Filed pursuant to Rule 424(b)(4)
Registration Nos. 333-272600 and 333-273361

PROSPECTUS

6,666,667 Shares

Common Stock

This is Turnstone Biologics Corp.'s initial public offering. We are selling 6,666,667 shares of our common stock.

The initial public offering price is $12.00 per share. Prior to this offering, there has been no public market for the shares of our common stock. Our common stock has been approved for listing on the Nasdaq Global Market, or Nasdaq, under the symbol "TSBX."

We are an "emerging growth company" and a "smaller reporting company" as defined under the federal securities laws and, as such, have elected to comply with certain reduced public company disclosure standards. See the section titled "Prospectus Summary—Implications of Being an Emerging Growth Company and a Smaller Reporting Company."

Investing in our common stock involves risks that are described in the "Risk Factors" section beginning on page 16 of this prospectus.

	Per Share	Total
Public offering price	$12.00	$80,000,004
Underwriting discount(1)	$0.84	$5,600,000
Proceeds before expenses, to us	$11.16	$74,400,004

(1) We refer you to the section titled "Underwriting" beginning on page 231 of this prospectus for additional information regarding underwriting compensation.

The underwriters may also exercise their option to purchase up to an additional 1,000,000 shares of common stock from us, at the public offering price, less the underwriting discount, for 30 days after the date of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has 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 shares will be ready for delivery on or about July 25, 2023.

Joint Book-Running Managers

BofA Securities **Leerink Partners** **Piper Sandler**

The date of this prospectus is July 20, 2023.

TABLE OF CONTENTS

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.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus. This summary does not contain all of the information you should consider before investing in our common stock. You should read this entire prospectus carefully, including the sections titled "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations," "Special Note Regarding Forward-Looking Statements," and our consolidated financial statements and the related notes included elsewhere in this prospectus, before making an investment decision. Unless the context otherwise requires, references to "we," "us," "our," "the company" and "Turnstone USA" refer to Turnstone Biologics Corp., a Delaware corporation, and our wholly owned subsidiaries, Turnstone Biologics Inc., a corporation under the Canada Business Corporations Act, which we refer to in this prospectus as Turnstone Canada, and Myst Therapeutics, LLC, a Delaware limited liability company.

Overview

We are a clinical stage biotechnology company focused on developing new medicines to treat and cure patients with solid tumors. Approved immunotherapies represent a significant advancement in the treatment of solid tumors, but many patients either do not respond or experience relapsed disease following an initial response. We believe the most significant challenge to creating curative immunotherapies in these patients is the low numbers of T cells that can recognize and attack the tumor, which we refer to as tumor-reactive T cells. To address this problem, we are pioneering a differentiated approach to tumor infiltrating lymphocytes, or TILs. We are developing next generation TIL therapies by selecting the most potent (meaning able to mediate an anti-tumor response) and tumor-reactive T cells, which we refer to as Selected TILs. Unlike other approaches that rely on standard "bulk TILs" that have demonstrated objective responses in clinical trials only in limited tumor types, we are developing our Selected TILs for potential treatment across the majority of solid tumors. We have initiated two Phase 1 clinical trials for TIDAL-01, including a multi-site trial for the treatment of breast cancer, colorectal cancer, and uveal melanoma, and an investigator sponsored trial with H. Lee Moffitt Cancer Center and Research Institute, Inc., or Moffitt, in both cutaneous and non-cutaneous melanomas. We discuss the nature of this investigator-sponsored trial, including how this trial differs from a clinical trial sponsored by our company, as well as our roles and responsibilities in the trial, in more detail below. We intend to provide an initial clinical update across these two trials in mid-2024. We are also actively advancing our preclinical pipeline programs including TIDAL-02, our next Selected TIL program, and our TIDAL-01 viral immunotherapy combination program. We define objective response as a patient experiencing a partial response or complete response to any given therapy.

Solid tumors present a major burden to society, with high mortality and poor outcomes associated with more advanced disease. Several key factors, such as tumor heterogeneity (meaning differences in the characteristics, including variable tumor antigen expression, between cancer cells within a patient's tumor, between tumors within the same patient and/or between different patients' tumor(s)) and challenging tumor microenvironments, or TMEs, have made treatment of solid tumors more difficult than treatment of hematologic cancers. Immunotherapies that activate the immune system to enhance and/or create anti-tumor immune responses, such as immune checkpoint inhibitors, or ICIs, have improved outcomes for some patients. However, more than 85% of cancer patients fail to respond to ICI therapy. The effectiveness of ICIs is heavily dependent on the presence of tumor-reactive T cells that ICIs can reinvigorate, and many patients lack a sufficient number of T cells that recognize the target tumor. Therefore, we believe new treatments that can expand and enhance the patient's tumor-reactive T cells are needed.

TILs are a type of cell therapy that harness the patient's own immune cells to target their own tumors. TIL therapy involves the isolation of lymphocytes from the patient's tumor, expansion of the isolated cells outside the body, and then infusion of the cells back into the patient. TILs have the ability to penetrate, recognize, and kill cancer cells and offer potential to treat or cure solid tumors. Because TILs include an expansive breadth of lymphocytes that are specific to the patient's tumor antigens, we believe they have the potential to overcome tumor heterogeneity which often presents a significant challenge for other therapies. Clinical trials with standard "bulk

TILs," the first generation of TIL therapy that involves isolation and expansion of all of the TILs in the tumor sample, have shown objective responses in clinical trials in limited solid tumor types.

To date, several hundred patients in the United States have received bulk TIL therapies, with the greatest success observed in metastatic melanoma. In metastatic melanoma patients refractory to ICI therapy, specifically PD-(L)1 treatments (meaning monoclonal antibodies targeting the immune checkpoint PD-1), bulk TIL monotherapy has yielded objective response rates (meaning the percentage of patients experiencing a partial response or complete response in any given study) of approximately 30% to 50%, with complete response rates (meaning the percentage of patients with complete eradication of measurable disease in the patient and no new lesions) ranging from approximately 5% up to 20%. If a complete response lasts the lifespan of a patient it would be considered as a cure – in general clinical practice patients are referred to as "cured" if they remain in complete response for greater than five years as the probability of their disease recurrence is low. Beyond metastatic melanoma, bulk TIL therapy has demonstrated therapeutic potential in a limited number of solid tumors, including squamous cell carcinoma of the head and neck, cervical cancer, and non-small cell lung cancer. We believe that the activity of TILs is driven by the subset of tumor-reactive T cells, and that the key limitation for bulk TILs is the small number and proportion of tumor-reactive T cells that make up the bulk TIL product (reported median less than 3%, *Lowery et al., 2022*). We believe increasing the proportion and diversity of tumor-reactive T cells in a TIL product can expand the utility of TILs to a greater breadth of tumor types, where bulk TILs have not shown objective responses in clinical trials to date.

Our Solution: Selected TILs

We are developing next generation TIL therapies for the potential treatment of multiple solid tumors. There are no TIL therapies that have received FDA approval to date. To our knowledge, at present there are no therapies in clinical development that provide curative outcomes for the majority of patients in our chosen solid tumor indications. Our innovative Selected TIL approach focuses on selecting and expanding the most potent tumor-reactive T cells to overcome the limitations of bulk TILs. This approach expands upon work conducted in academia that demonstrated improved clinical responses for certain selected TILs in solid-tumor types where bulk TILs have not shown objective responses in clinical trials. We are leveraging this work to establish a standardized manufacturing process for large scale production of our Selected TILs.

Our Selected TIL approach employs the following foundational principles with the goal of yielding the greatest number and proportion of tumor-reactive T cells in our TIL product candidates:

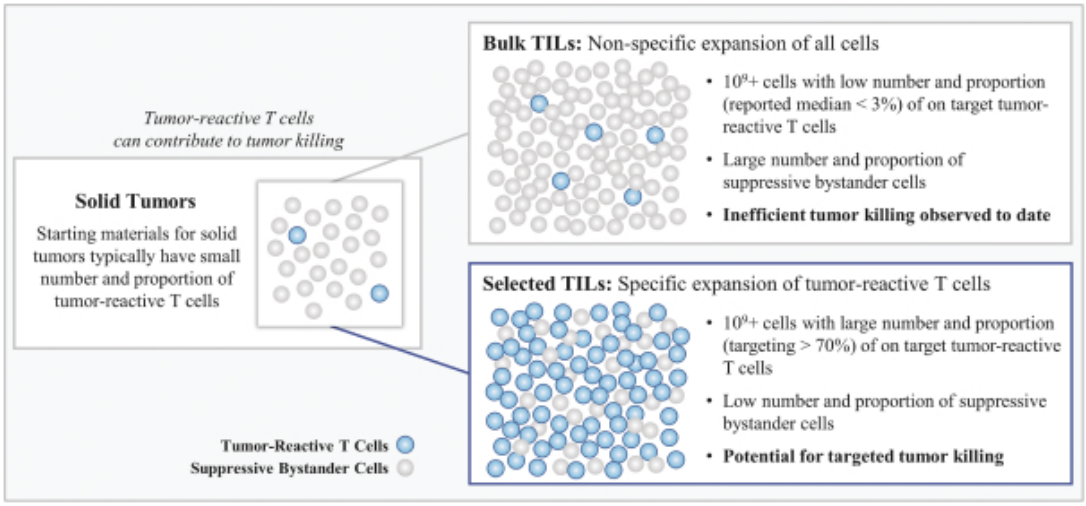
(1) *Unbiased identification of patient-specific tumor antigens:* We seek to identify the most comprehensive set of patient-specific tumor antigens. We use an unbiased identification process that aims to find and capture the greatest diversity of antigens with the potential to drive the most robust T cell response. Our proprietary approach is unlike other TIL products that are biased toward a specific subset or class of antigen(s), which may miss relevant tumor antigens or focus on the wrong targets.

(2) *Selection of greatest breadth of tumor-reactive T cells from patient extracted TILs:* Our goal is to capture and isolate the greatest number and proportion of a patient's tumor-reactive T cells that have the potential to attack and destroy heterogeneous solid tumors. We aim to select the greatest diversity of T cells by using a function-based screening process that confirms reactivity to the identified patient-specific tumor antigens rather than relying on a bioinformatics-based prediction algorithm that may not be truly predictive.

(3) *Expansion of tumor-reactive T cells and removal of non-tumor-reactive bystander cells:* We expand our selected tumor-reactive TIL population to magnitudes consistent with bulk TIL products and

actively remove unnecessary bystander cells. This selective expansion resulted in a substantially higher proportion of tumor-reactive T cells in the final product in comparison to the relatively infrequent tumor-reactive T cells that are routinely found in bulk TIL. Based on our non-clinical studies across multiple tumor samples to date, we have been able to achieve tumor-reactive T cell frequencies in our Selected TIL drug product of up to 62%, with a median frequency of 23%. With ongoing continuous process improvements as part of our manufacturing strategy we are targeting >70% tumor-reactive T cells in our drug product as we advance clinical development.

The potential advantages of Selected TILs over bulk TILs are depicted in the figure below.



The Selected TILs approach described above is inherently designed to select for and characterize the active TIL product—the tumor-reactive T cells. Bulk TIL approaches do not select for the active TIL product and have consequently faced challenges in product characterization and potency assay development. We define potency as the specific ability or capacity of the product, as indicated by appropriate laboratory tests or by adequately controlled clinical data obtained through the administration of the product in the manner intended, to effect a given result. We believe that our Selected TIL approach has the potential to facilitate the development of potency release assays to support regulatory requirements and avoid the characterization challenges of bulk TILs.

Supporting Clinical Evidence

We believe the growing body of prospective and translational clinical data in the TIL field supports the potential of our Selected TIL approach. Third-party studies have demonstrated that the anti-tumor activity of bulk TILs is driven by a small subset of tumor-reactive T cells in the bulk TIL product. Furthermore, clinical studies in academic centers utilizing rudimentary selection strategies for tumor-reactive T cells have reported responses including tumor regressions in a single patient bile duct study (*Tran et. al., 2014*) and a single patient colorectal cancer study (*Tran et. al., 2016*), one complete response and two partial responses out of six patients in a breast cancer study (*Zacharachis, et.al 2022*), and two complete responses and one partial response out of seven patients who received a TIL product with confirmed tumor reactivity, in a non-small cell lung cancer study (*Creelan et. al., 2021*). We define partial response as a patient experiencing a reduction in tumor size or volume as defined by the applicable standard, e.g. response evaluation criteria in solid tumors or RECIST, and no new lesions. A partial response does not indicate that a patient is cured of their disease.

Building a Product Pipeline to Further Enhance the Quality and Function of Selected TILs

Our Selected TIL approach sets us apart from others in the industry that are utilizing bulk TILs, including newer bulk TIL approaches that introduce genetic modifications and culture media additives to enhance TIL quality and function (meaning the viability of the TILs and their ability to produce cytotoxic and immune activating cytokines). We believe that without the optimal starting population of tumor-reactive T cells, further enhancements or modifications to bulk TILs are unlikely to succeed in extending their potential utility beyond the limited tumor types where bulk TILs have already shown objective responses in clinical trials. We are also expanding our product pipeline by making additional modifications to our proprietary Selected TILs and deploying them in differentiated combination strategies to further enhance TIL quality and function.

Modifications to Enhance TIL Quality

We are developing pipeline programs where we are evaluating enhanced culture conditions during the TIL production process to maintain and further improve TIL quality *ex vivo*. These enhanced culture conditions are designed to incorporate a mix of cytokines with the potential to rejuvenate dysfunctional and/or exhausted T cells.

Additionally, we plan to introduce functional genetic modifications into our pipeline programs that may drive potential for more sustained TIL quality and persistence, or ability of the TILs to survive and proliferate, *in vivo*. These gene edits will be designed to modify the tumor-reactive T cells to proliferate while resisting exhaustion post infusion, minimize their dependence on exogenous IL-2 for *in vivo* proliferation, and maintain their potential to kill tumors in suppressive tumor microenvironments. We are currently evaluating and prioritizing clinically informed targets for these genetic modifications.

Virus Combinations

Viral immunotherapy is a therapeutic modality with widespread potential to drive and modulate immune responses to solid tumors. Many viruses have inherent oncolytic activity that can be modulated through genetic engineering. These viruses preferentially infect, replicate within, and kill malignant tumor cells, and can induce broad immune responses. Viral immunotherapies are designed to convert immunologically unresponsive “cold” tumor microenvironments to more reactive “hot” tumor microenvironments and thereby enhance the activity of other immunotherapies.

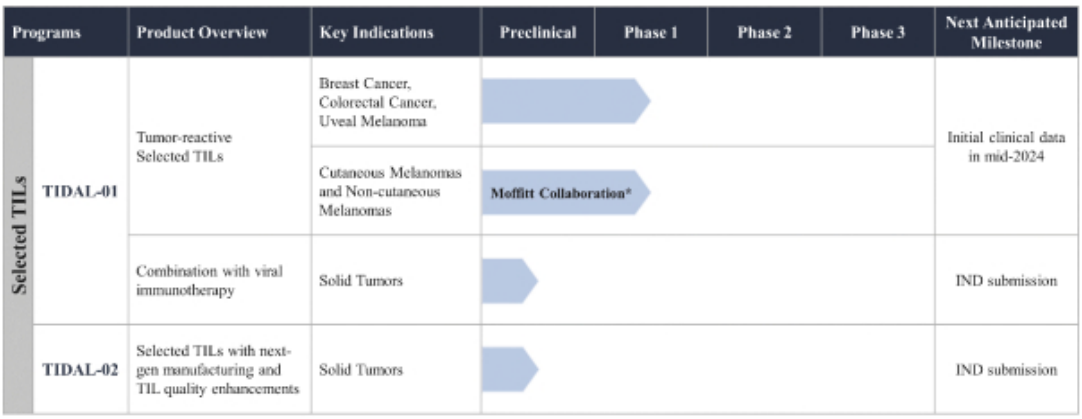
We are strongly positioned to combine our Selected TIL products with our proprietary viral immunotherapies utilizing two distinct approaches:

- viral immunotherapy pre-treatment (prior to TIL extraction): optimize TIL harvest and broaden access to indications that are currently less amenable to generating effective TIL products; and

- viral immunotherapy post-treatment (following delivery of the TIL product): optimize TIL trafficking and function and further increase the activity of our TIL therapies, if approved.

Our Pipeline

We are applying our Selected TIL approach for potential treatment of a wide range of solid tumors. We are developing a broad pipeline aimed at improving outcomes for patients, as illustrated in the chart below.



* Investigator sponsored trial at Moffitt Cancer Center

We are advancing TIDAL-01, our lead Selected TIL product candidate, for the treatment of multiple solid tumor indications. TIDAL-01 utilizes an unbiased identification and functional screening process to isolate and selectively expand the greatest breadth of tumor-reactive TILs from the patient's tumor. Our TIDAL-01 production process is designed to deliver at least 10^9 cells and targets greater than 70% functional and potent tumor-reactive T cells. We have initiated two Phase 1 clinical trials for TIDAL-01, including a multi-site trial for the treatment of breast cancer, colorectal cancer, and uveal melanoma, and an investigator sponsored trial with Moffitt in both cutaneous and non-cutaneous melanomas.

Investigator sponsored trials are clinical trials where the investigator of the trial is also the "sponsor" of the trial for regulatory purposes. An "investigator" conducts clinical investigations and is the person under whose immediate direction the study drug is administered or dispensed to patients. A "sponsor" initiates and takes responsibility for a clinical investigation. A person who both initiates and conducts a clinical trial, and is responsible for all regulatory requirements, is designated as a "sponsor-investigator" by the FDA. Clinical investigators at academic medical centers who initiate clinical trials with a lawfully marketed drug to be used in a patient population or indication not within the official labeling often fit within this designation. In addition, as is the case with our investigator-sponsored trials, a company may provide a sponsor-investigator with supply of its unapproved product candidate and funding for the trial. Investigators who initiate and conduct such trials are responsible for obtaining an IND from the FDA and for ensuring compliance with the IND and associated regulatory requirements. As provided by the FDA's regulations, the sponsor of a clinical trial is responsible for, among other things, selecting qualified investigators, providing them with the information they need to conduct the trial properly, ensuring proper monitoring of the trial, ensuring that the trial is conducted in accordance with the protocols contained in the IND, maintaining an effective IND with respect to the trial, and ensuring that the FDA and all participating investigators are promptly informed of significant new adverse effects or risks with respect to the drug. In contrast, in a company-sponsored trial, the pharmaceutical company whose drug will be studied is the sponsor of the trial and, as such, is responsible for ensuring compliance with all regulatory requirements, including obtaining the IND.

Under our multi-site trial, we control all aspects of our trial including, but not limited to, study protocol development, patient selection and enrollment, regulatory interactions, data release, and manufacturing through our industrial contract development and manufacturing organization, or CDMO. Under the investigator

sponsored trial, which is fully funded by us, Moffitt is solely responsible for regulatory interactions, trial conduct and manufacture of TIDAL-01 at the Moffitt Cancer Cell Therapy Facility, with input and support from us at Moffitt's discretion. Investigators at Moffitt are also solely responsible for the design of the trial and patient selection and enrollment, where we remain in close contact with the investigators to provide our input if appropriate. Any data disclosures will be made in collaboration with us and any improvements to the TIDAL-01 manufacturing process are solely at our discretion. We intend to provide an initial clinical update across these two trials in mid-2024.

Our next Selected TIL program, TIDAL-02, is being designed to encompass a next generation streamlined manufacturing process for tumor-reactive T cells and additional modifications to enhance TIL quality and function. We believe that TIDAL-02 has the potential to address the medical need in solid tumor indications that are distinct from and complementary to TIDAL-01. TIDAL-02 is currently in preclinical development.

We intend to evaluate the combination of TIDAL-01 with viral immunotherapy through two approaches: (1) treatment of the patient with viral immunotherapy prior to TIL extraction to optimize TIL harvest and broaden applicability to additional tumor types with low immune cell infiltration and (2) treatment of the patient with viral immunotherapy following treatment with TIDAL-01 to optimize TIL trafficking and infiltration into solid tumors and to support the anti-tumor functions of infiltrating immune cells. We are currently evaluating the optimal viral immunotherapy for combination with TIDAL-01 to advance into clinical development.

Our History and Team

We were founded in 2015 with the goal of developing medicines to treat and cure patients with solid tumors. Our initial scientific and technological focus was built around developing novel oncolytic viral immunotherapies. In late 2020, we acquired an innovative TIL platform and capabilities to expand our portfolio of cancer immunotherapies. Our TIL-based technology now represents the foundational therapeutic modality driving our current pipeline, though we continue to explore the synergistic potential of combining these two technologies in the pursuit of our mission.

We have assembled a team with extensive experience in complex biologics, drug discovery and development, manufacturing, and business and commercial product development. We are led by our Chief Executive Officer, Sammy Farah, M.B.A, Ph.D., who has 20 years of scientific, business, and executive management experience in the biotechnology industry at Synthetic Genomics, Immune Design, Versant Ventures, and Merck. Our research organization is led by our Chief Scientific Officer, Stewart Abbot, Ph.D., who brings over 20 years of research and development experience in cell-based and immune-oncology products from Adicet, Fate, Celgene and GE Healthcare. Our clinical development and regulatory organization is led by our interim Chief Medical Officer, Michael Burgess, MBChB, Ph.D., who has more than 20 years of experience building research and development teams and leading strategy and execution of clinical development at SpringWorks Therapeutics, Bristol-Myers Squibb, Roche, and Eli Lilly. Vijay Chiruvolu, Ph.D., our interim Chief Technology Officer who leads our technical operations organization, holds over 27 years of relevant industry experience in process development, manufacturing, supply chain, and quality at Instil Bio, Kite Pharma/Gilead Sciences, Scios, Avigen, Hoffmann-La Roche, Johnson & Johnson, and Amgen, and was responsible for the manufacturing and process teams that worked towards regulatory approval of two cell therapy products, Yescarta and Tecartus. Our Chief Business Officer, Saryah Azmat, brings over 10 years of experience in biopharmaceutical business development, corporate strategy and capital formation at Bristol Myers Squibb and Putnam Associates. Our Chief Legal Officer, P. Joseph Campisi, Jr., Esq., holds over 30 years of experience in mergers and acquisitions, collaborations, and securities offerings and corporate governance at Scorpion, Bristol Myers Squibb, and Pillsbury Winthrop; and Venkat Ramanan, Ph.D., our Chief Financial Officer, holds over 20 years of experience in biopharmaceutical finance and operations at Seagen, Gilead, and Amgen.

