of the SFA, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;
  - ii. where no consideration is or will be given for the transfer;
  - iii. where the transfer is by operation of law;
  - iv. as specified in Section 276(7) of the SFA; or
  - v. as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore.

#### **Kuwait**

Unless all necessary approvals from the Kuwait Ministry of Commerce and Industry required by Law No. 31/1990 "Regulating the Negotiation of Securities and Establishment of Investment Funds," its Executive Regulations and the various Ministerial Orders issued pursuant thereto or in connection therewith, have been given in relation to the marketing and sale of the shares, these may not be marketed, offered for sale, nor sold in the State of Kuwait. Neither this prospectus (including any related document), nor any of the information contained therein is intended to lead to the conclusion of any contract of whatsoever nature within Kuwait.

## **Dubai International Financial Center**

This prospectus relates to an Exempt Offer in accordance with the Offered Securities Rules of the Dubai Financial Services Authority (DFSA). This prospectus is intended for distribution only to persons of a type specified in the Offered Securities Rules of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus nor taken steps to verify the information set forth herein and has no responsibility for the prospectus. The shares to which this prospectus relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the shares offered should conduct their own due diligence on the shares. If you do not understand the contents of this prospectus you should consult an authorized financial advisor.

#### China

This prospectus may not be circulated or distributed in the People's Republic of China (PRC) and the ADSs may not be offered or sold, and will not offer or sell to any person for re-offering or resale directly or indirectly to any resident of the PRC except pursuant to applicable laws and regulations of the PRC.

#### Saudi Arabia

This prospectus may not be distributed in the Kingdom of Saudi Arabia except to such persons as are permitted under the Offers of Securities Regulations issued by the Capital Market Authority. The Capital Market Authority does not make any representation as to the accuracy or completeness of this prospectus, and expressly disclaims any liability whatsoever for any loss arising from, or incurred in reliance upon, any part of this prospectus. Prospective purchasers of the securities offered hereby should conduct their own due diligence on the accuracy of the information relating to the securities. If you do not understand the contents of this prospectus you should consult an authorized financial adviser.

#### Qatar

In the State of Qatar, the offer contained herein is made on an exclusive basis to the specifically intended recipient thereof, upon that person's request and initiative, for personal use only and shall in no way be construed as a general offer for the sale of securities to the public or an attempt to do business as a bank, an investment company or otherwise in the State of Qatar. This prospectus and the underlying securities have not been approved or licensed by the Qatar Central Bank or the Qatar Financial Center Regulatory Authority or any other regulator in the State of Qatar. The information contained in this prospectus shall only be shared with any third parties in Qatar on a need to know basis for the purpose of evaluating the contained offer. Any distribution of this prospectus by the recipient to third parties in Qatar beyond the terms hereof is not permitted and shall be at the liability of such recipient.

#### Israel

The shares of our common stock have not been approved or disapproved by the Israel Securities Authority (the ISA), nor have such shares been registered for sale in Israel. The shares of our common stock may not be offered or sold, directly or indirectly, to the public in Israel, absent the publication of a prospectus that has been approved by the ISA. The ISA has not issued permits, approvals or licenses in connection with this offering or publishing this prospectus, nor has it authenticated the details included herein, confirmed their reliability or completeness, or rendered an opinion as to the quality of the shares of common stock being offered. This document does not constitute a prospectus under the Israeli Securities Law and has not been filed with or approved by the ISA. In the State of Israel, this document may be distributed only to, and may be directed only at, and any offer of the shares common stock may be directed only at, (i) to the extent applicable, a limited number of persons in accordance with the Israeli Securities Law and (ii) investors listed in the first addendum to the Israeli Securities Law, or the Addendum, consisting primarily of joint investment in trust funds, provident funds, insurance companies, banks, portfolio managers, investment advisors, members of the Tel Aviv Stock Exchange Ltd., underwriters, venture capital funds, entities with equity in excess of NIS 50 million and "qualified individuals," each as defined in the Addendum (as it may be amended from time to time), collectively referred to as qualified investors (in each case purchasing for their own account or, where permitted under the Addendum, for the accounts of their clients who are investors listed in the Addendum). Qualified investors will be required to submit written confirmation that they fall within the scope of the Addendum, are aware of the meaning of same and agree to it.

## Hong Kong

No securities have been offered or sold, and no securities may be offered or sold, in Hong Kong, by means of any document, other than to persons whose ordinary business is to buy or sell shares or debentures, whether as principal or agent; or to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong (SFO) and any rules made under that Ordinance; or in other circumstances which do not result in the document being a "prospectus" as defined in the Companies Ordinance (Cap. 32) of Hong Kong (CO) or which do not constitute an offer or invitation to the public for the purpose of the CO or the SFO. No document, invitation or advertisement relating to the securities has been issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed

or read by, the public of Hong Kong (except if permitted under the securities laws of Hong Kong) other than with respect to securities which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" as defined in the SFO and any rules made under that Ordinance.

This prospectus has not been registered with the Registrar of Companies in Hong Kong. Accordingly, this prospectus may not be issued, circulated or distributed in Hong Kong, and the securities may not be offered for subscription to members of the public in Hong Kong. Each person acquiring the securities will be required, and is deemed by the acquisition of the securities, to confirm that he is aware of the restriction on offers of the securities described in this prospectus and the relevant offering documents and that he is not acquiring, and has not been offered any securities in circumstances that contravene any such restrictions.

#### **Switzerland**

The shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange (SIX) or on any other stock exchange or regulated trading facility in Switzerland. This prospectus has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this prospectus nor any other offering or marketing material relating to the securities or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this prospectus nor any other offering or marketing material relating to the offering, the Company or the securities have been or will be filed with or approved by any Swiss regulatory authority. In particular, this prospectus will not be filed with, and the offer of securities will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA, and the offer of securities has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes (CISA). The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of securities.

#### LEGAL MATTERS

The validity of the shares of our common stock offered in this prospectus will be passed upon for us by Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP, Boston, Massachusetts. Certain investment partnerships comprised of partners of Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP, own an interest representing less than one percent of the shares of our common stock. Davis Polk & Wardwell LLP, New York, New York, has acted as counsel for the underwriters in connection with this offering.

#### **EXPERTS**

The financial statements as of December 31, 2020 and 2019 and for the years then ended included in this prospectus have been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report appearing herein. Such financial statements have been so included in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

#### WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act, with respect to the shares of common stock offered by this prospectus. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits, schedules and amendments to the registration statement. Please refer to the registration statement and to the exhibits and schedules for further information with respect to the common stock offered by this prospectus. Statements contained in this prospectus regarding the contents of any contract, agreement or other document are only summaries. With respect to any contract, agreement or document that is filed as an exhibit to the registration statement, you should refer to the exhibit for a copy of the contract, agreement or document, and each statement in this prospectus regarding that contract, agreement or document is qualified by reference to the exhibit. The SEC maintains an Internet website that contains the registration statement of which this prospectus forms a part, as well as the exhibits thereto. These documents, along with future reports, proxy statements and other information about us, are available at the SEC's website, www.sec.gov. The information on the SEC's web site is not part of this prospectus, and any references to this web site or any other web site are inactive textual references only.

Upon completion of this offering, we will become subject to the information and reporting requirements of the Exchange Act, and, in accordance with this law, will be required to file periodic reports, proxy statements and other information with the SEC. These periodic reports, proxy statements and other information will be available on the SEC's website referred to above. We also maintain a website at www.tscan.com, at which you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. The information contained on, or that can be accessed through, our website is not a part of this prospectus. Investors should not rely on any such information in deciding whether to purchase our common stock. We have included our website address in this prospectus solely as an inactive textual reference.

# TSCAN THERAPEUTICS, INC.

# INDEX TO THE CONSOLIDATED FINANCIAL STATEMENTS

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#### 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, 2019 and 2020, the related consolidated statements of operations, convertible preferred stock and stockholders' 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, 2019 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 19, 2021

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

# TScan Therapeutics, Inc.

## **Consolidated Balance Sheets**

# (in thousands, except share and per share data)

|  | Decem     |           |
|--|-----------|-----------|
| A  | 2019      | 2020      |
| Assets Current assets:   |           |           |
|  | \$ 41,764 | \$ 34,791 |
| Cash and cash equivalents Prepaid expenses and other current assets  | 615       | 1,654     |
| • •  |           |           |
| Total current assets   | 42,379    | 36,445    |
| Property and equipment, net  | 1,640     | 5,659     |
| Right-of-use assets  | 4,769     | 6,873     |
| Restricted cash  | 595       | 595       |
| Long-term deposit  |           | 166       |
| Total assets   | \$ 49,383 | \$ 49,738 |
| Liabilities, Convertible Preferred Stock and Stockholders' Deficit   |           |           |
| Current liabilities:   |           |           |
| Accounts payable   | \$ 1,010  | \$ 2,910  |
| Accrued expenses and other current liabilities   | 943       | 2,494     |
| Operating lease liability, current portion   | 443       | 1,415     |
| Deferred revenue, current portion  |           | 10,627    |
| Total current liabilities  | 2,396     | 17,446    |
| Deferred revenue, net of current portion   | _         | 8,816     |
| Operating lease liability, net of current portion  | 4,444     | 6,019     |
| Other long-term liabilities  | _         | 238       |
| Total liabilities  | 6,840     | 32,519    |
| Commitments and contingencies (Note 10)  |           |           |
| Convertible preferred stock (Note 6)   | 59,681    | 59,681    |
| Stockholders' deficit:   | ,         | ĺ         |
| Common stock, \$0.0001 par value; 86,000,000 shares authorized; 12,021,875 and 12,907,933 shares issued; and |           |           |
| 5,271,875 and 9,314,183 shares outstanding as of December 31, 2019 and 2020, respectively                    | _         | 1         |
| Additional paid-in-capital   | 268       | 1,070     |
| Accumulated deficit  | (17,406)  | (43,533)  |
| Total stockholders' deficit  | (17,138)  | (42,462)  |
| Total liabilities, convertible preferred stock and stockholders' deficit                                     | \$ 49,383 | \$ 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  | l December 31, |
|---|-------------|----------------|
|   | 2019        | 2020           |
| Revenue:  |             |                |
| Collaboration and license revenue                             | \$ —        | \$ 1,085       |
| Operating expenses:   |             |                |
| Research and development                                      | 9,442       | 20,577         |
| General and administrative                                    | 4,768       | 6,741          |
| Total operating expenses                                      | 14,210      | 27,318         |
| Loss from operations  | (14,210)    | (26,233)       |
| Other income:   |             |                |
| Interest income   | 552         | 106            |
| Net loss  | \$ (13,658) | \$ (26,127)    |
| Net loss per share, basic and diluted                         | \$ (4.33)   | \$ (3.48)      |
| Weighted average common shares outstanding, basic and diluted | 3,157,800   | 7,511,378      |

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

# TScan Therapeutics, Inc.

# Consolidated Statements of Convertible Preferred Stock and Stockholders' Deficit

# (in thousands, except share and per share data)

|   | Convert<br>Preferred |          | Common Stock |        | Additional<br>Paid-In Accumulated |             | Total<br>Stockholders' |
|---|----------------------|----------|--------------|--------|-----------------------------------|-------------|------------------------|
|   | Shares               | Amount   | Shares       | Amount | Capital                           | Deficit     | Deficit                |
| Balance at January 1, 2019                              | 26,315,790           | \$24,874 | 562,500      | \$ —   | \$ 23                             | \$ (3,748)  | \$ (3,725)             |
| Issuance of Series B Preferred Stock (net of issuance   |                      |          |              |        |                                   |             |                        |
| costs of \$193)   | 31,601,732           | 34,807   | _            | _      | _                                 | _           | _                      |
| Issuance of common stock upon exercise of stock options | _                    | _        | 21,875       | _      | 5                                 | _           | 5                      |
| Vesting of restricted common stock                      | _                    | _        | 4,687,500    | _      |                                   | _           | _                      |
| Stock-based compensation expense                        | _                    | _        | _            | _      | 240                               | _           | 240                    |
| Net loss  |                      |          |              |        |                                   | (13,658)    | (13,658)               |
| Balances at December 31, 2019                           | 57,917,522           | 59,681   | 5,271,875    | _      | 268                               | (17,406)    | (17,138)               |
| Issuance of common stock upon exercise of stock options | _                    | _        | 1,167,308    | 1      | 287                               | _           | 288                    |
| Vesting of restricted common stock                      |                      |          | 2,875,000    | _      | _                                 | _           | _                      |
| Stock-based compensation expense                        | _                    | _        | _            | _      | 515                               | _           | 515                    |
| Net loss  | _                    | _        | _            | _      | _                                 | (26,127)    | (26,127)               |
| Balances at December 31, 2020                           | 57,917,522           | \$59,681 | 9,314,183    | \$ 1   | \$ 1,070                          | \$ (43,533) | \$ (42,462)            |

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

# TScan Therapeutics, Inc.

## **Consolidated Statements of Cash Flows**

# (in thousands)

|  | Year Ended<br>December 31, |           |  |
|--|----------------------------|-----------|--|
|  | 2019                       | 2020      |  |
| Cash flows from operating activities:  |                            |           |  |
| Net loss   | (13,658)                   | (26,127)  |  |
| Adjustment to reconcile net loss to net cash used in operating activities:     |                            |           |  |
| Depreciation expense   | 519                        | 1,230     |  |
| Stock-based compensation expense   | 240                        | 515       |  |
| Loss on sale of property and equipment   | 78                         | 2         |  |
| Changes in current assets and liabilities:                                     |                            |           |  |
| Prepaid expenses and other assets  | (459)                      | (1,205)   |  |
| Right-of-use assets and lease liabilities, net                                 | 115                        | 442       |  |
| Accounts payable   | 161                        | 1,127     |  |
| Accrued expense and other liabilities  | 482                        | 1,550     |  |
| Deferred revenue   |                            | 19,443    |  |
| Net cash used in operating activities  | (12,522)                   | (3,023)   |  |
| Cash flows from investing activities:  |                            |           |  |
| Purchases of property and equipment  | (1,247)                    | (4,238)   |  |
| Net cash used in investing activities  | (1,247)                    | (4,238)   |  |
| Cash flows from financing activities:  |                            |           |  |
| Proceeds from issuance of convertible preferred stock, net of issuance costs   | 34,807                     | _         |  |
| Proceeds from exercise of stock options  | 5                          | 288       |  |
| Net cash provided by financing activities                                      | 34,812                     | 288       |  |
| Net increase (decrease) in cash, cash equivalents and restricted cash          | 21,043                     | (6,973)   |  |
| Cash, cash equivalents, and restricted cash—beginning of year                  | 21,316                     | 42,359    |  |
| Cash, cash equivalents, and restricted cash—end of year                        | \$ 42,359                  | \$ 35,386 |  |
| Supplemental cash flow information:  | <u> </u>                   |           |  |
| Purchase of property and equipment in accounts payable and accrued liabilities | \$ 323                     | \$ 1,335  |  |
| Right-of-use-assets obtained in exchange for operating lease liabilities       | \$ 4,981                   | \$ 3,199  |  |

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

#### TSCAN THERAPEUTICS, INC.

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### 1. Nature of Business and Basis of Presentation

### Nature of Business

TScan Therapeutics, Inc. and subsidiary (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.

## 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 a going concern basis, which contemplates the 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 and with payments received under its license and collaboration agreements. Since its inception, the Company has incurred recurring losses, including net losses of \$13.7 million and \$26.1 million for the years ended December 31, 2019 and 2020, respectively. As of December 31, 2020, the Company had an accumulated deficit of \$43.5 million. The Company expects to continue to incur additional losses and negative operating cash flows in the foreseeable future. The Company expects that its cash and cash equivalents as of December 31, 2020, along with the net cash proceeds from the sale of shares of its convertible preferred stock in January 2021 (see Note 14) will be sufficient to fund the Company's operations for at least the next twelve months from the date of the issuance of the accompanying financial statements.

The Company is seeking to complete an initial public offering (IPO) of its common stock. Upon completion of a qualified public offering on specified terms, the Company's outstanding convertible preferred stock will automatically convert into shares of common stock (see Note 7). In the event the Company does not complete an IPO, the Company expects to seek additional funding through private equity financings, debt financings, strategic alliances and marketing, distribution, or licensing arrangements. The Company may not be able to obtain financing on acceptable terms, or at all, and may not be able to enter into collaborations or other arrangements. The terms of any financing may adversely affect the holdings or the rights of the Company's stockholders. If the Company is unable to secure funding, it could be forced to delay, reduce, or eliminate some or all of its research development programs, therapy portfolio expansion or commercialization efforts, which could adversely affect its business prospects. Although management continues to pursue these plans, there is no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations, if at all.

## **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.

## 2. Summary of Significant Accounting Policies

### **Basis of Presentation**

The Company's consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (US GAAP). Any reference in these notes to applicable guidance is meant to refer to the authoritative U.S. GAAP as found in the Accounting Standards Codification (ASC) and Accounting Standards Updates (ASUs) issued by 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 agreement, the Company is required to provide a letter of credit of \$0.6 million for the benefit of the landlord to serve as a security deposit. As of December 31, 2019 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 one financial institution often exceed federally insured limits. The Company places its cash in a financial institution 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.

## Deferred offering costs

The Company capitalizes certain legal, professional accounting and other third party fees that are directly associated with the proposed IPO as deferred offering costs. The deferred offering costs will be offset against the IPO proceeds upon the consummation of the IPO. In the event the IPO is abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the consolidated statements of operations. The Company had no deferred costs capitalized for the year ended on December 31, 2019 and an immaterial amount of deferred offering costs as of December 31, 2020.

## 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, 2019 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

As the preferred stock contains redemption features in a deemed liquidation event that are not solely within the control of the Company, the outstanding preferred stock has been classified outside of stockholders' deficit. The Company's convertible preferred stock is subject to a dividend when and if declared by the Board. From inception through December 31, 2020, no dividend has been declared.

### 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' deficit that result from transactions and economic events other than those with stockholders. For the years ended December 31, 2019 and 2020, 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):

|   | Decem   | ıber 31, |
|---|---------|----------|
|   | 2019    | 2020     |
| Laboratory equipment                            | \$1,836 | \$ 5,615 |
| Leasehold improvements                          | 19      | 493      |
| Office and computer equipment                   | 87      | 202      |
| Furniture and fixtures                          | 224     | 326      |
| Construction-in-progress                        |         | 778      |
| Property and equipment                          | 2,166   | 7,414    |
| Less: accumulated depreciation and amortization | (526)   | (1,755)  |
| Property and equipment, net                     | \$1,640 | \$ 5,659 |

Depreciation and amortization expense for the years ended December 31, 2019 and 2020 was \$0.5 million and \$1.2 million, respectively.

#### 4. Fair Value Measurements

The following table sets forth by level, within the fair value hierarchy, the assets (liabilities) carried at fair value (in thousands):

|                                     |                             | Fair value measurements                       |   |         |
|-------------------------------------|-----------------------------|---|---|---------|
|                                     | at December 31, 2019 using: |   |   |         |
|                                     | Level 1                     | Level 2                                       | Level 3                                       | Total   |
| Assets:                             |                             | <u> </u>                                      |   |         |
| Cash equivalents—money market funds | \$3,772                     | <u> </u>                                      | <u> </u>                                      | \$3,772 |
| Total financial assets              | \$3,772                     | <u>\$                                    </u> | <u>\$                                    </u> | \$3,772 |

The following table sets forth by level, within the fair value hierarchy, the assets (liabilities) carried at fair value (in thousands):

|                                     | Fair value measurements at<br>December 31, 2020 using: |         |         |          |
|-------------------------------------|--|---------|---------|----------|
|                                     | Level 1  | Level 2 | Level 3 | Total    |
| Cash equivalents—money market funds | \$33,748   | \$ —    | \$ —    | \$33,748 |
| Total of 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 assets and liabilities.

## 5. Accrued Expenses and Other Current Liabilities

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

|  | December 31, |         |
|--|--------------|---------|
|  | 2019         | 2020    |
| Accrued employee compensation and benefits           | \$840        | \$1,535 |
| Accrued consulting and professional services         | 8            | 189     |
| Accrued legal services and license fee               | 64           | 578     |
| Other  | 31           | 192     |
| Total accrued expenses and other current liabilities | \$943        | \$2,494 |

## 6. Convertible Preferred Stock

## Series A Preferred Stock

In 2018, the Company entered into the Series A Preferred Stock Purchase Agreement with its founding investors providing \$25 million in Series A Preferred Stock equity financing and issued 26,315,790 shares of Series A Preferred Stock. Issuance costs associated with the transaction were \$0.1 million.

## Series B Preferred Stock

In 2019, the Company entered into the Series B Preferred Stock Purchase Agreements providing \$35 million in Series B Preferred Stock equity financing and issued 31,601,732 shares of Series B Preferred Stock. Issuance costs associated with the transaction were \$0.2 million.