Since our inception, we have raised $362.0 million in capital, including approximately $172.0 million from preferred stock financings and $190.0 million in non-dilutive payments from strategic partnerships. We are supported by a syndicate that includes entities affiliated with Versant Venture Management, LLC, OrbiMed Private Investments VI, LP, entities affiliated with F-Prime Capital, and entities affiliated with FACIT Inc. Prospective investors should not rely on the investment decisions of our existing investors, as these investors may have different risk tolerances and have received their shares in prior offerings at prices lower than the price offered to the public in this offering. See the section titled "Certain Relationships and Related Party Transactions" for more information.

Our Strategy

Our mission is to develop new medicines to treat and cure patients with solid tumors using our next generation TIL therapy approach. We intend to achieve our mission by implementing the following strategies.

- Advance our lead Selected TIL product candidate, TIDAL-01, for the treatment of solid tumors. We are developing TIDAL-01 for the potential treatment of a broad range of solid tumor types, and we are pursuing a clinical development strategy designed to demonstrate benefit in multiple indications. We have initiated a Phase 1b clinical trial that will evaluate TIDAL-01 in solid tumors where bulk TILs have demonstrated limited to no objective responses in clinical trials to date, including breast cancer, colorectal cancer, and uveal melanoma. Additionally, we have also initiated our investigator sponsored Phase 1 clinical trial in collaboration with Moffitt that will evaluate TIDAL-01 in multiple types of melanoma including cutaneous melanomas, an indication where bulk TILs have shown objective responses in clinical trials. We are very early in our development efforts, and as we make progress, if we obtain positive results of sufficient magnitude from one or both trials, we intend to discuss, receive guidance and the appropriate acceptance from the relevant regulatory agency(ies) to determine if we will be advancing TIDAL-01 into pivotal trials, which are trials that are intended to secure regulatory approval for a product candidate.

- Develop TIDAL-02 and continue to build our pipeline of additional Selected TIL programs. We are expanding our portfolio by making modifications to our Selected TILs to streamline manufacturing and further enhance the quality and function of Selected TILs. This strategy is exemplified by our second Selected TIL program, TIDAL-02. This program is intended to employ a next generation rapid selection process, culture enhancements to improve and maintain TIL quality ex vivo, and/or functional gene edits to ensure durable enhancements to TIL quality and persistence *in vivo*, while minimizing dependance on exogenous IL-2 for *in vivo* proliferation. We intend to advance TIDAL-02 towards the clinic for the treatment of solid tumor indications that are distinct from and complementary to TIDAL-01, with the goal of moving into earlier lines of therapy. In addition to TIDAL-02, we have ongoing research efforts to further expand our pipeline of Selected TIL programs.

- Leverage viral immunotherapies to further increase the activity of Selected TILs across multiple solid tumors. Given our oncolytic virus expertise and our proprietary viral immunotherapies, we believe we are strongly positioned to be a leading company in using viral immunotherapy to further increase the activity of our TIL therapies, if approved. We plan to advance our TIDAL-01 and viral immunotherapy combination strategy to further expand the breadth and depth of response of our Selected TILs across multiple solid tumors. We also plan to explore additional Selected TIL and viral immunotherapy combinations.

- Commercialize and improve patient access to Selected TIL therapy through our CMC development expertise and manufacturing capabilities. We are expanding our in-house cell therapy process and analytical development capacity and capability, and in parallel assembling a network of external manufacturing and supply chain partners. We have designed a robust analytical characterization program to complement clinical development, support regulatory requirements and enable access to

our Selected TILs for a broad range of patients with solid tumors. Our intent is that all early-clinical stage Selected TIL product candidates are built upon a CMC foundation with clear line-of-sight to commercial viability, sequenced and staged appropriately with clinical progress.

- Support existing and opportunistically explore future strategic partnerships and collaborations to maximize the potential of our programs. We are leveraging relationships with three academic collaborators, including a strategic partnership with Moffitt, and collaborations with the National Cancer Institute, or NCI, and Centre hospitalier de l'Université de Montreal, or CHUM, to help support development of our Selected TIL approach and pipeline. Our academic relationships are designed to enable us to tap into the deep expertise within these leading institutes that have decades of research and clinical experience in developing TIL therapies. We plan to continue to explore opportunistic collaborations with both academic and industry partners to extend our reach and maximize the potential of our programs.

Risks Affecting Our Business

Our business is subject to a number of risks, including risks that may prevent us from achieving our business objectives or may adversely affect our business, results of operations and financial condition that you should consider before making a decision to invest in our common stock. These risks are discussed more fully in the section titled "Risk Factors" beginning on page 16 of this prospectus, and include the following:

- We have limited operating history, have incurred substantial net losses and anticipate that we will continue to incur net losses for the foreseeable future. We have no products approved for commercial sale, have never generated any revenue from product sales and may never be profitable.

- We will require additional capital in addition to the proceeds from this offering to fund our operations, and if we fail to obtain necessary capital on acceptable terms, or at all, we will not be able to complete the development and future commercialization of our current and any future product candidates.

- Our management, and our independent registered public accounting firm have concluded that there is substantial doubt as to our ability to continue as a going concern. As reflected in the audited consolidated financial statements and unaudited interim consolidated financial statements, each included elsewhere in this prospectus, we have incurred significant operating losses in the past, and we expect to continue to incur significant operating losses and negative cash flows for the foreseeable future. For the years ended December 31, 2022 and 2021, we reported a net loss of $30.8 million and a net income of $33.3 million, respectively. For the three months ended March 31, 2023 and 2022, we reported a net income of $0.1 million and a net loss of $12.6 million, respectively. Additionally, we will not receive any additional collaboration revenue under the research, option, and license agreement, or the AbbVie Agreement, with AbbVie Biotechnology Ltd., or AbbVie, or the discovery, collaboration and license agreement, or the Takeda Agreement, with Millennium Pharmaceuticals, Inc. (also known as Takeda Oncology), a wholly-owned subsidiary of Takeda Pharmaceutical Company Limited, or Takeda, in the future because these agreements have been terminated. Our ability to continue as a going concern is subject to our ability to obtain sufficient financing. If we cannot continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our combined financial statements, and it is likely that our stockholders may lose some or all of their investment in us. After this offering, we may not raise the funding we require such that substantial doubt about our ability to continue as a going concern continues. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional

funding on commercially reasonable terms or at all. If we cannot continue as a going concern, our stockholders may lose some or all of their investment in us.

- Our business is highly dependent on the success of our lead Selected TIL product candidate TIDAL-01, as well as our other current and any future product candidates. All of our product candidates will require significant additional preclinical or clinical development before we are able to seek regulatory approval for and launch a product commercially.
- If we fail to develop and receive approval for our existing or any additional future product candidates, our commercial opportunity could be limited which could adversely affect our business, results of operations and financial condition.
- Unfavorable global economic conditions, including any adverse macroeconomic conditions or geopolitical events, including the COVID-19 pandemic, the conflict between Ukraine and Russia, and recent bank failures affecting the financial services industry, could adversely affect our business, financial condition, results of operations or liquidity, either directly or through adverse impacts on certain of the third parties on which we rely to conduct certain aspects of our preclinical studies or clinical trials.
- Clinical development involves a lengthy and expensive process, with uncertain outcomes. We may incur significant costs and/or experience delays in completing, or ultimately be unable to complete, the development of our current and future product candidates, including our lead product candidates.
- Preclinical development is uncertain. Our preclinical programs may experience delays or generate unfavorable data, and may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these programs on a timely basis or at all, and any of these events would adversely affect our business, results of operations and financial condition.
- Our product candidates are based on a novel approach to the treatment of cancer, which makes it difficult to predict the time and cost of product candidate development.
- The manufacture of our product candidates is complex, and we may encounter difficulties in production, particularly with respect to process development, quality control, or scaling-up of any future manufacturing capabilities. If we, or any of our third-party manufacturers encounter such difficulties, our ability to provide supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.
- We face significant competition and if we fail to compete effectively, our business, results of operations and financial condition could be adversely affected.
- Negative developments in the fields of immuno-oncology and TIL-based immunotherapy could damage public perception of our product candidates and adversely affect our business, results of operations and financial condition.
- We have relied and expect to continue to rely on third parties to conduct certain aspects of our preclinical studies, to conduct our clinical trials and to conduct investigator sponsored clinical trials of our product candidates. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, comply with regulatory requirements or terminate the relationship, we may not be able to obtain regulatory approval of or commercialize any potential product candidates.

- The regulatory approval process for our product candidates in the United States, and other jurisdictions is currently uncertain and will be lengthy, time-consuming and inherently unpredictable, and we may experience significant delays in the clinical development and regulatory approval, if any, of our product candidates.

- Our success depends in part on our ability to protect our intellectual property. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to ensure their protection.

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

- No public market for our common stock currently exists, and we do not know whether an active, liquid and orderly trading market will develop for our common stock, or what the market price of our common stock will be, and as a result it may be difficult for you to sell your shares of our common stock.

- Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

- Pursuant to a letter agreement, or the Takeda Letter Agreement, dated June 29, 2023, Takeda has agreed to submit a non-binding indication of interest to participate in this offering by purchasing at the public offering price per share the number of shares of our common stock with an aggregate value of $8.0 million or such lesser amount as determined by us in our sole discretion, or the Takeda IPO Shares. The Takeda IPO Shares will not be subject to a lock-up agreement. Any transfers or sales of the Takeda IPO Shares may cause the price of our common stock to decline. See the section titled “Certain Relationships and Related Party Transactions—Public Offering Participation Rights.”

Our Corporate Information

Turnstone Biologics Inc. was incorporated as a Canadian corporation on March 27, 2014. On December 13, 2018, we incorporated Turnstone Biologics Corp., a corporation under the laws of the State of Delaware. On December 14, 2018, we completed a reorganization from Canada to the United States, which we refer to as the Reorganization. In connection with the Reorganization, all of the shareholders of Turnstone Canada exchanged their shares in Turnstone Canada for shares of our new incorporated Delaware entity, as a result of which Turnstone Canada became our wholly owned subsidiary. Our principal executive offices are located at 9310 Athena Circle, Suite 300, La Jolla, California 92037, and our telephone number is (347) 897-5988. Our website address is www.turnstonebio.com. The information contained on, or accessible through, our website is not incorporated by reference into this prospectus, and you should not consider any information contained on, or that can be accessed through, our website as part of this prospectus or in deciding whether to purchase our common stock.

We own various U.S. federal trademark applications and unregistered trademarks, including our company name. All other trademarks or trade names referred to in this prospectus are the property of their respective owners. Solely for convenience, the trademarks and trade names in this prospectus are referred to without the symbols ® and ™, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.

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

We qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. An emerging growth company may take advantage of relief from certain reporting requirements and other burdens that are otherwise applicable generally to public companies. These provisions include:

- reduced obligations with respect to financial data, including presenting only two years of audited financial statements and only two years of selected financial data in this prospectus;
- an exception from compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act;
- reduced disclosure about our executive compensation arrangements in our periodic reports, proxy statements and registration statements, including the registration statement of which this prospectus forms a part;
- exemptions from the requirements of holding non-binding advisory votes on executive compensation or golden parachute arrangements; and
- an exemption from compliance with the requirements of the Public Company Accounting Oversight Board regarding the communication of critical audit matters in the auditor's report on the financial statements.

We may take advantage of these provisions for up to five years or such earlier time that we no longer qualify as an emerging growth company. We would cease to qualify as an emerging growth company on the date that is the earliest of (i) the last day of the fiscal year in which we have total annual gross revenue of $1.235 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of this offering; (iii) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a "large accelerated filer" under the rules of the U.S. Securities and Exchange Commission, or SEC, which means the market value of our common stock that is held by non-affiliates exceeds $700.0 million as of the prior June 30th. We may choose to take advantage of some but not all of these reduced reporting burdens. For example, we may take advantage of the exemption from auditor attestation on the effectiveness of our internal control over financial reporting. To the extent that we take advantage of these reduced reporting burdens, the information that we provide stockholders may be different than you might obtain from other public companies in which you hold equity interests.

In addition, under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to avail ourselves of this exemption, and, as a result, our operating results and financial statements may not be comparable to the operating results and financial statements of companies who have adopted the new or revised accounting standards.

We are also a "smaller reporting company" as defined in the Securities Exchange Act of 1934, as amended, or the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and our common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

The Offering	
Common stock offered by us	6,666,667 shares.
Option to purchase additional shares	We have granted the underwriters an option, exercisable for 30 days after the date of this prospectus, to purchase up to 1,000,000 additional shares from us.
Common stock to be outstanding immediately after this offering	22,188,682 shares (or 23,188,682 shares if the underwriters exercise their option to purchase additional shares of common stock in full).
Reserved share program	At our request, an affiliate of BofA Securities, Inc., a participating underwriter, has reserved for sale, at the initial public offering price, up to 5.0% of the shares offered by this prospectus for sale to some of our directors, officers, employees, and certain other related parties to us. If these persons purchase reserved shares it will reduce the number of shares available for sale to the general public. Any reserved shares that are not so purchased will be offered by the underwriters to the general public on the same terms as the other shares offered by this prospectus. For more information, see "Underwriting."
Use of proceeds	We estimate that the net proceeds from this offering will be approximately $70.1 million (or approximately $81.3 million if the underwriters exercise their option to purchase additional shares in full), based on the initial public offering price of $12.00 per share, after deducting the 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, cash equivalents and short-term investments, as follows: (i) approximately $74 million to $78 million to fund the continued development of TIDAL-01 in our two Phase 1 clinical trials for the treatment of breast cancer, colorectal cancer, uveal melanoma and other non-cutaneous and cutaneous melanomas, including through initial clinical data update in mid-2024 and continued development into the second quarter of 2025, (ii) approximately $16 million to $21 million to advance our TIDAL-02 program through candidate declaration and TIDAL-01 and viral immunotherapy combination program through an investigational new drug application, or IND, and (iii) the remaining proceeds, if any, for working capital and general corporate purposes. We may also use a portion of the remaining net proceeds and our existing cash, cash equivalents and short-term investments, to in-license, acquire, or invest in complementary businesses, technologies, products, or assets. However, we have no current commitments or obligations to do so. See the section titled "Use of Proceeds."
Risk factors	See the section titled "Risk Factors" beginning on page 16 and the other information included in this prospectus for a discussion of factors you should consider carefully before deciding to invest in our common stock.

Nasdaq Global Market symbol "TSBX"

The number of shares of our common stock to be outstanding after this offering is based on 15,522,015 shares of our common stock outstanding as of March 31, 2023, after giving effect to the conversion of all outstanding shares of our convertible preferred stock into 12,493,879 shares of our common stock in connection with the closing of this offering, and excludes:

- 2,495,301 shares of our common stock issuable upon the exercise of outstanding stock options as of March 31, 2023, with a weighted-average exercise price of $8.86 per share;
- 186,043 shares of our common stock issuable upon the exercise of outstanding stock options granted subsequent to March 31, 2023, with a weighted-average exercise price of $16.53 per share;
- 275,163 shares of our common stock reserved for future issuance to Moffitt contingent on the achievement of certain clinical and regulatory milestones pursuant to our Alliance Agreement (as defined below) with Moffitt;
- 2,722,887 shares of our common stock reserved for future issuance under our 2023 Equity Incentive Plan, or 2023 Plan, which became effective upon the execution of the underwriting agreement for this offering, as well as any automatic increases in the number of shares of common stock reserved for future issuance under this plan; and
- 222,287 shares of our common stock reserved for future issuance under our 2023 Employee Stock Purchase Plan, or ESPP, which became effective upon the execution of the underwriting agreement for this offering, as well as any automatic increases in the number of shares of common stock reserved for future issuance under this plan.

Unless otherwise indicated, this prospectus reflects and assumes the following:

- the conversion of all outstanding shares of our convertible preferred stock into an aggregate of 12,493,879 shares of our common stock immediately prior to the closing of this offering;
- a 1-for-7.9872 reverse stock split of our common stock effected on July 14, 2023;
- no exercise of the outstanding options described above;
- no exercise by the underwriters of their option to purchase up to 1,000,000 additional shares of our common stock; and
- the filing and effectiveness of our amended and restated certificate of incorporation immediately following the closing of this offering and the adoption of our amended and restated bylaws immediately prior to the closing of this offering.

Summary Consolidated Financial Data

The following tables set forth our summary financial data for the periods and as of the dates indicated. We have derived the summary consolidated statements of operations and comprehensive income (loss) data for the years ended December 31, 2022 and 2021 from our audited consolidated financial statements included elsewhere in this prospectus. We have derived the summary consolidated statements of operations and comprehensive income (loss) data for the three months ended March 31, 2023 and 2022 and the summary consolidated balance sheet data as of March 31, 2023 from our unaudited interim consolidated financial statements to be included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that should be expected in the future, and the consolidated statements of operations and comprehensive income (loss) data for the three months ended March 31, 2023 are not necessarily indicative of the results to be expected for the full year ending December 31, 2023 or any other period. You should read the following summary consolidated financial data together with our consolidated financial statements and the related notes included elsewhere in this prospectus and the information in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" contained elsewhere in this prospectus.

	Year Ended December 31,		Three Months Ended March 31,	
	2022	2021	2023	2022
			(unaudited)	
Consolidated Statements of Operations and Comprehensive Income (Loss) Data (in thousands):				
Collaboration revenue	$ 73,300	$ 101,293	$ 19,306	$ 10,718
Operating expenses:				
Research and development	$ 86,703	$ 54,754	$ 15,668	$ 18,701
General and administrative	18,223	13,546	4,032	4,698
Total operating expenses	104,926	68,300	19,700	23,399
Income (loss) from operations	(31,626)	32,993	(394)	(12,681)
Other income (expense), including provision for income taxes, net	792	276	462	65
Net income (loss)	$ (30,834)	$ 33,269	$ 68	$ (12,616)
Net income (loss) per share of common stock attributable to common stockholders, basic(1)	$ (12.49)	$ 1.62	$ —	$ (5.56)
Net income (loss) per share of common stock attributable to common stockholders, diluted(1)	$ (12.49)	$ 1.29	$ —	$ (5.56)
Weighted-average number of shares used in computing net earnings, basic	2,484,569	2,149,550	2,786,017	2,279,287
Weighted-average number of shares used in computing net earnings, diluted	2,484,569	2,702,347	2,786,017	2,279,287
Pro forma net income (loss) per share of common stock attributable to common stockholders, basic and diluted(2)	$ (2.06)		$ 0.00	
Pro forma weighted-average shares of common stock outstanding, basic(2)	14,978,444		15,279,895	
Pro forma weighted-average shares of common stock outstanding, diluted(2)	14,978,444		15,718,491	

(1) See Note 12 to our audited consolidated financial statements and Note 12 to our unaudited interim consolidated financial statements, each included elsewhere in this prospectus, for an explanation of the method used to calculate basic and diluted net loss per share and the weighted-average number of shares used in the computation of the per share amounts.

(2) Pro forma basic and diluted net income (loss) per share of common stock attributable to common stockholders has been prepared to give effect to adjustments to our capital structure arising in connection with the completion of this offering and is calculated by dividing pro forma net income (loss) per share of common stock attributable to common stockholders by the pro forma weighted-average shares of common stock outstanding for the period. The unaudited pro forma net income (loss) attributable to common stockholders used in the calculation of unaudited pro forma basic and diluted net income (loss) per share of common stock attributable to common stockholders is equal to net income (loss) attributable to common stockholders. The unaudited pro forma basic and diluted weighted-average common shares outstanding used in the calculation of unaudited pro forma basic and diluted net income (loss) per share for the three months ended March 31, 2023 and for the year ended December 31, 2022 have been prepared to reflect the conversion of all of the outstanding

shares of our convertible preferred stock into an aggregate of 12,493,879 shares of our common stock as if the offering had occurred on January 1, 2022.

	As of March 31, 2023		
	Actual	Pro Forma(1) (unaudited)	Pro Forma As Adjusted(2)
Balance Sheet Data (in thousands):			
Cash, cash equivalents and short-term investments	$ 63,969	$ 63,969	$ 134,060
Working capital(3)	60,031	60,031	130,122
Total assets	92,263	92,263	162,354
Redeemable convertible preferred stock	171,964	—	—
Accumulated deficit	(121,490)	(121,490)	(121,490)
Total stockholders' (deficit) equity	(100,223)	71,741	141,832

(1) Pro forma balance sheet data reflects (i) the conversion of all outstanding shares of our convertible preferred stock into an aggregate of 12,493,879 shares of common stock and the related reclassification of the carrying value of our convertible preferred stock to permanent equity in connection with the closing of this offering and (ii) the filing and effectiveness of our amended and restated certificate of incorporation that will be in effect immediately following the closing of this offering.

(2) Pro forma as adjusted balance sheet data reflects the pro forma items described immediately above and our issuance and sale of shares of common stock in this offering at the initial public offering price of $12.00 per share, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

(3) We define working capital as current assets less current liabilities. See our consolidated financial statements and the related notes included elsewhere in this prospectus for further details regarding our current assets and current liabilities.

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this prospectus, including our consolidated financial statements and the related notes, and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could adversely affect our business, results of operations and financial condition. In any such event, the market price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial also may impair our business, results of operations and financial condition.

Risks Related to Our Business

We have limited operating history, have incurred substantial net losses and anticipate that we will continue to incur net losses for the foreseeable future. We have no products approved for commercial sale, have never generated any revenue from product sales and may never be profitable.