As of each balance sheet date, the preferred stock consisted of the following (in thousands, except for share data):

|   | December 31, 2019                |   |                                |                           |   |
|---|----------------------------------|---|--------------------------------|---------------------------|---|
|   | Preferred<br>Stock<br>Authorized | Preferred<br>Stock<br>Issued and<br>Outstanding | Carrying<br>Value              | Liquidation<br>Preference | Common<br>stock<br>issuable<br>upon<br>conversion |
| Series A Preferred Stock                          | 26,315,790                       | 26,315,790                                      | \$ 24,874                      | \$ 27,622                 | 26,315,790  |
| Series B Preferred Stock                          | 31,601,732                       | 31,601,732                                      | 34,807                         | 36,138                    | 31,601,732  |
|   | 57,917,522                       | 57,917,522                                      | \$ 59,681                      | \$ 63,760                 | 57,917,522  |
|   |                                  |   |                                |                           |   |
|   |                                  | De  | ecember 31, 202                | 0                         |   |
|   | Preferred<br>Stock<br>Authorized | Preferred<br>Stock<br>Issued and<br>Outstanding | ecember 31, 202 Carrying Value | Liquidation Preference    | Common<br>stock<br>issuable<br>upon<br>conversion |
| Series A Preferred Stock                          | Stock                            | Preferred<br>Stock<br>Issued and                | Carrying                       | Liquidation               | stock<br>issuable<br>upon                         |
| Series A Preferred Stock Series B Preferred Stock | Stock<br>Authorized              | Preferred<br>Stock<br>Issued and<br>Outstanding | Carrying<br>Value              | Liquidation<br>Preference | stock<br>issuable<br>upon<br>conversion           |

The terms and conditions of the Series A Preferred Stock and Series B Preferred Stock (collectively the Preferred Stock) are as follows:

#### Dividends

Dividends shall accrue at the rate of 8% compounded annually and are cumulative in nature (Accruing Dividends). Dividends are payable only when and if declared by the Board. The Company shall not declare, pay, or set aside any dividends on shares of any class of common stock, unless the holders of the Preferred Stock shall first receive dividends on each outstanding share of Preferred Stock in the amount of the accrued dividends unpaid as of such date. No dividends have been declared or paid as of December 31, 2019 and 2020. The cumulative dividends at December 31, 2020 totaled \$8.9 million.

#### Liquidation

In the event of any liquidation, dissolution, or winding-up of the Company, which would include the sale of the Company, the holders of the Preferred Stock are entitled to a liquidation preference. The amount to be paid to the holders of Preferred Stock is an amount equal to the greater of (i) the original purchase price per share, plus all Accruing Dividends accrued but unpaid thereon applicable to the series of Preferred Stock (which Accruing Dividends shall be paid out in cash), whether or not declared, together with any other dividends declared but unpaid thereon or (ii) such amount per share as would have been payable had all shares of Preferred Stock been converted to common stock prior to such liquidation, dissolution, or winding up of the Company. The original issue purchase price per share of the Series A Preferred Stock was \$0.95 per share, and the original issue price of the Series B Preferred Stock was \$1.10 per share. The holders of the Series B Preferred Stock are entitled to receive their respective liquidation preference with respect to the Series B Preferred Stock in full before any liquidation preference is paid upon the shares of Series A Preferred Stock. Any assets remaining following the preferential distribution to the holders of Series A Preferred Stock and Series B Preferred Stock would be available for distribution ratably among the holders of common stock.

#### Voting

The holders of the Preferred Stock are entitled to the number of votes equal to the number of shares of common stock into which the shares of the Preferred Stock held by each holder are then convertible. The holders of Preferred Stock are entitled to vote together with the holders of the Company's common stock, as a single class, on all matters submitted to a vote of stockholders. In addition, the holders of Series A Preferred Stock are entitled to elect four (4) directors and holders of Series B Preferred Stock are entitled to elect two (2) directors.

#### Conversion

The holders of Preferred Stock shall have the right to convert, at the option of the holder, at any time, into shares of common stock by dividing the preferred stock original issuance price by the conversion price in effect at the time. The initial Series A Preferred Stock conversion price is \$0.95 and the initial Series B Preferred Stock conversion price is \$1.10, subject in each case to certain adjustments to reflect the issuance of common stock, options, warrants, or other rights to subscribe for or to purchase shares of the Company's common stock for a consideration per share less than the conversion price then in effect. In addition, each share of Series A Preferred Stock and Series B Preferred Stock will automatically convert into shares of common stock at the applicable conversion ratio in effect upon the earlier of (a) the closing of a Qualified IPO (as defined in the Company's certificate of incorporation) or (b) the date and time, or the occurrence of an event, specified by vote or written consent of the holders of at least fifty-nine percent (59%) of the then outstanding shares of Preferred Stock (voting together as a single class, and not as separate series, and on an as converted to common stock basis).

#### Redemption

The Preferred Stock is not redeemable at the option of the holder. However, upon certain change in control events that are outside of the Company's control, including liquidation, sale or transfer of control of the Company, holders of the Preferred Stock can cause redemption of the Preferred Stock. Shares of Preferred Stock must be redeemed by the Company in an amount equal to the liquidation preference for each series of Preferred Stock. The Company classifies its Preferred Stock outside of stockholders' deficit as certain change in control events are outside the Company's control. As there is no certain redemption date and the redemption feature can only be triggered in the event of a liquidation, sale, or transfer of control of the Company or similar event, the Company has concluded that it is not probable that the Preferred Stock will become redeemable and as such does not accrete the Preferred Stock to the redemption value.

## 7. Stock Based Compensation

On April 20, 2018, the Company adopted the 2018 Stock Plan (the 2018 Plan). The 2018 Plan, as amended, provides for the issuance of up to 12,089,548 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. At December 31, 2020, there were 236,708 shares of common stock available for issuance under the 2018 Plan.

## **Stock Options**

In general, stock options typically vest over four years and have a maximum term is 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.

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 during the years ended December 31, 2019 and 2020, were as follows:

|  | 2019  | 2020  |
|--|-------|-------|
| Risk-free interest rate                        | 2.07% | 0.85% |
| Expected term (in years)                       | 6.00  | 6.05  |
| Expected dividend yield                        | 0%    | 0%    |
| Expected volatility of underlying common stock | 62%   | 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:

| Stock<br>Options | Weighted<br>Average<br>Exercise<br>Price   | Average<br>Remaining<br>Life<br>(in Years)  | •   | trinsic<br>Value<br>10usands)   |
|------------------|--|---|---|---|
| 10,585,801       | \$ 0.27  | 9.45  | \$  | 301   |
| 2,979,200        | 0.46   |   |   |   |
| (1,167,308)      | 0.25   |   |   |   |
| (544,853)        | 0.29   |   |   |   |
| 11,852,840       | \$ 0.32  | 8.74  | \$  | 3,799   |
| 11,852,840       | \$ 0.32  | 8.74  | \$  | 3,799   |
| 1,341,863        | \$ 0.25  | 8.87  | \$  | 71  |
| 2,973,359        | \$ 0.27  | 8.42  | \$  | 1,103   |
|                  | Options 10,585,801 2,979,200 (1,167,308) (544,853) 11,852,840 11,852,840 1,341,863 | Stock<br>Options         Average<br>Exercise<br>Price           10,585,801         \$ 0.27           2,979,200         0.46           (1,167,308)         0.25           (544,853)         0.29           11,852,840         \$ 0.32           11,841,863         \$ 0.25 | Stock Options         Average Exercise Price (in Years)         Remaining Life (in Years)           10,585,801         \$ 0.27         9.45           2,979,200         0.46         (1,167,308)         0.25           (544,853)         0.29         8.74           11,852,840         \$ 0.32         8.74           11,341,863         \$ 0.25         8.87 | Stock Options         Average Exercise Price Price         Remaining Life (in Years) (in the State of Stat |

The weighted average grant date calculated value of stock options granted for the years ended on December 31, 2019 and 2020 were \$0.16 and \$0.29 per share, respectively.

## **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 \$0.0001 per share. A summary of the activity for the year ended December 31, 2020 is as follows:

|   | Number of<br>Shares | Weighted<br>Average<br>Grant<br>Date Fair<br>Value |
|---|---------------------|--|
| Unvested restricted stock as of January 1, 2020   | 6,750,000           | \$ 0.00  |
| Granted   |                     | _  |
| Vested  | (2,875,000)         | 0.00   |
| Forfeitured                                       | (281,250)           | 0.00   |
| Unvested restricted stock as of December 31, 2020 | 3,593,750           | \$ 0.00  |

The aggregate fair value of restricted stock awards that vested during the years ended December 31, 2019 and 2020 was nominal.

## **Stock-Based Compensation Expense**

Stock-based compensation expense was as follows (in thousands):

|                            | Year          | Year Ended   |  |
|----------------------------|---------------|--------------|--|
|                            |               | December 31, |  |
|                            | 2019          | 2020         |  |
| Research and development   | 2019<br>\$110 | \$248        |  |
| General and administrative | 130           | 267          |  |
|                            | \$240         | \$515        |  |

As of December 31, 2020, there was \$1.7 million of unrecognized stock-based compensation expense related to unvested stock options and restricted common stock, which is estimated to be recognized over a period of 2.76 years.

## 8. Income Taxes

During the years ended December 31, 2019 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:

|                                     | Decembe | er 31,  |
|-------------------------------------|---------|---------|
|                                     | 2019    | 2020    |
| Tax at U.S. statutory rate          | 21.0%   | 21.0%   |
| Changes from statutory rate:        |         |         |
| State taxes, net of federal benefit | 6.3%    | 7.8%    |
| Tax credits                         | 5.7%    | 3.8%    |
| Stock-based compensation            | (0.3)%  | (0.3)%  |
| Change in valuation allowance       | (32.5)% | (32.3)% |
| Other                               | (0.2)%  | 0.0%    |
| 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):

|                                      | Decen     | December 31, |  |
|--------------------------------------|-----------|--------------|--|
|                                      | 2019      | 2020         |  |
| Deferred tax assets:                 |           |              |  |
| Net operating loss carryforwards     | \$ 3,760  | \$ 4,755     |  |
| Tax credits                          | 715       | 2,087        |  |
| Deferred revenue                     | _         | 5,312        |  |
| Depreciation and amortization        | 20        | 105          |  |
| Start up costs                       | 520       | 617          |  |
| Stock-based compensation             | 17        | 40           |  |
| Lease liability                      | 1,353     | 2,031        |  |
| Other deferred tax assets            | 230       | 664          |  |
| Total deferred tax assets            | 6,615     | 15,611       |  |
| Deferred tax liabilities:            |           |              |  |
| Right-of-use assets                  | (1,320)   | (1,878)      |  |
| Valuation allowance                  | (5,295)   | (13,733)     |  |
| Net deferred tax asset & liabilities | <u>\$</u> | <u>\$</u>    |  |

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 \$4.3 and \$8.4 million during the years ended December 31, 2019 and 2020, respectively.

As of December 31, 2020, the Company had U.S. federal net operating loss carryforwards of approximately \$17.6 million. The U.S. federal net operating losses have an indefinite life carryforward. As of December 31, 2020, the Company had Massachusetts net operating loss carryforwards of approximately \$16.7 million that expire at various dates through 2040. As of December 31, 2020, the Company had U.S. R&D federal credit carryforwards of approximately \$1.5 million that expire at various dates through 2040. As of December 31, 2020, the Company had U.S. state R&D tax credit carryforwards of approximately \$0.8 million that expire at various dates through 2035.

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, 2019 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. At December 31, 2020, 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. Under the Novartis Agreement, the Company 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 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 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.

As of December 31, 2020, 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 year ended December 31, 2020, the Company recognized \$0.8 million of revenue associated with the Novartis Agreement based on performance completed during that period. Additionally, during the year ended December 31, 2020, the Company incurred \$0.2 million 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, 2020, the Company had current and long-term deferred revenue of \$10.6 million and \$8.8 million, respectively due to Novartis Agreement.

#### Qiagen

On November 5, 2020, the Company entered into an Option and Exclusive License Agreement with QIAGEN Sciences, LLC (Qiagen), pursuant to which Company licensed to Qiagen intellectual property relating to specific, identified peptides to enable Qiagen to develop and commercialize diagnostics related to COVID-19. The Company has not identified any performance obligations under this agreement other than the delivery of certain intellectual property that was delivered at the inception of the agreement. Qiagen paid the Company a nominal upfront non-refundable payment of \$0.2 million with the potential for additional payments that become payable upon successful achievement of certain clinical and commercial milestones achieved by Qiagen. The initial payment is included in revenue for the period and the additional payments will not be recognized until the milestones are probable of being achieved.

### Poseida Therapeutics

On October 19, 2020, the Company entered into an arrangement with Poseida Therapeutics, Inc. (Poseida), pursuant to which Poseida paid the Company a nominal fee in exchange for certain data. The Company does not have any remaining performance obligations under this arrangement and does not expect future revenues to be significant.

#### 10. Commitments and Contingencies

#### Leases

The Company leases for laboratory and office space with a term that expires in 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.

Additional, laboratory and office space was 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 recorded as a long-term asset.

## Summary of lease cost

The Company lease costs is \$0.6 million and \$1.3 million for the years ended December 31, 2019 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):

|   | December 31, |         |
|---|--------------|---------|
|   | 2019         | 2020    |
| Cash paid for amounts included in the measurement of lease liabilities: |              |         |
| Operating cash flows for operating leases                               | \$679        | \$1,478 |

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

|  | 1cai c    | nucu         |  |
|--|-----------|--------------|--|
|  | Deceml    | December 31, |  |
|  | 2019      | 2020         |  |
| Weighted-average remaining lease term (in years) | 4.5 years | 4.4 years    |  |
| Weighted-average discount rate                   | 8.0%      | 8.0%         |  |

Vear ended

The following table represents the maturity of the Company's operating lease liabilities as of December 31, 2020 (in thousands):

#### Year Ending December 31,

|  | Operating                  |
|--|----------------------------|
| 2021                                       | \$ 1,948                   |
| 2022                                       | 2,075                      |
| 2023                                       | 2,131                      |
| 2024                                       | 1,812                      |
| 2025                                       | 729                        |
| Thereafter                                 | 184<br>8,879               |
| Total future minimum lease payments        | 8,879                      |
| Less: imputed interest                     | (1,445)                    |
| Present value of operating lease liability | (1,445)<br><u>\$ 7,434</u> |
|  |                            |

### **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 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. The Company is negotiating an amendment of the license agreement with BWH. The potential amendment would include an exclusive license to new technology and certain changes to the fee and royalty structure that the Company does not expect to have a material impact on the financial statements.

## **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 affiliatedentities 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 \$0.1 million and \$0.2 million were recorded for the years ended December 31, 2019 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 amounts):

|   | Year ended<br>December 31, |             |
|---|----------------------------|-------------|
|   | 2019                       | 2020        |
| Numerator:  |                            |             |
| Net loss  | \$ (13,658)                | \$ (26,127) |
| Denominator:  |                            |             |
| Weighted-average common shares outstanding, basic and diluted | 3,157,800                  | 7,511,378   |
| Net loss per share, basic and diluted                         | \$ (4.33)                  | \$ (3.48)   |

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:

|   | Year ended<br>December 31, |            |
|---|----------------------------|------------|
|   | 2019                       | 2020       |
| Series A Preferred Stock (as converted to common stock) | 26,315,790                 | 26,315,790 |
| Series B Preferred Stock (as converted to common stock) | 31,601,732                 | 31,601,732 |
| Unvested restricted common stock                        | 6,750,000                  | 3,593,750  |
| Options to purchase common stock                        | 10,585,801                 | 11,852,840 |
|   | 75,253,323                 | 73,364,112 |

## 13. Related-Party Transactions

Certain employees of Longwood Fund, a stockholder of the Company, including board of directors member Christoph Westphal, provided management services to the Company. Personnel and consulting expenses of \$0.6 million were recognized in general and administrative expenses for year ended on December 31, 2019. No such expenses were incurred for year ended on December 31, 2020.

The Company has received professional services from founders of the Company. Consulting expenses of \$0.3 million and \$0.2 million were recognized in general and administrative expenses for the years ended December 31, 2019 and 2020, respectively.

Novartis and its affiliates held shares of the Preferred Stock and entered into the Novartis Agreement discussed in Note 9.

## 14. Subsequent Events

For the year ended December 31, 2020, the Company evaluated subsequent events as of March 19, 2021, the date the audited consolidated financial statements were issued.

## Series C Preferred Stock financing

On January 15, 2021, the Company entered into the Series C Preferred Stock Purchase Agreement and completed the sale of \$100 million in Series C Preferred Stock. The Company authorized and sold 70,136,064 shares of Series C Preferred Stock with an issue price of \$1.43 per share. In connection with the issuance of Series C Preferred Stock, the Company increased the authorized number of shares of common stock, resulting in 165,210,543 authorized common shares as of January 15, 2021.

## Increase in shares available for issuance under the 2018 Plan

On January 15, 2021, the number of shares of common stock authorized for issuance under the 2018 Plan was increased from 12,089,548 shares to 22,609,958 shares.

#### Grant of stock options under the 2018 Plan

On January 27, 2021, the Company granted options with service-based vesting criteria for the purchase of an aggregate of 8,410,509 shares of common stock, at an exercise price of \$0.71 per share.

On March 16, 2021, the Company granted options with service-based vesting criteria for the purchase of an aggregate of 635,000 shares of common stock, at an exercise price of \$1.41 per share.

#### PART II

#### **Information not Required in Prospectus**

#### Item 13. Other Expenses of Issuance and Distribution

The following table presents the costs and expenses, other than underwriting discounts and commissions, payable in connection with this offering. All amounts are estimates except the SEC registration fee, the FINRA filing fee and listing fee.

| SEC registration fee              | \$<br>10,910.00 |
|-----------------------------------|-----------------|
| FINRA filing fee                  | 15,500.00       |
| Exchange listing fee              | 25,000.00       |
| Printing and engraving expenses   | *               |
| Legal fees and expenses           | *               |
| Accounting fees and expenses      | *               |
| Transfer agent and registrar fees | *               |
| Miscellaneous fees and expenses   | *               |
| Total                             | \$<br>*         |

To be completed by amendment.

## Item 14. Indemnification of Directors and Officers

Section 145 of the Delaware General Corporation Law authorizes a court to award, or a corporation's board of directors to grant, indemnity to directors and officers under certain circumstances and subject to certain limitations. The terms of Section 145 of the Delaware General Corporation Law are sufficiently broad to permit indemnification under certain circumstances for liabilities, including reimbursement of expenses incurred, arising under the Securities Act of 1933, as amended, or the Securities Act.

As permitted by the Delaware General Corporation Law, the Registrant's amended and restated certificate of incorporation and amended and restated bylaws contain provisions relating to the limitation of liability and indemnification of directors and officers. The amended and restated certificate of incorporation provides that the Registrant's directors will not be personally liable to the Registrant or the Registrant's stockholders for monetary damages for any breach of fiduciary duty as a director, except for liability:

- for any breach of the director's duty of loyalty to the Registrant or the Registrant's stockholders;
- for acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- in respect of unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the Delaware General Corporation Law; or
- for any transaction from which the director derives any improper personal benefit.

The Registrant's amended and restated certificate of incorporation also provides that if Delaware law is amended after the approval by the Registrant's stockholders of the certificate of incorporation to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of the Registrant's directors will be eliminated or limited to the fullest extent permitted by Delaware law.

The Registrant's amended and restated bylaws provide that the Registrant will indemnify its directors and officers to the fullest extent permitted by Delaware law, as it now exists or may in the future be amended, against

all expenses and liabilities reasonably incurred in connection with their service for or on the Registrant's behalf. The Registrant's amended and restated bylaws provide that the Registrant shall advance the expenses incurred by a director or officer in advance of the final disposition of an action or proceeding, and permit the Registrant to secure insurance on behalf of any director, officer, employee, or other enterprise agent for any liability arising out of his or her action in that capacity, whether or not Delaware law would otherwise permit indemnification.

The Registrant intends to enter into indemnification agreements with each of its directors and executive officers and certain other key employees, a form of which is attached as Exhibit 10.1. The form of agreement provides that the Registrant will indemnify each of its directors, executive officers and such other key employees against any and all expenses incurred by that director, executive officer, or other key employee because of his or her status as one of the Registrant's directors, executive officers, or other key employees, to the fullest extent permitted by Delaware law, the Registrant's restated certificate of incorporation and the Registrant's amended and restated bylaws. In addition, the form agreement provides that, to the fullest extent permitted by Delaware law, the Registrant will advance all expenses incurred by its directors, executive officers and other key employees in connection with a legal proceeding.