We are a clinical stage biotechnology company with a limited operating history. We were formed in 2014 and we have devoted substantially all of our efforts and financial resources to organizing and staffing our company, business planning, raising capital, discovering product candidates and securing related intellectual property rights, and conducting research and development activities for our Selected TIL programs and product candidates. Consequently, we have no meaningful operations upon which to evaluate our business and predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing program candidates. Investment in biotechnology product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. We have not yet demonstrated the ability to progress any product candidate through clinical trials, we have no products approved for commercial sale and we have not generated any revenue from product sales to date. We continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are not profitable and we have incurred overall net losses since our inception through March 31, 2023. For the years ended December 31, 2022 and 2021, we reported a net loss of $30.8 million and a net income of $33.3 million, respectively. For the three months ended March 31, 2023 and 2022, we reported a net income of $0.1 million and a net loss of $12.6 million, respectively. As of December 31, 2022 and March 31, 2023, we had an accumulated deficit of $121.6 million and $121.5 million, respectively. Additionally, we will not receive any additional collaboration revenue under the AbbVie Agreement or the Takeda Agreement in the future because these agreements have been terminated. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of our Selected TIL programs, and seek regulatory approvals for our product candidates.

We anticipate that our expenses will increase substantially if, and as, we:

- advance the development of our lead Selected TIL product candidate TIDAL-01 through two Phase 1 clinical trials and, if the results are favorable, into further clinical development;
- actively advance our other preclinical pipeline programs, including TIDAL-02, our next Selected TIL program and our TIDAL-01 and viral immunotherapy combination program;
- seek regulatory approvals for any product candidates that successfully complete clinical trials, if any;
- increase the amount of research and development activities to identify and develop Selected TIL product candidates;

- hire additional clinical, quality control and scientific personnel;
- expand our operational, financial and management systems and increase personnel, including personnel to support our clinical development, manufacturing and commercialization efforts and our operations as a public company;
- maintain, expand and protect our intellectual property portfolio;
- expand our external manufacturing relationships;
- oversee and maintain our manufacturing infrastructure;
- establish a sales, marketing, medical affairs and distribution infrastructure to commercialize any products for which we may obtain marketing approval and intend to commercialize on our own or jointly with third parties; and
- invest in or in-license enabling technologies.

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

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 and market additional product candidates. We also 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' (deficit) equity and working capital.

We will require additional capital in addition to the proceeds from this offering to fund our operations, and if we fail to obtain necessary capital on acceptable terms, or at all, we will not be able to complete the development and future commercialization of our current and any future product candidates.

Our operations have consumed substantial amounts of cash since our inception. We expect to continue to spend substantial amounts of cash to conduct further research and development, preclinical studies and clinical trials of our current and future product candidates, to seek regulatory approvals for our product candidates and to launch and commercialize any products if we receive regulatory approval.

We have initiated two Phase 1 clinical trials for our lead Selected TIL product candidate, TIDAL-01, including a multi-site trial for the treatment of breast cancer, colorectal cancer, and uveal melanoma, and an investigator sponsored trial with Moffitt in both cutaneous and non-cutaneous melanomas. We intend to provide an initial clinical update across these two trials in mid-2024. We are also developing TIDAL-02, our next Selected TIL program, which is currently in preclinical development and we intend to evaluate the combination of TIDAL-01 with viral immunotherapy. We are currently evaluating the optimal viral immunotherapy for combination with TIDAL-01 to advance into clinical development.

As of March 31, 2023, we had approximately $64.0 million in cash, cash equivalents and short-term investments. Based on our current operating plan, we expect that the net proceeds from this offering, together with our cash, cash equivalents and short-term investments, will enable us to fund our operations into the second quarter of 2025. However, our future capital requirements and the period for which our existing resources will support our operations may vary significantly from what we expect, and we will in any event require additional capital in order to complete clinical development of any of our current programs. Our monthly spending levels will vary based on new and ongoing development and corporate activities. Because the length of time and activities associated with development of our programs and product candidates is highly uncertain, we are unable to estimate the actual funds we will require for development and any approved marketing and future commercialization activities, if any. Our future capital requirements will depend on many factors, including:

- the costs of conducting clinical trials;
- the progress of preclinical development for our programs and clinical trials of our current earlier-stage product candidates;
- the costs of manufacturing;
- the scope, progress, results and costs of discovery, preclinical development, laboratory testing and clinical trials for other potential product candidates we may develop, if any;
- the costs, timing and outcome of regulatory review of our product candidates;
- our ability to establish and maintain collaborations and partnerships on favorable terms, if at all;
- the achievement of milestones or occurrence of other developments that trigger payments to us or by us under any collaboration agreements we might have at such time;
- the costs of preparing, filing and prosecuting patent applications, obtaining, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our headcount growth and associated costs as we expand our business operations and research and development activities;
- the cost of operating as a public company;
- our ability to mitigate the impact of adverse macroeconomic conditions or geopolitical events, including the COVID-19 pandemic, the ongoing conflict between Ukraine and Russia, recent bank failures or other factors on our preclinical and clinical development or operations;
- the costs and timing of future commercialization activities, if any, including product sales, marketing, manufacturing and distribution, if we receive marketing approval for any of our product candidates;
- our ability to achieve sufficient market acceptance, adequate coverage and reimbursement from third-party payors and adequate market share; and
- the amount of revenue, if any, received from commercial sales of our product candidates, if any of our product candidates receive marketing approval.

We do not have any committed external source of funds or other support for our development efforts and additional funding may not be available on acceptable terms, or at all. Market volatility resulting from

adverse macroeconomic conditions or geopolitical events, including the COVID-19 pandemic, the ongoing conflict between Ukraine and Russia, recent bank failures or other factors may further adversely impact our ability to access capital as and when needed. Until we can generate sufficient product or royalty revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other arrangements. If we raise additional funds through public or private equity offerings, the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. Further, to the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, your ownership interest will be diluted. In addition, any debt financing may subject us to fixed payment obligations and covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. We also could be required to seek collaborators for our current or future product candidates at an earlier stage than otherwise would be desirable or relinquish our rights to product candidates or technologies that we otherwise would seek to develop or commercialize ourselves. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may need to significantly delay, scale back or discontinue the development or future commercialization of one or more of our product candidates, if approved, or one or more of our other research and development initiatives and we may need to undertake additional workforce reductions or restructuring activities in the future. Any of the above events could adversely affect our business, results of operations and financial condition and cause the price of our common stock to decline.

Our management and our independent registered public accounting firm have concluded that there is substantial doubt as to our ability to continue as a going concern. If we cannot continue as a going concern, our stockholders may lose some or all of their investment in our company.

Our audited consolidated financial statements and unaudited interim consolidated financial statements, each included elsewhere in this prospectus, were prepared assuming that we will continue as a going concern. The going concern basis of presentation assumes that we will continue in operation for the foreseeable future and will be able to realize our assets and satisfy our liabilities in the normal course of business and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or amounts and classification of liabilities that may result from our inability to continue as a going concern. As reflected in the audited consolidated financial statements and unaudited interim consolidated financial statements, each included elsewhere in this prospectus, we have incurred significant operating losses in the past, and we expect to continue to incur significant operating losses and negative cash flows for the foreseeable future. For the years ended December 31, 2022 and 2021, we reported a net loss of $30.8 million and a net income of $33.3 million, respectively. For the three months ended March 31, 2023 and 2022, we reported a net income of $0.1 million and a net loss of $12.6 million, respectively. As of December 31, 2022 and March 31, 2023, we had an accumulated deficit of $121.6 million and $121.5 million, respectively. Additionally, we will not receive any additional collaboration revenue under the AbbVie Agreement or the Takeda Agreement in the future because these agreements have been terminated. As of March 31, 2023, our management concluded that, based on our expected operating losses and negative cash flows, there is substantial doubt about our ability to continue as a going concern for the 12 months after the date the unaudited interim consolidated financial statements were issued. Our ability to continue as a going concern is subject to our ability to obtain sufficient financing. If we cannot continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our combined financial statements, and it is likely that our stockholders may lose some or all of their investment in us. After this offering, we may not raise the funding we require such that substantial doubt about our ability to continue as a going concern continues. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding on commercially reasonable

terms or at all. If we cannot continue as a going concern, our stockholders may lose some or all of their investment in us.

Our business is highly dependent on the success of our lead Selected TIL product candidate TIDAL-01, as well as our other current and any future product candidates. All of our product candidates will require significant additional preclinical or clinical development before we are able to seek regulatory approval for and launch a product commercially.

We are very early in our development efforts. If TIDAL-01 or any future product candidates encounter safety or efficacy problems, manufacturing failures, development delays or regulatory issues or other problems, our development plans and business may be significantly harmed.

We have initiated two Phase 1 clinical trials for our lead Selected TIL product candidate, TIDAL-01, including a multi-site trial for the treatment of breast cancer, colorectal cancer, and uveal melanoma, and an investigator sponsored trial with Moffitt in both cutaneous and non-cutaneous melanomas. We intend to provide an initial clinical update across these two trials in mid-2024. We are also developing TIDAL-02, our next Selected TIL program, which is currently in preclinical development and we intend to evaluate the combination of TIDAL-01 with viral immunotherapy. We are currently evaluating the optimal viral immunotherapy for combination with TIDAL-01 to advance into clinical development.

Our current and any future product candidates will require additional preclinical or clinical development, regulatory review and approval in one or more jurisdictions, substantial investment, and access to sufficient commercial manufacturing capacity and significant marketing efforts before we can generate any revenue from product sales. We may not have the financial resources to continue development of, or to modify existing or enter into new collaborations for, any product candidate if we experience any issues that delay or prevent regulatory approval of, or our ability to commercialize, our product candidates, including:

- negative or inconclusive results from our preclinical studies or clinical trials or the clinical trials of others for product candidates similar to ours, leading to a decision or requirement to conduct additional preclinical testing or clinical trials or abandon a program;
- product-related side effects experienced by subjects in our clinical trials or by individuals using products or immunotherapies similar to our product candidates;
- delays in submitting INDs or comparable foreign applications or delays or failure in obtaining the necessary authorizations or approvals from regulators to commence a clinical trial, or a suspension or termination of a clinical trial once commenced;
- conditions imposed by the FDA or comparable foreign regulatory authorities regarding the scope or design of our clinical trials;
- delays in enrolling subjects in clinical trials;
- high drop-out rates of subjects from clinical trials;
- inadequate supply or quality of product candidates or other materials necessary for the conduct of our clinical trials;
- greater than anticipated clinical trial costs;
- poor effectiveness of or safety issues associated with our product candidates during clinical trials;

- unfavorable FDA or comparable foreign regulatory authorities' inspection and review of a clinical trial site;
- failure of our third-party contractors or investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner, or at all;
- potential disruptions caused by the COVID-19 pandemic or other health pandemics or epidemics, including difficulties in initiating clinical sites, enrolling and retaining participants, diversion of healthcare resources away from clinical trials, travel or quarantine policies that may be implemented, and other factors;
- delays and changes in regulatory requirements, policy and guidelines, including the imposition of additional regulatory oversight around clinical testing generally or with respect to our technology in particular;
- varying interpretations of data by the FDA or comparable foreign regulatory authorities;
- manufacturing failures, including our TIL selection process, resulting in a less effective product candidate in the tumor indications we are pursuing; or
- unsuccessful improvements to our internal manufacturing processes.

The occurrence of any of the above events could adversely affect our business, results of operations and financial condition.

If we fail to develop and receive approval for our existing or any additional future product candidates, our commercial opportunity could be limited which could adversely affect our business, results of operations and financial condition.

Developing, obtaining marketing approval for, and commercializing any product candidates will require substantial additional funding beyond the net proceeds of this offering and will be subject to the risks of failure inherent in medical product development. We may not be able to successfully advance any of our existing product candidates or any additional product candidates through the development process.

Even if we obtain approval from the FDA or comparable foreign regulatory authorities to market our existing or any additional product candidates for the treatment of solid tumors or any other indication, any such product candidates may not be successfully commercialized, widely accepted in the marketplace, or more effective than other commercially available alternatives. If we are unable to successfully develop and commercialize our existing or any additional product candidates, our commercial opportunity may be limited and our business, results of operations and financial condition may be adversely affected.

Unfavorable global economic conditions, including any adverse macroeconomic conditions or geopolitical events, including the COVID-19 pandemic, the conflict between Ukraine and Russia, and recent bank failures affecting the financial services industry, could adversely affect our business, financial condition, results of operations or liquidity, either directly or through adverse impacts on certain of the third parties on which we rely to conduct certain aspects of our preclinical studies or clinical trials.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. Global economic and business activities continue to face widespread uncertainties, and global credit and financial markets have experienced extreme volatility and disruptions in the past several years, including severely diminished liquidity and credit availability, rising inflation and monetary supply shifts, rising interest rates, labor shortages, declines in consumer confidence, declines in economic growth, increases in

unemployment rates, recession risks, and uncertainty about economic and geopolitical stability. A severe or prolonged economic downturn, or additional global financial or political crises, could result in a variety of risks to our business, including delayed clinical trials or preclinical studies, delayed approval of our product candidates, delayed ability to obtain patents and other intellectual property protection, weakened demand for our product candidates, if approved, or our ability to raise additional capital when needed on acceptable terms, if at all. The extent of the impact of these conditions on our operational and financial performance, including our ability to execute our business strategies and initiatives in the expected timeframe, as well as that of third parties upon whom we rely, will depend on future developments which are uncertain and cannot be predicted. A weak or declining economy also could strain our suppliers, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business. Furthermore, our stock price may decline due in part to the volatility of the stock market and the general economic downturn.

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation, or FDIC, as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership, and on May 1, 2023, First Republic Bank was also swept into receivership. Although a statement by the Department of the Treasury, the Federal Reserve and the FDIC indicated that all depositors of Silicon Valley Bank would have access to all of their money after only one business day of closure, including funds held in uninsured deposit accounts, borrowers under credit agreements, letters of credit and certain other financial instruments with Silicon Valley Bank, Signature Bank or any other financial institution that is placed into receivership by the FDIC may be unable to access undrawn amounts thereunder. If any of the banks which hold our cash deposits were to be placed into receivership, we may be unable to access such funds. As of March 31, 2023, all of our cash on deposit was maintained at two financial institutions in the United States, and our current deposits are in excess of federally insured limits. If further failures in financial institutions occur where we hold deposits, we could experience additional risk. Any such loss or limitation on our cash, cash equivalents and short-term investments would adversely affect our business. In addition, if any of the third parties on which we rely to conduct certain aspects of our preclinical studies or clinical trials are unable to access funds pursuant to such instruments or lending arrangements with such a financial institution, such parties' ability to fulfill their obligations to us could be adversely affected.

If we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

We may evaluate various acquisitions and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness, contractual obligations or contingent liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;

- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party, their regulatory compliance status, and their existing products or product candidates and marketing approvals; and
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business. Any of the foregoing may adversely affect our business, results of operations and financial condition.

We may not realize the expected benefits from our recent workforce reductions and it could result in total costs and expenses that are greater than expected and could disrupt our business.

In October 2022, we implemented a plan to consolidate our operations, which included a move to San Diego, California and a reduction in our workforce. In addition, in June 2023, we conducted an additional reduction in our workforce. The changes to our operations and the reductions in workforce may yield unintended consequences and costs, such as the loss of institutional knowledge and expertise, attrition beyond our intended reductions in force, and a reduction in morale among our remaining employees, all of which may have an adverse effect on our development activities, our business, results of operations or financial condition. If we are unable to realize the expected operational efficiencies, our business, results of operations and financial condition would be adversely affected. In addition, to the extent we do not realize such anticipated operational efficiencies, we may need to undertake additional workforce reductions or restructuring activities in the future. Furthermore, our reductions in force may be disruptive to our operations. For example, our workforce reductions could yield unanticipated consequences, such as attrition beyond planned staff reductions, increased difficulties in our day-to-day operations and reduced employee morale. If employees who were not affected by the reductions in force seek alternative employment, this could result in our seeking contractor support at unplanned additional expense or harm our productivity. Our workforce reductions could also harm our ability to attract and retain qualified management, scientific, clinical, and manufacturing personnel who are critical to our business. Any failure to attract or retain qualified personnel could prevent us from successfully developing our potential product candidates. We may also discover that the reductions in workforce could make it difficult for us to pursue new opportunities and initiatives and require us to hire qualified replacement personnel, which may require us to incur additional and unanticipated costs and expenses. Our failure to successfully accomplish any of the above activities and goals may have a material adverse impact on our business, results of operations and financial condition.

Our ability to use our net operating loss carryforwards to offset future income could be subject to limitation.

As of December 31, 2022, we had approximately $2.3 million of U.S. federal and $1.0 million of state net operating loss, or NOL, carryforwards. Our U.S. federal NOL carryforwards can be carried forward indefinitely, but use of such carryforwards is limited to 80% of taxable income. If not utilized, our state NOL carryforwards will begin to expire at various dates beginning in 2038. These NOL carryforwards could expire unused and be unavailable to offset future income tax liabilities if we are not able to generate sufficient taxable income to utilize our state NOL carryforwards before they expire. We have recorded a full valuation allowance related to our carryforwards due to the uncertainty of the ultimate realization of the future benefits of those assets.

Furthermore, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, the amount of benefits from our NOL carryforwards may be impaired or limited if we incur a cumulative ownership change of more than 50% over a three-year period. The completion of this offering, and future offerings of our securities may trigger such an ownership change. In addition, because we will need to raise substantial additional funding to finance our operations, we may in the future undergo further ownership changes. We have not conducted an analysis as to whether such a change of ownership has occurred, but if such a change has occurred or occurs in the future, we will be limited regarding the amount of NOL carryforwards that can be utilized annually in the future to offset taxable income. Any such annual limitation may significantly reduce the value of our NOL carryforwards before they expire, which could result in greater tax liabilities than we would incur in the absence of such a limitation.

We may have exposure to greater-than-anticipated tax liabilities, which could seriously harm our business.

The tax laws applicable to our international business activities, including the laws of the United States and other jurisdictions, are subject to change and uncertain interpretation. The U.S. government may enact significant changes to the taxation of business entities including, among others, the imposition of additional minimum taxes and an increase in the corporate tax rate. Any such change could have a significant impact on our cash flow.

Our income tax obligations are based on our corporate operating structure and third-party and intercompany arrangements, including the manner in which we develop, value, and use our intellectual property and the valuations of our intercompany transactions. The taxing authorities of the jurisdictions in which we operate may challenge our methodologies for valuing developed technology, intercompany arrangements, or transfer pricing, which could increase our worldwide effective tax rate and the amount of taxes we pay and seriously harm our business. Taxing authorities also may determine that the manner in which we operate our business is not consistent with how we report our income, which could increase our effective tax rate and the amount of taxes we pay and seriously harm our business. In addition, our future income taxes could fluctuate because of earnings being lower than anticipated in jurisdictions that have lower statutory tax rates and higher than anticipated in jurisdictions that have higher statutory tax rates, by changes in the valuation of our deferred tax assets and liabilities. We are subject to regular review and audit by U.S. federal and state and foreign tax authorities. Any adverse outcome from a review or audit could seriously harm our business. In addition, determining our worldwide provision for income taxes and other tax liabilities requires significant judgment by management, and there are many transactions where the ultimate tax determination is uncertain. Although we believe that our estimates are reasonable, the ultimate tax outcome may differ from the amounts recorded in our financial statements for such period or periods and may seriously harm our business.

Exchange rate fluctuations may adversely affect our business, results of operations and financial condition.

We have operations, including employing a portion of our workforce, in Ottawa, Canada. Owing to the international scope of our operations, fluctuations in exchange rates between the U.S. dollar and the Canadian dollar may adversely affect our business, results of operations and financial condition. As a result, our business and the price of our common stock may be affected by fluctuations in foreign exchange rates, which may have a significant impact on our results of operations and cash flows from period to period. Currently, we do not have any exchange rate hedging arrangements in place.

Risks Related to Our Operations

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

As of June 30, 2023, we had 112 full-time employees. As our clinical development and future commercialization plans and strategies develop, and as we transition into operating as a public company, we may

need to hire additional managerial, clinical, regulatory, sales, marketing, financial, legal and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our development efforts effectively, including the clinical and FDA or comparable foreign regulatory authorities review process for our current product candidates and any future product candidates, while complying with our contractual obligations to contractors and other third parties;
- developing and managing our internal manufacturing operations effectively and in a cost-effective manner while increasing production capabilities for our product candidates to commercial levels;
- identifying and establishing additional facilities for our operations; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to commercialize our product candidates, if approved, will depend, in part, on our ability to effectively manage any future growth. Our management may 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 contract manufacturers and companies focused on antibody development and discovery activities. The services of independent organizations, advisors and consultants may not continue to be available to us on a timely or cost-efficient basis when needed, and we may not be able to find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality, accuracy or quantity of the services provided is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain, or may be substantially delayed in obtaining, regulatory approval of our product candidates or otherwise advance our business. We may not 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, consultants and contractors as necessary, we may not be able to successfully implement the tasks necessary to further develop and commercialize our current or any future product candidates, if approved, and, accordingly, may not achieve our research, development and future commercialization goals, which could adversely affect our business.

If we lose key management or other scientific or medical personnel, or if we fail to recruit additional highly skilled personnel, our business, results of operations and financial condition could be adversely affected.

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 executive officers and other members of our management team, including our President and Chief Executive Officer, Sammy Farah, M.B.A., Ph.D. We do not currently maintain “key person” life insurance on the lives of our executives or any of our employees. This lack of insurance means that we may not have adequate compensation for the loss of the services of these individuals. The loss of the services of any of our executive officers or other members of our management team, including our scientific and medical personnel, and our inability to find suitable replacements in a timely manner could result in delays in product development and adversely affect our business, results of operations and financial condition.

We conduct our operations at our facility in San Diego, California. This region is headquarters to many other biopharmaceutical and biotechnology companies and many academic and research institutions.

Competition for skilled personnel in our industry is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all.

To induce valuable employees to remain 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. Generally, employment agreements with our key employees provide for at-will employment, which means that such employee 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 scientific and medical personnel.