Reference is made to the underwriting agreement contained in Exhibit 1.1 to this registration statement, indemnifying the Registrant's directors and officers against limited liabilities. In addition, Section 2.8 of the Registrant's fourth amended and restated investors' rights agreement, or the IRA, contained in Exhibit 4.2 to this registration statement provides for indemnification of certain of the Registrant's stockholders against liabilities described in the Registrant's IRA and Section 2.6 of the Registrant's registration rights agreement with the BBA Funds contained in Exhibit 4.3 to this registration statement provides for indemnification of the BBA Funds against liabilities described in such agreement.

The Registrant currently carries and intends to continue to carry liability insurance for its directors and officers.

#### Item 15. Recent sales of Unregistered Securities

The following list sets forth information regarding all unregistered securities sold by the Registrant in the three years preceding this registration statement. No underwriters were involved in the sales and the certificates representing the securities sold and issued contain legends restricting transfer of the securities without registration under the Securities Act or an applicable exemption from registration.

#### Stock Plan Related Issuances

- (a) From April 30, 2018 through April 30, 2021, the Registrant granted to its directors, officers, employees, consultants and other service providers stock options to purchase an aggregate of 24,766,208 shares of common stock upon the exercise of options under the Registrant's 2018 Stock Plan at exercise prices per share ranging from \$0.24 to \$1.70, for an aggregate exercise price of approximately \$13.6 million.
- (b) From April 30, 2018 through April 30, 2021, the Registrant issued an aggregate of 2,080,299 shares of common stock upon the exercise of options, at exercise prices ranging from \$0.24 to \$0.30 per share, for an aggregate exercise price of approximately \$0.5 million.

Sales of Convertible Preferred Stock and Common Stock

(c) In June 2018 and December 2018, the Registrant issued and sold an aggregate of 26,315,790 shares of its Series A convertible preferred stock at a purchase price of \$0.95 per share for an aggregate purchase price of approximately \$25.0 million.

Exhibit

- (d) In July 2019, August 2019 and November 2019, the Registrant issued and sold an aggregate of 31,601,732 shares of its Series B convertible preferred stock at a purchase price of \$1.10 per share for an aggregate purchase price of approximately \$35.0 million.
- (e) In January 2021, the Registrant issued and sold an aggregate of 70,136,064 shares of its Series C convertible preferred stock at a purchase price of \$1.4258 per share for an aggregate purchase price of approximately \$100.0 million.

No underwriters were involved in the foregoing issuances of securities. The offers, sales and issuances of the securities described in Items (a) and (b) above were exempt from registration under the Securities Act under either (1) Rule 701 in that the transactions were under compensatory benefit plans and contracts relating to compensation as provided under Rule 701 or (2) Section 4(a)(2) of the Securities Act or Regulation D promulgated thereunder as transactions by an issuer not involving any public offering. The recipients of such securities were the Registrant's directors, officers, employees, consultants or other service providers and received the securities under the Registrant's 2018 Stock Plan. The recipients of securities in each of these transactions represented their intention to acquire the securities for investment only and not with view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions.

The offers, sales and issuances of the securities described in Items (c), (d) and (e) above were exempt from registration under the Securities Act under Section 4(a)(2) of the Securities Act or Regulation D promulgated thereunder as transactions by an issuer not involving a public offering. The recipients of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions was an accredited person and had adequate access, through employment, business or other relationships, to information about the registrant.

## Item 16. Exhibits and Financial Statement Schedules

(a) Exhibits. The following exhibits are included herein or incorporated herein by reference:

| Description  |
|--|
| Form of Underwriting Agreement.  |
| Fourth Amended and Restated Certificate of Incorporation of Registrant, as currently in effect.  |
| Form of Amended and Restated Certificate of Incorporation of Registrant, to be effective upon completion of this offering.                     |
| Bylaws of Registrant, as currently in effect.  |
| Form of Amended and Restated Bylaws of Registrant, to be effective upon completion of this offering.   |
| Fourth Amended and Restated Investors' Rights Agreement, dated January 15, 2021, by and among the Registrant and the other parties thereto.    |
| Registration Rights Agreement made as of January 15, 2021 by and between the Registrant and the other parties thereto.                         |
| Amended and Restated Nominating Agreement, dated April 22, 2021, by and among the Registrant, Baker Brothers Life Sciences, L.P. and 667, L.P. |
| Opinion of Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP.  |
|  |

| Number | Description  |
|--------|--|
| 10.1*  | Form of Indemnification Agreement between the Registrant and each of its directors and executive officers.   |
| 10.2*  | 2018 Stock Plan, as amended, and forms of agreements thereunder.   |
| 10.3*  | 2021 Equity Incentive Plan and form of agreements thereunder.  |
| 10.4   | 2021 Employee Stock Purchase Plan.   |
| 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. |
| 10.6*  | Lease by and between PPF OFF 828-830 Winter Street LLC and the Registrant, dated August 13, 2019.  |
| 10.7#* | Option & Exclusive License Agreement by and between the Registrant and QIAGEN Sciences LLC, dated as of November 5, 2020.                              |
| 10.8#* | Collaboration and License Agreement by and between the Registrant and Novartis Institutes for Biomedical Research, dated as of March 27, 2020.         |
| 10.9#* | Non-Exclusive License Agreement by and between the Registrant and Provincial Health Services Authority, dated as of October 15, 2020.                  |
| 10.10* | Amended and Restated Royalty Agreement, dated as of June 12, 2018.   |
| 10.11* | Services Agreement by and between Christoph Westphal and the Registrant, dated October 9, 2018.  |
| 10.12* | Amendment No. 1 to Services Agreement Services Agreement by and between Christoph Westphal and the Registrant, dated June 24, 2019.                    |
| 10.13* | Employment Agreement, dated April 23, 2021, by and between the Registrant and David Southwell.   |
| 10.14* | Employment Letter Agreement, dated April 23, 2021, by and between the Registrant and Gavin MacBeath, Ph.D.   |
| 10.15* | Employment Letter Agreement, dated April 8, 2019, by and between the Registrant and Henry Rath.  |
| 10.16* | Separation Agreement, dated January 26, 2021, by and between the Registrant and Henry Rath.  |
| 10.17* | Employment Letter Agreement, dated April 23, 2021, by and between the Registrant and William Desmarais.  |
| 10.18* | Form of Management Cash Incentive Plan.  |
| 23.1   | Consent of Deloitte & Touche LLP, Independent Registered Public Accounting Firm.   |
| 23.2^  | Consent of Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP (contained in Exhibit 5.1).   |
| 24.1*  | Power of Attorney (included on signature page).  |
|        |  |

<sup>\*</sup> Previously filed.^ To be filed by amendment.

<sup>#</sup> Certain portions of this agreement have been omitted because the omitted portions are both not material and consists of the type of information that the Registrant both customarily and actually treats as private and confidential.

(b) Financial Statement Schedules. All schedules have been omitted because the information required to be presented in them is not applicable or is shown in the financial statements or related notes.

## Item 17. Undertakings

The undersigned registrant hereby undertakes to provide to the underwriter at the closing specified in the underwriting agreements certificates in such denominations and registered in such names as required by the underwriter to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended, may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

The undersigned registrant hereby undertakes that:

- (1) For purposes of determining any liability under the Securities Act of 1933, as amended, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act of 1933, as amended, shall be deemed to be part of this registration statement as of the time it was declared effective.
- (2) For the purpose of determining any liability under the Securities Act of 1933, as amended, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

# **SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Waltham, Commonwealth of Massachusetts, on this 30th day of April, 2021.

# TScan Therapeutics, Inc.

/s/ David Southwell
David Southwell
Chief Executive Officer

# POWER OF ATTORNEY

Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

| <u>Signature</u>                    | <u>Title</u>  | <u>Date</u>    |
|-------------------------------------|---|----------------|
| /s/ David Southwell David Southwell | Chief Executive Officer and Director (Principal Executive Officer and Principal Financial and Principal Accounting Officer) | April 30, 2021 |
| * Timothy Barberich                 | _ Chairman  | April 30, 2021 |
| * Stephen Biggar, M.D., Ph.D.       | Director  | April 30, 2021 |
| * Katina Dorton                     | Director  | April 30, 2021 |
| * Ittai Harel                       | Director  | April 30, 2021 |
| * Andrew Hedin                      | Director  | April 30, 2021 |

| Signature                         | <u>Title</u> | <u>Date</u>    |
|-----------------------------------|--------------|----------------|
| * Brian Silver                    | Director     | April 30, 2021 |
| * Nandita Shangari, Ph.D.         | Director     | April 30, 2021 |
| * Christoph Westphal, M.D., Ph.D. | Director     | April 30, 2021 |

\*By: /s/ David Southwell

David Southwell Attorney-in-fact [ ] Shares

# TScan Therapeutics, Inc.

# COMMON STOCK (PAR VALUE \$0.0001 PER SHARE)

# UNDERWRITING AGREEMENT

[ ], 2021

Morgan Stanley & Co. LLC Jefferies LLC Cowen and Company, LLC Barclays Capital Inc.

as Representatives of the several Underwriters listed in Schedule I hereto

- c/o Morgan Stanley & Co. LLC 1585 Broadway New York, New York 10036
- c/o Jefferies LLC 520 Madison Avenue New York, New York 10022
- c/o Cowen and Company, LLC 599 Lexington Avenue New York, New York 10022
- c/o Barclays Capital Inc.745 Seventh AvenueNew York, New York 10019

#### Ladies and Gentlemen:

TScan Therapeutics, Inc., a Delaware corporation (the "Company"), proposes to issue and sell to the several Underwriters named in Schedule I hereto (the "Underwriters") an aggregate of [ ] shares of its voting common stock (par value \$0.0001 per share) (the "Firm Shares").

The Company also proposes to issue and sell to the several Underwriters not more than an additional [ ] shares of its voting common stock (par value \$0.0001 per share) (the "Additional Shares") if and to the extent that Morgan Stanley & Co. LLC, Jefferies LLC, Cowen and Company, LLC, and Barclays Capital Inc., as representatives of the offering (the "Representatives"), shall have determined to exercise, on behalf of the Underwriters, the right to purchase such shares of voting common stock granted to the Underwriters in Section 2 hereof. The Firm Shares and the Additional Shares are hereinafter collectively referred to as the "Shares." The shares of voting common stock (par value \$0.0001 per share) of the Company to be outstanding after giving effect to the sales contemplated hereby are hereinafter referred to as the "Common Stock."

The Company has filed with the Securities and Exchange Commission (the "Commission") a registration statement on Form S-1 (File No. 333-[ ]), including a preliminary prospectus, relating to the Shares. The registration statement as amended at the time it becomes effective, including the information (if any) deemed to be part of the registration statement at the time of effectiveness pursuant to Rule 430A under the Securities Act of 1933, as amended (the "Securities Act"), is hereinafter referred to as the "Registration Statement"; the prospectus in the form first used to confirm sales of Shares (or in the form first made available to the Underwriters by the Company to meet requests of purchasers pursuant to Rule 173 under the Securities Act) is hereinafter referred to as the "Prospectus." If the Company has filed an abbreviated registration statement to register additional shares of Common Stock pursuant to Rule 462(b) under the Securities Act (a "Rule 462 Registration Statement"), then any reference herein to the term "Registration Statement" shall be deemed to include such Rule 462 Registration Statement.

For purposes of this Agreement, "free writing prospectus" has the meaning set forth in Rule 405 under the Securities Act, "preliminary prospectus" shall mean each prospectus used prior to the effectiveness of the Registration Statement, and each prospectus that omitted information pursuant to Rule 430A under the Securities Act that was used after such effectiveness and prior to the execution and delivery of this Agreement, "Time of Sale Prospectus" means the preliminary prospectus contained in the Registration Statement at the time of its effectiveness together with the documents and pricing information set forth in Schedule II hereto, and "broadly available road show" means a "bona fide electronic road show" as defined in Rule 433(h)(5) under the Securities Act that has been made available without restriction to any person. For purposes of this Agreement, (a) except where otherwise expressly provided, the term "affiliate" has the meaning set forth in Rule 405 under the Securities Act; (b) the term "business day" means any day other than a day on which banks are permitted or required to be closed in New York City; and (c) the term "subsidiary" has the meaning set forth in Rule 405 under the Securities Act. As used herein, the terms "Registration Statement," "preliminary prospectus," "Time of Sale Prospectus" and "Prospectus" shall include the documents, if any, incorporated by reference therein as of the date hereof.

Morgan Stanley & Co. LLC (the "**DSP Underwriter**") has agreed to reserve a portion of the Shares to be purchased by it under this Agreement for sale to the Company's directors, officers, employees and business associates and other parties related to the Company (collectively, "**Participants**"), as set forth in each of the Time of Sale Prospectus and the Prospectus under the heading "Underwriters" (the "**Directed Share Program**"). The Shares to be sold by the DSP Underwriter and its affiliates pursuant to the Directed Share Program, at the direction of the Company, are referred to hereinafter as the "**Directed Shares**". Any Directed Shares not orally confirmed for purchase by any Participant by the end of the business day on which this Agreement is executed will be offered to the public by the Underwriters as set forth in the Prospectus.

1. Representations and Warranties. The Company represents and warrants to and agrees with each of the Underwriters that:

- (a) The Registration Statement has become effective; no stop order suspending the effectiveness of the Registration Statement is in effect, and no proceedings for such purpose or pursuant to Section 8A under the Securities Act are pending before or, to the Company's knowledge, threatened by the Commission.
- (b) (i) The Registration Statement, when it became effective, did not contain and, as amended or supplemented, if applicable, will not contain, as of the date of such amendment or supplement, any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading, (ii) the Registration Statement and the Prospectus comply and, as amended or supplemented, if applicable, will, as of the date of such amendment or supplement, comply in all material respects with the Securities Act and the applicable rules and regulations of the Commission thereunder, (iii) the Time of Sale Prospectus does not, and at the time of each sale of the Shares in connection with the offering when the Prospectus is not yet available to prospective purchasers and at the Closing Date (as defined in Section 4), the Time of Sale Prospectus, as then amended or supplemented by the Company, if applicable, will not, contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading, (iv) each broadly available road show, if any, when considered together with the Time of Sale Prospectus, does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading and (v) the Prospectus, as of its date, does not contain and, as amended or supplemented, if applicable, will not contain, as of the date of such amendment or supplement, any untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading, except that the representations and warranties set forth in this paragraph do not apply to statements or omissions in the Registration Statement, the Time of Sale Prospectus or the Prospectus based upon information relating to any Underwriter furnished to the Company in writing by such Underwriter through the Representatives expressly for use therein.
- (c) The Company is not an "ineligible issuer" in connection with the offering pursuant to Rules 164, 405 and 433 under the Securities Act. Any free writing prospectus that the Company is required to file pursuant to Rule 433(d) under the Securities Act has been, or will be, filed with the Commission in accordance with the requirements of the Securities Act and the applicable rules and regulations of the Commission thereunder. Each free writing prospectus, if any, that the Company has filed, or is required to file, pursuant to Rule 433(d) under the Securities Act or that was prepared by or on behalf of or used or referred to by the Company complies or, if filed after the effective time of this Agreement, will comply as of the date of such filing in all material respects with the requirements of the Securities Act and the applicable rules and regulations of the Commission thereunder. Except for the free writing prospectuses, if any, identified in Schedule II hereto, and electronic road shows, if any, each furnished to the Representatives before first use, the Company has not prepared, used or referred to, and will not, without the Representatives' prior consent, prepare, use or refer to, any free writing prospectus.

- (d) The Company has been duly incorporated, is validly existing as a corporation in good standing under the laws of the jurisdiction of its incorporation, has the corporate power and authority to own or lease its property and to conduct its business as described in each of the Registration Statement, the Time of Sale Prospectus and the Prospectus and is duly qualified to transact business and is in good standing (to the extent the concept of good standing is applicable in such jurisdiction) in each jurisdiction in which the conduct of its business or its ownership or leasing of property requires such qualification, except to the extent that the failure to be so qualified or be in good standing (to the extent the concept of good standing is applicable in such jurisdiction) would not reasonably be expected to, singly or in the aggregate, have a material adverse effect on the Company and its subsidiaries, taken as a whole.
- (e) Each subsidiary of the Company has been duly incorporated, organized or formed, is validly existing as a corporation or other business entity in good standing under the laws of the jurisdiction of its incorporation (to the extent the concept of good standing is applicable in such jurisdiction), organization or formation, has the corporate or other business entity power and authority to own or lease its property and to conduct its business as described in each of the Registration Statement, the Time of Sale Prospectus and the Prospectus and is duly qualified to transact business and is in good standing in each jurisdiction (to the extent the concept of good standing is applicable in such jurisdiction) in which the conduct of its business or its ownership or leasing of property requires such qualification, except to the extent that the failure to be so qualified or be in good standing (to the extent the concept of good standing is applicable in such jurisdiction) would not reasonably be expected to have a material adverse effect on the Company and its subsidiaries, taken as a whole; all of the issued shares of capital stock or other equity interests of each subsidiary of the Company have been duly and validly authorized and issued (to the extent such concepts are applicable in such jurisdictions), are fully paid and non-assessable and are owned directly or indirectly by the Company, free and clear of all liens, encumbrances, equities or claims.
  - (f) This Agreement has been duly authorized, executed and delivered by the Company.
- (g) The authorized capital stock of the Company conforms as to legal matters to the description thereof contained in each of the Registration Statement, the Time of Sale Prospectus and the Prospectus.

- (h) The shares of Common Stock outstanding prior to the issuance of the Shares have been duly authorized and are validly issued, fully paid and non-assessable.
- (i) The Shares have been duly authorized and, when issued, delivered and paid for in accordance with the terms of this Agreement, will be validly issued, fully paid and non-assessable, and the issuance of the Shares will not be subject to any preemptive or similar rights that have not been validly waived.
- (j) The execution and delivery by the Company of, and the performance by the Company of its obligations under, this Agreement will not contravene any provision of (i) applicable law, (ii) the certificate of incorporation and bylaws of the Company (iii) any agreement or other instrument binding upon the Company or any of its subsidiaries that is material to the Company and its subsidiaries, taken as a whole, or (iv) any judgment, order or decree of any governmental body, agency or court having jurisdiction over the Company or any subsidiary, except, in the cases of clauses (i), (iii) and (iv), as would not, individually or in the aggregate, reasonably be expected to have a material adverse effect on the Company and its subsidiaries, taken as a whole, or adversely affect the ability of the Company to perform its obligations under this Agreement, and no consent, approval, authorization or order of, or qualification with, any governmental body, agency or court is required for the performance by the Company of its obligations under this Agreement, except such as have been previously obtained or validly waived, or may be required by the securities or Blue Sky laws of the various states in connection with the offer and sale of the Shares.
- (k) There has not occurred any material adverse change, or any development involving a prospective material adverse change, in the condition, financial or otherwise, or in the earnings, business or operations of the Company and its subsidiaries, taken as a whole, from that set forth in the Time of Sale Prospectus.
- (l) There are no legal or governmental proceedings pending or, to the knowledge of the Company, threatened to which the Company or any of its subsidiaries is a party or to which any of the properties of the Company or any of its subsidiaries is subject other than proceedings accurately described in all material respects in each of the Registration Statement, the Time of Sale Prospectus and the Prospectus and proceedings that would not reasonably be expected to, singly or in the aggregate, have a material adverse effect on the Company and its subsidiaries, taken as a whole, or on the power or ability of the Company to perform its obligations under this Agreement or to consummate the transactions contemplated by each of the Registration Statement, the Time of Sale Prospectus and the Prospectus or that are required to be described in the Registration Statement, the Time of Sale Prospectus and are not so described in all material respects; and there are no statutes, regulations, contracts or other documents to which the Company or any of its subsidiaries is

subject or by which the Company or any of its subsidiaries is bound that are required to be described in the Registration Statement, the Time of Sale Prospectus or the Prospectus or to be filed as exhibits to the Registration Statement that are not described in all material respects or filed as required.

- (m) Each preliminary prospectus filed as part of the Registration Statement as originally filed or as part of any amendment thereto, or filed pursuant to Rule 424 under the Securities Act, complied when so filed in all material respects with the Securities Act and the applicable rules and regulations of the Commission thereunder.
- (n) The Company is not, and after giving effect to the offering and sale of the Shares and the application of the proceeds thereof as described in each of the Registration Statement, the Time of Sale Prospectus and the Prospectus will not be, required to register as an "investment company" as such term is defined in the Investment Company Act of 1940, as amended.
- (o) The Company and each of its subsidiaries (i) are in compliance with any and all applicable foreign, federal, state and local laws and regulations relating to the protection of human health and safety, the environment or hazardous or toxic substances or wastes, pollutants or contaminants ("Environmental Laws"), (ii) have received all permits, licenses or other approvals required of them under applicable Environmental Laws to conduct their respective businesses and (iii) are in compliance with all terms and conditions of any such permit, license or approval, except where such noncompliance with Environmental Laws, failure to receive required permits, licenses or other approvals or failure to comply with the terms and conditions of such permits, licenses or approvals would not, singly or in the aggregate, be reasonably expected to have a material adverse effect on the Company and its subsidiaries, taken as a whole.
- (p) There are no costs or liabilities associated with Environmental Laws (including, without limitation, any capital or operating expenditures required for clean-up, closure of properties or compliance with Environmental Laws or any permit, license or approval, any related constraints on operating activities and any potential liabilities to third parties) which would, singly or in the aggregate, be reasonably expected to have a material adverse effect on the Company and its subsidiaries, taken as a whole.
- (q) Except as validly waived or complied with in connection of the sale of the Shares contemplated hereby, there are no contracts, agreements or understandings between the Company and any person granting such person the right to require the Company to file a registration statement under the Securities Act with respect to any securities of the Company or to require the Company to include such securities with the Shares registered pursuant to the Registration Statement.

- (r) (i) None of the Company or any of its subsidiaries or controlled affiliates, or any director, officer, or employee thereof, or, to the Company's knowledge, any agent or representative of the Company or of any of its subsidiaries or controlled affiliates, has taken or will take any action in furtherance of an offer, payment, promise to pay, or authorization or approval of the payment, giving or receipt of money, property, gifts or anything else of value, directly or indirectly, to any government official (including any officer or employee of a government or government-owned or controlled entity or of a public international organization, or any person acting in an official capacity for or on behalf of any of the foregoing, or any political party or party official or candidate for political office) ("Government Official") in order to influence official action, or to any person in violation of any applicable anti-corruption laws; (ii) the Company and each of its subsidiaries and controlled affiliates have conducted their businesses in compliance with applicable anti-corruption laws and have instituted and maintained and will continue to maintain policies and procedures reasonably designed to promote and achieve compliance with such laws and with the representations and warranties contained herein; and (iii) neither the Company nor any of its subsidiaries will use, directly or indirectly, the proceeds of the offering in furtherance of an offer, payment, promise to pay, or authorization of the payment or giving of money, or anything else of value, to any person in violation of any applicable anti-corruption laws.
- (s) The operations of the Company and each of its subsidiaries are and have been conducted at all times in material compliance with all applicable financial recordkeeping and reporting requirements, including those of the Bank Secrecy Act, as amended by Title III of the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (USA PATRIOT Act), and the applicable anti-money laundering statutes of jurisdictions where the Company and each of its subsidiaries conduct business, the rules and regulations thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any governmental agency (collectively, the "Anti-Money Laundering Laws"), and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or any of its subsidiaries with respect to the Anti-Money Laundering Laws is pending or, to the best knowledge of the Company, threatened.
- (t) (i) None of the Company, any of its subsidiaries, or any director, officer, or employee thereof, or, to the Company's knowledge, any agent, controlled affiliate or representative of the Company or any of its subsidiaries, is an individual or entity ("**Person**") that is, or is owned or controlled by one or more Persons that are:
  - (A) the subject of any sanctions administered or enforced by the U.S. Department of the Treasury's Office of Foreign Assets Control, the United Nations Security Council, the European Union, Her Majesty's Treasury, or other relevant sanctions authority (collectively, "Sanctions"), or

- (B) located, organized or resident in a country or territory that is the subject of Sanctions (including, without limitation, Crimea, Cuba, Iran, North Korea and Syria).
- (ii) The Company will not, directly or indirectly, use the proceeds of the offering, or lend, contribute or otherwise make available such proceeds to any subsidiary, joint venture partner or other Person:
  - (A) to fund or facilitate any activities or business of or with any Person or in any country or territory that, at the time of such funding or facilitation, is the subject of Sanctions; or
  - (B) in any other manner that will result in a violation of Sanctions by any Person (including any Person participating in the offering, whether as underwriter, advisor, investor or otherwise).
- (iii) The Company and each of its subsidiaries have not knowingly engaged in, are not now knowingly engaged in, and will not knowingly engage in, any dealings or transactions with any Person, or in any country or territory, that at the time of the dealing or transaction is or was the subject of Sanctions.
- (u) Subsequent to the respective dates as of which information is given in each of the Registration Statement, the Time of Sale Prospectus and the Prospectus, (i) the Company and its subsidiaries, taken as a whole, have not incurred any material liability or obligation, direct or contingent, nor entered into any material transaction; (ii) the Company has not purchased any of its outstanding capital stock, other than from employees or other service providers in connection with such person's termination of service from the Company or its subsidiaries pursuant to the existing terms of the agreements or equity compensation plans described in the Time of Sale Prospectus or in exercise of the Company's right of first refusal upon a proposed transfer, nor declared, paid or otherwise made any dividend or distribution of any kind on its capital stock other than ordinary and customary dividends; and (iii) there has not been any material change in the capital stock (other than the exercise or conversion of equity awards, warrants or convertible notes or loans or grants of equity awards or forfeiture of equity awards outstanding as of such respective dates as of which information is given in each of the Registration Statement, the Time of Sale Prospectus and the Prospectus, in each case granted pursuant to the equity compensation plans described in the Time of Sale Prospectus), short-term debt or long-term debt of the Company and its subsidiaries, taken as a whole, except in each case as described in each of the Registration Statement, the Time of Sale Prospectus and the Prospectus and the Prospectus and the

- (v) The Company and its subsidiaries do not own any real property. The Company and its subsidiaries have good and marketable title to all personal property (excluding intellectual property, which is addressed exclusively in Section 1(w)) owned by them which is material to the business of the Company and its subsidiaries, taken as a whole, in each case free and clear of all liens, encumbrances and defects except such as do not materially diminish the value of such property and do not interfere in any material respect with the use made and proposed to be made of such property by the Company and its subsidiaries; and any real property and buildings held under lease by the Company and its subsidiaries are held by them under valid, subsisting and, to the knowledge of the Company, enforceable leases with such exceptions as are not material and do not interfere in any material respect with the use made and proposed to be made of such property and buildings by the Company and its subsidiaries, in each case except as described in the Registration Statement, the Time of Sale Prospectus and the Prospectus.
- (w) Except as described in the Registration Statement, the Time of Sale Prospectus or the Prospectus and except as would not reasonably be expected to have a material adverse effect on the Company and its subsidiaries taken as a whole, (i) the Company and its subsidiaries own, have a valid license to use, or can acquire on commercially reasonable terms adequate rights to use, all patents, inventions, copyrights, know how (including trade secrets and other unpatented and/or unpatentable proprietary or confidential information, systems or procedures), trademarks, service marks and trade names and all other intellectual property and proprietary rights (including all registrations and applications for registration of, and all goodwill associated with, any of the foregoing) (collectively, "Intellectual Property Rights") used in or reasonably necessary to the conduct of their respective businesses as now conducted by them and as proposed in the Registration Statement, Time of Sale Prospectus and Prospectus to be conducted by them; (ii) there is no pending or, to the Company's knowledge, threatened action, suit, proceeding or claim by others challenging the validity, scope or enforceability of, or any rights of the Company or any of its subsidiaries in, any such Intellectual Property Rights owned by or exclusively licensed to the Company and to the knowledge of the Company, all such Intellectual Property Rights are valid and enforceable; (iii) neither the Company nor any of its subsidiaries has received any written notice alleging any infringement, misappropriation or other violation of Intellectual Property Rights and there is no pending action, suit, proceeding or claim alleging that the Company or any of its subsidiaries has infringed, misappropriated or otherwise violated any Intellectual Property Rights; (iv) to the Company's knowledge, no third party is infringing, misappropriating or otherwise violating, or has infringed, misappropriated or otherwise violated, any Intellectual Property Rights owned by or exclusively licensed to the Company or any of its subsidiaries; (v) to the Company's knowledge, neither the Company nor any of its subsidiaries infringes, misappropriates or otherwise violates, or has infringed, misappropriated or otherwise violated, any Intellectual Property Rights; (vi) all employees or contractors engaged in the development of Intellectual Property Rights on behalf

of the Company or any of its subsidiaries have executed an invention assignment agreement whereby such employees or contractors presently assign all of their right, title and interest in and to such Intellectual Property Rights to the Company or its applicable subsidiary, and to the Company's knowledge no such agreement has been breached or violated; and (vii) the Company and its subsidiaries use, and have used, reasonable efforts in accordance with normal industry practice to appropriately maintain the confidentiality of all Intellectual Property Rights of the Company and its subsidiaries the value of which to the Company or any of its subsidiaries is contingent upon maintaining the confidentiality thereof, and no such Intellectual Property Rights have been disclosed other than to employees, representatives and agents of the Company or any of its subsidiaries, all of whom are bound by written confidentiality agreements.

- (x) Except as described in each of the Registration Statement, the Time of Sale Prospectus and the Prospectus and except as would not reasonably be expected to have a material adverse effect on the Company and its subsidiaries, taken as a whole, (i) the Company and its subsidiaries use and have used any and all software and other materials distributed under a "free," "open source," or similar licensing model (including but not limited to the MIT License, Apache License, GNU General Public License, GNU Lesser General Public License and GNU Affero General Public License) ("**Open Source Software**") in compliance with all license terms applicable to such Open Source Software; and (ii) neither the Company nor any of its subsidiaries uses or distributes or has used or distributed any Open Source Software in any manner that requires or has required (A) the Company or any of its subsidiaries to permit reverse engineering of any software code or other technology owned by the Company or any of its subsidiaries to be (1) disclosed or distributed in source code form, (2) licensed for the purpose of making derivative works or (3) redistributed at no charge.
- (y) Except as described in each of the Registration Statement, the Time of Sale Prospectus and the Prospectus and except as would not reasonably be expected to have a material adverse effect on the Company and its subsidiaries, taken as a whole, (i) the Company and each of its subsidiaries have complied and are presently in compliance with all internal and external privacy policies of the Company and its subsidiaries, contractual obligations, industry standards and applicable laws, statutes, judgments, orders, rules and regulations of any court or arbitrator or other governmental or regulatory authority, in each case, relating to the collection, use, transfer, import, export, storage, protection, disposal and disclosure by the Company or any of its subsidiaries of personal, personally identifiable, household, sensitive, confidential or regulated data or information ("Data Security Obligations", and such data and information, "Personal Data"); (ii) the Company and its subsidiaries have not received any written notification of or written complaint regarding and are unaware of any other facts that, individually or in the aggregate, would reasonably indicate non-compliance with any Data Security Obligation by the Company or any of its subsidiaries; and (iii) there is no action, suit or proceeding by or before any court or governmental agency, authority or body pending or, to the Company's knowledge, threatened alleging non-compliance with any Data Security Obligation by the Company or any of its subsidiaries.

- (z) Except as described in each of the Registration Statement, the Time of Sale Prospectus and the Prospectus and except as would not reasonably be expected to have a material adverse effect on the Company and its subsidiaries, taken as a whole, (i) the Company and each of its subsidiaries' respective information technology assets and equipment, computers, systems, networks, hardware, software, internet websites, applications, technology, data and databases (including Personal Data of their respective customers, employees, suppliers, vendors and any thirdparty sensitive or confidential data maintained, processed or stored by or on behalf of the Company or any of its subsidiaries) used in connection with the operation of the Company's and its subsidiaries' respective businesses as currently conducted by them (collectively, "IT Systems and **Data**") are adequate for, and operate and perform as reasonably required in connection with the operation of the business of the Company and its subsidiaries as currently conducted, free and clear of all bugs, errors, defects, Trojan horses, time bombs, malware and other corruptants; (ii) the Company and each of its subsidiaries have taken commercially reasonable technical and organizational measures necessary to protect the IT Systems and Data, and have used reasonable efforts to establish and maintain, and have established, maintained, implemented and complied with, reasonable information technology, information security, cyber security and data protection controls, policies and procedures, including oversight, access controls, encryption, technological and physical safeguards and business continuity/disaster recovery and security plans, consistent with industry standards and practices, that are designed to protect against and prevent breach, destruction, loss, unauthorized distribution, use, access, disablement, misappropriation or modification, or other compromise or misuse of or relating to any IT Systems and Data ("Breach"); and (iii) there has been no such Breach, and the Company and its subsidiaries have not been notified of and have no knowledge of any event or condition that would reasonably be expected to result in any such Breach.
- (aa) No material labor dispute with the employees of the Company or any of its subsidiaries exists or, to the knowledge of the Company, is imminent; and the Company is not aware of any existing, threatened or imminent labor disturbance by the employees of any of its principal suppliers, manufacturers or contractors that would reasonably be expected have a material adverse effect on the Company and its subsidiaries, taken as a whole.
- (bb) The Company and each of its subsidiaries are insured by insurers of recognized financial responsibility against such losses and risks and in such amounts as, in the reasonable judgment of the Company, are prudent and customary in the businesses in which they are engaged; neither the Company nor any of its subsidiaries has been refused any insurance coverage sought or applied

for; and neither the Company nor any of its subsidiaries has any reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue its business at a cost that would not, singly or in the aggregate, reasonably be expected to have a material adverse effect on the Company and its subsidiaries, taken as a whole.

- (cc) The Company and each of its subsidiaries possess all certificates, authorizations and permits issued by the appropriate federal, state or foreign regulatory authorities necessary to conduct their respective businesses except where the failure to obtain such certificates, authorizations or permits would not, individually or in the aggregate, be reasonably expected to have a material adverse effect on the Company and its subsidiaries, taken as a whole, and neither the Company nor any of its subsidiaries has received any notice of proceedings relating to the revocation or modification of any such certificate, authorization or permit which, singly or in the aggregate, if the subject of an unfavorable decision, ruling or finding, would have a material adverse effect on the Company and its subsidiaries, taken as a whole.
- (dd) Except as would not reasonably be expected to have a material adverse effect on the Company and its subsidiaries, taken as a whole, the Company has operated at all times and is currently in compliance with all applicable statutes, rules and regulations of the U.S. Food and Drug Administration (the "FDA") and applicable foreign regulatory authorities, including the European Medicines Agency and the UK Medicines & Healthcare products Regulatory Agency (collectively, the "Regulatory Authorities"), including, without limitation:
  - (iv) the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder;
  - (v) applicable federal, state, local and foreign health care laws, including the U.S. Anti-Kickback Statute (42 U.S.C. Section 1320a-7b(b)), the Civil Monetary Penalties Law (42 U.S.C. § 1320a-7a), the U.S. Civil False Claims Act (31 U.S.C. Section 3729 et seq.), all applicable federal, state, local and all foreign criminal laws relating to health care fraud and abuse, including but not limited to false statements relating to health care matters (42 U.S.C. Section 1320a-7b(a)), 18 U.S.C. Sections 286 and 287, and the health care fraud criminal provisions under the U.S. Health Insurance Portability and Accountability Act of 1996 ("HIPAA") (42 U.S.C. Section 1320d et seq.), the exclusion laws, the statutes, regulations and directives of applicable government funded or sponsored healthcare programs, and the regulations promulgated pursuant to such statutes;
    - (vi) the Standards for Privacy of Individually Identifiable Health Information, the Security Standards, and the Standards for

Electronic Transactions and Code Sets promulgated under HIPAA, the Health Information Technology for Economic and Clinical Health Act (42 U.S.C. Section 17921 et seq.), and the regulations promulgated thereunder and any state or non-U.S. counterpart thereof or any other law or regulation the purpose of which is to protect the privacy of individuals or prescribers;

- (vii) the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, the regulations promulgated thereunder;
  - (viii) the U.S. Controlled Substances Act (21 U.S.C. Section 801 et seq.);
  - (ix) the Clinical Laboratories Improvement Act of 1967, as amended) ("CLIA");
- (x) licensure, quality, safety and accreditation requirements under applicable federal, state, local or foreign laws or regulatory bodies; and
- (xi) all other local, state, federal, national, supranational and foreign laws, relating to the regulation of the Company and the ownership, testing, development, manufacture, packaging, processing, use, distribution, marketing, labeling, promotion, sale, offer for sale, storage, import, export or disposal of any product under development, manufactured or distributed by the Company; (clauses (i) through (viii), collectively, "Health Care Laws").
- (ee) (i) Except as would not reasonably be expected to have a material adverse effect on the Company and its subsidiaries, taken as a whole, the studies, tests and preclinical and clinical trials conducted by or, to the Company's knowledge, on behalf of or sponsored by the Company or in which the Company has participated, were, and if still pending are being conducted in accordance with standard medical and experimental protocols, procedures and controls pursuant to accepted professional scientific research standards and procedures, and all applicable Health Care Laws, the rules and regulations of the Regulatory Authorities and, to the extent required, current Good Clinical Practices and Good Laboratory Practices; (ii) the descriptions of the results of such studies and trials contained in the Registration Statement, the Time of Sale Prospectus or the Prospectus are accurate and complete in all material respects and fairly present the data derived from such trials and studies; (iii) the Company has no knowledge of any other studies or trials not described in the Registration Statement, the Time of Sale Prospectus and the Prospectus, the results of which are materially inconsistent with or call into question the results described or referred to in the Registration Statement, the Time of Sale Prospectus, and has provided the Underwriters with all substantive written notices, correspondence

and summaries of all other communications provided to the Company from the Regulatory Authorities; and (iv) the Company has not received any written notices or correspondence from any Regulatory Authority or any other governmental entity requiring the termination, material modification or suspension of any studies or trials that are described in the Registration Statement, the Time of Sale Prospectus and the Prospectus or the results of which are referred to in the Registration Statement, the Time of Sale Prospectus and the Prospectus.

- (ff) Except as would not reasonably be expected to have a material adverse effect on the Company and its subsidiaries, taken as a whole, (i) the Company has filed, obtained, maintained or submitted all reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments as required by any Health Care Laws, and, all such reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments were timely, complete, accurate and not misleading on the date filed (or were corrected or supplemented by a subsequent submission); (ii) the Company has not received written notice of any claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any court or arbitrator or Regulatory Authority, other governmental entity or third party alleging that any Company or product operation or activity is in violation of any Health Care Laws, including, without limitation, any FDA Form 483, notice of adverse finding, warning letter, untitled letter or other correspondence or notice from the FDA or any other Regulatory Authority or governmental entity, nor, to the Company's knowledge, is any such claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action threatened; (iii) the Company is not a party to any corporate integrity agreements, monitoring agreements, consent decrees, settlement orders, or similar agreements with or imposed by any Regulatory Authority or other governmental entity; and (iv) neither the Company nor its employees, officers or directors has been excluded, suspended or debarred from participation in any U.S. federal health care program or human clinical research or, to the knowledge of the Company, is subject to an inquiry, investigation, proceeding or other similar action by a Regulatory Authority or other governmental entity that could reasonably be expected to result in debarment, suspension, or exclusion.
- (gg) The Company's clinical laboratory tests are conducted in material compliance with all applicable Health Care Laws, and, to the extent applicable, the respective counterparts thereof promulgated by governmental authorities in countries outside the United States. The Company has not received written notice from any Regulatory Authority alleging or asserting noncompliance with any applicable Health Care Law. To the Company's knowledge, neither the FDA nor any other governmental authority is considering such action.
- (hh) The financial statements included in each of the Registration Statement, the Time of Sale Prospectus and the Prospectus, together with the related schedules and notes thereto, comply as to form in all material respects

with the applicable accounting requirements of the Securities Act and present fairly in all material respects the consolidated financial position of the Company and its subsidiaries as of the dates shown and its results of operations and cash flows for the periods shown, and such financial statements have been prepared in conformity with generally accepted accounting principles in the United States ("U.S. GAAP") applied on a consistent basis throughout the periods covered thereby except for any normal year-end adjustments in the Company's quarterly financial statements. The other financial information included in each of the Registration Statement, the Time of Sale Prospectus and the Prospectus has been derived from the accounting records of the Company and its consolidated subsidiaries and presents fairly in all material respects the information shown thereby The statistical, industry-related and market-related data included in each of the Registration Statement, the Time of Sale Prospectus and the Prospectus are based on or derived from sources which the Company reasonably and in good faith believes are reliable and accurate and such data is consistent with the sources from which they are derived, in each case in all material respects and, to the extent required, the Company has obtained the written consent to the use of such data from such sources.

- (ii) Deloitte & Touche LLP, who have certified certain financial statements of the Company and its subsidiaries and delivered its report with respect to the audited consolidated financial statements and schedules filed with the Commission as part of the Registration Statement and included in each of the Registration Statement, the Time of Sale Prospectus and the Prospectus, is an independent registered public accounting firm with respect to the Company within the meaning of the Securities Act and the applicable rules and regulations thereunder adopted by the Commission and the Public Company Accounting Oversight Board (United States).
- (jj) The Company and its subsidiaries, taken as a whole, maintain a system of internal accounting controls sufficient to provide reasonable assurance that (i) transactions are executed in accordance with management's general or specific authorizations; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with U.S. GAAP and to maintain asset accountability; (iii) access to assets is permitted only in accordance with management's general or specific authorization; and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences. Except as described in the Time of Sale Prospectus, since the end of the Company's most recent audited fiscal year, there has been (i) no material weakness in the Company's internal control over financial reporting (whether or not remediated) and (ii) no change in the Company's internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.
- (kk) Except as described in the Registration Statement of the Time of Sale Prospectus, the Company has not sold, issued or distributed any shares of

Common Stock during the six-month period preceding the date hereof, including any sales pursuant to Rule 144A under, or Regulation D or S of, the Securities Act, other than shares issued pursuant to employee benefit plans, qualified stock option plans or other employee compensation plans or pursuant to outstanding options, rights or warrants.