Our internal information technology systems, or those of our third-party contract research organizations, contract manufacturing organizations and other contractors and consultants, may fail or suffer security breaches, loss or leakage of data and other disruptions, which could result in a material disruption of our development programs, compromise sensitive information related to our business or prevent us from accessing critical information, potentially exposing us to liability, and could adversely affect our business, results of operations and financial condition.

We are increasingly dependent upon information technology systems to operate our business. In the ordinary course of business, we collect, store and transmit confidential information (including, but not limited to, intellectual property, confidential and proprietary business information and personal information). It is critical that we do so in a secure manner to maintain the confidentiality and integrity of all such information. We also have outsourced elements of our operations to third parties, and as a result we manage a significant number of third-party contractors who have access to our confidential information.

Despite the implementation of security measures, given the size and complexity and the increasing amounts of confidential information that our information technology systems maintain, such systems and those of our third-party contract research organizations, or CROs, and contract manufacturing organizations and other contractors and consultants are potentially vulnerable to attack, breakdown, damage or interruption from service interruptions, system malfunction, natural disasters, terrorism, war and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our employees, contractors, consultants, business partners and/or other third parties, or from cyberattacks by malicious third parties (including the deployment of harmful malware, ransomware, malicious code, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information), which may compromise our information technology system infrastructure or lead to data leakage. We may face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. 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 reputational damage and the further development and future commercialization of our current product candidates or any future product candidates could be delayed.

We and certain of our service providers are from time to time subject to cyberattacks and security incidents. While we do not believe that we have experienced any significant system failure, accident or security breach, our data protection efforts and our investment in information technology may not in the future prevent

significant cyber incidents in our systems and those of our third-party contract research organizations and contract manufacturing organizations and other contractors and consultants that could adversely affect our business, results of operations and financial condition. For example, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs and the development of our product candidates could be delayed. In addition, the loss of clinical trial data for any of our product candidates could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data. Furthermore, significant disruptions of or security breaches in our internal information technology systems and those of our third-party contract research organizations and contract manufacturing organizations and other contractors and consultants could result in the loss, misappropriation and/or unauthorized access, use, or disclosure of, or the prevention of access to, confidential information (including trade secrets or other intellectual property, proprietary business information and personal information), which could result in financial, legal, business and reputational harm to us. For example, any such event that leads to unauthorized access, use, or disclosure of personal information, including personal information regarding our clinical trial subjects or employees, could harm our reputation directly, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could result in significant legal and financial exposure and reputational damages that could adversely affect our business, results of operations and financial condition. Further, we do not currently maintain cybersecurity liability insurance coverage.

Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could adversely affect our business, results of operations and financial condition.

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 (1) comply with the laws of the FDA or comparable foreign regulatory authorities, (2) provide true, complete and accurate information to the FDA or comparable foreign regulatory authorities, (3) comply with manufacturing standards we have established, (4) comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws, or (5) report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA or comparable foreign regulatory authorities' approval of any of our product candidates and begin commercializing those products in the United States or abroad, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws 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. It is not always possible to identify and deter misconduct by our employees, independent contractors, consultants, commercial partners and vendors. The precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in any of the following: the imposition of civil, criminal and administrative penalties, damages, monetary fines, individual imprisonment, disgorgement, possible exclusion from participation in government healthcare programs, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm, diminished profits and future earnings and the curtailment of our operations.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit future commercialization of our product candidates, if approved, which could adversely affect our business, results of operations and financial condition.

We face an inherent risk of product liability as a result of testing our product candidates, including our current and any of our future product candidates in clinical trials and will face an even greater risk if we

commercialize any products, if approved. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical trials, manufacturing, marketing or sale. Any such product liability claims could 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 also could be asserted under state consumer protection acts. Product liability claims could delay or prevent completion of our development programs. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit future commercialization of our product candidates, if approved. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

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

Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the future commercialization, if approved, of products we develop alone or with collaborators. We need to obtain additional insurance for clinical trials as our current pre-clinical and any future pre-clinical programs enter the clinical development phase. However, we may be unable to obtain, or may obtain on unfavorable terms, clinical trial insurance in amounts adequate to cover any liabilities from any of our clinical trials. Our insurance policies also may have various deductibles and exclusions, and we may be subject to a product liability claim for which we have no coverage. We may need 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, enforcing such indemnification provisions may cause diversion of management's time and our resources and such indemnification may not be available or adequate should any claim arise.

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 adversely affect our business, results of operations and financial condition.

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

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

Our insurance policies may be inadequate and potentially expose us to unrecoverable risks.

We have limited director and officer insurance and commercial insurance policies. Any significant insurance claims would have a material adverse effect on our business, results of operations and financial condition. Insurance availability, coverage terms and pricing continue to vary with market conditions. We endeavor to obtain appropriate insurance coverage for insurable risks that we identify; however, we may fail to correctly anticipate or quantify insurable risks, we may not be able to obtain appropriate insurance coverage, and insurers may not respond as we intend to cover insurable events that may occur. We have observed rapidly changing conditions in the insurance markets relating to nearly all areas of traditional corporate insurance. Such conditions have resulted in higher premium costs, higher policy deductibles and lower coverage limits. For some risks, we may not have or maintain insurance coverage because of cost or availability.

Our operations are concentrated in one location, and we or the third parties upon whom we depend may be adversely affected by earthquakes, pandemics or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our current operations are predominantly located in San Diego, California. Any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, health epidemic, including the COVID-19 pandemic, power shortage, telecommunication failure or other natural or manmade accidents or incidents that result in us being unable to fully utilize our facilities, or the manufacturing facilities of our third-party contract

manufacturers, may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of our product candidates or interruption of our business operations. Earthquakes, pandemics or other natural disasters could further disrupt our operations and have a material and adverse effect on our business, results of operations and financial condition. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our research facilities or the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, could have a material adverse effect on our business. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, the amounts of insurance may not be sufficient to satisfy any damages and losses. If our facilities, or the manufacturing facilities of our third-party contract manufacturers, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs may be harmed and our clinical trials may be delayed. Any business interruption may adversely affect our business, results of operations and financial condition.

Risks Related to Research and Development

The successful development of biopharmaceuticals is highly uncertain.

The successful development of biotechnology is highly uncertain and is dependent on numerous factors, many of which are beyond our control. Product candidates that appear promising in the early phases of development may fail to reach the market for several reasons including:

- preclinical study results may show the product candidate to be less effective than desired or to have harmful or problematic side effects;
- clinical trial results may show the product candidates to be less effective than expected (*e.g.*, a clinical trial could fail to meet its primary endpoint(s)), to have unacceptable side effects or toxicities or to have effects in humans that differ from previously observed effects in lab animals;
- failure to receive the necessary regulatory approvals or a delay in receiving such approvals. Among other things, such delays may be caused by slow enrollment in clinical trials, patients withdrawing from clinical trials, length of time to achieve trial endpoints, additional time requirements for data analysis, or BLA, preparation, discussions with the FDA or comparable foreign regulatory authorities and any such request for additional preclinical or clinical data, or unexpected safety or manufacturing issues or failures;
- manufacturing costs, formulation issues, pricing or reimbursement issues, or other factors that make a product candidate uneconomical; and
- the proprietary rights of others and their competing products and technologies that may prevent or otherwise make it uneconomical for one or more of our product candidates from being commercialized, if approved.

The length of time necessary to complete clinical trials and to apply for marketing approval for a final decision by a regulatory authority varies significantly from one product candidate to the next and may be difficult to predict. Even if we are successful in getting market approval, commercial success of any approved products

also will depend in large part on the availability of coverage and adequate reimbursement from third-party payors, including government payors such as the Medicare and Medicaid programs, commercial insurers, and managed care organizations, which may be affected by existing and future healthcare reform measures designed to reduce the cost of healthcare. Third-party payors could require us to conduct additional studies, including post-marketing studies related to the cost effectiveness of a product, to qualify for reimbursement, which could be costly and divert our resources. If third-party payors were to decide to not provide coverage and adequate reimbursement levels for any of our products, if approved, market acceptance and commercial success would be reduced.

In addition, if any of our product candidates are approved for marketing, we will be subject to significant regulatory obligations regarding the submission of safety and other post-marketing information and reports and registration, and will need to continue to comply (or ensure that our third-party providers comply) with cGMPs or similar foreign requirements and good clinical practices, or GCPs, for any clinical trials that we conduct post-approval. GCPs are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, clinical investigators and trial sites. In addition, there always is the risk that we or a regulatory authority might identify previously unknown problems with a product post-approval, such as adverse events of unanticipated severity or frequency. Compliance with these requirements is costly, and any failure to comply or other issues with our product candidates following approval, if any, could adversely affect our business, results of operations and financial condition.

Clinical development involves a lengthy and expensive process, with uncertain outcomes. We may incur significant costs and/or experience delays in completing, or ultimately be unable to complete, the development of our current and future product candidates, including our lead product candidates.

To obtain the requisite regulatory approvals to commercialize any product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our product candidates are safe, pure and potent or effective in humans. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain.

Differences in trial design between early-stage clinical trials and later-stage clinical trials make it difficult to extrapolate the results of earlier clinical trials to later clinical trials. Moreover, clinical data often are susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in clinical trials have nonetheless failed to obtain marketing approval of their products.

Successful completion of clinical trials is a prerequisite to submitting a BLA, to the FDA, a Marketing Authorization Application, or MAA, to the European Medicines Agency, or EMA, and similar marketing applications to comparable foreign regulatory authorities, for each product candidate and, consequently, the ultimate approval and commercial marketing of any product candidates. We do not know whether any of our clinical trials will be completed on schedule, if at all.

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

- regulators or institutional review boards, or IRBs, or ethics committees may not authorize us or our investigators to commence or continue a clinical trial or conduct a clinical trial at a prospective trial site;

- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective CROs the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;

- clinical trials of any product candidates may fail to show safety, purity or potency, or produce negative or inconclusive results and we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials or we may decide to abandon product development programs;

- we may experience manufacturing failures, including in our TIL selection process, resulting in a less effective product candidate in the tumor indications we are pursuing;

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

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

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

- the cost of clinical trials of any product candidates may be greater than we anticipate;

- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate to initiate or complete a given clinical trial; for example, the process development for TILs is very complicated and requires significant logistics, and any issues with this process could delay our trials;

- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators, or IRBs or ethics committees to suspend or terminate the trials, or reports from clinical testing of other therapies may raise safety or efficacy concerns about our product candidates; and

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

We also could encounter delays if a clinical trial is suspended or terminated by us, the IRBs or ethics committees of the institutions in which such trials are being conducted, or the FDA or comparable foreign regulatory authorities, or recommended for suspension or termination by the Data Safety Monitoring Board, or DSMB, or foreign equivalent for such trial. A suspension or termination may be imposed by the FDA or comparable foreign 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 resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product or treatment, failure to establish or achieve clinically meaningful trial endpoints, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials also may ultimately lead to the denial of regulatory approval of our product candidates. Further, the FDA or comparable foreign regulatory authorities may disagree with our clinical trial design and our interpretation of data from clinical trials, or may change the requirements for approval even after they have reviewed and commented on the design for our clinical trials.

Our product development costs will increase if we experience delays in clinical testing or marketing approvals. We do not know whether any of our clinical trials will need to be restructured or will be completed on schedule, or at all. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates and may allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize our product candidates and harming our business and results of operations. Any delays in our clinical development programs may adversely affect our business, results of operations and financial condition.

In addition, the FDA's and comparable foreign regulatory authorities' policies with respect to clinical trials may change and additional government regulations may be enacted. For instance, the regulatory landscape related to clinical trials in the European Union, or EU, recently evolved. The EU Clinical Trials Regulation, or CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. While the Clinical Trials Directive required a separate clinical trial application, or CTA, to be submitted in each EU member state, to both the competent national health authority and an independent ethics committee, the CTR introduces a centralized process and only requires the submission of a single application to all EU member states concerned. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each EU member state, leading to a single decision per EU member state. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all EU member states concerned, and a separate assessment by each EU member state with respect to specific requirements related to its own territory, including ethics rules. Each EU member state's decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed. The CTR includes a transition period. The extent to which ongoing clinical trials will be governed by the CTR varies. For clinical trials whose CTA was made under the Clinical Trials Directive before January 31, 2022, the Clinical Trials Directive will continue to apply on a transitional basis for three years. Additionally, sponsors could submit a clinical trial application under either the Clinical Trials Directive or the CTR until January 31, 2023 and, if authorized, those will be governed by the Clinical Trials Directive until January 31, 2025. By that date, all ongoing trials will become subject to the provisions of the CTR. Compliance with the CTR requirements by us and our third-party service providers, such as CROs, may impact our developments plans and may increase our operating costs.

The regulatory framework in the United Kingdom, or UK, in relation to clinical trials is derived from existing EU legislation (as implemented into UK law, through secondary legislation). On January 17, 2022, the UK Medicines and Healthcare products Regulatory Agency, or MHRA, launched an eight-week consultation on reframing the UK legislation for clinical trials. The consultation closed on March 14, 2022. The reframe aims to streamline clinical trials approvals, enable innovation, enhance clinical trials transparency, enable greater risk proportionality, and promote patient and public involvement in clinical trials. On March 21, 2023, the MHRA published the outcome of the consultation with its responses. The MHRA may aim for a partial alignment to the CTR although there may be partial divergence from the Regulation which is intended to maintain regulatory flexibility. While opting for regulatory flexibility may facilitate conduct of clinical trials in the UK, divergence from the CTR may increase the administrative burden for clinical trials conducted at sites in both the UK and the EU. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be impacted.

Preclinical development is uncertain. Our preclinical programs may experience delays or generate unfavorable data, and may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these programs on a timely basis or at all, and any of these events would adversely affect our business, results of operations and financial condition.

Before we can commence clinical trials for any product candidate in our preclinical programs, we must complete extensive preclinical studies that support our planned INDs in the United States, or similar applications in other jurisdictions. Our preclinical studies may not be completed on a timely basis and have an unfavorable outcome, and the FDA and comparable foreign regulatory authorities may not accept our proposed clinical

programs, or the outcome of our preclinical studies may not ultimately support the further development of our preclinical programs. As a result, we may not be able to submit INDs or similar applications for our preclinical programs on the timelines we expect, if at all, and submission of INDs or similar applications may not result in the FDA or comparable foreign regulatory authorities allowing clinical trials to begin.

Our product candidates are based on a novel approach to the treatment of cancer, which makes it difficult to predict the time and cost of product candidate development.

We have concentrated substantially all of our recent research and development efforts on product candidates based on our Selected TIL approach, and our future success depends largely on the successful development of these approaches. Any development problems we experience in the future may cause significant delays or unanticipated costs, and such development problems may not be solved. Should we encounter development problems, including unfavorable preclinical or clinical trial results, the FDA and comparable foreign regulatory authorities may refuse to authorize us to conduct additional clinical trials, and even if they do, they may not approve our product candidates, or may require additional information, tests, or trials, which could significantly delay product development and significantly increase our research and development costs. Moreover, even if we are able to provide to the FDA or comparable foreign regulatory authorities the requested information or trials, the FDA or comparable foreign regulatory authorities may not accept them and may not approve our product candidates. We also may experience delays in developing a sustainable, reproducible and scalable manufacturing process, or developing or qualifying and validating product release assays, other testing and manufacturing methods, and our equipment and facilities in a timely manner. This may prevent us from completing our clinical trials or commercializing our product candidates on a timely or profitable basis, if at all.

In addition, the clinical trial requirements of the FDA and comparable foreign regulatory authorities and the criteria these regulators use to evaluate the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the potential products. The FDA and comparable foreign regulatory authorities have limited experience with the approval of Selected TIL immunotherapies. There are no TIL therapies that have received FDA approval to date.

The manufacture of our product candidates is complex, and we may encounter difficulties in production, particularly with respect to process development, quality control, or scaling-up of any future manufacturing capabilities. If we, or any of our third-party manufacturers encounter such difficulties, our ability to provide supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.

Our product candidates are biologics and the process of manufacturing our product candidates is complex, highly regulated and subject to multiple risks. The manufacture of our product candidates involves complex processes, including harvesting tumor fragments from patients, isolating the T-cells from the tumor fragments, multiplying the T-cells to obtain the desired dose, and ultimately infusing the T-cells back into a patient. As a result of the complexities, the cost to manufacture biologics is generally higher than traditional small molecule chemical compounds, and the manufacturing process is less reliable and is more difficult to reproduce. Further, as a result of the complexities, we may not be able to successfully manufacture Selected TILs, which could result in any of our product candidates not being differentiated from a bulk TIL product, and as a result, any of our product candidates may not be effective in the tumor indications that we are pursuing. Moreover, our manufacturing process is susceptible to product loss or failure due to logistical issues associated with the collection of tumor fragments, or starting material, from the patient, shipping such material to the manufacturing site, shipping the final product back to the patient, and infusing the patient with the product, manufacturing issues associated with the differences in patient starting material, interruptions in the manufacturing process, contamination, equipment failure, assay failures, improper installation or operation of equipment, vendor or operator error, inconsistency in cell growth, meeting pre-specified release criteria, and variability in product characteristics. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects, and other supply disruptions. If for any reason we lose a patient’s

starting material, or later developed product at any point in the process, or if any product does not meet the applicable specifications, the manufacturing process for that patient will need to be restarted, including resection of the proper amount of tumor fragment and the resulting delay may adversely affect that patient's outcome. If microbial, viral, environmental or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination.

Because our product candidates are manufactured specifically for each individual patient, we will be required to maintain a chain of identity with respect to the patient's tumor as it moves from the patient to the manufacturing facility, through the manufacturing process, and back to the patient. Maintaining such a chain of identity is difficult and complex, and failure to do so could result in adverse patient outcomes, loss of product, or regulatory action including withdrawal of our products from the market. Further, as product candidates are developed through preclinical studies to late-stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered along the way to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials or otherwise necessitate the conduct of additional studies.

As a result of these challenges, we may experience delays in our clinical development and/or commercialization plans, if approved. Furthermore, we may ultimately be unable to reduce the cost of goods for our product candidates to levels that will allow for an attractive return on investment if and when those product candidates are commercialized.

The manufacture of cell therapy products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of cell therapy products often encounter difficulties in production, particularly in scaling up initial production. These problems include difficulties with production costs and yields, quality control, including stability of the product candidate and quality assurance testing, shortages of qualified personnel, and compliance with strictly enforced federal, state, local and foreign regulations.

Externally, to support both TIDAL-01 and TIDAL-02, we have formed deep partnerships across a global network of contract development and manufacturing organizations, or CDMOs, that specialize in bioprocess development, testing, cGMP manufacturing, formulation and filling, packaging, controlled temperature storage, and distribution. For TIDAL-01, this includes a close partnership with the Cell Therapy Facility at Moffitt Cancer Center, responsible for cGMP manufacturing, testing, release, and distribution of Selected TIL to the clinical investigators at Moffitt under our investigator sponsored clinical trial. We have separate partnerships, fully controlled and supervised by us, for the sequencing and peptide manufacturing portions of the TIDAL-01 manufacturing process. In parallel, we have completed a technology transfer of the TIDAL-01 Selected TIL manufacturing process to a U.S.-based CDMO, Charles River Laboratories. Any problems or delays we, Moffitt or our CDMOs experience in preparing for commercial scale manufacturing of a product candidate or component may result in a delay in the FDA or comparable foreign regulatory authority approval of the product candidate or may impair our ability to manufacture commercial quantities or such quantities at an acceptable cost, which could result in the delay, prevention, or impairment of clinical development and commercialization of our product candidates, if approved, and could adversely affect our business.

Moreover, we may not succeed in maintaining our relationships with our current CDMOs or establishing relationships with additional or alternative CDMOs. Our product candidates may compete with other products and product candidates for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that are both capable of manufacturing for us and willing to do so. If our CDMOs should cease manufacturing for us, we would experience delays in obtaining sufficient quantities of our product candidates for

clinical trials and, if approved, commercial supply. Further, our CDMOs may breach, terminate, or not renew its agreements with us. If we were to need to find alternative manufacturing facilities it would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. The commercial terms of any new arrangement could be less favorable than our existing arrangements and the expenses relating to the transfer of necessary technology and processes could be significant.

We are ultimately responsible for the manufacture of our product candidates. A failure to comply with these requirements may result in regulatory enforcement actions against our manufacturers or us, including fines and civil and criminal penalties, which could result in imprisonment, suspension or restrictions of production, injunctions, delay or denial of product approval or supplements to approved products, clinical holds or termination of clinical trials, warning or untitled letters, regulatory authority communications warning the public about safety issues with the biologic, refusal to permit the import or export of the products, product seizure, detention, or recall, operating restrictions, suits under the civil False Claims Act, corporate integrity agreements, consent decrees, or withdrawal of product approval.

Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidate, impair commercialization efforts, increase our cost of goods, and have an adverse effect on our business, results of operations and financial condition.

Cell-based therapies and biologics rely on the availability of reagents, specialized equipment, and other specialty materials, which may not be available to us on acceptable terms or at all. For some of these reagents, equipment, and materials, we rely or may rely on sole source vendors or a limited number of vendors, which could impair our ability to manufacture and supply our products.

Manufacturing our product candidates requires many reagents, which are substances used in our manufacturing processes to bring about chemical or biological reactions, and other specialty materials and equipment, some of which are manufactured or supplied by small companies with limited resources and experience to support commercial biologics production. We currently depend on a limited number of vendors for certain materials and equipment used in the manufacture of our product candidates. Some of these suppliers may not have the capacity to support clinical trials and commercial products manufactured under cGMPs by biopharmaceutical firms or may otherwise be ill-equipped to support our needs. We also do not have supply contracts with many of these suppliers and may not be able to obtain supply contracts with them on acceptable terms or at all. Accordingly, we may experience delays in receiving key materials and equipment to support clinical or commercial manufacturing.

For some of these reagents, equipment, and materials, we rely and may in the future rely on sole source vendors or a limited number of vendors. An inability to continue to source product from any of these suppliers, which could be due to a number of issues, including regulatory actions or requirements affecting the supplier, adverse financial or other strategic developments experienced by a supplier, labor disputes or shortages, unexpected demands, or quality issues, could adversely affect our ability to satisfy demand for our product candidates, which could adversely and materially affect our product sales and operating results or our ability to conduct clinical trials, either of which could significantly harm our business.