- (ll) The Registration Statement, the Prospectus, the Time of Sale Prospectus and any preliminary prospectus comply, and any amendments or supplements thereto will comply in all material respects, with any applicable laws or regulations of foreign jurisdictions in which the Prospectus, the Time of Sale Prospectus or any preliminary prospectus, as amended or supplemented, if applicable, are distributed in connection with the Directed Share Program.
- (mm) No consent, approval, authorization or order of, or qualification with, any governmental body or agency, other than those obtained, is required in connection with the offering of the Directed Shares in any jurisdiction where the Directed Shares are being offered.
- (nn) The Company has not offered, or caused the DSP Underwriter or any DSP Underwriter Entity as defined in Section 9 to offer, Shares to any person pursuant to the Directed Share Program with the specific intent to unlawfully influence (i) a customer or supplier of the Company to alter the customer's or supplier's level or type of business with the Company, or (ii) a trade journalist or publication to write or publish favorable information about the Company or its products.
- (oo) The Company and each of its subsidiaries have filed all federal, state, local and foreign tax returns required to be filed through the date of this Agreement or have requested extensions thereof (except where the failure to file would not be reasonably expected to, singly or in the aggregate, have a material adverse effect on the Company and its subsidiaries, taken as a whole) and have paid all taxes required to be paid thereon (except for cases in which the failure to file or pay would not be reasonably expected to, singly or in the aggregate, have a material adverse effect on the Company and its subsidiaries, taken as a whole, or, except as currently being contested in good faith and for which reserves required by U.S. GAAP have been created in the financial statements of the Company), and no tax deficiency has been determined adversely to the Company or any of its subsidiaries which, singly or in the aggregate, has had (nor does the Company nor any of its subsidiaries have any notice or knowledge of any tax deficiency which would reasonably be expected to be determined adversely to the Company or its subsidiaries and which would reasonably be expected to have) a material adverse effect on the Company and its subsidiaries, taken as a whole.
- (pp) Neither the Company nor any of its subsidiaries has any securities rated by any "nationally recognized statistical rating organization," as such term is defined in Section 3(a)(62) of the Securities Exchange Act of 1934, as amended (the "Exchange Act").

- (qq) From the time of initial confidential submission of the Registration Statement to the Commission through the date hereof, the Company has been and is an "emerging growth company," as defined in Section 2(a) of the Securities Act (an "Emerging Growth Company").
- (rr) The Company (i) has not alone engaged in any Testing-the-Waters Communication with any person other than Testing-the-Waters Communications with the consent of the Representatives with entities that are reasonably believed to be qualified institutional buyers within the meaning of Rule 144A under the Securities Act or institutions that are reasonably believed to be accredited investors within the meaning of Rule 501 under the Securities Act and (ii) has not authorized anyone other than the Representatives to engage in Testing-the-Waters Communications. The Company reconfirms that the Representatives have been authorized to act on its behalf in undertaking Testing-the-Waters Communications. The Company has not distributed any Testing-the-Waters Communication that is a written communication within the meaning of Rule 405 under the Securities Act other than those listed on Schedule III hereto. "Testing-the-Waters Communication" means any oral or written communication with potential investors undertaken in reliance on Section 5(d) or Rule 163B of the Securities Act.
- (ss) As of the time of each sale of the Shares in connection with the offering when the Prospectus is not yet available to prospective purchasers, none of (A) the Time of Sale Prospectus, (B) any free writing prospectus, when considered together with the Time of Sale Prospectus, and (C) any individual Testing-the-Waters Communication, when considered together with the Time of Sale Prospectus, included, includes or will include an untrue statement of a material fact or omitted, omits or will omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; provided, however, that this representation and warranty shall not apply to any statements or omissions made in reliance upon and in conformity with information furnished in writing to the Company by an Underwriter through or on behalf of the Representatives for use therein it being understood and agreed that the only such information furnished by the Underwriters through the Representatives consists of the information described as such in Section 8(b) below.
- 2. *Agreements to Sell and Purchase*. The Company hereby agrees to sell to the several Underwriters, and each Underwriter, upon the basis of the representations and warranties herein contained, but subject to the terms and conditions hereinafter stated, agrees, severally and not jointly, to purchase from the Company the respective numbers of Firm Shares set forth in Schedule I hereto opposite its name at \$[ ] a share (the "**Purchase Price**").

On the basis of the representations and warranties contained in this Agreement, and subject to its terms and conditions, the Company agrees to sell to the Underwriters the Additional Shares, and the Underwriters shall have the right to purchase, severally

and not jointly, up to [ ] Additional Shares at the Purchase Price, provided, however, that the amount paid by the Underwriters for any Additional Shares shall be reduced by an amount per share equal to any dividends declared by the Company and payable on the Firm Shares but not payable on such Additional Shares. The Representatives may exercise this right on behalf of the Underwriters in whole or from time to time in part by giving written notice not later than 30 days after the date of this Agreement. Any exercise notice shall specify the number of Additional Shares to be purchased by the Underwriters and the date on which such shares are to be purchased. Each purchase date must be at least one business day after the written notice is given and may not be earlier than the closing date for the Firm Shares nor later than ten business days after the date of such notice. Additional Shares may be purchased as provided in Section 4 hereof solely for the purpose of covering over-allotments made in connection with the offering of the Firm Shares. On each day, if any, that Additional Shares are to be purchased (an "Option Closing Date"), each Underwriter agrees, severally and not jointly, to purchase the number of Additional Shares (subject to such adjustments to eliminate fractional shares as the Representatives may determine) that bears the same proportion to the total number of Additional Shares to be purchased on such Option Closing Date as the number of Firm Shares set forth in Schedule I hereto opposite the name of such Underwriter bears to the total number of Firm Shares.

3. Terms of Public Offering. The Company is advised by the Representatives that the Underwriters propose to make a public offering of their respective portions of the Shares as soon after the Registration Statement and this Agreement have become effective as in the Representatives' judgment is advisable. The Company is further advised by the Representatives that the Shares are to be offered to the public initially at \$[ ] a share (the "Public Offering Price") and to certain dealers selected by the Representatives at a price that represents a concession not in excess of \$[ ] a share under the Public Offering Price, and that any Underwriter may allow, and such dealers may reallow, a concession, not in excess of \$[ ] a share, to any Underwriter or to certain other dealers.

4. Payment and Delivery. Payment for the Firm Shares shall be made to the Company in Federal or other funds immediately available in New York City against delivery of such Firm Shares for the respective accounts of the several Underwriters at 10:00 a.m., New York City time, on [ ], 2021, or at such other time on the same or such other date, not later than [ ], 2021, as shall be designated in writing by the Representatives. The time and date of such payment are hereinafter referred to as the "Closing Date."

Payment for any Additional Shares shall be made to the Company in Federal or other funds immediately available in New York City against delivery of such Additional Shares for the respective accounts of the several Underwriters at 10:00 a.m., New York City time, on the date specified in the corresponding notice described in Section 2 or at such other time on the same or on such other date, in any event not later than [ ], 2021, as shall be designated in writing by the Representatives.

The Firm Shares and Additional Shares shall be registered in such names and in such denominations as the Representatives shall request in writing not later than one full business day prior to the Closing Date or the applicable Option Closing Date, as the case may be. The Firm Shares and Additional Shares shall be delivered to the Representatives on the Closing Date or an Option Closing Date, as the case may be, for the respective accounts of the several Underwriters, with any transfer taxes payable in connection with the transfer of the Shares to the Underwriters duly paid, against payment of the Purchase Price therefor.

5. *Conditions to the Underwriters' Obligations*. The obligations of the Company to sell the Shares to the Underwriters and the several obligations of the Underwriters to purchase and pay for the Shares on the Closing Date are subject to the condition that the Registration Statement shall have become effective not later than [ ] (New York City time) on the date hereof.

The several obligations of the Underwriters are subject to the following further conditions:

- (a) Subsequent to the execution and delivery of this Agreement and prior to the Closing Date:
- (i) no order suspending the effectiveness of the Registration Statement shall be in effect, and to the Company's knowledge, no proceeding for such purpose or pursuant to Section 8A under the Securities Act shall be pending before or threatened by the Commission; and
- (ii) there shall not have occurred any change, or any development involving a prospective change, in the condition, financial or otherwise, or in the earnings, business or operations of the Company and its subsidiaries, taken as a whole, from that set forth in the Time of Sale Prospectus that, in the Representatives' judgment, is material and adverse and that makes it, in the Representatives' judgment, impracticable to market the Shares on the terms and in the manner contemplated in the Time of Sale Prospectus.
- (b) The Underwriters shall have received on the Closing Date a certificate, dated the Closing Date and signed on behalf of the Company by an executive officer of the Company, to the effect set forth in Section 5(a)(i) above and to the effect that the representations and warranties of the Company contained in this Agreement are true and correct as of the Closing Date and that the Company has complied with all of the agreements and satisfied all of the conditions on its part to be performed or satisfied hereunder on or before the Closing Date. The officer signing and delivering such certificate may rely upon the best of his or her knowledge as to proceedings threatened.

- (c) The Underwriters shall have received on the Closing Date (i) an opinion and (ii) negative assurance letter of Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP, outside counsel for the Company, dated the Closing Date, in form and substance reasonably satisfactory to the Representatives.
- (d) The Underwriters shall have received on the Closing Date an opinion of Foley Hoag LLP, outside intellectual property counsel for the Company, dated the Closing Date, in form and substance reasonably satisfactory to the Representatives.
- (e) The Underwriters shall have received on the Closing Date (i) an opinion and (ii) negative assurance letter of Davis Polk & Wardwell LLP, counsel for the Underwriters, dated the Closing Date, in form and substance reasonably satisfactory to the Representatives.

With respect to the negative assurance letters to be delivered pursuant to Sections 5(c) and 5(d) above, Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP and Davis Polk & Wardwell LLP may state that their opinions and beliefs are based upon their participation in the preparation of the Registration Statement, the Time of Sale Prospectus and the Prospectus and any amendments or supplements thereto and review and discussion of the contents thereof, but are without independent check or verification, except as specified.

The opinions of Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP and Davis Polk & Wardwell LLP described in Sections 5(c) and 5(d) above, respectively, shall be rendered to the Underwriters at the request of the Company and shall so state therein.

- (f) The Underwriters shall have received, on each of the date hereof and the Closing Date, a letter dated the date hereof or the Closing Date, as the case may be, in form and substance satisfactory to the Underwriters, from Deloitte & Touche LLP, independent public accountants, containing statements and information of the type ordinarily included in accountants' "comfort letters" to underwriters with respect to the financial statements and certain financial information contained in the Registration Statement, the Time of Sale Prospectus and the Prospectus; provided that the letter delivered on the Closing Date shall use a "cut-off date" not earlier than the date hereof.
- (g) The "lock-up" agreements, each substantially in the form of Exhibit A hereto, between the Representatives and certain stockholders, officers and directors of the Company relating to restrictions on sales and certain other dispositions of shares of Common Stock or certain other securities, delivered to the Representatives on or before the date hereof (the "Lock-up Agreements"), shall be in full force and effect on the Closing Date.

- (h) The several obligations of the Underwriters to purchase Additional Shares hereunder are subject to the delivery to the Representatives on the applicable Option Closing Date of the following:
  - (i) a certificate, dated the Option Closing Date and signed by an executive officer of the Company, confirming that the certificate delivered on the Closing Date pursuant to Section 5(b) hereof remains true and correct as of such Option Closing Date;
  - (ii) an opinion and negative assurance letter of Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP, outside counsel for the Company, dated the Option Closing Date, relating to the Additional Shares to be purchased on such Option Closing Date and otherwise to the same effect as the opinion required by Section 5(c) hereof;
  - (iii) an opinion of Foley Hoag LLP, outside intellectual property counsel for the Company, dated the Option Closing Date, relating to the Additional Shares to be purchased on such Option Closing Date and otherwise to the same effect as the opinion required by Section 5(d) hereof;
  - (iv) an opinion and negative assurance letter of Davis Polk & Wardwell LLP, counsel for the Underwriters, dated the Option Closing Date, relating to the Additional Shares to be purchased on such Option Closing Date and otherwise to the same effect as the opinion required by Section 5(e) hereof;
  - (v) a letter dated the Option Closing Date, in form and substance satisfactory to the Underwriters, from Deloitte LLP, independent public accountants, substantially in the same form and substance as the letter furnished to the Underwriters pursuant to Section 5(f) hereof; provided that the letter delivered on the Option Closing Date shall use a "cut-off date" not earlier than two business days prior to such Option Closing Date; and
  - (vi) such other documents as the Representatives may reasonably request, including with respect to the good standing of the Company and its significant subsidiaries, the due authorization and issuance of the Additional Shares to be sold on such Option Closing Date and other matters related to the issuance of such Additional Shares.
- 6. Covenants of the Company. The Company covenants with each Underwriter as follows:
- (a) To furnish to the Representatives without charge, five signed copies of the Registration Statement (including exhibits thereto) and for delivery to each other Underwriter a conformed copy of the Registration Statement

(without exhibits thereto) and to furnish to the Representatives in New York City, without charge, prior to 10:00 a.m. New York City time on the business day next succeeding the date of this Agreement and during the period mentioned in Section 6(e) or 6(f) below, as many copies of the Time of Sale Prospectus, the Prospectus and any supplements and amendments thereto or to the Registration Statement as the Representatives may reasonably request.

- (b) Before amending or supplementing the Registration Statement, the Time of Sale Prospectus or the Prospectus, to furnish to the Representatives a copy of each such proposed amendment or supplement and not to file any such proposed amendment or supplement to which the Representatives reasonably object, and to file with the Commission within the applicable period specified in Rule 424(b) under the Securities Act any prospectus required to be filed pursuant to such Rule.
- (c) To furnish to the Representatives a copy of each proposed free writing prospectus to be prepared by or on behalf of, used by, or referred to by the Company and not to use or refer to any proposed free writing prospectus to which the Representatives reasonably object.
- (d) Not to take any action that would result in an Underwriter or the Company being required to file with the Commission pursuant to Rule 433(d) under the Securities Act a free writing prospectus prepared by or on behalf of the Underwriter that the Underwriter otherwise would not have been required to file thereunder.
- (e) If the Time of Sale Prospectus is being used to solicit offers to buy the Shares at a time when the Prospectus is not yet available to prospective purchasers and any event shall occur or condition exist as a result of which it is necessary to amend or supplement the Time of Sale Prospectus in order to make the statements therein, in the light of the circumstances, not misleading, or if any event shall occur or condition exist as a result of which the Time of Sale Prospectus conflicts with the information contained in the Registration Statement then on file, or if, in the opinion of counsel for the Underwriters, it is necessary to amend or supplement the Time of Sale Prospectus to comply with applicable law, forthwith to prepare, file with the Commission and furnish, at its own expense, to the Underwriters and to any dealer upon request, either amendments or supplements to the Time of Sale Prospectus so that the statements in the Time of Sale Prospectus as so amended or supplemented will not, in the light of the circumstances when the Time of Sale Prospectus is delivered to a prospective purchaser, be misleading or so that the Time of Sale Prospectus, as amended or supplemented, will no longer conflict with the Registration Statement, or so that the Time of Sale Prospectus, as amended or supplemented, will comply with applicable law.
- (f) If, during such period after the first date of the public offering of the Shares as in the opinion of counsel for the Underwriters the Prospectus (or in

lieu thereof the notice referred to in Rule 173(a) of the Securities Act) is required by law to be delivered in connection with sales by an Underwriter or dealer, any event shall occur or condition exist as a result of which it is necessary to amend or supplement the Prospectus in order to make the statements therein, in the light of the circumstances when the Prospectus (or in lieu thereof the notice referred to in Rule 173(a) of the Securities Act) is delivered to a purchaser, not misleading, or if, in the opinion of counsel for the Underwriters, it is necessary to amend or supplement the Prospectus to comply with applicable law, forthwith to prepare, file with the Commission and furnish, at its own expense, to the Underwriters and to the dealers (whose names and addresses the Representatives will furnish to the Company) to which Shares may have been sold by the Representatives on behalf of the Underwriters and to any other dealers upon request, either amendments or supplements to the Prospectus so that the statements in the Prospectus as so amended or supplemented will not, in the light of the circumstances when the Prospectus (or in lieu thereof the notice referred to in Rule 173(a) of the Securities Act) is delivered to a purchaser, be misleading or so that the Prospectus, as amended or supplemented, will comply with applicable law.

- (g) To endeavor to qualify the Shares for offer and sale under the securities or Blue Sky laws of such jurisdictions as the Representatives shall reasonably request; provided, however, that nothing contained herein shall require the Company to qualify to do business in any jurisdiction, execute a general consent to service of process in any jurisdiction or to subject itself to taxation in any jurisdiction in which it is not otherwise subject.
- (h) To make generally available (which may be satisfied by filing with the Commission on its Electronic Data Gathering, Analysis and Retrieval System) to the Company's security holders and to the Representatives as soon as practicable an earnings statement covering a period of at least twelve months beginning with the first fiscal quarter of the Company occurring after the date of this Agreement which shall satisfy the provisions of Section 11(a) of the Securities Act and the rules and regulations of the Commission thereunder.
- (i) To comply with all applicable securities and other laws, rules and regulations in each jurisdiction in which the Directed Shares are offered in connection with the Directed Share Program.
- (j) Whether or not the transactions contemplated in this Agreement are consummated or this Agreement is terminated, to pay or cause to be paid all expenses incident to the performance of its obligations under this Agreement, including: (i) the fees, disbursements and expenses of the Company's counsel and the Company's accountants in connection with the registration and delivery of the Shares under the Securities Act and all other fees or expenses in connection with the preparation and filing of the Registration Statement, any preliminary prospectus, the Time of Sale Prospectus, the Prospectus, any free writing prospectus prepared by or on behalf of, used by, or referred to by the Company and amendments and supplements to any of the foregoing, including all printing

costs associated therewith, and the mailing and delivering of copies thereof to the Underwriters and dealers, in the quantities hereinabove specified, (ii) all costs and expenses related to the transfer and delivery of the Shares to the Underwriters, including any transfer or other similar taxes payable thereon, (iii) the reasonable, documented cost of printing or producing any Blue Sky or Legal Investment memorandum in connection with the offer and sale of the Shares under state securities laws and all expenses in connection with the qualification of the Shares for offer and sale under state securities laws as provided in Section 6(g) hereof, including filing fees and the reasonable, documented fees and disbursements of counsel for the Underwriters in connection with such qualification and in connection with the Blue Sky or Legal Investment memorandum, (iv) all filing fees and the reasonable fees and disbursements of counsel to the Underwriters incurred in connection with the review and qualification of the offering of the Shares by the Financial Industry Regulatory Authority (provided, that, the amount payable by the Company with respect to fees and disbursements of counsel for the Underwriters pursuant to subsections (iii) and (iv) shall not exceed \$45,000 in the aggregate), (v) all fees and expenses in connection with the preparation and filing of the registration statement on Form 8-A relating to the Common Stock and all costs and expenses incident to listing the Shares on the NASDAQ Global Market, (vi) the cost of printing certificates representing the Shares, (vii) the costs and charges of any transfer agent, registrar or depositary, (viii) the costs and expenses of the Company relating to investor presentations on any "road show" undertaken in connection with the marketing of the offering of the Shares, including, without limitation, expenses associated with the preparation or dissemination of any electronic road show, expenses associated with the production of road show slides and graphics, fees and expenses of any consultants engaged in connection with the road show presentations with the prior approval of the Company, travel and lodging expenses of the representatives and officers of the Company and any such consultants, and fifty percent (50%) the cost of any aircraft chartered in connection with the road show (the remaining fifty percent (50%) of the cost of such aircraft to be paid by the Underwriters), (ix) the document production charges and expenses associated with printing this Agreement, (x) all reasonable, documented fees and disbursements of counsel incurred by the Underwriters in connection with the Directed Share Program and stamp duties, similar taxes or duties or other taxes, if any, incurred by the Underwriters in connection with the Directed Share Program and (xi) all other costs and expenses incident to the performance of the obligations of the Company hereunder for which provision is not otherwise made in this Section. It is understood, however, that except as provided in this Section, Section 8 entitled "Indemnity and Contribution," Section 9 entitled "Directed Share Program Indemnification" and the last paragraph of Section 11 below, the Underwriters will pay all of their costs and expenses, including fees and disbursements of their counsel, stock transfer taxes payable on resale of any of the Shares by them and any advertising expenses connected with any offers they may make and all travel and lodging expenses of the Underwriters or any of their employees incurred by them in connection with participation in investor presentations on any "road show" undertaken in connection with the marketing of the offering of the Shares, other than the cost of aircraft chartered in connection with the roadshow, for which the Underwriters agree to pay for the other one-half not paid for by the Company, as described above.

- (k) The Company will promptly notify the Representatives if the Company ceases to be an Emerging Growth Company at any time prior to the later of (i) completion of the distribution of the Shares within the meaning of the Securities Act and (ii) completion of the Restricted Period (as defined in this Section 6).
- (l) If at any time following the distribution of any Testing-the-Waters Communication that is a written communication within the meaning of Rule 405 under the Securities Act there occurred or occurs an event or development as a result of which such Testing-the-Waters Communication included or would include an untrue statement of a material fact or omitted or would omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances existing at that subsequent time, not misleading, the Company will promptly notify the Representatives and will promptly amend or supplement, at its own expense, such Testing-the-Waters Communication to eliminate or correct such untrue statement or omission.
- (m) The Company will deliver to each Underwriter (or its agent), on the date of execution of this Agreement, a properly completed and executed Certification Regarding Beneficial Owners of Legal Entity Customers, together with copies of identifying documentation, and the Company undertakes to provide such additional supporting documentation as each Underwriter may reasonably request in connection with the verification of the foregoing Certification.

The Company also covenants with each Underwriter that, without the prior written consent of the Representatives on behalf of the Underwriters, it will not, and will not publicly disclose an intention to, during the period ending 180 days after the date of the Prospectus (the "Restricted Period"), (1) offer, pledge, sell, contract to sell, sell any option or contract to purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of Common Stock or any securities convertible into or exercisable or exchangeable for Common Stock or (2) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the Common Stock, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of Common Stock or such other securities, in cash or otherwise or (3) file any registration statement with the Commission relating to the offering of any shares of Common Stock or any securities convertible into or exercisable or exchangeable for Common Stock.

The restrictions contained in the preceding paragraph shall not apply to (A) the Shares to be sold hereunder, (B) the issuance by the Company of shares of

Common Stock upon the exercise of an option or warrant, the settlement of restricted stock units or share value award, or the conversion of a convertible loan, note or other security outstanding on the date hereof as described in each of the Time of Sale Prospectus and Prospectus, (C) the grant of options, restricted stock units, share value awards or any other type of equity award described in the Time of Sale Prospectus and the Prospectus pursuant to employee benefit plans in effect on the date hereof and described in the Time of Sale Prospectus and the Prospectus, or the issuance of shares of Common Stock by the Company (whether upon the exercise of stock options or other equity awards) to employees, officers, directors, advisors or consultants of the Company pursuant to employee benefit plans in effect on the date hereof and described in the Time of Sale Prospectus and the Prospectus; provided that each recipient of shares of Common Stock or any securities convertible into or exercisable or exchangeable for shares of Common Stock pursuant to this clause (C) shall execute a lock-up agreement substantially in the form of Exhibit A hereto, (D) the filing by the Company of a registration statement on Form S-8 relating to issuance, vesting, exercise or settlement of equity awards granted or to be granted pursuant to any employee benefit plan in effect on the date hereof and described in the Time of Sale Prospectus, (E) the issuance of or entry into an agreement to issue shares of Common Stock or any securities convertible into or exercisable or exchangeable for Common Stock in connection with one or more mergers, acquisitions or securities, businesses, property or other assets, products or technologies, joint ventures, commercial relationships or other strategic corporate transactions or alliances; provided that the aggregate amount of Common Stock or any securities convertible into or exercisable or exchangeable for Common Stock (on an as-converted, as-exercised or as-exchanged basis) that the Company may issue or agree to issue pursuant to this paragraph shall not exceed 5% of the total number of shares of Common Stock of the Company issued and outstanding immediately following the completion of the transactions contemplated by this Agreement determined on a fully diluted basis, and provided further, that each recipient of shares of Common Stock or any securities convertible into or exercisable or exchangeable for shares of Common Stock pursuant to this clause (E) shall execute a lock-up agreement substantially in the form of Exhibit A hereto, or (F) facilitating the establishment of a trading plan on behalf of a shareholder, officer or director of the Company pursuant to Rule 10b5-1 under the Exchange Act for the transfer of shares of Common Stock, provided that (i) such plan does not provide for the transfer of shares of Common Stock during the Restricted Period and (ii) to the extent a public announcement or filing under the Exchange Act, if any, is required of or voluntarily made by the Company regarding the establishment of such plan, such announcement or filing shall include a statement to the effect that no transfer of shares of Common Stock may be made under such plan during the Restricted Period.

If the Representatives, in their sole discretion, agree to release or waive the restrictions on the transfer of Shares set forth in a Lock-up Agreement for an officer or director of the Company and provides the Company with notice of the impending release or waiver at least three business days before the effective date of the release or waiver, the Company agrees to announce the impending release or waiver by a press release substantially in the form of Exhibit B hereto through a major news service at least two business days before the effective date of the release or waiver.

7. *Covenants of the Underwriters*. Each Underwriter, severally and not jointly, covenants with the Company not to take any action that would result in the Company being required to file with the Commission under Rule 433(d) a free writing prospectus prepared by or on behalf of such Underwriter that otherwise would not be required to be filed by the Company thereunder, but for the action of the Underwriter.

## 8. Indemnity and Contribution.

- (a) The Company agrees to indemnify and hold harmless each Underwriter, each person, if any, who controls any Underwriter within the meaning of either Section 15 of the Securities Act or Section 20 of the Exchange Act, and each affiliate of any Underwriter within the meaning of Rule 405 under the Securities Act from and against any and all losses, claims, damages and liabilities (including, without limitation, any legal or other expenses reasonably incurred in connection with defending or investigating any such action or claim) that arise out of, or are based upon, any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement or any amendment thereof, any preliminary prospectus, the Time of Sale Prospectus or any amendment or supplement thereto, any issuer free writing prospectus as defined in Rule 433(h) under the Securities Act, any Company information that the Company has filed, or is required to file, pursuant to Rule 433(d) under the Securities Act, any "road show" as defined in Rule 433(h) under the Securities Act (a "road show"), the Prospectus or any amendment or supplement thereto, or any Testing-the-Waters Communication or arise out of, or are based upon, any omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading, except insofar as such losses, claims, damages or liabilities arise out of, or are based upon, any such untrue statement or omission or alleged untrue statement or omission made in reliance upon and in conformity with any information relating to any Underwriter furnished to the Company in writing by such Underwriter through the Representatives expressly for use therein, it being understood and agreed that the only such information furnished by the Underwriters through the Representatives consists of the information described as such in paragraph (b) below.
- (b) Each Underwriter agrees, severally and not jointly, to indemnify and hold harmless the Company, its directors, its officers who sign the Registration Statement and each person, if any, who controls the Company within the meaning of either Section 15 of the Securities Act or Section 20 of the Exchange Act to the same extent as the foregoing indemnity from the Company to such Underwriter, but only with reference to information relating to such Underwriter furnished to the Company in writing by such Underwriter through

the Representatives expressly for use in the Registration Statement, any preliminary prospectus, the Time of Sale Prospectus, any issuer free writing prospectus, road show, or the Prospectus or any amendment or supplement thereto, it being understood and agreed that the only such information furnished by any Underwriter through the Representatives consists of the following information in the Time of Sale Prospectus and the Prospectus: (i) the concession figure appearing in the third paragraph under the caption "Underwriters" and (ii) the thirteenth paragraph under the caption "Underwriters" concerning stabilization.

(c) In case any proceeding (including any governmental investigation) shall be instituted involving any person in respect of which indemnity may be sought pursuant to Section 8(a) or 8(b), such person (the "indemnified party") shall promptly notify the person against whom such indemnity may be sought (the "indemnifying party") in writing and the indemnifying party, upon request of the indemnified party, shall retain counsel reasonably satisfactory to the indemnified party to represent the indemnified party and any others the indemnifying party may designate in such proceeding and shall pay the reasonably incurred and documented fees and disbursements of such counsel related to such proceeding. In any such proceeding, any indemnified party shall have the right to retain its own counsel, but the fees and expenses of such counsel shall be at the expense of such indemnified party unless (i) the indemnifying party and the indemnified party shall have mutually agreed in writing to the retention of such counsel or (ii) the named parties to any such proceeding (including any impleaded parties) include both the indemnifying party and the indemnified party and representation of both parties by the same counsel would be inappropriate due to actual or potential differing interests between them. It is understood that the indemnifying party shall not, in respect of the legal expenses of any indemnified party in connection with any proceeding or related proceedings in the same jurisdiction, be liable for the fees and expenses of more than one separate firm (in addition to any local counsel) for all such indemnified parties and that all such fees and expenses shall be reimbursed as they are incurred. Such firm shall be designated in writing by the Representatives, in the case of parties indemnified pursuant to Section 8(a), and by the Company, in the case of parties indemnified pursuant to Section 8(b). The indemnifying party shall not be liable for any settlement of any proceeding effected without its written consent, but if settled with such consent or if there be a final judgment for the plaintiff, the indemnifying party agrees to indemnify the indemnified party from and against any loss or liability by reason of such settlement or judgment. Notwithstanding the foregoing sentence, if at any time an indemnified party shall have requested an indemnifying party to reimburse the indemnified party for fees and expenses of counsel as contemplated by the second and third sentences of this paragraph, the indemnifying party agrees that it shall be liable for any settlement of any proceeding effected without its written consent if (i) such settlement is entered into more than 30 days after receipt by such indemnifying party of the aforesaid request and (ii) such indemnifying party shall not have reimbursed the indemnified party in accordance with such request prior to the date of such settlement. No indemnifying party shall, without the prior

written consent of the indemnified party, effect any settlement of any pending or threatened proceeding in respect of which any indemnified party is or could have been a party and indemnity could have been sought hereunder by such indemnified party, unless such settlement (x) includes an unconditional release of such indemnified party from all liability on claims that are the subject matter of such proceeding and (y) does not include a statement as to or an admission of fault, culpability or a failure to act by or on behalf of any indemnified party.

- (d) To the extent the indemnification provided for in Section 8(a) or 8(b) is unavailable to an indemnified party or insufficient in respect of any losses, claims, damages or liabilities referred to therein, then each indemnifying party under such paragraph, in lieu of indemnifying such indemnified party thereunder, shall contribute to the amount paid or payable by such indemnified party as a result of such losses, claims, damages or liabilities (i) in such proportion as is appropriate to reflect the relative benefits received by the indemnifying party or parties on the one hand and the indemnified party or parties on the other hand from the offering of the Shares or (ii) if the allocation provided by clause 8(d)(i) above is not permitted by applicable law, in such proportion as is appropriate to reflect not only the relative benefits referred to in clause 8(d)(i) above but also the relative fault of the Company on the one hand and of the Underwriters on the other hand in connection with the statements or omissions that resulted in such losses, claims, damages or liabilities, as well as any other relevant equitable considerations. The relative benefits received by the indemnifying party or parties on the one hand and the indemnified party or parties on the other hand in connection with the offering of the Shares shall be deemed to be in the same respective proportions as the net proceeds from the offering of the Shares (after deducting underwriting discounts and commissions but before deducting expenses) received by the Company and the total underwriting discounts and commissions received by the Underwriters, in each case as set forth in the table on the cover of the Prospectus, bear to the aggregate Public Offering Price of the Shares. The relative fault of the indemnifying party or parties on the one hand and the indemnified party or parties on the other hand shall be determined by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or the omission or alleged omission to state a material fact relates to information supplied by the Company or by the Underwriters and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such statement or omission. The Underwriters' respective obligations to contribute pursuant to this Section 8 are several in proportion to the respective number of Shares they have purchased hereunder, and not joint.
- (e) The Company and the Underwriters agree that it would not be just or equitable if contribution pursuant to this Section 8 were determined by *pro rata* allocation (even if the Underwriters were treated as one entity for such purpose) or by any other method of allocation that does not take account of the equitable considerations referred to in Section 8(d). The amount paid or payable by an indemnified party as a result of the losses, claims, damages and liabilities referred

to in Section 8(d) shall be deemed to include, subject to the limitations set forth above, any legal or other expenses reasonably incurred by such indemnified party in connection with investigating or defending any such action or claim. Notwithstanding the provisions of this Section 8, no Underwriter shall be required to contribute any amount in excess of the amount by which the total price at which the Shares underwritten by it and distributed to the public were offered to the public exceeds the amount of any damages that such Underwriter has otherwise been required to pay by reason of such untrue or alleged untrue statement or omission or alleged omission. No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. The remedies provided for in this Section 8 are not exclusive and shall not limit any rights or remedies which may otherwise be available to any indemnified party at law or in equity.

- (f) The indemnity and contribution provisions contained in this Section 8 and the representations, warranties and other statements of the Company contained in this Agreement shall remain operative and in full force and effect regardless of (i) any termination of this Agreement, (ii) any investigation made by or on behalf of any Underwriter, any person controlling any Underwriter or any affiliate of any Underwriter or by or on behalf of the Company, its officers or directors or any person controlling the Company and (iii) acceptance of and payment for any of the Shares.
- 9. Directed Share Program Indemnification. (a) The Company agrees to indemnify and hold harmless the DSP Underwriter, each person, if any, who controls the DSP Underwriter within the meaning of either Section 15 of the Securities Act or Section 20 of the Exchange Act and each affiliate of the DSP Underwriter within the meaning of Rule 405 of the Securities Act (the "DSP Underwriter Entities") from and against any and all losses, claims, damages and liabilities (including, without limitation, any legal or other expenses reasonably incurred and documented in connection with defending or investigating any such action or claim) (i) that arise out of, or are based upon, any untrue statement or alleged untrue statement of a material fact contained in any material prepared by or with the consent of the Company for distribution to Participants in connection with the Directed Share Program or arise out of, or are based upon, any omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading; (ii) that arise out of, or are based upon, the failure of any Participant to pay for and accept delivery of Directed Shares that the Participant agreed to purchase; or (iii) related to, arising out of, or in connection with the Directed Share Program, other than losses, claims, damages or liabilities (or expenses relating thereto) that are finally judicially determined to have resulted from the bad faith or gross negligence of DSP Underwriter Entities.
  - (b) In case any proceeding (including any governmental investigation) shall be instituted involving any DSP Underwriter Entity in respect of which indemnity may be sought pursuant to Section 9(a), the DSP Underwriter Entity seeking indemnity, shall promptly notify the Company in writing and the

Company, upon request of the DSP Underwriter Entity, shall retain counsel reasonably satisfactory to the DSP Underwriter Entity to represent the DSP Underwriter Entity and any others the Company may designate in such proceeding and shall pay the reasonably incurred and documented fees and disbursements of such counsel related to such proceeding. In any such proceeding, any DSP Underwriter Entity shall have the right to retain its own counsel, but the fees and expenses of such counsel shall be at the expense of such DSP Underwriter Entity unless (i) the Company shall have agreed to the retention of such counsel or (ii) the named parties to any such proceeding (including any impleaded parties) include both the Company and the DSP Underwriter Entity and representation of both parties by the same counsel would be inappropriate due to actual or potential differing interests between them. The Company shall not, in respect of the legal expenses of the DSP Underwriter Entities in connection with any proceeding or related proceedings in the same jurisdiction, be liable for the reasonably incurred and documented fees and expenses of more than one separate firm (in addition to any local counsel) for all DSP Underwriter Entities. Any such separate firm for the DSP Underwriter Entities shall be designated in writing by the DSP Underwriter. The Company shall not be liable for any settlement of any proceeding effected without its written consent, but if settled with such consent or if there be a final judgment for the plaintiff, the Company agrees to indemnify the DSP Underwriter Entities from and against any loss or liability by reason of such settlement or judgment. Notwithstanding the foregoing sentence, if at any time a DSP Underwriter Entity shall have requested the Company to reimburse it for reasonably incurred and documented fees and expenses of counsel as contemplated by the second and third sentences of this paragraph, the Company agrees that it shall be liable for any settlement of any proceeding effected without its written consent if (i) such settlement is entered into more than 30 days after receipt by the Company of the aforesaid request and (ii) the Company shall not have reimbursed the DSP Underwriter Entity in accordance with such request prior to the date of such settlement. The Company shall not, without the prior written consent of the DSP Underwriter, effect any settlement of any pending or threatened proceeding in respect of which any DSP Underwriter Entity is or could have been a party and indemnity could have been sought hereunder by such DSP Underwriter Entity, unless such settlement includes an unconditional release of the DSP Underwriter Entities from all liability on claims that are the subject matter of such proceeding.

(c) To the extent the indemnification provided for in Section 9(a) is unavailable to a DSP Underwriter Entity or insufficient in respect of any losses, claims, damages or liabilities referred to therein, then the Company in lieu of indemnifying the DSP Underwriter Entity thereunder, shall contribute to the amount paid or payable by the DSP Underwriter Entity as a result of such losses, claims, damages or liabilities (i) in such proportion as is appropriate to reflect the relative benefits received by the Company on the one hand and the DSP Underwriter Entities on the other hand from the offering of the Directed Shares or

- (ii) if the allocation provided by clause 9(c)(i) above is not permitted by applicable law, in such proportion as is appropriate to reflect not only the relative benefits referred to in clause 9(c)(i) above but also the relative fault of the Company on the one hand and of the DSP Underwriter Entities on the other hand in connection with any statements or omissions that resulted in such losses, claims, damages or liabilities, as well as any other relevant equitable considerations. The relative benefits received by the Company on the one hand and the DSP Underwriter Entities on the other hand in connection with the offering of the Directed Shares shall be deemed to be in the same respective proportions as the net proceeds from the offering of the Directed Shares (before deducting expenses) and the total underwriting discounts and commissions received by the DSP Underwriter Entities for the Directed Shares, bear to the aggregate Public Offering Price of the Directed Shares. If the loss, claim, damage or liability is caused by an untrue or alleged untrue statement of a material fact or the omission or alleged omission to state a material fact, the relative fault of the Company on the one hand and the DSP Underwriter Entities on the other hand shall be determined by reference to, among other things, whether the untrue or alleged untrue statement or the omission or alleged omission relates to information supplied by the Company or by the DSP Underwriter Entities and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such statement or omission.
- (d) The Company and the DSP Underwriter Entities agree that it would not be just or equitable if contribution pursuant to this Section 9 were determined by *pro rata* allocation (even if the DSP Underwriter Entities were treated as one entity for such purpose) or by any other method of allocation that does not take account of the equitable considerations referred to in Section 9(c). The amount paid or payable by the DSP Underwriter Entities as a result of the losses, claims, damages and liabilities referred to in the immediately preceding paragraph shall be deemed to include, subject to the limitations set forth above, any legal or other expenses reasonably incurred by the DSP Underwriter Entities in connection with investigating or defending any such action or claim. Notwithstanding the provisions of this Section 9, no DSP Underwriter Entity shall be required to contribute any amount in excess of the amount by which the total price at which the Directed Shares distributed to the public were offered to the public exceeds the amount of any damages that such DSP Underwriter Entity has otherwise been required to pay. The remedies provided for in this Section 9 are not exclusive and shall not limit any rights or remedies which may otherwise be available to any indemnified party at law or in equity.
- (e) The indemnity and contribution provisions contained in this Section 9 shall remain operative and in full force and effect regardless of (i) any termination of this Agreement, (ii) any investigation made by or on behalf of any DSP Underwriter Entity or the Company, its officers or directors or any person controlling the Company and (iii) acceptance of and payment for any of the Directed Shares.

10. Termination. The Underwriters may terminate this Agreement by notice given by the Representatives to the Company, if after the execution and delivery of this Agreement and prior to or on the Closing Date or any Option Closing Date, as the case may be, (i) trading generally shall have been suspended or materially limited on, or by, as the case may be, any of the New York Stock Exchange, the NYSE American, the NASDAQ Global Market, the Chicago Board of Options Exchange, the Chicago Mercantile Exchange, or the Chicago Board of Trade, (ii) trading of any securities of the Company shall have been suspended on any exchange or in any over-the-counter market, (iii) a material disruption in securities settlement, payment or clearance services in the United States shall have occurred, (iv) any moratorium on commercial banking activities shall have been declared by Federal or New York State authorities or (v) there shall have occurred any outbreak or escalation of hostilities, or any change in financial markets or any calamity or crisis that, in the Representatives' judgment, is material and adverse and which, singly or together with any other event specified in this clause (v), makes it, in the Representatives' judgment, impracticable or inadvisable to proceed with the offer, sale or delivery of the Shares on the terms and in the manner contemplated in the Time of Sale Prospectus or the Prospectus.

11. Effectiveness; Defaulting Underwriters. This Agreement shall become effective upon the execution and delivery hereof by the parties hereto.