Changes in product candidate manufacturing, formulation or analytical methods may result in additional costs or delay, which could adversely affect our business, results of operations and financial condition.

As product candidates are developed through preclinical studies to later-stage clinical trials towards approval and future commercialization, it is common that various aspects of the development program, such as manufacturing methods, formulation or analytical methods, are altered throughout the development process in an effort to optimize processes and results. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered

materials or utilizing different analytical methods. Such changes also may require additional testing, or notification to, or authorization by the FDA or a comparable foreign regulatory authority. This could delay completion of clinical trials, require the conduct of bridging clinical trials or studies, require the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and/or jeopardize our ability to commence product sales and generate revenue.

Use of our product candidates could be associated with side effects, adverse events or other properties or safety risks, which could cause us to suspend or discontinue clinical trials, abandon a product candidate, delay or preclude approval, prevent market acceptance, limit the commercial profile of an approved label or result in other significant negative consequences that could severely harm our business, results of operations and financial condition.

Before obtaining regulatory approvals for the commercial sale of any of our products, we must demonstrate through lengthy, complex and expensive preclinical studies and clinical trials that our current product candidates, including our lead product candidates, and any future product candidate are both safe, pure and potent, or effective for use in such product candidate's target indication. Clinical testing is expensive, can take many years to complete and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. 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. In addition, initial success in clinical trials may not be indicative of results obtained when such trials are completed. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Product candidates in later stages of clinical trials may fail to generate desired safety and efficacy data despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that commence clinical trials are never approved and there can be no assurance that any of our clinical trials will ultimately be successful or support further clinical development of our current product candidates or any of our future product candidates or ultimately their approval.

Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by our product candidates could cause us or regulatory authorities 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 comparable foreign regulatory authorities. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, results of operations and financial condition significantly.

If our product candidates are associated with undesirable side effects or have unexpected characteristics in preclinical studies or clinical trials we may need to interrupt, delay or abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Treatment-related side effects could also affect patient recruitment or the ability of enrolled subjects to complete the trial, or result in potential product liability claims. Any of these occurrences may prevent us from achieving or maintaining market acceptance of the affected product candidate and may harm our business, results of operations and financial condition significantly.

Patients in our ongoing and planned clinical trials may in the future suffer significant adverse events or other side effects not observed in our preclinical studies or previous clinical trials. In addition, if our product candidates are used in combination with other therapies, our product candidates may exacerbate adverse events associated with the therapy. Patients treated with our product candidates may also be undergoing surgical, radiation or chemotherapy treatments, which can cause side effects or adverse events that are unrelated to our product candidate, but may still impact the success of our clinical trials. The inclusion of critically ill patients in

our clinical trials may result in deaths or other adverse medical events due to other therapies or medications that such patients may be using or due to the gravity of such patients' illnesses.

If significant adverse events or other side effects are observed in any of our current or future clinical trials, we may have difficulty recruiting patients to the clinical trials, patients may drop out of our trials, or we may be required to abandon the trials or our development efforts of that product candidate altogether. We, the FDA, other comparable foreign regulatory authorities or an IRB or ethics committee may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage trials have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the product candidate from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance due to its tolerability versus other therapies. Any of these developments could materially harm our business, results of operations and financial condition.

Additionally, if any of our product candidates receives regulatory approval, and we or others later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result. For example, the FDA could require us to adopt a Risk Evaluation and Mitigation Strategy, or REMS, to ensure that the benefits of treatment with such product candidate outweigh the risks for each potential patient, which may include, among other things, a communication plan to health care practitioners, patient education, extensive patient monitoring or distribution systems and processes that are highly controlled, restrictive and more costly than what is typical for the industry. Other potentially significant negative consequences include that:

- we may be forced to suspend marketing of that product, or decide to remove the product from the marketplace, if approved;
- regulatory authorities may withdraw or change their approvals of that product;
- regulatory authorities may require additional warnings on the label or limit access of that product to selective specialized centers with additional safety reporting and with requirements that patients be geographically close to these centers for all or part of their treatment;
- we may be required to create a medication guide outlining the risks of the product for patients, or to conduct post-marketing studies;
- we may be required to change the way the product is administered;
- we could be subject to fines, injunctions, or the imposition of criminal or civil penalties, or be sued and held liable for harm caused to subjects or patients; and
- the product may become less competitive, and our reputation may suffer.

Any of these events could diminish the usage or otherwise limit the commercial success of our product candidates and prevent us from achieving or maintaining market acceptance of the affected product candidate, if approved by applicable regulatory authorities.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected, which could adversely affect our business, results of operations and financial condition.

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, among other things, on our ability

to enroll a sufficient number of patients who remain in the trial until its conclusion. The enrollment of patients depends on many factors, including:

- the patient eligibility and exclusion criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to trial sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will withdraw from the trials before completion.

In addition, our clinical trials will compete with other clinical trials for patient participation 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 trials may instead opt to enroll in a trial being conducted by one of our competitors. For example, we will compete with various other cancer therapies, including combinations studies, and as of December 2021, there were over 4,600 combination studies of checkpoint inhibitors underway, including with monoclonal antibodies, cell therapies, cancer vaccines and other therapies. Public perception of TIL-based immunotherapies also may adversely influence willingness of subjects to participate in clinical trials. Furthermore, because 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 sites.

Further, if we implement improvements to our manufacturing process, we may decide to slow or limit enrollment while we are implementing such improvements. While we would expect such implementation to only be temporary, any resulting enrollment delays may adversely affect our business, results of operations and financial condition.

Delays in patient enrollment may result in increased costs or may affect the timing or outcome of our future clinical trials, which could prevent completion of these trials and adversely affect our business, results of operations and financial condition.

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

From time to time, we may publicly disclose preliminary or topline data from our clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the topline or preliminary data we previously published. As a result, topline and preliminary data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our clinical trials. Interim data from these trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as subject enrollment continues and more data become available. Adverse differences between interim data and top-line, preliminary, or final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock.

Further, others, including regulatory authorities, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product, and our company in general. In addition, the information we choose to publicly disclose regarding a particular clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the interim, topline, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for and commercialize our product candidates may be harmed, which could harm our business, results of operations or financial condition.

Due to our limited resources and access to capital, we must prioritize development of certain programs and product candidates; these decisions may prove to be wrong and may adversely affect our business, results of operations and financial condition.

Because we have limited financial and human resources, we intend to initially focus on research programs and product candidates for a limited set of indications. For example, we are initially focused on the development of our lead Selected TIL product candidate TIDAL-01 in breast cancer, colorectal cancer, uveal melanoma and both cutaneous and non-cutaneous melanomas. Because TIL therapy is a relatively new and expanding area of novel therapeutic interventions, there are many uncertainties related to development, marketing, reimbursement and the commercial potential for our product candidates. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential or a greater likelihood of success. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate 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 product candidate.

We may for a number of reasons fail to identify viable new product candidates for clinical development from our current or future research programs. If we fail to identify additional potential product candidates, our business, results of operations and financial condition could be adversely affected.

Research programs to pursue the development of our existing and planned product candidates for additional indications and to identify new product candidates and disease targets require substantial technical, financial and human resources whether they are ultimately successful or not. Our research programs may initially show promise in identifying potential indications and/or product candidates, yet fail for a number of reasons to yield results for clinical development, including:

- the research methodology used may not be successful in identifying potential indications and/or product candidates;
- potential product candidates may, after further study, be shown to have harmful adverse effects or other characteristics that indicate they are unlikely to be effective products against the indicated disease; or
- it may take greater human and financial resources than we will possess to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product

candidates through internal research programs, thereby limiting our ability to develop, diversify and expand our product portfolio.

Accordingly, we may never be able to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, which could materially adversely affect our future growth and prospects. We may focus our efforts and resources on potential product candidates or other potential programs that ultimately prove to be unsuccessful.

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

Regulatory authorities in some jurisdictions, including the United States and the EU, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a biologic as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States, or a patient population of 200,000 or more in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States.

In the United States, orphan drug designation entitles a party to financial incentives such as tax advantages and user fee waivers. Opportunities for grant funding toward clinical trial costs may also be available for clinical trials of drugs or biologics for rare diseases, regardless of whether the biologics are designated for the orphan use. In addition, if a biologic with an orphan drug designation subsequently receives the first marketing approval for the disease or condition for which it has such designation, the product is entitled to a seven-year period of marketing exclusivity, which precludes the FDA from approving another marketing application for the same drug for the same disease or condition for that time period, except in limited circumstances. If our competitors are able to obtain orphan drug exclusivity prior to us, for products that constitute the “same drug” and treat the same diseases or conditions as our product candidates, we may not be able to have competing products approved by the applicable regulatory authority for a significant period of time.

In the EU, the European Commission, following a related opinion of the EMA Committee for Orphan Medicinal Products, may orphan drug designation for medicinal products to be developed for the diagnosis, prevention or treatment of diseases that are life-threatening or chronically debilitating, for which either no satisfactory method of diagnosis, prevention, or treatment exists, or if such method exists, the medicinal product is of significant benefit to those affected by such condition. To benefit from such designation, either the prevalence of the condition must not be more than five in 10,000 people across the EU or, if more prevalent, it must be unlikely that the marketing of the medicinal product would generate sufficient returns to justify the investment needed for its development.

If a drug with orphan designation subsequently receives the first marketing approval for the indication for which it has such designation, the drug may be entitled to a period of marketing exclusivity. This precludes the FDA or the EMA from accepting another marketing application for the same drug or, in the case of the EMA, a similar drug, for the same indication during this time period. The applicable period is seven years in the United States and ten years in the EU. The period which may be extended by six months in the United States and two years in the EU for products that have complied with the respective regulatory agency’s agreed upon pediatric investigation plan. The exclusivity period in the EU can be reduced to six years if at the end of the fifth year a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable that market exclusivity is no longer justified.

We may seek orphan designation for certain of our product candidates. However, we may be unsuccessful in obtaining orphan drug designation for these and may be unable to maintain the benefits associated with orphan drug designation, even if we do obtain such designation. Even if we obtain orphan drug

designation and obtain orphan drug exclusivity for any of our product candidates, that exclusivity may not effectively protect those product candidates from competition because different products can be approved for the same disease or condition. Even after an orphan drug is granted orphan exclusivity and approved, the FDA can subsequently approve a later application for the same drug for the same disease or condition before the expiration of the seven-year exclusivity period if the FDA concludes that the later drug is clinically superior in that it is shown to be safer in a substantial portion of the target populations, more effective or makes a major contribution to patient care. Similarly, the European Commission can approve a similar drug for the same therapeutic indication during the 10-year-exclusivity if we consent thereto, if we are unable to supply sufficient quantities of the drug in the EU, or if the similar product is demonstrated to be safer, more effective or otherwise clinically superior to ours. In addition, 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. Moreover, orphan-drug-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 we are unable to manufacture sufficient quantities of the product to meet the needs of patients with the rare disease or condition. The exclusivity period in the EU can be reduced to six years if at the end of the fifth year a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

We may attempt to secure approval from the FDA or comparable foreign regulatory authorities through the use of accelerated approval pathways. If we are unable to obtain such approval, we may be required to conduct additional clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if we receive accelerated approval from the FDA or comparable foreign regulatory authorities, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA or comparable foreign regulatory authorities may seek to withdraw accelerated approval.

We may in the future seek an accelerated approval for our one or more of our product candidates. However, because our product candidates are in early development, there can be no assurance that the FDA would approve any form of application for expedited review for any of our product candidates. Under the accelerated approval program, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that provides meaningful clinical benefit over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor’s agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the product’s clinical benefit. If such post-approval studies fail to confirm the product’s clinical benefit, the FDA may withdraw its approval. Furthermore, the FDA’s accelerated approval pathways do not guarantee an accelerated review by the FDA, and even if our product candidates could be granted a designation or qualify for expedited development, it would not increase the likelihood that such product candidate will receive FDA approval.

In the EU, under the centralized procedure, the EMA’s Committee for Medicinal Products for Human Use may perform an accelerated assessment of a marketing authorization application. Applicants requesting an

accelerated assessment procedure must justify that the product candidate is expected to be of major public health interest, particularly from the point of view of therapeutic innovation.

Prior to seeking accelerated approval for any of our product candidates, we intend to seek feedback from the FDA or similar foreign regulatory authorities and will otherwise evaluate our ability to seek and receive accelerated approval. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit a BLA or similar application for accelerated approval or any other form of expedited development or review. Similarly, there can be no assurance that after subsequent FDA or similar foreign regulatory authorities' feedback we will continue to pursue or apply for accelerated approval or any other form of expedited development or review, even if we initially decide to do so. Furthermore, if we decide to submit an application for accelerated approval or other expedited development or review for our product candidates, there can be no assurance that such submission or application will be accepted or that any expedited development or review will be granted on a timely basis, or at all. The FDA or other comparable foreign regulatory authorities could also require us to conduct further studies prior to considering our application or granting approval of any type. A failure to obtain accelerated approval or any other form of expedited development or review for our product candidate would result in a longer time period to commercialization of such product candidate, if any, could increase the cost of development of such product candidate, and could harm our competitive position in the marketplace.

The FDA and other regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses.

If any of our product candidates are approved and we are found to have improperly promoted off-label uses of those products, we may become subject to significant liability. The FDA and other foreign regulatory authorities strictly regulate the promotional claims that may be made about prescription products, such as our product candidates, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or such other foreign regulatory authorities as reflected in the product's approved labeling. If we receive marketing approval for a product candidate, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability. The U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The government has also required companies to enter into consent decrees or imposed permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

Risks Related to the Biotechnology Industry

We face significant competition and if we fail to compete effectively, our business, results of operations and financial condition could be adversely affected.

The biotechnology and pharmaceutical industries are characterized by intense competition, fierce defense of intellectual property and rapidly advancing technologies. Our competitors may be able to develop other therapies or drugs that are able to achieve similar or better results than our product candidates. Our competitors include major pharmaceutical, specialty pharmaceutical and existing or emerging biotechnology companies, academic institutions, governmental agencies, and public and private research institutions. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations and well-established sales forces, and other biopharmaceutical companies may compete by establishing collaborative arrangements with these large companies. Smaller or early-stage companies also may prove to be significant competitors, particularly as they develop novel approaches to treating disease indications that our product candidates also are focused on treating. Established biotechnology companies may also invest heavily to accelerate discovery and development of novel

therapeutics or to in-license novel therapeutics that could make the product candidates that we develop obsolete. Mergers and acquisitions in the biotechnology industry 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 efficacy, safety, tolerability, reliability, durability, convenience of use, price and reimbursement.

We anticipate competing with other companies that are focused on treating disease indications that our product candidates also are focused on treating. A competitor may develop technologies focused on the same disease pathway as our technology or may focus on treating the targeted disease in a completely different manner. Our competitors may also seek and obtain patent rights to their technologies that are similar to ours, and such patent rights may in the future affect the direction of our product development or require us to negotiate a license to such patent rights. To the extent a new drug is developed by a competitor that is more efficacious than any product candidate developed by us, this could reduce or negate the need for our product candidate. In addition, while we believe our product candidates may be used in conjunction with existing or emerging standard of care in certain disease indications, as companies continue to improve upon existing standards of care, more efficacious drug therapies could become available, reducing or completely negating the benefit of our product candidates. Our competitors also may include companies that are or will be developing therapies for the same therapeutic areas that we are targeting within our early pipeline.

We face competition from segments of the pharmaceutical, biotechnology and other related markets that pursue the development of TIL or other cell therapies for the treatment of solid tumors. Our competitors include, among others:

- companies that are developing TIL therapies such as Iovance Biotherapeutics, Inc., Achilles Therapeutics plc, Instil Bio, Inc., KSQ Therapeutics, Inc., Lyell Immunopharma, Inc., Obsidian Therapeutics, Inc., Intima Bioscience, Inc. and others; and

- companies focused on CAR-T and TCR-T cell therapies for solid-tumors, such as Adaptimmune Therapeutics PLC, Adicet Bio, Inc., Alaunos Therapeutics, Inc., Atara Biotherapeutics, Inc., and Immatics N.V.

In addition, we are aware of other privately held biotechnology companies are evaluating neoantigen directed T cell approaches. Further, there are companies utilizing other cell-based approaches that may be competitive to our product candidates. More effective small molecules, cancer vaccines and other approaches may be developed and used as first line or second line treatments, which would reduce the opportunity for our Selected TIL therapies. 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 methods. 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 Selected TIL product 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 Selected TIL product candidates may not be competitive with them.

Even if we obtain regulatory approval of our product candidates, the availability and price of our competitors' products as well as limits on health insurance reimbursements for our product candidates 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. We believe our ability to successfully compete will depend on our ability to rapidly develop new product candidates, manufacture product supply, successfully enroll patients in clinical trials, gain regulatory approval in target indications, establish collaborations, successfully market and commercialize, and secure and protect intellectual property rights.

Negative developments in the fields of immuno-oncology and TIL-based immunotherapy could damage public perception of our product candidates and adversely affect our business, results of operations and financial condition.

The commercial success of our product candidates will depend in part on public acceptance of the use of cancer immunotherapies and TIL-based immunotherapies. Adverse events in clinical trials of our product candidates or in clinical trials of others developing similar products and the resulting publicity, as well as any other negative developments in the field of immuno-oncology and TIL-based immunotherapy that may occur in the future, could result in a decrease in demand for any product candidates that we may develop. These events also could result in the suspension, discontinuation, or clinical hold of or modification to our clinical trials. If public perception is influenced by claims that the use of cancer immunotherapies and TIL-based immunotherapies is unsafe, whether related to our therapies or those of our competitors, our product candidates may not be accepted by the general public or the medical community and potential clinical trial subjects may be discouraged from enrolling in our clinical trials. As a result, we may not be able to continue or may be delayed in conducting our development programs.

Future negative developments in the field of immuno-oncology or the biotechnology industry also could result in greater governmental regulation, stricter labeling requirements and potential regulatory delays in the testing or approvals of our products. Any increased scrutiny could delay or increase the costs of obtaining marketing approval for any of our product candidates.

Even if a product candidate we develop receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success and any revenue that we generate from its sales could be limited.

We have never commercialized a product candidate for any indication. If our current product candidates, including our lead product candidates, or any future product candidate we develop receives marketing approval, whether as a single agent or in combination with other therapies, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors, and others in the medical community. If the product candidates we develop do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of any of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- efficacy and potential advantages compared to alternative treatments;
- the ability to offer our products, if approved, for sale at competitive prices;
- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;

- the ability to obtain sufficient third-party payor coverage and adequate reimbursement; and
- the prevalence and severity of any side effects.

If our product candidates, if approved, do not achieve an adequate level of market acceptance, our business, results of operations and financial condition may be adversely affected.

The size of the potential commercial opportunities for our product candidates is difficult to estimate and, if any of our assumptions are inaccurate, the actual markets for our product candidates may be smaller than our estimates.

The potential commercial opportunities for our product candidates are difficult to estimate and will depend in large part on the drugs with which our product candidates are co-administered and the success of competing therapies and therapeutic approaches. In particular, the commercial opportunity for TIL-based therapies is hard to estimate given that it is an emerging field with no approved TIL therapies. Our estimates of the potential commercial opportunities are predicated on many assumptions, which may include industry knowledge and publications, third-party research reports, and other surveys. The number of patients in the United States and other major markets and elsewhere may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our product candidates or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our business, results of operations and financial condition. Although we believe that our internal assumptions are reasonable, these assumptions involve the exercise of significant judgment on the part of our management, are inherently uncertain, and their reasonableness has not been assessed by an independent source. If any of the assumptions proves to be inaccurate, the actual markets for our product candidates could be smaller than our estimates of the potential commercial opportunities, which could adversely affect our business, results of operations and financial condition.

Risks Related to Our Reliance on Third Parties

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

We depend upon on a significant number of third parties, including independent investigators, to conduct certain aspects of our preclinical studies and our clinical trials under agreements with universities, medical institutions, CROs, strategic partners and others. Pursuant to our collaboration agreement with Moffitt, Moffitt's TIDAL-01 IND utilizes product candidate produced by Moffitt, which will be supporting the trial with dedicated cleanroom capacity and manufacturing priority at its on-site facility for TIDAL-01 production. We also utilize CROs to manage certain aspects of our studies, which are conducted at third party clinical sites by third party investigators.

We expect to need to negotiate budgets and contracts with such third parties, which may result in delays to our development timelines and increased costs. We will rely especially heavily on third parties over the course of our clinical trials, and, as a result, will have limited control over and limited visibility into their day-to-day activities, including with respect to their compliance with the clinical protocol. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with GCP requirements. Upon inspection, such regulatory authorities may determine that any of our clinical trials do not comply with the GCP requirements. If we or any of these third parties fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may

require us to suspend or terminate these trials or perform additional preclinical studies or clinical trials before approving our marketing applications if at all. In addition, our clinical trials must be conducted with biologic product produced under cGMP or similar foreign requirements and may require a large number of patients, whom we may not be able to recruit.

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

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

If any of our relationships with these third-party CROs or other similar organizations expires or is terminated, we may not be able to enter into arrangements with alternative CROs or other third parties or to do so on commercially reasonable terms, if at all. Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a sometime lengthy transition period when a new CRO begins work. As a result, delays may occur, which can materially impact our ability to meet our desired development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not adversely affect our business, results of operations and financial condition.

Furthermore, we have relied on, and in the future may rely on, separate institutions to conduct and sponsor clinical trials relating to our product candidates. We will not control the design or conduct of the investigator sponsored trials, and it is possible that the FDA or comparable foreign regulatory authorities will not view these investigator sponsored trials as providing adequate support for future clinical trials, whether controlled by us or third parties, for any one or more reasons, including elements of the design or execution of the trials or safety concerns or other trial results.