If, on the Closing Date or an Option Closing Date, as the case may be, any one or more of the Underwriters shall fail or refuse to purchase Shares that it has or they have agreed to purchase hereunder on such date, and the aggregate number of Shares which such defaulting Underwriter or Underwriters agreed but failed or refused to purchase is not more than one-tenth of the aggregate number of the Shares to be purchased on such date, the other Underwriters shall be obligated severally in the proportions that the number of Firm Shares set forth opposite their respective names in Schedule I bears to the aggregate number of Firm Shares set forth opposite the names of all such non-defaulting Underwriters, or in such other proportions as the Representatives may specify, to purchase the Shares which such defaulting Underwriter or Underwriters agreed but failed or refused to purchase on such date; provided that in no event shall the number of Shares that any Underwriter has agreed to purchase pursuant to this Agreement be increased pursuant to this Section 11 by an amount in excess of one-ninth of such number of Shares without the written consent of such Underwriter. If, on the Closing Date, any Underwriter or Underwriters shall fail or refuse to purchase Firm Shares and the aggregate number of Firm Shares with respect to which such default occurs is more than one-tenth of the aggregate number of Firm Shares to be purchased on such date, and arrangements satisfactory to the Representatives, the Company for the purchase of such Firm Shares are not made within 36 hours after such default, this Agreement shall terminate without liability on the part of any non-defaulting Underwriter or the Company. In any such case either the Representatives or the Company shall have the right to postpone the Closing Date, but in no event for longer than seven days, in order that the required changes, if any, in the Registration Statement, in the Time of Sale Prospectus, in the Prospectus or in any other documents or arrangements may be effected. If, on an Option Closing Date, any Underwriter or Underwriters shall fail or refuse to purchase Additional Shares and the aggregate number of Additional Shares with respect to which such default occurs is more than one-tenth of the aggregate number of Additional Shares to be purchased on such Option Closing Date, the non-defaulting

Underwriters shall have the option to (i) terminate their obligation hereunder to purchase the Additional Shares to be sold on such Option Closing Date or (ii) purchase not less than the number of Additional Shares that such non-defaulting Underwriters would have been obligated to purchase in the absence of such default. Any action taken under this paragraph shall not relieve any defaulting Underwriter from liability in respect of any default of such Underwriter under this Agreement.

If this Agreement shall be terminated by the Underwriters, or any of them, because of any failure or refusal on the part of the Company to comply with the terms or to fulfill any of the conditions of this Agreement, or if for any reason the Company shall be unable to perform its obligations under this Agreement (other than by reason of a default by the Underwriters), the Company will reimburse the Underwriters or such Underwriters as have so terminated this Agreement with respect to themselves, severally, for all out-of-pocket expenses (including the fees and disbursements of their counsel) reasonably incurred by such Underwriters in connection with this Agreement or the offering contemplated hereunder.

- 12. *Entire Agreement*. (a) This Agreement, together with any contemporaneous written agreements and any prior written agreements (to the extent not superseded by this Agreement) that relate to the offering of the Shares, represents the entire agreement between the Company, on the one hand, and the Underwriters, on the other, with respect to the preparation of any preliminary prospectus, the Time of Sale Prospectus, the Prospectus, the conduct of the offering, and the purchase and sale of the Shares.
  - (b) The Company acknowledges that in connection with the offering of the Shares: (i) the Underwriters have acted at arm's length, are not agents of, and owe no fiduciary duties to, the Company or any other person, (ii) the Underwriters owe the Company only those duties and obligations set forth in this Agreement, any contemporaneous written agreements and prior written agreements (to the extent not superseded by this Agreement), if any, (iii) the Underwriters may have interests that differ from those of the Company, and (iv) none of the activities of the Underwriters in connection with the transactions contemplated herein constitutes a recommendation, investment advice, or solicitation of any action by the Underwriters with respect to any entity or natural person. The Company waives to the full extent permitted by applicable law any claims it may have against the Underwriters arising from an alleged breach of fiduciary duty in connection with the offering of the Shares.
- 13. Recognition of the U.S. Special Resolution Regimes. (a) In the event that any Underwriter that is a Covered Entity becomes subject to a proceeding under a U.S. Special Resolution Regime, the transfer from such Underwriter of this Agreement, and any interest and obligation in or under this Agreement, will be effective to the same extent as the transfer would be effective under the U.S. Special Resolution Regime if this Agreement, and any such interest and obligation, were governed by the laws of the United States or a state of the United States.

(b) In the event that any Underwriter that is a Covered Entity or a BHC Act Affiliate of such Underwriter becomes subject to a proceeding under a U.S. Special Resolution Regime, Default Rights under this Agreement that may be exercised against such Underwriter are permitted to be exercised to no greater extent than such Default Rights could be exercised under the U.S. Special Resolution Regime if this Agreement were governed by the laws of the United States or a state of the United States.

For purposes of this Section a "BHC Act Affiliate" has the meaning assigned to the term "affiliate" in, and shall be interpreted in accordance with, 12 U.S.C. § 1841(k). "Covered Entity" means any of the following: (i) a "covered entity" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 252.82(b); (ii) a "covered bank" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 382.2(b). "Default Right" has the meaning assigned to that term in, and shall be interpreted in accordance with, 12 C.F.R. §§ 252.81, 47.2 or 382.1, as applicable. "U.S. Special Resolution Regime" means each of (i) the Federal Deposit Insurance Act and the regulations promulgated thereunder and (ii) Title II of the Dodd-Frank Wall Street Reform and Consumer Protection Act and the regulations promulgated thereunder.

- 14. Counterparts. This Agreement may be signed in two or more counterparts, each of which shall be an original, with the same effect as if the signatures thereto and hereto were upon the same instrument. Counterparts may be delivered via facsimile, electronic mail (including any electronic signature covered by the U.S. federal ESIGN Act of 2000, Uniform Electronic Transactions Act, the Electronic Signatures and Records Act or other applicable law, e.g., www.docusign.com) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.
  - 15. Applicable Law. This Agreement shall be governed by and construed in accordance with the internal laws of the State of New York.
- 16. *Headings*. The headings of the sections of this Agreement have been inserted for convenience of reference only and shall not be deemed a part of this Agreement.
- 17. Notices. All communications hereunder shall be in writing and effective only upon receipt and if to the Underwriters shall be delivered, mailed or sent to each of the Representatives at Morgan Stanley & Co. LLC, 1585 Broadway, New York, New York 10036, Attention: Equity Syndicate Desk, with a copy to the Legal Department, Jefferies LLC, 520 Madison Avenue, New York, New York 10022, Attention: General Counsel, Cowen and Company, LLC, Attention: Head of Equity Capital Markets (fax: (646) 562-1249), with a copy to the General Counsel (fax: (646) 562-1124), and Barclays Capital Inc., 745 Seventh Avenue, New York, New York 10019, Attention: Syndicate Registration (fax: 646-834-8133) and if to the Company shall be delivered, mailed or sent to TScan Therapeutics, Inc., 830 Winter Street, Waltham, Massachusetts 02451.

Very truly yours,

TSCAN THERAPEUTICS, INC.

By:

Name: David Southwell Title: Chief Executive Officer

| Morgan Stanley & Co. LLC, Jefferies LLC, Cowen and Company, LLC, and Barclays Capital Inc. |                            |
|--|----------------------------|
| Acting severally on behalf of themselves and the several Underwriters in                   | named in Schedule I hereto |
| By: Morgan Stanley & Co. LLC   |                            |
| By:  |                            |
| Name:  |                            |
| Title:   |                            |
|  |                            |
| By: Jefferies LLC  |                            |
|  |                            |
| By:  |                            |
| Name:  |                            |
| Title:   |                            |
|  |                            |
| By: Cowen and Company, LLC   |                            |
|  |                            |
| By:  |                            |
| Name:  |                            |
| Title:   |                            |
|  |                            |
| By: Barclays Capital Inc.  |                            |
| D-v.   |                            |
| By:  |                            |
| Name:<br>Title:  |                            |
| mue:   |                            |
|  | 37                         |

Accepted as of the date hereof

# SCHEDULE I

| Underwriter              | Number of Firm Shares<br>To Be Purchased |
|--------------------------|--|
| Morgan Stanley & Co. LLC |  |
| Jefferies LLC            |  |
| Cowen and Company, LLC   |  |
| Barclays Capital Inc.    |  |
|                          |  |
| Total:                   |  |

# **Time of Sale Prospectus**

Preliminary Prospectus issued [ ], 2021
 Pricing Information:

 Firm Shares: [ ]
 Additional Shares: [ ]
 Public Offering Price: [ ]

III-1

# **Written Testing-The-Waters Communications**

1. Testing-the-Waters presentation [ ], 2021

A-1

**EXHIBIT A** 

# FORM OF LOCK-UP LETTER

A-1

#### FORM OF WAIVER OF LOCK-UP

|  |   | 2021 |
|--|---|------|
|  | • | 2021 |

[Name and Address of Officer or Director Requesting Waiver]

Dear Mr./Ms. [Name]:

This letter is being delivered to you in connection with the offering by TScan Therapeutics, Inc. (the "Company") of \_\_\_\_\_ shares of voting common stock, \$0.0001 par value (the "Common Stock"), of the Company and the lock-up letter dated \_\_\_\_, 20\_\_ (the "Lock-up Letter"), executed by you in connection with such offering, and your request for a [waiver] [release] dated \_\_\_\_, 2021, with respect to \_\_\_\_ shares of Common Stock (the "Shares").

Morgan Stanley & Co. LLC, Jefferies LLC, Cowen and Company, LLC, and Barclays Capital Inc. hereby agree to [waive] [release] the transfer restrictions set forth in the Lock-up Letter, but only with respect to the Shares, effective \_\_\_\_\_\_, 2021; provided, however, that such [waiver] [release] is conditioned on the Company announcing the impending [waiver] [release] by press release through a major news service at least two business days before effectiveness of such [waiver] [release]. This letter will serve as notice to the Company of the impending [waiver] [release].

Except as expressly [waived] [released] hereby, the Lock-up Letter shall remain in full force and effect.

Very truly yours,

Morgan Stanley & Co. LLC, Jefferies LLC, Cowen and Company, LLC, and Barclays Capital Inc.

MORGAN STANLEY & CO. LLC

By:
Name:
Title:

JEFFERIES LLC,

By:
Name:
Title:

COWEN AND COMPANY, LLC

By:
Name:
Title:

BARCLAYS CAPITAL INC.

By:

Acting severally on behalf of themselves and the several Underwriters named in Schedule I hereto

cc: Company

Name: Title:

### FORM OF PRESS RELEASE

TScan Therapeutics, Inc. [Date], 2021

TScan Therapeutics, Inc. (the "Company") announced today that Morgan Stanley & Co. LLC, Jefferies LLC, Cowen and Company, LLC, and Barclays Capital Inc., the joint book-running managers in the Company's recent public sale of \_\_\_\_\_ shares of voting common stock, are [waiving][releasing] a lock-up restriction with respect to \_\_\_\_ shares of the Company's voting common stock held by [certain officers or directors] [an officer or director] of the Company. The [waiver][release] will take effect on \_\_\_\_, 2021, and the shares may be sold on or after such date.

This press release is not an offer for sale of the securities in the United States or in any other jurisdiction where such offer is prohibited, and such securities may not be offered or sold in the United States absent registration or an exemption from registration under the United States Securities Act of 1933, as amended.

TSCAN THERAPEUTICS, INC.

2021 EMPLOYEE STOCK PURCHASE PLAN

(AS ADOPTED ON APRIL 22, 2021)

#### TSCAN THERAPEUTICS, INC.

#### 2021 EMPLOYEE STOCK PURCHASE PLAN

#### SECTION 1. PURPOSE OF THE PLAN.

The Board adopted the Plan effective as of the IPO Date. The purpose of the Plan is to provide Eligible Employees with an opportunity to increase their proprietary interest in the success of the Company by purchasing Stock from the Company on favorable terms and to pay for such purchases through payroll deductions or other approved contributions.

### SECTION 2. ADMINISTRATION OF THE PLAN.

- (a) **General**. The Plan may be administered by the Board or one or more Committees to which the Board (or an authorized Board committee) has delegated authority. If administration is delegated to a Committee, the Committee shall have the powers theretofore possessed by the Board, including, to the extent permitted by applicable law, the power to delegate to a sub-committee any of the administrative powers the Committee is authorized to exercise (and references in this Plan to either the Board or the Administrator shall hereafter also encompass the Committee or subcommittee, as applicable). The Board may abolish the Committee's delegation at any time and the Board shall at all times also retain the authority it has delegated to the Committee. Each Committee shall comply with rules and regulations applicable to it, including under the rules of any exchange on which the Stock is traded, and shall have the authority and be responsible for such functions as have been assigned to it.
- (b) **Powers of the Administrator**. Subject to the terms of the Plan, and in the case of a Committee, subject to the specific duties delegated to the Committee, the Administrator shall have the power to establish the terms and conditions of Offering Periods (which need not be identical) under the Plan, to interpret the Plan and make all other policy decisions relating to the operation of the Plan. The Administrator may adopt such rules, guidelines and forms as it deems appropriate to implement the Plan.
- (c) **Effects of Administrator's Decisions**. The Administrator's decisions, determinations and interpretations shall be final and binding on all interested parties.
- (d) **Governing Law**. The Plan shall be governed by, and construed in accordance with, the laws of the State of Delaware (except its choice of law provisions).

#### SECTION 3. STOCK OFFERED UNDER THE PLAN.

(a) **Authorized Shares**. The number of shares of Stock available for purchase under the Plan shall be 2,086,000 shares of the Company's Stock (subject to adjustment pursuant to Subsection (c) below), plus the additional shares described in Subsection (b) below. Shares of Stock issued pursuant to the Plan may be authorized but unissued shares or treasury shares.

- (b) **Annual Increase in Shares**. On the first day of each fiscal year of the Company during the term of the Plan, commencing on January 1, 2022 and ending on (and including) January 1, 2041, the aggregate number of shares of Stock that may be issued under the Plan shall automatically increase by a number equal to the least of (i) one percent (1%) of the total number of shares of Stock actually issued and outstanding on the last day of the preceding fiscal year, (ii) 2,000,000 shares of Stock (subject to adjustment pursuant to Subsection (c) below), or (iii) a number of shares of Stock determined by the Board.
- (c) **Anti-Dilution Adjustments**. In the event that any dividend or other distribution (whether in the form of cash, stock or other securities or other property), recapitalization, stock split, reverse stock split, reorganization, merger, consolidation, split-up, spin-off, combination, reclassification, repurchase, or exchange of Stock or other securities of the Company, or other similar change in the corporate structure of the Company affecting the Stock and effected without receipt or payment of consideration by the Company occurs, then in order to prevent dilution or enlargement of the benefits or potential benefits intended to be made available under the Plan, there will be a proportionate adjustment of the number and class of Stock that may be delivered under the Plan, the Purchase Price per share and the number of shares and class of Stock covered by each option under the Plan which has not yet been exercised, and the numerical limits of Sections 3(a), 3(b)(ii) and 9(c).
- (d) **Reorganizations**. In the event of a Corporate Reorganization, the outstanding rights to purchase Stock under any Offering Period then in progress may be continued, assumed or substituted by the surviving entity or its parent. If such acquirer refuses to continue, assume or substitute for any such rights, then a new Purchase Date for such Offering Period(s) will be set prior to the effective time of the Corporate Reorganization, the Participants' accumulated contributions will be applied to purchase Stock on such date, and any such Offering Periods shall terminate immediately after such purchase. In the event a new Purchase Date is set under this Section 3(d), Participants will be given notice of the new Purchase Date. The Plan shall in no event be construed to restrict in any way the Company's right to undertake a dissolution, liquidation, merger, consolidation or other reorganization.

#### SECTION 4. ENROLLMENT AND PARTICIPATION.

- (a) Offering Periods and Purchase Periods.
  - (i) **Base Offering Periods**. The Administrator may from time to time establish Offering Periods (consisting of one or more Purchase Periods) of such frequency and duration as it may deem appropriate (the "*Base Offering Periods*"); provided that a Base Offering Period shall in no event be longer than 27 months (or such other period as may be imposed under applicable tax law). Each Base Offering Period shall contain such terms and conditions (consistent with the Plan) as the Administrator deems appropriate. Within the limits of the Plan, the Administrator may change the frequency, duration and other terms and conditions of the Base Offering Periods as it deems appropriate from time to time. The Base Offering Periods are intended to qualify under Code Section 423.

- (ii) Additional Offering Periods. At the discretion of the Administrator, additional Offering Periods (the "Additional Offering Periods") may be conducted under the Plan including, if necessary or advisable in the sole discretion of the Administrator, under a separate sub-plan or sub-plans, permitting grants to Eligible Employees of certain Participating Companies (each, a "Sub-Plan"). Such Additional Offering Periods will be designed to achieve desired tax objectives in particular locations outside the United States or to comply with local laws applicable to offerings in such foreign jurisdictions and may, but need not, qualify under Code Section 423. The Administrator shall determine the commencement and duration of each Additional Offering Period, and Additional Offering Periods may be consecutive or overlapping. The other terms and conditions of each Additional Offering Period shall be those set forth in this Plan document or in terms and conditions approved by the Administrator with respect to such Additional Offering Period (whether or not set forth in a written Sub-Plan), with such changes or additional features as the Administrator determines necessary to comply with local law. Each Additional Offering Period (whether or not set forth in a written Sub-Plan) shall be considered a separate plan from the Plan (the "Statutory Plan"). The total number of Shares authorized to be issued under the Plan as provided in Section 3 above applies in the aggregate to both the Statutory Plan and any Additional Offering Period. Unless otherwise superseded by the terms and conditions approved by the Administrator with respect to an Additional Offering Period, the provisions of this Plan document shall govern the operation of any offering conducted hereunder.
- (iii) **Separate Offerings**. Each Base Offering Period and each Additional Offering Period conducted under the Plan is intended to constitute a separate "offering" for purposes of Code Section 423.
- (iv) **Equal Rights and Privileges**. To the extent an Offering Period is intended to qualify under Code Section 423, all participants in such Offering Period shall have the same rights and privileges with respect to their participation in such Offering Period in accordance with Code Section 423 and the regulations thereunder except for differences that may be mandated by local law and are consistent with the requirements of Code Section 423(b)(5).
- (b) **Enrollment**. In the case of any individual who qualifies as an Eligible Employee on the first day of any Offering Period, he or she may elect to become a Participant on such day by filing the prescribed enrollment form with the Company. The enrollment form shall be filed in the prescribed manner during the applicable Enrollment Period for such Offering Period. The Administrator may establish other procedures for enrollment by Eligible Employees.
  - (c) **Duration of Participation**. Once enrolled in the Plan, a Participant shall continue to participate in the Plan until he or she:
    - Reaches the end of the Offering Period or Purchase Period, as applicable, in which his or her employee contributions were discontinued under Section 5(c) or 9(b);

- (ii) Withdraws from the Plan under Section 6(a); or
- (iii) Ceases to be an Eligible Employee.

A Participant whose employee contributions were discontinued automatically under Section 9(b) shall automatically resume participation as described therein. In all other cases, a former Participant may again become a Participant, if he or she then is an Eligible Employee, by following the procedure described in Subsection (b) above.

- (d) **Applicable Offering Period**. For purposes of calculating the Purchase Price under Section 8(b), the applicable Offering Period shall be determined as follows:
  - (i) Once a Participant is enrolled in the Plan for an Offering Period, such Offering Period shall continue to apply to him or her until the earliest of (A) the end of such Offering Period, (B) the end of his or her participation under Subsection (c) above, or (C) re-enrollment for a subsequent Offering Period under Paragraph (ii) or (iii) below.
  - (ii) Any other provision of the Plan notwithstanding, the Administrator (at its sole discretion) may determine prior to the commencement of any new Offering Period that all Participants shall be re-enrolled for such new Offering Period. In addition, the Administrator may structure an Offering Period so that in the event that the Fair Market Value of a Share on the first day of the Offering Period for which the Participant is enrolled is higher than on the first day of any subsequent Offering Period, the Participant shall automatically be re-enrolled for such subsequent Offering Period.
  - (iii) When a Participant reaches the end of an Offering Period but his or her participation is to continue, then such Participant shall automatically be re-enrolled for the Offering Period that commences immediately after the end of the prior Offering Period.

## SECTION 5. EMPLOYEE CONTRIBUTIONS.

(a) **Commencement of Payroll Deductions**. A Participant may purchase shares of Stock under the Plan by means of payroll deductions or (if so approved by the Administrator with respect to all Participants in a Base Offering Period) other approved contributions in form and substance satisfactory to the Administrator. Payroll deductions or other approved contributions shall commence as soon as reasonably practicable after the Company has received the prescribed enrollment form. In jurisdictions where payroll deductions are not permitted under local law, Participants may purchase shares of Stock by making contributions in the form that is acceptable and approved by the Administrator.