Such arrangements will provide us certain information rights with respect to the investigator sponsored trials, including access to and the ability to use and reference the data, including for our own regulatory filings, resulting from the investigator sponsored trials. However, we do not have control over the timing and reporting of the data from investigator sponsored trials, nor do we own the data from the investigator sponsored trials. If we are unable to confirm or replicate the results from the investigator sponsored trials or if negative results are obtained, we would likely be further delayed or prevented from advancing further clinical development of our product candidates. Further, if investigators or institutions breach their obligations with respect to the clinical development of our product candidates, or if the data proves to be inadequate compared to the firsthand knowledge we might have gained had the investigator sponsored trials been sponsored and conducted by us, then our ability to design and conduct any future clinical trials ourselves may be adversely affected.

Additionally, the FDA or comparable foreign regulatory authorities may disagree with the sufficiency of our right of reference to the preclinical, manufacturing, or clinical data generated by these investigator sponsored

trials, or our interpretation of preclinical, manufacturing, or clinical data from these investigator sponsored trials. If so, the FDA or comparable foreign regulatory authorities may require us to obtain and submit additional preclinical, manufacturing, or clinical data before we may initiate our planned trials and/or may not accept such additional data as adequate to initiate our planned trials.

Because we currently rely on third-party manufacturing and supply partners, our supply of research and development, preclinical and clinical development materials may become limited or interrupted or may not be of satisfactory quantity or quality.

We have relied and expect to continue to rely on third-party CDMOs to manufacture some of our preclinical product candidate supplies and to manufacture all of our clinical trial product supplies. Externally, to support TIDAL-01, we have formed deep partnerships across a global network of CDMOs that specialize in bioprocess development, testing, cGMP manufacturing, formulation and filling, packaging, controlled temperature storage, and distribution. For TIDAL-01, this includes a close partnership with the Cell Therapy Facility at Moffitt Cancer Center, responsible for cGMP manufacturing, testing, release, and distribution of Selected TIL to the clinical investigators at Moffitt under our investigator sponsored clinical trial. We have separate partnerships, fully controlled and supervised by us, for the sequencing and peptide manufacturing portions of the TIDAL-01 manufacturing process. In parallel, we have completed a technology transfer of the TIDAL-01 Selected TIL manufacturing process to a U.S.-based CDMO, Charles River Laboratories.

Our preclinical and clinical development product supplies may be limited, interrupted, or not of satisfactory quality or may not continue to be available at acceptable prices. In particular, any replacement of our manufacturers could require significant effort and expertise because there may be a limited number of qualified replacements; this could be particularly problematic where we rely on one CDMO for the manufacture of TIDAL-01.

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

To the extent that we have existing, or enter into future, manufacturing arrangements with third parties, we will depend on these third parties to perform their obligations in a timely manner consistent with contractual and regulatory requirements, including those related to quality control and assurance. If we are unable to obtain or maintain third-party manufacturing for product candidates, or to do so on commercially reasonable terms, if at all, we may not be able to develop and commercialize our product candidates successfully, if approved. Also, our

or a third-party's failure to execute on our manufacturing requirements and comply with cGMPs or similar requirements could adversely affect our business in a number of ways, including:

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

Failure to maintain cGMPs or similar requirements can result in a contractor receiving FDA or comparable foreign regulatory authorities sanctions, which can impact our ability to operate, obtain or maintain regulatory approvals, or lead to delays in any clinical development programs or future commercialization of any approved products. In addition, any delay in contracting for fill and finish services, or failure of the contract manufacturer to perform the services as needed, may delay any clinical trials, registration and launches, which could adversely affect our business, results of operations and financial condition.

Our current and future collaborations are and will be important to our business. If we are unable to enter into new collaborations, or if these or any of our current collaborations are not successful, our business, results of operations and financial condition could be adversely affected.

A part of our strategy is to strategically evaluate and, as we deem appropriate, enter into additional partnerships in the future, including potentially with major biotechnology or pharmaceutical companies. For example, we entered into a collaboration agreement with Moffitt in connection for the development of TIDAL-01 and an alliance agreement with Moffitt in order to further expand our relationship and support our existing agreements with Moffitt. We have limited capabilities for product development and do not yet have any capability for commercialization. Accordingly, we may continue to enter into collaborations with other companies in the future to provide us with important technologies and funding for our programs and technology.

Our current collaborations and any future collaborations we enter into may pose a number of risks, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs or license arrangements based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as a strategic transaction that may divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;

- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products and product candidates if the collaborators believe that the competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;

- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates, if approved;

- collaborators may fail to comply with applicable regulatory requirements regarding the development, manufacture, distribution or marketing of a product candidate or product;

- collaborators with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval, if any, may not commit sufficient resources to the marketing and distribution of such product or products;

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

- collaborators may seek to amend or modify the terms of any collaboration;

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

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

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

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

If our collaborations do not result in the successful discovery, development and future commercialization of product candidates, if approved, or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under such collaboration. All of the risks relating to product development, regulatory approval and future commercialization described in this “Risk Factors” section and elsewhere in this prospectus also apply to the activities of our therapeutic collaborators. Additionally, if one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and our perception in the business and financial communities could be adversely affected.

We face significant competition in seeking appropriate partners for our product candidates, and the negotiation process is time-consuming and complex. In order for us to successfully partner our product candidates, potential partners must view these product candidates as economically valuable in markets they determine to be attractive in light of the terms that we are seeking and other available products for licensing by other companies.

Collaborations are complex, expensive and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Additionally, our collaboration agreements may contain non-competition provisions that could limit our ability to enter into strategic collaborations with future collaborators or restrict our ability to commercialize products on our own, if approved.

If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization, if approved, or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or future commercialization activities at our own expense. If we elect to increase our expenditures to fund development or future 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 or do not have sufficient funds or expertise to undertake the necessary development and future commercialization activities, we may not be able to further develop our product candidates, bring them to market, if approved, and generate revenue from sales of drugs or continue to develop our technology, and our business, results of operations and financial condition could be adversely affected. Even if we are successful in our efforts to establish new strategic partnerships, the terms that we agree upon may not be favorable to us, and we may not be able to maintain such strategic partnerships if, for example, development or approval of a product candidate is delayed or sales of any approved product are disappointing. Any delay in entering into new strategic partnership agreements related to our product candidates could delay the development and future commercialization of our product candidates, if approved, and reduce their competitiveness even if they reach the market.

Our reliance on third parties, such as manufacturers, may subject us to risks relating to manufacturing scale-up and may cause us to undertake substantial obligations, including financial obligations.

As we continue to grow and advance our product candidates through preclinical and clinical trials, we will need to scale our operations accordingly. For example, as we conduct clinical trials of our product candidates, we need to manufacture them in large quantities. We, or any manufacturing partners, may be unable to successfully increase the manufacturing capacity for any of our product candidates in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities. If we, or any manufacturing partners, are unable to successfully scale up the manufacture of our product candidates in sufficient quality and quantity, the development, testing, and clinical trials of that product candidate may be delayed or infeasible, and regulatory approval or commercial launch of any resulting product may be delayed or not obtained, which could adversely affect our business, results of operations and financial condition.

Risks Related to Government Regulation

The regulatory approval process for our product candidates in the United States and other jurisdictions is currently uncertain and will be lengthy, time-consuming and inherently unpredictable, and we may experience significant delays in the clinical development and regulatory approval, if any, of our product candidates.

The research, testing, manufacturing, labeling, approval, selling, import, export, marketing and distribution of drug products, including biologics like immunotherapies and, cell therapies, are subject to extensive regulation by the FDA in the United States and other regulatory authorities. We are not permitted to market any such products in the United States until we obtain approval of a BLA from the FDA or comparable marketing applications from comparable foreign regulatory authorities. We have not previously submitted a BLA to the FDA, or similar marketing application to comparable foreign authorities. A BLA and similar foreign

applications must include extensive preclinical and clinical data and supporting information to establish that the product candidate is safe, pure and potent (or effective) for each desired indication. A BLA and similar foreign application also must include significant information regarding the chemistry, manufacturing and controls for the product, and the manufacturing facilities must complete a successful pre-license inspection.

The FDA also has the authority to require a panel of experts, referred to as an Advisory Committee, to deliberate on the adequacy of the safety and efficacy data to support approval. The opinion of the Advisory Committee, although not binding, could have a significant impact on our ability to obtain approval of any product candidates that we develop based on the completed clinical trials. Similar decisions may also be taken by foreign regulatory authorities and have similar impact.

In addition, clinical trials can be delayed or terminated for a variety of reasons, including delays or failures related to:

- obtaining regulatory authorization to begin a clinical trial, if applicable;
- the availability of financial resources to begin 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 trial sites;
- obtaining approval at each clinical trial site by an independent IRB or ethics committee;
- recruiting suitable patients in sufficient number to participate in a trial in a timely manner;
- having patients complete a trial or return for post-treatment follow-up;
- clinical trial sites deviating from trial protocol, not complying with GCP requirements or dropping out of a trial;
- addressing any patient safety concerns that arise during the course of a clinical trial;
- addressing any conflicts with new or existing laws or regulations;
- our ability to obtain and maintain patient consents;
- adding new clinical trial sites; or
- manufacturing qualified materials under cGMPs or similar regulations for use in clinical trials.

Patient enrollment is a significant factor in the timing of clinical trials and is affected by many factors. Further, a clinical trial may be suspended or terminated by us, the IRBs or ethics committees for the institutions in which such trials are being conducted, or the FDA or comparable foreign regulatory authorities, or recommended for suspension or termination by the DSMB for such trial, 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 comparable foreign 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 adversely affected, and our ability to generate product revenue will be delayed or terminated. In addition, any delays in completing any 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.

We may fail to obtain regulatory approval of our product candidates.

The general approach for FDA and equivalent foreign approval of a new biologic is to obtain dispositive data from two well-controlled, Phase 3 clinical trials of the relevant biologic in the relevant patient population. Phase 3 clinical trials typically involve hundreds of patients, have significant costs and take years to complete.

Our clinical trials results may not support approval. In addition, our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that our product candidates are safe and effective for any of their proposed indications;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that our product candidates' clinical and other benefits outweigh their safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- 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 regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- 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.

In addition, the FDA and comparable foreign regulatory authorities may change their approval policies and new regulations may be enacted, which could delay or prevent our ability to obtain approval. If any of our product candidates fail to achieve regulatory approval due to the above factors, or otherwise, any such failure would adversely affect our business, results of operations and financial condition.

Our relationships with healthcare providers and physicians and third-party payors may be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors in the United States and elsewhere play a primary role in the recommendation and prescription of pharmaceutical products. Our current and future arrangements with healthcare providers, third-party payors and customers can expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, which may constrain the business or financial arrangements and relationships through which we research, and if approved, sell, market and distribute our products. In particular, the research of our product candidates, as well as the promotion, sales and marketing of

our product candidates is 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 applicable federal, state and foreign healthcare laws and regulations 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. A person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. The federal Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other;

- the federal civil and criminal false claims laws, including the federal False Claims Act or FCA, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment to, or approval by Medicare, Medicaid, or other federal healthcare programs, knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or an obligation to pay or transmit money to the federal government, or knowingly and improperly avoiding or decreasing or concealing an obligation to pay money to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government healthcare programs if they are deemed to "cause" the submission of false or fraudulent claims. In addition, 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 FCA. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional 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 (*e.g.*, 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. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating the health care fraud statute under HIPAA without actual knowledge of the statute or specific intent to violate it;

- the federal Physician Payments Sunshine Act and its implementing regulations, which require some 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 the United States Department of Health and Human Services, or HHS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (such as physician assistants and nurse practitioners), and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and may be broader in scope than their federal equivalents; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and local laws that require the registration of pharmaceutical sales representatives.

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

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Federal, state and foreign enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions, significant fines and penalties and settlements in the healthcare industry. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and may divert our management's attention from the operation of our business.

It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from participation in federal and state funded healthcare programs, contractual damages and the curtailment or restricting of our operations, as well as 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. Any action for violation of these laws, even if successfully defended, could cause us to incur significant legal expenses and divert management's attention from the operation of our business. Prohibitions or restrictions on sales or withdrawal of future marketed products could adversely affect our business, results of operations and financial condition.

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, or comparable regulatory authorities in foreign jurisdictions also must approve the manufacturing, marketing and promotion of the product candidate in those jurisdictions. Approval 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 some 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 our products also is subject to approval.

We also may 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 products 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, which could adversely affect our business, results of operations and financial condition.

Even if we receive regulatory approval of any 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.

If any of our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post- marketing studies and submission of safety, efficacy and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities. In addition, we will be subject to continued compliance with cGMPs and similar requirements outside the United States and GCP requirements for any clinical trials that we conduct post-approval.

Manufacturers and manufacturers' facilities are required to comply with extensive FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMPs or similar regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMPs or similar requirements and adherence to commitments made in any BLA, other marketing application, and previous responses to inspection observations. Accordingly, we and others with which we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 (post-approval) clinical trials and surveillance to monitor the safety and efficacy of the product candidate. The FDA or comparable foreign regulatory authorities may also require a REMS program as a condition of approval of our product candidates or similar risk management measures, which could entail requirements for long-term patient follow-up, 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, we will need to comply with requirements of any such programs including submissions of safety and other post-marketing information and reports and registration.

The FDA or comparable foreign regulatory authorities may impose consent decrees or 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 our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information or a "black box" warning; imposition of post-market studies or clinical trials 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 our products, withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;

- refusal by the FDA or comparable foreign regulatory authorities 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 and comparable foreign regulatory authorities strictly regulate marketing, labeling, advertising, and promotion of products that are placed on the market. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and comparable foreign regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses and a company that is found to have improperly promoted off-label uses may be subject to significant civil, criminal and administrative liability. The policies of the FDA and comparable regulatory authorities 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 our business, results of operations and financial condition could be adversely affected.

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

The success of our product candidates, if approved, depends on the availability of coverage and adequate reimbursement from third-party payors. We cannot be certain that coverage and reimbursement will be available for, or accurately estimate the potential revenue from, our product candidates or assure that coverage and reimbursement will continue to be available for any product that we may develop that receives coverage and adequate reimbursement from one or more third-party payors. Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Accordingly, coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance.

Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor’s determination that use of a product is:

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

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. As a result, obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our products on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for a

given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payors may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of product candidates. Patients are unlikely to use our product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our product candidates. There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates. In addition, companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or biological products. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or biological products, will apply to companion diagnostics.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. 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, in July 2021, the Biden administration released an executive order, “Promoting Competition in the American Economy,” with multiple provisions aimed at prescription drugs. In response to President Biden’s executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect to experience pricing pressures in connection with the sale of all of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, cost containment initiatives and additional legislative changes.

Ongoing healthcare legislative and regulatory reform measures may adversely affect our business, results of operations and financial condition.

Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (1) changes to our manufacturing arrangements; (2) additions or modifications to product labeling; (3) the recall or discontinuation of our products; (4) post-marketing approvals or compliance programs or (5) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect our business, results of operations and financial condition.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, was passed by Congress, which substantially changes the way health care is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA, among other things, subjected biological products to potential competition by lower-cost biosimilars, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by manufacturers under the

Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs, and created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

Since its enactment, certain provisions the ACA have been subject to executive, judicial and congressional challenges. On June 17, 2021, the U.S. Supreme Court dismissed the most recent challenge to the ACA on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling, President Biden issued an executive order that initiated a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental authorities to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. On August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and through a newly established manufacturer discount program. It is unclear how other healthcare reform measures of the Biden administration, if any, will impact our business.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things included aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect on April 1, 2013, and, due to subsequent legislative amendments, will stay in effect through 2032 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. Further, the IRA, among other things, (1) directs HHS to negotiate the price of certain single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented. It is currently unclear how the IRA will be implemented but it is likely to have a significant effect on the pharmaceutical industry. Further, in response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the Centers for Medicare & Medicaid Services, or CMS, Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future.

These laws, and future state and federal healthcare reform measures may be adopted in the future, any of which may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

EU drug marketing and reimbursement regulations may materially affect our ability to market and receive coverage for our products in the EU member states.

We intend to seek approval to market our product candidates in the United States and we may also seek to do so in selected foreign jurisdictions, including the EU. If we obtain approval in one or more foreign jurisdictions for our product candidates, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the EU, the pricing of medicinal products is subject to governmental control and other market regulations which could put pressure on the pricing and usage of our product candidates. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. Some countries provide that products may be marketed only after a reimbursement decision has been taken by the relevant regulatory authority. In addition, market acceptance and sales of our product candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for our product candidates and may be affected by existing and future health care reform measures.

Much like the federal Anti-Kickback Statute prohibition in the United States, 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. Infringement of these laws could result in substantial fines and imprisonment.

Payments made to physicians and healthcare organization in certain EU member states must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and/or 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.

In addition, in most foreign countries, including the EU, the requirements governing drug pricing and reimbursement vary widely from country to country. For example, the EU provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. Reference pricing used by various EU member states and parallel distribution, or arbitrage between low-priced and high-priced EU member states, can further reduce prices. An EU member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. In some countries, we may be required to conduct a clinical study or other studies that compare the cost-effectiveness of any of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the EU do not follow price structures of the United States and generally prices tend to be significantly lower. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If pricing is set at unsatisfactory levels or if reimbursement of our products is unavailable or limited in scope or amount, our revenues from sales by us or our strategic partners and the potential profitability of any of our product candidates in those countries would be negatively affected.

In December 2021, Regulation No. 2021/2282 on Health Technology Assessment, or HTA, amending Directive 2011/24/EU, was adopted. This regulation which will apply from January 12, 2025 intends to boost cooperation among EU member states in assessing health technologies, including new medicinal products, and providing the basis for cooperation at the EU level for joint clinical assessments in these areas. The regulation foresees a three-year transitional period and will permit EU member states to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical

assessment of the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU member states will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement.

Disruptions at the FDA and other national and foreign government authorities caused by funding shortages or global health concerns, such as COVID-19, could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA and comparable foreign regulatory authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's and foreign regulatory authorities' ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's and comparable foreign regulatory authorities' ability to perform routine functions. Average review times at the FDA and comparable foreign regulatory authorities have fluctuated in recent years as a result. In addition, government funding of other government authorities that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other national and foreign authorities also may slow the time necessary for new biologics or modifications to approved biologics to be reviewed and/or approved by necessary government authorities, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory authorities, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the COVID-19 pandemic, in March 2020, the FDA announced its intention to postpone most inspections of foreign manufacturing facilities, and on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, in July 2020, the FDA resumed certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA utilized this risk-based assessment system to assist in determining when and where it was safest to conduct prioritized domestic inspections. Additionally, on April 15, 2021, the FDA began conducting voluntary remote interactive evaluations of certain drug manufacturing facilities and clinical research sites, among other facilities in circumstances where the FDA determines that such remote evaluation would be appropriate based on mission needs and travel limitations. In May 2021, the FDA outlined a detailed plan to move toward a more consistent state of inspectional operations, and in July 2021, the FDA resumed standard inspectional operations of domestic facilities. Since that time, the FDA has continued to monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates as it adapts to the evolving COVID-19 pandemic.

Regulatory authorities outside the United States have adopted 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 product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated.

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. 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 the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product.

There is a risk that any of our product candidates approved as a biological product under a BLA would not qualify for the 12-year period of exclusivity or that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. If competitors are able to obtain marketing approval for biosimilars referencing our candidates, if approved, our products may become subject to competition from such biosimilars, with the attendant competitive pressure and potential adverse consequences.

Actual or perceived failures to comply with applicable data protection, privacy and security laws, regulations, standards and other requirements could adversely affect our business, results of operations, and financial condition.

The global data protection landscape is rapidly evolving, and we are or may become subject to numerous state, federal and foreign laws, requirements and regulations governing the collection, use, disclosure, retention, and security of personal information, such as information that we may collect in connection with clinical trials. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or perception of their requirements may have on our business. Any failure or perceived failure by us to comply with federal, state or foreign laws or regulations, our internal policies and procedures or our contracts governing our processing of personal information could result in negative publicity, government investigations and enforcement actions, claims by third parties and damage to our reputation, any of which could have a material adverse effect on our business, results of operation, and financial condition.

We may become subject to or affected by new or additional data protection laws and regulations and face increased scrutiny or attention from regulatory authorities. In the United States, HIPAA as amended by the Health Information Technology for Economic and Clinical Health Act, or collectively, HIPAA, imposes, among other things, certain standards relating to the privacy, security, transmission and breach reporting of individually identifiable health information. Most healthcare providers, including research institutions from which we obtain patient health information, are subject to privacy and security regulations promulgated under HIPAA. While we do not believe that we are currently acting as a covered entity or business associate under HIPAA and thus are not directly regulated under HIPAA, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered healthcare provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information.

Certain states have also adopted comparable privacy and security laws and regulations. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. For example, the California Consumer Privacy Act of 2018, or CCPA, went into effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. Further, the California Privacy Rights Act, or CPRA, generally went into effect on January 1, 2023 and significantly amends the CCPA and

imposes additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It also creates a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. Similar laws have passed in Virginia, Colorado, Utah, Iowa and Connecticut and have been proposed in other states and at the federal level, reflecting a trend toward more stringent privacy legislation in the United States. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging. In the event that we are subject to or affected by HIPAA, the CCPA, the CPRA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

We are also or may become subject to rapidly evolving data protection laws, rules and regulations in foreign jurisdictions. For example, in Europe, the EU and the UK General Data Protection Regulations (respectively, the EU GDPR and UK GDPR; together, the GDPR) each impose strict requirements for processing the personal data of individuals within the European Economic Area, or EEA, and/or the UK. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million under the EU GDPR and £17.5 million under the UK GDPR or 4% of the annual global revenues of the noncompliant company, whichever is greater. In addition to these fines, supervisory authorities have extensive audit and inspection rights, and powers to order temporary or permanent bans on all or some processing of personal data carried out by noncompliant actors; the GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints, seek judicial remedies and obtain compensation for damages resulting from violations of the GDPR. We could be subject to potentially overlapping or divergent enforcement actions for certain actual or perceived violations. Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States. In July 2020, the Court of Justice of the EU, or CJEU, limited how organizations could lawfully transfer personal data from the EU/EEA to the United States by invalidating the Privacy Shield for purposes of international transfers. To facilitate such transfers a new set of standard contractual clauses, or SCCs, was issued by the European Commission but these apply only to transfers of personal data outside the EEA under the EU GDPR. Organizations are now required to comply with onerous obligations to determine the additional measures that need to be implemented and maintained to supplement such safeguards to protect the transferred personal data effectively. In March 2022, the US and EU announced a new regulatory regime intended to replace the invalidated regulations; however, this new EU-US Data Privacy Framework has not been implemented beyond an executive order signed by President Biden on October 7, 2022 on Enhancing Safeguards for United States Signals Intelligence Activities. European court and regulatory decisions subsequent to the CJEU decision of July 2020 have taken a restrictive approach to international data transfers. As supervisory authorities issue further guidance on personal data export mechanisms, and/or start taking enforcement action, we could suffer additional costs, complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations. The GDPR may impose additional responsibility and liability in relation to personal data that we process and we may be required to put in place additional mechanisms, at significant cost and diversion of management attention, to ensure compliance with the new data protection rules. This may be onerous and adversely affect our business, results of operations and financial condition.

Although we work to comply with applicable laws, regulations and standards, our contractual obligations and other legal obligations, these requirements are evolving and may be modified, interpreted and applied in an inconsistent manner from one jurisdiction to another, and may conflict with one another or other legal obligations with which we must comply. Any failure or perceived failure by us or our employees, representatives, contractors, consultants, collaborators, or other third parties to comply with such requirements or adequately address privacy and security concerns, even if unfounded, could result in additional cost and liability to us, damage our reputation, and adversely affect our business and results of operations.

Additional laws and regulations governing international operations could adversely affect our business, results of operations and financial condition.

If we further expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The Foreign Corrupt Practices Act, or the FCPA prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate and other related parties 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 certain accounting provisions requiring the company 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.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our research and development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The U.S. Securities and Exchange Commission, or the SEC, also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

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

Among other matters, U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations, which are collectively referred to as Trade Laws, prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government authorities or government-affiliated hospitals, universities, and other organizations. We also expect our non-U.S. activities to increase over time. We plan to engage third parties for clinical trials and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals, and we can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities.

Risks Related to Our Intellectual Property

Our success depends in part on our ability to protect our intellectual property. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to ensure their protection.

As of May 2, 2023, we own or exclusively license 14 issued U.S. patents and 96 issued foreign patents in 21 countries. We currently own or exclusively license 13 pending U.S. patent applications, 8 U.S. provisional applications, and 121 pending foreign patent applications in 26 other countries. Our commercial success will depend in large part on obtaining and maintaining patent, trademark and trade secret protection of our proprietary technologies and our product candidates, their respective components, formulations, combination therapies, methods used to manufacture them and methods of treatment, as well as successfully defending these patents against third-party challenges. Our ability to stop unauthorized third parties from making, using, selling, offering to sell or importing our product candidates is dependent upon the extent to which we have rights under valid and enforceable patents that cover these activities. If we are unable to secure and maintain patent protection for any product or technology we develop, or if the scope of the patent protection secured is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to commercialize any product candidates we may develop may be adversely affected.

The patenting process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications in all jurisdictions at a reasonable cost or in a timely manner. Moreover, obtaining such protection in a timely manner, or at all, may be affected by factors or events beyond our control, such as a prolonged economic downturn, or global financial or political crises, whether or not related to the ongoing COVID-19 pandemic or the ongoing political unrest between Russia and the Ukraine. In addition, we may not pursue or obtain patent protection in all relevant markets. It also is possible that we will fail to identify and file on patentable aspects of our research and development output before it is too late to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, contract research organizations, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach these agreements and disclose such results before a patent application is filed, thereby jeopardizing our ability to seek patent protection. If we delay in filing a patent application, and a competitor files a patent application on the same or a similar technology before we do, we may face a limited ability to secure patent rights. Or we may not be able obtain a patent on such technology at all. Even if we can patent the technology, we may be able to patent only a limited scope of the technology, and the limited scope may be inadequate to protect our product candidates, or to block competitor products or product candidates that are similar to ours. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or license to third parties and are reliant on our licensors or licensees.

Composition of matter patents for biological and pharmaceutical product candidates often provide a strong form of intellectual property protection for those types of products, as such patents provide protection without regard to any method of use. Method of use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product 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 infringe or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute.

Certain of our programs may involve combination therapies. Composition of matter and method of use patents directed to combination therapies may be subject to heightened patentability standards and, therefore, may be difficult to issue worldwide.

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. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. 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 may not have been the first to file any patent application related to our product candidates. Furthermore, for United States applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third-party or instituted by the United States patent office, or USPTO, to determine who was the first to invent any of the subject matter covered by the patent claims of our applications.

We may not be the first to invent the inventions covered by pending patent applications and, if we are not, we may be subject to priority disputes. We may be required to disclaim part or all of the term of certain patents or all of the term of certain patent applications. 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, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. No assurance can be given that if challenged, our patents 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 our patents. We may analyze patents or patent applications of our competitors that we believe are relevant to our activities, and consider that we are free to operate in relation to our product candidates, but our competitors may achieve issued claims, including in patents we consider to be unrelated, which block our efforts or may potentially result in our product candidates or our activities infringing such claims. The possibility exists that others will develop products which have the same effect as our products on an independent basis which do not infringe our patents or other intellectual property rights, or will design around the claims of patents that we have had issued that cover our products.

Recent or future changes in patent-related case law and/or patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. For example, under the enacted Leahy-Smith America Invents Act, or America Invents Act, enacted in 2013, 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 includes a number of other significant changes to U.S. patent law, including provisions that affect the way patent applications are prosecuted, redefine prior art and establish a new post-grant review system. The effects of these changes are currently 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, became effective in March 2013. In addition, the courts have yet to address many of these provisions and the applicability of the act and new regulations on specific patents discussed herein have not been determined and would need to be reviewed. However, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

Recent changes in European law have caused uncertainty regarding our European patent portfolios. In particular, in 2012, the European Patent Package, or EU Patent Package, regulations were passed with the goal of providing for a single pan-European Unitary Patent, and a new European Unified Patent Court, or UPC, for

litigation of European patents. The EU Patent Package was ratified in February 2023 and currently covers 17 member states. On June 1, 2023, all European patents, including those issued prior to ratification, will by default automatically fall under the jurisdiction of the UPC and allow for the possibility of obtaining pan-European injunctions, and further will be at risk of a central revocation proceeding at the UPC in participating UPC states. Under the EU Patent Package, patent holders are permitted to "opt-out" of the UPC on a patent-by-patent basis during an initial seven-year period after the EU Patent Package is ratified, with the proviso that an "opt-out" is no longer available for EP patents for which a revocation has been initiated before the UPC. Owners of European patent applications who receive notice of grant after the EU Patent Package is ratified could, for the UPC contracting states, either obtain a Unitary Patent or validate the patent nationally and file an opt-out demand. The EU Patent Package may increase the uncertainties and costs surrounding the enforcement or defense of our issued European patents and pending applications. The full impact on future European patent filing strategy and the enforcement or defense of our issued European patents in member states and/or the UPC is not known.

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

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 our patents;
- the active biological ingredients in our current product candidates will 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, may fail to meet our obligations to the U.S. government in regards to any in-licensed patents and patent applications funded by U.S. government grants, leading to the loss of patent rights;
- we or our licensors, as the case may be, might not have been the first to file patent applications for the inventions we own or control;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not result in issued patents;
- it is possible that there are prior public disclosures that could invalidate our or our licensors' patents, as the case may be, or parts of our or their patents;
- it is possible that a court could find the disclosure of our owned or -in-licensed patents is not sufficient to support the scope of issued claims, thereby invalidating the claims;
- it is possible that others may circumvent our owned or in-licensed patents;
- it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our products or technology similar to ours;
- the laws of foreign countries may not protect our or our licensors', as the case may be, proprietary rights to the same extent as the laws of the United States;

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

- our competitors might conduct research and development activities in the United States and other foreign countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights and then use the information learned from such activities to develop competitive product candidates for sale in our major commercial markets;

- the claims of our owned or in-licensed issued patents or patent applications, if and when issued, may not cover our product candidates;

- our owned or in-licensed issued patents may not provide us with any competitive advantages, may be narrowed in scope, or be held invalid or unenforceable as a result of legal challenges by third parties;

- we may need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose;

- the inventors of our owned or in-licensed patents or patent applications may become involved with competitors, develop products or processes which design around our patents, or become hostile to us or the patents or patent applications on which they are named as inventors;

- it is possible that our owned or in-licensed patents or 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 these patents or patents issuing from these patent applications to be held invalid or unenforceable;

- we have engaged in scientific collaborations in the past, and will continue to do so in the future. Such collaborators may develop adjacent or competing products to ours that are outside the scope of our patents;

- we may not develop additional proprietary technologies for which we can obtain patent protection;

- it is possible that 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, including if others obtain patents claiming subject matter similar to or improving that covered by our patents and patent applications.

Any difficulties we encounter in defending, or resulting inability to protect, our proprietary rights and technology, may adversely affect our business, results of operations and financial condition.

We depend on intellectual property licensed from third parties and termination of any of these licenses could result in the loss of significant rights, which could adversely affect our business, results of operations and financial condition.

We are dependent on patents, know-how and proprietary technology, both our own and licensed from others. Any termination of these licenses could result in the loss of significant rights and could harm our ability to commercialize our product candidates.

Disputes also may 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 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 rights to third parties under collaborative development relationships;
- the priority of invention of patented technology;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and future commercialization of our product candidates, and what activities satisfy those diligence obligations; and
- the ownership of and rights to use inventions and know-how resulting from the joint or individual creation or use of intellectual property by our licensors and us and our partners.

In addition, certain of our current and future agreements with third parties may limit or delay our ability to consummate certain transactions, may impact the value of those transactions, or may limit our ability to pursue certain activities. For example, we may enter into license agreements that are not assignable or transferable, or that require the licensor's express consent in order for an assignment or transfer to take place. 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 generally also are 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 are described in this "Risk Factors" section. If we or our licensors fail to adequately protect this intellectual property, our business, results of operations and financial condition could be adversely affected.

If we fail to comply with our obligations under our patent licenses with third parties, we could lose license rights that are important to our business, which could adversely affect our business, results of operations and financial condition.

We are a party to license agreements pursuant to which we in-license patent and patent applications, know-how, trade secrets and data rights for our product candidates. These existing licenses impose on us various diligence, milestone payment, royalty, insurance and other obligations. If we fail to comply with these obligations, our licensors may have the right to terminate the license, in which event we would not be able to develop or market the products covered by such licensed intellectual property.

Our licensors retain certain rights under their agreements with us, including the right to use the underlying technology for noncommercial academic and research use, to publish general scientific findings from research related to the technology, and to make customary scientific and scholarly disclosures of information relating to the technology. It is difficult to monitor whether our licensors limit their use of the technology to these uses, and we could incur substantial expenses to enforce our rights to our licensed technology in the event of misuse.

We may also enter into license agreements with third parties under which we are a sublicensee. If our sublicensor fails to comply with its obligations under its upstream license agreement with its licensor, the

licensor may have the right to terminate the upstream license, which may terminate our sublicense. If this were to occur, we would no longer have rights to the applicable intellectual property unless we are able to secure our own direct license with the owner of the relevant rights, which we may not be able to do on reasonable terms, or at all, which may impact our ability to continue to develop and commercialize our product candidates incorporating the relevant intellectual property.

We may have limited control over the maintenance and prosecution of these in-licensed patents and patent applications, activities or any other intellectual property that may be related to our in-licensed intellectual property. For example, such activities by these licensors may not have been or may not be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. Our licensors may not successfully prosecute the patent applications to which we are licensed in a manner consistent with the best interests of our business. 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 the licensors' infringement proceeding or defense activities may be less vigorous than had we conducted them ourselves.

If we are unable to protect the confidentiality of our trade secrets, our business, results of operations and financial condition could be adversely affected.

In addition to patent and other intellectual property protection, we rely heavily upon know-how and trade secret protection, as well as non-disclosure agreements and invention assignment agreements with our employees, consultants and third parties, to protect our confidential and proprietary information, especially where we do not believe patent protection is appropriate or obtainable. Elements of our product candidates, including processes for their preparation and manufacture, may involve proprietary know-how, information, or technology that is not covered by patents and that may not be patentable, and thus for these aspects we may consider trade secrets and know-how to be our primary intellectual property. We may also rely on trade secret protection as temporary protection for concepts that may be included in a future patent filing. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using physical and technological security measures. Such measures may not, for example, in the case of misappropriation of a trade secret by an employee or third-party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may be expensive and not provide an adequate remedy to protect our interests fully. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our competitive position could be harmed.

In addition, courts outside the United States are sometimes less willing to protect trade secrets. We may need to share our proprietary information, including trade secrets, with future business partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors. If we choose to go to court to stop a third-party from using any of our trade secrets, we may incur substantial costs. These lawsuits may consume our time and other resources even if we are successful. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees, consultants and current and potential business partners, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology.

Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors and current and

potential business partners to execute confidentiality agreements upon the commencement of employment, consulting or other applicable relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual or entity during the course of the party's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. Any disclosure, either intentional or unintentional, by our employees or third-party consultants and vendors that we engage to perform research, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market. Because we expect to rely on third parties in the development and manufacture of our product candidates, we must, at times, share trade secrets with them, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed. 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 sole and exclusive property. We also have adopted policies and conduct training that provides guidance on our expectations, and our advice for best practices, in protecting our trade secrets.

We cannot prevent other companies from licensing some of the same intellectual properties that we have licensed or from otherwise duplicating our business model and operations.

Since parties we have licenses with are developing therapies to similar technologies, they may make their methods and data available to third parties, who may want to enter into our line of business and compete against us. We currently do not have any exclusive rights to our entire product portfolio that could be used to prevent third parties from duplicating our business plan or from otherwise directly competing against us. No assurance can be given that our existing exclusive rights are or will be sufficient to prevent others from competing with us and developing substantially similar products.

Third-party claims of intellectual property infringement may prevent or delay our product discovery and development efforts.

Our commercial success depends in part on our ability to research, develop, manufacture, market and sell our current and any future product candidates and use our proprietary technologies without infringing the 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, as well as administrative proceedings for challenging patents, including interference, derivation, *inter partes* review, post grant review, and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. 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 proprietary 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. We are further aware of certain patents, and patent applications in the United States and elsewhere that contain claims that, if issued in their present form, may cover our TIL products or their methods of use or manufacture. We, along with a number of third parties in the TIL cell therapy field, have been involved in opposition proceedings in Europe with respect to some of these patents. 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. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be 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 its intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement and other 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, which we may have to pay if a court decides that the product candidate or technology at issue infringes on or 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 such third-party (and no such license may be available), we may have to pay substantial royalties, upfront fees and other amounts, and/or grant cross-licenses to intellectual property rights for our products; and
- redesigning our product candidates or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

Some of our competitors 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 adversely affect our business, results of operations and financial condition.

Third parties may assert that we are employing their proprietary technology without authorization. Generally, conducting clinical trials and other development activities in the United States is protected under the Safe Harbor exemption as set forth in 35 U.S.C. § 271. If and when one of our product candidates is approved by the FDA, that certain third-party may then seek to enforce its patent by filing against us a patent infringement lawsuit. 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. There may be third-party patents of which we currently are unaware with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. We have conducted freedom to operate analyses with respect to only certain of our products and services and we cannot guarantee that our analyses are complete and thorough, nor can we be sure that we have identified each and every patent and pending application in the United States and abroad that is relevant or necessary to the commercialization of our products and services. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe.

In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents 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, the holders of any such patents may be able to block our ability to commercialize the product candidate unless we obtained a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, the holders of any such patent may be able to block our ability to develop and commercialize the product candidate unless we obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable. In either 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. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and, if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. This type of litigation or proceeding could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other intellectual property related proceedings could adversely affect our business, results of operations and financial condition.

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. In addition, if our product candidates are found to infringe the intellectual property rights of third parties, these third parties may also assert infringement claims against our licensees and other parties with whom we have business relationships, and we may be required to indemnify those parties for any damages they suffer as a result of these claims. If any of these claims succeed, we may be required to pay damages on behalf of those parties or may be required to obtain licenses for the products they use. Defense of these claims, regardless of their merit, would 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. Any such license may not be available at all or may not be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow future commercialization of our product candidates, if approved. 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, which could adversely affect our business, results of operations and financial condition.

Third parties may assert that our employees, consultants or other third parties have wrongfully used, disclosed confidential information, misappropriated trade secrets or are in breach of non-competition or non-solicitation agreements.

As is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously employed at universities or other biopharmaceutical or pharmaceutical companies, including our competitors or potential competitors. Although no material claims against us currently are pending or threatened, and although we try to ensure that our employees, consultants and other third parties do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants, independent contractors or current or potential business partners have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties, or are in breach of any non-competition or non-solicitation agreements. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities.

We may be subject to claims that former employees, collaborators, or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our product candidates or as a result of questions regarding co-ownership of potential joint inventions. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. 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 third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, results of operations and financial condition.

In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and, if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. This type of litigation or proceeding could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other intellectual property related proceedings could adversely affect our business, results of operations and financial condition.

We may not be successful in obtaining or maintaining necessary rights to develop current and any future product candidates on acceptable terms.

Because our programs may involve additional product candidates that may require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license or use these proprietary rights.

Our product candidates also may require specific formulations to work effectively and efficiently and these rights may be held by others. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties 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 expenses 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.

Additionally, we sometimes collaborate with academic institutions and governmental authorities 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, results of operations and financial condition could be adversely affected.

The licensing and acquisition of third-party intellectual property rights is a highly competitive area, and companies, which may be more established, or have greater resources than we do, also may be pursuing strategies to license or acquire third-party intellectual property rights that we 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. There can be no assurance that we will be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to acquire.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or insufficient written description. 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. For the patents and patent applications that we have licensed, we may have limited or no right to participate in the defense of any licensed patents against challenge by a third party. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on our current or future product candidates. Such a loss of patent protection could harm our business.

In addition, in an infringement proceeding, a court may decide that one or more of our patents is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. Moreover, our ability to successfully pursue infringement claims or otherwise enforce intellectual property that we license from or co-own with another party may require the participation and co-operation of the co-owner or licensor, and may be impaired or prohibited if such participation or co-operation is insufficient or cannot be secured.

We may choose to challenge the patentability of claims in a third-party's U.S. patent by requesting that the USPTO review the patent claims in an *ex-parte* re-exam, *inter partes* review or post-grant review proceedings. These proceedings are expensive and may consume our time or other resources. We may choose to challenge a third-party's patent in patent opposition proceedings in the European Patent Office, or EPO, or another foreign patent office. The costs of these opposition proceedings could be substantial, and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO, EPO or other patent office then we may be exposed to litigation by a third-party alleging that the patent may be infringed by our product candidates or proprietary technologies.

In addition, because some patent applications in the United States may be maintained in secrecy until the patents are issued, patent applications in the United States and many foreign jurisdictions are typically not

published until 18 months after filing, and publications in the scientific literature often lag behind actual discoveries, others may have filed patent applications for technology covered by our owned and in-licensed issued patents or our pending applications, and we or, if applicable, a licensor may not have been the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering our products or technology similar to ours. Any such patent application may have priority over our owned and in-licensed patent applications or patents, which could require us to obtain rights to issued patents covering such technologies. For applications that have claims entitled to a priority date before March 16, 2013, if another party has filed a U.S. patent application on inventions similar to those owned by or in-licensed to us, we or, in the case of in-licensed technology, the licensor may have to participate in an interference proceeding declared by the USPTO to determine priority of invention in the United States. If we or one of our licensors is a party to an interference proceeding involving a U.S. patent application on inventions owned by or in-licensed to us, we may incur substantial costs, divert management's time and expend other resources, even if we are successful.

Interference proceedings provoked by third parties or brought by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could result in a loss of our current patent rights and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Litigation or interference proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States.

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. 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 substantial adverse effect on the price of our common stock.

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

Periodic maintenance fees, renewal fees, annuity fees, and various other governmental fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent application process and following the issuance of a patent. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market, which could adversely affect our business, results of operations and financial condition.

Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court or the USPTO.

If we or one of our licensing partners initiate legal proceedings against a third-party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate, as applicable, is invalid and/or unenforceable. In patent litigation in the United States, defendant

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. Third parties also may 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, derivation proceedings and equivalent proceedings in foreign jurisdictions (*e.g.*, opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they 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, there may be 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 the patent protection on our product candidates. Such a loss of patent protection could adversely affect our business, results of operations and financial condition.

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

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. In addition, the United States has enacted and is currently implementing the America Invents Act. Moreover, recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in other 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 our existing patents and patents that we might obtain in the future. For example, in the case of *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 these decisions or any future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patents. Similarly, any adverse changes in the patent laws of other jurisdictions could adversely affect our business, results of operations and financial condition.

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

We have limited intellectual property rights outside the United States. 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 have a different scope and strength than those in the United States. Moreover, obtaining such protection in a timely manner, or at all, may be affected by factors or events beyond our control, such as a prolonged economic downturn, or global financial or political crises, whether or not related to the ongoing COVID-19 pandemic or the ongoing political unrest between Russia and the Ukraine. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in 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 may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but where enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from competing.

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, which could make it difficult for us to stop the infringement of our patents or marketing of competing products against third parties in violation of our proprietary rights generally. The initiation of proceedings by third parties to challenge the scope or validity of our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business. Proceedings to enforce our patent and other intellectual property rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing 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. Similarly, if our trade secrets are disclosed in a foreign jurisdiction, competitors worldwide could have access to our proprietary information and we may be without satisfactory recourse. Such disclosure could have a material adverse effect on our business. Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. In addition, certain countries, including China and India, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensors may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to a third party, which could materially diminish the value of those patents. In addition, many countries limit the enforceability of patents against government authorities or government contractors. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce 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 incur substantial costs as a result of litigation or other proceedings relating to patents, and we may be unable to protect our rights to our products and technology.