- (b) **Amount of Payroll Deductions**. An Eligible Employee shall designate on the prescribed enrollment form the portion of his or her Compensation that he or she elects to have withheld for the purchase of Stock. Such portion shall be a whole percentage of the Eligible Employee's Compensation, but not less than 1% nor more than 15% (or such lesser percentage established by the Administrator for an Offering Period).
- (c) **Reducing Withholding Rate or Discontinuing Payroll Deductions.** If a Participant wishes to reduce his or her rate of payroll withholding, such Participant may do so by filing a new enrollment form with the Company in the manner prescribed by the Administrator. The new withholding rate shall be effective as soon as reasonably practicable after the Company has received such form. The new withholding rate may be 0% or any whole percentage of the Participant's Compensation, but not more than his or her old withholding rate. The Administrator may limit the number of times a Participant may elect to reduce his or her rate of withholding during any Offering Period and/or Purchase Period. Unless a different rule is established for an Offering Period, no Participant shall make more than one election under this Subsection (c) during any Purchase Period. (In addition, employee contributions may be discontinued automatically pursuant to Section 9(b).)
- (d) **Increasing Withholding Rate**. Unless the Administrator establishes a different rule for an Offering Period, a Participant may not increase his or her rate of payroll withholding during a Purchase Period. If a Participant wishes to increase his or her rate of payroll withholding, such Participant may do so by filing a new enrollment form with the Company at least fifteen (15) calendar days prior to commencement of a Purchase Period (or such other period as is specified by the Administrator). The new withholding rate shall be effective on the first day of the next-upcoming Purchase Period in which the Participant participates. The new withholding rate may be any whole percentage of the Participant's Compensation, but not less than 1% nor more than the maximum amount established for the Offering Period.

#### SECTION 6. WITHDRAWAL FROM THE PLAN.

- (a) **Withdrawal**. A Participant may elect to withdraw from the Plan (and the Offering Period in which he or she is participating) by filing the prescribed form with the Company in the prescribed manner at least fifteen (15) calendar days prior to a Purchase Date (or such other period as is specified by the Administrator). As soon as reasonably practicable thereafter, payroll deductions or other approved contributions shall cease and the entire amount credited to the Participant's Plan Account with respect to such Offering Period shall be refunded to him or her in cash, without interest (except as otherwise required by the laws of the local jurisdiction). No partial withdrawals from an Offering Period shall be permitted.
- (b) **Re-Enrollment After Withdrawal**. A former Participant who has withdrawn from the Plan shall not be a Participant until he or she re-enrolls in the Plan under Section 4(b) during an Enrollment Period. Re-enrollment may be effective only at the commencement of an Offering Period.

#### SECTION 7. CHANGE IN EMPLOYMENT STATUS.

- (a) **Termination of Employment**. Termination of employment as an Eligible Employee for any reason, including death, shall be treated as an automatic withdrawal from the Plan under Section 6(a).
- (b) **Transfers of Employment**. If a Participant transfers employment from a Participating Company that is participating in a Base Offering Period to a Participating Company that is participating in an Additional Offering Period, he or she will immediately cease to participate in the Base Offering Period, as applicable; however, such Participant's Plan Account will be transferred to the Additional Offering Period, and such Participant will immediately join such Additional Offering Period on the terms and conditions applicable to such Additional Offering Period, except for any modifications required by applicable law. If a Participant transfers employment from a Participating Company that is participating in an Additional Offering Period to a Participating Company that is participating in the Base Offering Period, he or she will continue to participate in the Additional Offering Period until the earlier of (i) the end of such Additional Offering Period, or (ii) the commencement of the first Base Offering Period in which he or she is eligible. If a Participant transfers employment from a Participating Company to a Related Corporation that is not a Participating Company, he or she shall be deemed to have withdrawn from the Plan pursuant to Section 6(a).
- (c) **Leave of Absence**. For purposes of the Plan, employment shall not be deemed to terminate when the Participant goes on a military leave, a sick leave or another *bona fide* leave of absence, if the leave was approved by the Company in writing. Employment, however, shall be deemed to terminate on the first day following three months after the Participant goes on a leave, unless a contract or statute guarantees his or her right to return to work. Employment shall be deemed to terminate in any event when the approved leave ends, unless the Participant immediately returns to work.
- (d) **Death**. In the event of the Participant's death, the amount credited to his or her Plan Account shall be paid in cash, without interest (unless otherwise required by the laws of the local jurisdiction), to a beneficiary designated by him or her for this purpose on the prescribed form or, if none, to the Participant's estate. Such form shall be valid only if it was filed with the Company at the prescribed location before the Participant's death.

#### SECTION 8. PLAN ACCOUNTS AND PURCHASE OF SHARES.

- (a) Plan Accounts. The Company shall maintain a Plan Account on its books in the name of each Participant. Whenever an amount is deducted from the Participant's Compensation under the Plan, such amount shall be credited to the Participant's Plan Account. Unless otherwise required by the laws of the local jurisdiction, (i) amounts credited to Plan Accounts shall not be trust funds and may be commingled with the Company's general assets and applied to general corporate purposes, and (ii) no interest shall be credited to Plan Accounts.
- (b) **Purchase Price**. The Administrator shall establish the Purchase Price for each Offering Period; provided, however, that the Purchase Price for each share of Stock purchased on a Purchase Date shall not be less than the lower of:
  - (i) 85% of the Fair Market Value of such share on the first trading day of such Offering Period; or

- (ii) 85% of the Fair Market Value of such share on the Purchase Date.
- (c) **Number of Shares Purchased.** On each Purchase Date, each Participant shall be deemed to have elected to purchase the number of shares of Stock calculated in accordance with this Subsection (c), unless the Participant has previously elected to withdraw from the Offering Period in accordance with Section 6(a). The amount then in the Participant's Plan Account shall be divided by the Purchase Price, and the number of shares that results shall be purchased from the Company with the funds in the Participant's Plan Account. The foregoing number of shares of Stock that may be purchased by a Participant are subject to the limitations set forth in Subsection (d) below and in Section 9. The Administrator may determine with respect to all Participants in an Offering Period that any fractional share, as calculated under this Subsection (c), shall be (i) rounded down to the next lower whole share or (ii) credited as a fractional share.
- (d) Available Shares Insufficient. In the event that the aggregate number of shares that all Participants elect to purchase with respect to a particular Purchase Period exceeds (i) the number of shares of Stock that were available under Section 3 above for sale under the Plan on the first day of the applicable Offering Period, or (ii) the number of shares that were available under Section 3 above for sale under the Plan on the applicable Purchase Date, then the number of shares to which each Participant is entitled shall be determined by multiplying the number of shares available for issuance by a fraction. The numerator of such fraction is the number of shares that all Participants have elected to purchase. The Company may make a pro rata allocation of the shares available on the first day of an applicable Offering Period pursuant to the preceding sentence, notwithstanding any authorization of additional shares for issuance under the Plan by the Company's stockholders subsequent to such date. In the event of a pro-rata allocation under this Section (d), the Administrator may determine in its discretion to continue all Offering Periods then in effect or terminate all Offering Periods then in effect pursuant to Section 14.
- (e) **Issuance of Stock**. The shares of Stock purchased by a Participant under the Plan will be registered in the name of such Participant. The Company may permit or require that shares be deposited directly with a broker designated by the Company or to a designated agent of the Company, and the Company may utilize electronic or automated methods of share transfer. The Company may require that shares be retained with such broker or agent for a designated period of time and/or may establish other procedures to permit tracking of disqualifying dispositions of such shares. (The two preceding sentences shall apply whether or not the Participant is required to pay income tax in the United States.)
- (f) **Tax Withholding.** To the extent required by applicable federal, state, local or foreign law, a Participant shall make arrangements satisfactory to the Company for the satisfaction of any withholding tax obligations that arise in connection with the Plan. The Company shall not be required to issue any shares of Stock under the Plan until such obligations, if any, are satisfied.

- (g) **Unused Cash Balances**. Subject to the final sentence of Section 8(c), any amount remaining in a Participant's Plan Account at the end of a Purchase Period solely by reason of the inability to purchase a fractional share will be carried over to the next Offering Period or Purchase Period, as applicable. Any amount remaining in the Participant's Plan Account that represents the Purchase Price for whole shares that could not be purchased by reason of Subsections (c) or (d) above or Section 9(b) shall be refunded to the Participant in cash, without interest (except as otherwise required by the laws of the local jurisdiction).
- (h) **Stockholder Approval**. Any other provision of the Plan notwithstanding, no shares of Stock shall be purchased under the Plan unless and until the Company's stockholders have approved the adoption of the Plan.

#### SECTION 9. PLAN LIMITATIONS.

- (a) **Five Percent Limit**. Any other provision of the Plan notwithstanding, no Participant shall be granted a right to purchase Stock under the Plan if, immediately after such right is granted, such Participant would own stock possessing 5% or more of the total combined voting power or value of all classes of stock of the Company or any Related Corporation, applying the stock attribution rules of Code Section 424(d), and including any stock in which the Participant may purchase under outstanding options as stock owned by such Participant.
- (b) **Dollar Limit.** As specified by Code Section 423(b)(8), no Participant shall be entitled to accrue rights to purchase Stock pursuant to any such rights outstanding under the Plan if and to the extent such accrual, when aggregated with (i) rights to purchase Stock accrued under any other right to purchase Stock under the Plan, and (ii) similar rights accrued under other employee stock purchase plans (within the meaning of Code Section 423) of the Company or any Related Corporation, would otherwise permit such Participant to purchase more than \$25,000 worth of Stock of the Company or any Related Corporation (determined on the basis of the Fair Market Value per share on the date such rights are granted, and which, with respect to the Plan, will be determined as of the beginning of the respective Offering Period) for each calendar year such rights are at any time outstanding.

If a Participant is precluded by this Subsection (b) from purchasing additional Stock under the Plan, then his or her employee contributions shall automatically be discontinued and shall automatically resume at the beginning of the next Purchase Period with a scheduled Purchase Date in the next calendar year, provided that he or she is an Eligible Employee at the beginning of such Purchase Period.

(c) **Purchase Period Share Purchase Limit.** The Administrator may establish one or more limits on the number of shares of Stock that may be purchased during any Offering Period and/or Purchase Period, including individual limits and/or aggregate limits. Unless the Administrator provides otherwise with respect to an Offering Period, any other provision of the Plan notwithstanding, no Participant shall purchase more than 7,500 shares of Stock with respect to any Purchase Period.

#### SECTION 10. RIGHTS NOT TRANSFERABLE.

The rights of any Participant under the Plan, or any Participant's interest in any Stock or moneys to which he or she may be entitled under the Plan, shall not be transferable by voluntary or involuntary assignment or by operation of law, or in any other manner other than by beneficiary designation or the laws of descent and distribution. If a Participant in any manner attempts to transfer, assign or otherwise encumber his or her rights or interest under the Plan, other than by beneficiary designation or the laws of descent and distribution, then such act shall be treated as an election by the Participant to withdraw from the Plan under Section 6(a).

#### SECTION 11. NO RIGHTS AS AN EMPLOYEE.

Nothing in the Plan or in any right granted under the Plan shall confer upon the Participant any right to continue in the employ of a Participating Company for any period of specific duration or interfere with or otherwise restrict in any way the rights of the Participating Companies or of the Participant, which rights are hereby expressly reserved by each, to terminate his or her employment at any time and for any reason, with or without cause.

### SECTION 12. NO RIGHTS AS A STOCKHOLDER.

A Participant shall have no rights as a stockholder with respect to any shares of Stock that he or she may have a right to purchase under the Plan until such shares have been purchased on the applicable Purchase Date.

## SECTION 13. SECURITIES LAW REQUIREMENTS.

Shares of Stock shall not be issued, and the Company shall have no liability for failure to issue shares of Stock, under the Plan unless the issuance and delivery of such shares comply with (or are exempt from) all applicable requirements of law, including (without limitation) the Securities Act of 1933, as amended, the rules and regulations promulgated thereunder, state securities laws and regulations, and the regulations of any stock exchange or other securities market on which the Company's securities may then be traded.

### SECTION 14. AMENDMENT OR DISCONTINUANCE.

(a) **General Rule.** The Administrator, in its sole discretion, may amend, suspend, or terminate the Plan, or any part thereof, at any time and for any reason. If the Plan is terminated, the Administrator, in its discretion, may elect to terminate all outstanding Offering Periods either immediately or upon completion of the purchase of shares of Stock on the next Purchase Date, or may elect to permit Offering Periods to expire in accordance with their terms (and subject to any adjustment pursuant to Section 3(c) or (d)). If the Offering Periods are terminated prior to expiration, all amounts then credited to Participants' accounts which have not been used to purchase shares of Stock will be returned to the Participants (without interest thereon, except as otherwise required by the laws of the local jurisdiction) as soon as administratively practicable.

- (b) Administrator's Discretion. Without stockholder consent and without limiting Subsection (a) above, the Administrator will be entitled to change the Offering Periods, limit the frequency and/or number of changes in the amount withheld during an Offering Period, establish the exchange ratio applicable to amounts withheld in a currency other than U.S. dollars, permit payroll withholding in excess of the amount designated by a Participant in order to adjust for delays or mistakes in the Company's processing of properly completed withholding elections, establish reasonable waiting and adjustment periods and/or accounting and crediting procedures to ensure that amounts applied toward the purchase of Stock for each Participant properly correspond with amounts withheld from the Participant's Compensation, amend any outstanding purchase rights or clarify any ambiguities regarding the terms of any Offering Period to enable the purchase rights to qualify under and/or comply with Section 423 of the Code, and establish such other limitations or procedures as it determines in its sole discretion advisable which are consistent with the Plan. The actions of the Administrator pursuant to this paragraph will not be considered to alter or impair the purchase rights granted under an Offering Period as they are to be deemed part of the initial terms of such Offering Period and purchase rights.
- (c) **Accounting Consideration**. In the event the Administrator determines that the ongoing operation of the Plan may result in unfavorable financial accounting consequences, the Administrator may, in its discretion and, to the extent necessary or desirable, modify, amend or terminate the Plan to reduce or eliminate such accounting consequence including, but not limited to:
  - (i) Amending the Plan to conform with the safe harbor definition under Financial Accounting Standards Board Accounting Standards Codification Topic 718 (or successor provision), including with respect to an Offering Period underway at the time;
  - (ii) Altering the Purchase Price for any Offering Period including an Offering Period underway at the time of the change in Purchase Price:
  - (iii) Shortening any Offering Period (and any Purchase Periods encompassed by such Offering Period) by setting a new Purchase Date, including with respect to an Offering Period underway at the time of the Administrator's action;
  - (iv) Reducing the maximum percentage of Compensation a Participant may elect to set aside as payroll deductions; and
  - (v) Reducing the maximum number of shares of Stock a Participant may purchase during any Purchase Period.

Such modifications or amendments will not require stockholder approval or the consent of any Plan Participants. The actions of the Administrator pursuant to this paragraph will not be considered to alter or impair the purchase rights granted under an Offering Period as they are to be deemed part of the initial terms of such Offering Period and purchase rights.

(d) **Stockholder Approval**. Except as provided in Section 3, any increase in the aggregate number of shares of Stock that may be issued under the Plan shall be subject to the

approval of the Company's stockholders. In addition, any other amendment of the Plan shall be subject to the approval of the Company's stockholders to the extent required under Section 14(e) or by any applicable law or regulation.

(e) **Plan Termination**. The Plan shall terminate automatically 20 years after its adoption by the Board, unless (i) the Plan is extended by the Board and (ii) the extension is approved within 12 months by a vote of the stockholders of the Company.

#### SECTION 15. DEFINITIONS.

- (a) "Administrator" means the Board or any Committee administering the Plan in accordance with Section 2.
- (b) "Board" means the Board of Directors of the Company, as constituted from time to time.
- (c) "Code" means the Internal Revenue Code of 1986, as amended.
- (d) "Committee" means a committee of one or more members of the Board, or of other individuals satisfying applicable laws, appointed by the Board to administer the Plan.
  - (e) "Company" means TScan Therapeutics, Inc., a Delaware corporation.
- (f) "Compensation" means, unless otherwise determined by the Administrator with respect to an Offering Period, those components of a Participant's cash compensation (prior to reductions pursuant to Code Sections 125, 132(f) or 401(k)) that are regular and recurring, *including* cash base salary or base hourly pay *but* excluding any overtime pay or shift differentials, commissions, annual cash incentive compensation, and annual cash bonuses, and *further excluding* extraordinary cash items (such as one-time bonuses), as well as all non-cash items, moving or relocation allowances, cost-of-living or tax equalization payments, car allowances, tuition reimbursements, imputed income attributable to cars or life insurance, severance pay, fringe benefits, contributions or benefits received under employee benefit plans, payments for or related to equity compensation, and any similar items. The Administrator shall determine whether a particular item is included in Compensation.

## (g) "Corporate Reorganization" means:

- (i) The consummation of a merger or consolidation of the Company with or into another entity or any other corporate reorganization; or
- (ii) The sale, transfer or other disposition of all or substantially all of the Company's assets or the complete liquidation or dissolution of the Company.
- (h) "Eligible Employee" means a common law employee of a Participating Company, provided, however, that the Administrator may exclude one or more of the following categories of employees (where exclusion of such employees is permitted by applicable law) from any Offering Period: (i) employees who have been employed less than two years (or any

shorter period of time established for an Offering Period), (ii) employees who are customarily employed twenty (20) or less hours per week (or any lesser number of hours per week established for an Offering Period), (iii) employees who are customarily employed for five (5) months or less in a calendar year (or any lesser number of months in a calendar year established for an Offering Period), (iv) "highly compensated employees" (within the meaning of Code Section 414(q)) or (v) "highly compensated employees" (within the meaning of Code Section 414(q)) with compensation above a certain level and/or who are subject to the disclosure requirements of Section 16(a) of the Exchange Act. In addition, an individual shall not be considered an Eligible Employee if his or her participation in the Plan is prohibited by the law of any country that has jurisdiction over him or her or if complying with the laws of the applicable foreign jurisdiction would cause the Plan or an Offering Period to violate the requirements of Code Section 423. With respect to a Base Offering Period, any criteria used to determine Eligible Employees shall be determined in a manner consistent with Code Section 423. In the case of an Offering Period that is not intended to qualify under Code Section 423, the Administrator may exclude any individual(s) from participation if the Administrator determines the participation of such individual(s) is not advisable or practicable.

- (i) "Enrollment Period" means a period prior to the start of an Offering Period during which Eligible Employees must submit the required enrollment forms to participate in such Offering Period, which period shall end at least five (5) business days (or such other date as may be specified in advance by the Administrator) prior to the start of the Offering Period.
  - (j) "Exchange Act" means the Securities Exchange Act of 1934, as amended.
- (k) "Fair Market Value" means the price at which Stock was last sold in the principal U.S. market for the Stock on the applicable date or, if the applicable date was not a trading day, on the last trading day prior to the applicable date. If Stock is no longer traded on a public U.S. securities market, the Fair Market Value shall be determined by the Administrator in good faith on such basis as it deems appropriate. The Administrator's determination shall be conclusive and binding on all persons.
- (l) "IPO Date" means the effective date of the registration statement filed by the Company with the Securities and Exchange Commission for its initial offering of Stock to the public.
- (m) "Offering Period" means any period, including as the context requires the Base Offering Periods and Additional Offering Periods, with respect to which the right to purchase Stock may be granted under the Plan, as determined pursuant to Section 4(a).
  - (n) "Participant" means an Eligible Employee who participates in the Plan or any Sub-Plan, as provided in Section 4.
- (o) "Participating Company" means (i) the Company and (ii) each present or future Subsidiary designated by the Administrator as a Participating Company.
  - (p) "Plan" means this TScan Therapeutics, Inc. 2021 Employee Stock Purchase Plan, as it may be amended from time to time.

- (q) "Plan Account" means the account established for each Participant pursuant to Section 8(a).
- (r) "Purchase Date" means the last trading day of a Purchase Period.
- (s) "Purchase Period" means a period within an Offering Period (which for an Offering Period with only a single Purchase Period would be coterminous with the Offering Period) during which contributions may be made toward the purchase of Stock under the Plan, as determined pursuant to Section 4(a).
  - (t) "Purchase Price" means the price at which Participants may purchase Stock under the Plan, as determined pursuant to Section 8(b).
  - (u) "Related Corporation" means any "parent corporation" of the Company as defined in Code Section 424(e) or any Subsidiary.
  - (v) "Stock" means the common stock of the Company.
- (w) "Subsidiary" means any corporation (other than the Company) in an unbroken chain of corporations beginning with the Company, if each of the corporations other than the last corporation in the unbroken chain owns stock possessing 50% or more of the total combined voting power of all classes of stock in one of the other corporations in such chain.

## CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the use in this Registration Statement No. 333-255491 on Form S-1 of our report dated March 19, 2021, relating to the financial statements of TScan Therapeutics, Inc. We also consent to the reference to us under the heading "Experts" in such Registration Statement.

/s/ Deloitte & Touche LLP

Boston, Massachusetts April 30, 2021