If we or our licensors choose to go to court to stop a third-party from using the inventions claimed in our owned or in-licensed patents, that third-party may ask the court to rule that the patents are invalid and/or should not be enforced against that third-party. These lawsuits are expensive and would consume time and other resources even if we or they, as the case may be, were successful in stopping the infringement of these patents. In addition, there is a risk that the court will decide that these patents are not valid and that we or they, as the case may be, do not have the right to stop others from using the inventions. An adverse determination in any such proceeding could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us. An unfavorable result at the USPTO, EPO or other patent office may result in the loss of our right to exclude others from practicing one or more of our inventions in the relevant country or jurisdiction, which could adversely affect our business, results of operations and financial condition.

There also is the risk that, even if the validity of these patents is upheld, the court will refuse to stop the third-party on the ground that such third-party's activities do not infringe our owned or in-licensed patents. In addition, the U.S. Supreme Court recently has changed some legal principles that affect patent applications, granted patents and assessment of the eligibility or validity of these patents. As a consequence, issued patents may be found to contain invalid claims according to the newly revised eligibility and validity standards. Some of our owned or in-licensed patents may be subject to challenge and subsequent invalidation or significant narrowing of claim scope in proceedings before the USPTO, or during litigation, under the revised criteria which also could make it more difficult to obtain patents.

We, or our licensors, may not be able to detect infringement against our owned or in-licensed patents, as the case may be, which may be especially difficult for manufacturing processes or formulation patents. Even if we or our licensors detect infringement by a third-party of our owned or in-licensed patents, we or our licensors, as the case may be, may choose not to pursue litigation against or settlement with the third-party. If we, or our licensors, later sue such third-party for patent infringement, the third-party may have certain legal defenses available to it, which otherwise would not be available except for the delay between when the infringement was

first detected and when the suit was brought. Such legal defenses may make it impossible for us or our licensors to enforce our owned or in-licensed patents, as the case may be, against such third-party.

If another party questions the patentability of any of our claims in our owned or in-licensed U.S. patents, the third-party can request that the USPTO review the patent claims such as in an *inter partes* review, *ex parte* re-exam or post-grant review proceedings. These proceedings are expensive and may result in a loss of scope of some claims or a loss of the entire patent. In addition to potential USPTO review proceedings, we may become a party to patent opposition proceedings at the EPO or similar proceedings in other foreign patent offices, where either our owned or in-licensed foreign patents are challenged.

In the future, we may be involved in similar proceedings challenging the patent rights of others, and the outcome of such proceedings is highly uncertain.

An adverse determination in any such proceeding may result in our inability to manufacture or commercialize products without infringing third-party patent rights. The costs of these opposition or similar proceedings could be substantial, and may result in a loss of scope of some claims or a loss of the entire patent.

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

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional application filing date. Various extensions such as patent term adjustments and/or extensions, may be available, but the life of a patent, and the protection it affords, is limited. For instance, a patent term extension based on regulatory delay may be available in the United States. However, only a single patent can be extended for each marketing approval, and any patent can be extended only once, for a single product. Moreover, the scope of protection during the period of the patent term extension does not necessarily extend to all claims, but instead only to claims that cover the product as approved. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including biosimilars. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

As of May 2, 2023, we own or in-license patent applications covering our proprietary technologies and our product candidates that if issued as patents are expected to expire between 2039 and 2044, without taking into account any possible patent term adjustments or extensions. However, the USPTO or relevant foreign patent offices may not grant any of these patent applications. If issued, the patents may expire before, or soon after, our first product achieves marketing approval in the United States or foreign jurisdictions. Further, if issued, the patents may expire before, or soon after, any regulatory protection afforded our first approved product through data and/or market exclusivity in the United States or foreign jurisdictions. Upon the expiration of any such patents, if issued, we may lose the right to exclude others from practicing these inventions. The expiration of these patents also could adversely affect our business, results of operations and financial condition.

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

Our trademarks or trade names may be challenged, opposed, infringed, circumvented, invalidated, cancelled, declared generic, determined not to entitled to registration, or determined to be infringing on other marks. During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in foreign jurisdictions. Although we would be given an opportunity to respond to those rejections, we may be

unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. Any trademark litigation could be expensive. In addition, we could be found liable for significant monetary damages, including treble damages, disgorgement of profits and attorneys' fees, if we are found to have willfully infringed a trademark.

Moreover, any name we propose to use with our product candidates in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA (or an equivalent administrative body in a foreign jurisdiction) objects to any of our proposed proprietary product names, it may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark.

We may not be able to protect our rights to our trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business, results of operations and financial condition could be adversely affected.

Risks Related to Our Common Stock and This Offering

No public market for our common stock currently exists, and we do not know whether an active, liquid and orderly trading market will develop for our common stock, or what the market price of our common stock will be, and as a result it may be difficult for you to sell your shares of our common stock.

Prior to this offering there has been no public market for shares of our common stock. Our common stock has been approved for listing on Nasdaq under the symbol "TSBX." An active trading market for our shares may never develop or be sustained following this offering. You may not be able to sell your shares quickly or at the market price if trading in shares of our common stock is not active. The initial public offering price for our common stock was determined through negotiations with the underwriters, and the negotiated price may not be indicative of the market price of the common stock after the offering. As a result of these and other factors, you may be unable to resell your shares of our common stock at or above the initial public offering price, at the time you wish to sell them, or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your shares. Further, an inactive market also may impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic partnerships or acquire companies or products by using our shares of common stock as consideration.

The price of our common stock may be volatile, and you could lose all or part of your investment.

The trading price of our common stock following this offering is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this prospectus, these factors include:

- the progress, conduct, enrollment or results of our two Phase 1 clinical trials for TIDAL-01;
- any termination of, loss of rights or disputes or disagreements arising under our collaboration, partnership and strategic alliance agreements;

- any delay in identifying additional product candidates from our current and future development programs;
- any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings;
- adverse results or delays in future clinical trials;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- adverse regulatory decisions, including failure to receive regulatory approval of our current product candidates or any future product candidate;
- changes in laws or regulations applicable to our current product candidates or any future product candidate, including but not limited to clinical trial requirements for approvals;
- adverse development concerning our competitors, particularly those developing TIL-based therapies;
- adverse developments concerning our manufacturers;
- adverse developments concerning our manufacturing process, including manufacturing failures;
- our inability to obtain adequate product supply for any approved product or inability to do so at acceptable prices;
- our inability to establish collaborations or other strategic relationships, if needed;
- our ability to successfully develop and the costs associated with the development of our internal manufacturing processes;
- our failure to commercialize our product candidates, if approved;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to the use of our current product candidates or any future product candidate;
- introduction of new products or services offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our ability to effectively manage our growth;
- actual or anticipated variations in quarterly operating results;
- our cash position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;

- publication of research reports about us or our industry, or our or a competitor's product candidates in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- changes in the market valuations of similar companies;
- volatility and instability in the financial and capital markets;
- overall performance of the equity markets, including the effects of geopolitical events;
- sales of our common stock by us, our insiders, or other stockholders in the future, or issuances by us of shares of our common stock in connection with strategic transactions;
- expiration of market standoff or lock-up agreements described in the section titled "Underwriting";
- conditions and trends in the biotechnology and other industries;
- trading volume of our common stock;
- changes in accounting practices;
- ineffectiveness of our internal controls;
- disputes or other developments relating to intellectual property and other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- changes in the structure of healthcare payment systems, including coverage and adequate reimbursement for any approved drug;
- global or regional public health emergencies, including the ongoing COVID-19 pandemic or other pandemics, natural disasters, or major catastrophic events;
- adverse macroeconomic conditions or geopolitical events, including the COVID-19 pandemic, the conflict between Ukraine and Russia, and recent bank failures;
- the occurrence of any of the risks described in this section titled "Risk Factors"; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and the market for biotechnology companies in particular, have experienced extreme price and volume fluctuations that often have been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. If the market price of our common stock following this offering does not exceed the initial public offering price, you may not realize any return on your investment in our common stock and you may lose some or all of your investment. In the past, securities class action litigation often has been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which could adversely affect our business, results of operations and financial condition.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We currently anticipate that we will retain future earnings for the research, development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any future debt or other financing arrangements may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Any return to stockholders therefore will be limited to the appreciation of in the price of our common stock.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

Based on 15,522,015 shares of our common stock outstanding as of March 31, 2023, after giving effect to the conversion of all outstanding shares of our convertible preferred stock into 12,493,879 shares of our common stock, prior to this offering, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 48.4% of our voting stock. Immediately following the completion of this offering, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates will beneficially hold, in the aggregate, approximately 34.6% of our outstanding common stock (assuming no exercise of the underwriters' option to purchase additional shares of our common stock and no exercise of outstanding options). These stockholders, acting together, would be able to significantly influence all matters requiring stockholder approval. For example, these stockholders would be able to significantly influence elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This level of control may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

Participation in this offering by certain of our directors and existing stockholders would reduce the available public float of our shares.

Certain of our directors and existing stockholders, including stockholders affiliated with our directors and who own 5% or more of our outstanding capital stock, have indicated an interest in purchasing shares of our common stock in this offering at the initial public offering price. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters may determine to sell more, fewer or no shares in this offering to any of these directors or stockholders, or any of these directors or stockholders may determine to purchase more, fewer or no shares in this offering. To the extent these directors and existing stockholders purchase any shares in this offering, such purchase could reduce the available public float of our shares because such directors and stockholders may be restricted from selling the shares by restrictions under applicable securities laws. As a result, any purchase of shares by such directors and stockholders in this offering may reduce the liquidity of our common stock relative to what it would have been had these shares been purchased by investors that were not directors or existing stockholders.

If you purchase our common stock in this offering, you will incur immediate and substantial dilution in the book value of your shares.

The initial public offering price will be substantially higher than the pro forma as adjusted net tangible book value per share of our common stock after this offering. Investors purchasing common stock in this offering will pay a price per share that substantially exceeds the pro forma as adjusted net tangible book value per share after this offering. As a result, investors purchasing common stock in this offering will incur immediate dilution of $5.61 per share, based on the initial public offering price of $12.00 per share, representing the difference between our pro forma as adjusted net tangible book value per share after giving effect to this offering and the initial public offering price. Further, investors purchasing common stock in this offering will contribute

approximately 31.7% of the total amount invested by stockholders since our inception, but will own only approximately 30.0% of the shares of common stock outstanding after this offering.

This dilution is due to our investors who purchased shares prior to this offering having paid substantially less when they purchased their shares than the price offered to the public in this offering. To the extent outstanding restricted stock awards vest or outstanding options are exercised, there will be further dilution to new investors. Additionally, pursuant to the Myst Merger Agreement, within 45 days of the closing of this offering, we will be obligated to pay the Myst Holders (as defined below) an aggregate amount equal to $3.0 million pursuant to the Myst Merger Agreement (as defined below). Further, within 45 days of the achievement of the third milestone under the Myst Merger Agreement, we are obligated to pay the Myst Holder an aggregate amount equal to $20.0 million. At our election, we may pay either of these milestone considerations in cash or in shares of our common stock. If we elect to pay the Myst Holders either of these milestone considerations, if and when achieved, in the form of shares of our common stock, then our existing stockholders will experience further dilution. As a result of the dilution to investors purchasing shares in this offering, investors may receive significantly less than the purchase price paid in this offering, if anything, in the event of our liquidation. For a further description of the dilution that you will experience immediately after this offering, see the section titled “Dilution.”

We are an emerging growth company and a smaller reporting company, and the reduced reporting requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors.

We are an emerging growth company, as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports and proxy statements, and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years following the year in which we complete this offering, although circumstances could cause us to lose that status earlier. 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 $1.235 billion and (c) in which we are deemed to be a large accelerated filer, which requires the market value of our common stock that is held by non-affiliates to exceed $700.0 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. Investors may 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.

Under the JOBS Act, emerging growth companies also can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to avail ourselves of this exemption, and, as a result, our operating results and financial statements may not be comparable to the operating results and financial statements of companies who have adopted the new or revised accounting standards.

We also are 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 $700.0 million and our annual revenue is less than $100.0 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 $250.0 million or (ii) our annual revenue is less than $100.0 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700.0 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.

Conflicts of interest may arise because some members of our board of directors are representatives of our principal stockholders.

Certain of our principal stockholders or their affiliates are venture capital funds or other investment vehicles that could invest in entities that directly or indirectly compete with us. As a result of these relationships, when conflicts arise between the interests of the principal stockholders or their affiliates and the interests of other stockholders, members of our board of directors that are representatives of the principal stockholders may not be disinterested.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

If our stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the lock-up and other legal restrictions on resale discussed in this prospectus lapse, the trading price of our common stock could decline. Based on shares of common stock outstanding as of March 31, 2023, upon the completion of this offering we will have outstanding a total of 22,188,682 shares of common stock. Of these shares, only the shares of common stock sold in this offering by us, plus any shares sold upon exercise of the underwriters' option to purchase additional shares, will be freely tradable without restriction in the public market immediately following this offering.

The lock-up agreements pertaining to this offering will expire 180 days from the date of this prospectus, subject to earlier release of all or a portion of the shares at the sole discretion of BofA Securities, Inc., Leerink Partners LLC and Piper Sandler & Co. After the lock-up agreements expire, based upon the number of shares of common stock, on an as-converted basis, outstanding as of March 31, 2023, up to an additional 15,522,015 shares of common stock will be eligible for sale in the public market. Approximately 80.5% of these additional shares are beneficially held by directors, executive officers and their affiliates and will be subject to certain limitations of Rule 144 under the Securities Act of 1933, as amended, or the Securities Act. Pursuant to the Takeda Letter Agreement, Takeda has agreed to submit a non-binding indication of interest to participate in this offering by purchasing at the public offering price per share the number of shares of our common stock with an aggregate value of $8.0 million or such lesser amount as determined by us in our sole discretion, or the Takeda IPO Shares. The Takeda IPO Shares will not be subject to a lock-up agreement. Any transfers or sales of the Takeda IPO Shares may cause the price of our common stock to decline. Under the Takeda Agreement, Takeda's original equity commitment of up to $20.0 million was partially fulfilled in June 2021 by Takeda's purchase of 1,830,335 shares of our Series D preferred stock at a purchase price of $2.73174 per share for aggregate gross proceeds of approximately $5.0 million, and all of Takeda's remaining obligations under the Takeda Agreement expired upon the termination the Takeda Agreement on July 6, 2023. Takeda's agreement to participate in this offering or a concurrent private placement will expire on July 31, 2023. See the section titled "Certain Relationships and Related Party Transactions—Public Offering Participation Rights."

In addition, shares of common stock that are either subject to outstanding options or reserved for future issuance under our existing equity compensation plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements and Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

After this offering, the holders of 13,250,522 shares of our common stock will be entitled to rights with respect to the registration of their shares under the Securities Act as provided under the terms of the Second Amended and Restated Investors' Rights Agreement, or the Rights Agreement, between us and the holders of our

convertible preferred stock, or in the case of Langer (as defined below), under the Myst Merger Agreement, in each case, subject to the 180-day lock-up agreements described above. See the section titled "Description of Capital Stock—Registration Rights." Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

We have broad discretion in the use of our existing cash and the net proceeds from this offering and may not use them effectively.

Following this offering, our management will have broad discretion in the application of our existing cash and the net proceeds from this offering, including for any of the purposes described in the section titled "Use of Proceeds," and you will not have the opportunity as part of your investment decision to assess whether such proceeds are being used appropriately. Because of the number and variability of factors that will determine our use of our existing cash and the net proceeds from this offering, their ultimate use may vary substantially from their currently intended use. Our management might not apply our existing cash and the net proceeds from this offering in ways that ultimately increase the value of your investment. The failure by our management to apply these funds effectively could harm our business. Pending their use, we may invest the net proceeds from this offering in short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our stockholders. If we do not invest or apply the net proceeds from this offering in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause our stock price to decline.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of our company more difficult, limit attempts by our stockholders to replace or remove our current management and limit the market price of our common stock.

Provisions in our amended and restated certificate of incorporation, as they will be in effect immediately following the closing of this offering, and our amended and restated bylaws, as they will be in effect immediately prior to the closing of this offering, may have the effect of delaying or preventing a change of control or changes in our board of directors and management. Our amended and restated certificate of incorporation and amended and restated bylaws will include provisions that:

- authorize our board of directors to issue, without further action by the stockholders, shares of undesignated preferred stock with terms, rights and preferences determined by our board of directors that may be senior to our common stock;
- require that any action to be taken by our stockholders be effected at a duly called annual or special meeting and not by written consent;
- specify that special meetings of our stockholders can be called only by directors representing a majority of the total authorized size of our board of directors, the chairperson of our board of directors, our chief executive officer or our president;
- establish an advance notice procedure for stockholder proposals to be brought before an annual meeting, including proposed nominations of persons for election to our board of directors;
- establish that our board of directors is divided into three classes, with each class serving three-year staggered terms;
- prohibit cumulative voting in the election of directors, therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose;

- provide that our directors may be removed for cause only upon the vote of at least 66 2/3% of our outstanding shares of voting stock;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum; and
- require the approval of our board of directors or the holders of at least 66 2/3% of our outstanding shares of voting stock to amend our bylaws and certain provisions of our certificate of incorporation.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, or DGCL, which generally, subject to certain exceptions, prohibits a Delaware corporation from engaging in any of a broad range of business combinations with any "interested" stockholder for a period of three years following the date on which the stockholder became an "interested" stockholder. Any of the foregoing provisions could limit the price that investors might be willing to pay in the future for shares of our common stock, and they could deter potential acquirers of our company, thereby reducing the likelihood that holders of our common stock would receive a premium for their shares of our common stock in an acquisition.

Our amended and restated certificate of incorporation will provide that the Court of Chancery of the State of Delaware and the federal district court for the District of Delaware of the United States will be the exclusive forums 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 the following types of actions or proceedings under Delaware statutory or common law:

- 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 under the DGCL, our amended and restated certificate of incorporation, or our amended and restated bylaws;
- any action seeking to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation, or our amended and restated bylaws;
- any action to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware; and
- any action asserting a claim against us that is governed by the internal-affairs doctrine.

This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation will further provide 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. While the Delaware courts have

determined that such choice of forum provisions are facially valid and several state trial courts have enforced such provisions and required that suits asserting Securities Act claims be filed in federal court, there is no guarantee that courts of appeal will affirm the enforceability of such provisions and a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and the provisions may not be enforced by a court in those other jurisdictions. If a court were to find either exclusive forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with litigating Securities Act claims in state court, or both state and federal court, which could seriously harm our business, results of operations and financial condition.

This exclusive forum provision may result in increased costs to stockholders to bring a claim. Further, this exclusive forum provision 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, which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find either exclusive-forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could seriously harm our business.

General Risk Factors

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

As a public company, we will incur significant legal, accounting, compliance and other expenses that we did not incur as a private company. We will be subject to the reporting requirements of the Exchange Act, which will require, among other things, that we file with the SEC annual, quarterly, and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and Nasdaq to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as "say on pay" and proxy access. Emerging growth companies and smaller reporting companies are exempted from certain of these requirements, but we may be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

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

If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely financial statements could be impaired, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

We are not currently required to comply with the rules of the SEC implementing Section 404 of the Sarbanes-Oxley Act and are therefore not required to make a formal assessment of the effectiveness of our internal control over financial reporting for that purpose. Upon becoming a public company, we will be required to comply with the SEC's rules implementing Sections 302 and 404 of the Sarbanes-Oxley Act, which will require management to certify financial and other information in our quarterly and annual reports and provide an annual management report on the effectiveness of internal control over financial reporting. Although we will be required to disclose changes made in our internal control over financial reporting on a quarterly basis, we will not be required to make our first annual assessment of our internal control over financial reporting until our second annual report on Form 10-K. However, as an emerging growth company, our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting until the later of the year following our first annual report required to be filed with the SEC or the date we are no longer an emerging growth company. When we lose our status as an "emerging growth company" and reach an accelerated filer threshold, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for our management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the requirements of being a reporting company under the Exchange Act, we may need to upgrade our information technology systems; implement additional financial and management controls, reporting systems and procedures; and hire additional accounting and finance staff. If we or, if required, our auditors are unable to conclude that our internal control over financial reporting is effective, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

There may be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting once that firm begins its Section 404 reviews, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

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

Upon the completion of this offering, we will become subject to the periodic reporting requirements of the Exchange Act. We must design our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. Any disclosure controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make any related party transaction disclosures. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected. In addition, we do not have a formal risk management program for identifying and addressing risks to our business in other areas.

We could be subject to securities class action litigation, which is expensive and could divert management attention.

The market price of our common stock is likely to be volatile. The stock market in general, and Nasdaq and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of companies. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs (including the cost to defend against, and any potential adverse outcome resulting from any such proceeding), damage to our reputation, and a diversion of management's attention and resources from other business concerns, which could harm our business.

Our failure to meet Nasdaq's continued listing requirements could result in a delisting of our common stock.

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

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 securities or industry analysts commence coverage of our company, the trading price for our stock would likely be negatively impacted. In the event securities or industry analysts initiate coverage, if one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which would likely cause our stock price and trading volume to decline.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements about us and our industry. All statements other than statements of historical facts contained in this prospectus, including statements regarding our future results of operations and financial position, business strategy, research and development costs; the anticipated timing, costs and conduct of preclinical studies and clinical trials for our Selected TIL programs and product candidates; the timing and likelihood of regulatory filings and approvals for our product candidates; our ability to commercialize our product candidates, if approved; the potential benefits of our strategic collaborations and our ability to enter into strategic arrangements; the timing and likelihood of success, plans and objectives of management for future operations; future results of anticipated product development efforts; our expected future financing needs; and expected uses of the net proceeds from this offering, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “would,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplate,” “believe,” “estimate,” “predict,” “potential” or “continue” or the negative of these terms or other similar expressions. The forward-looking statements in this prospectus are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, results of operations and financial condition. These forward-looking statements speak only as of the date of this prospectus and are subject to a number of risks, uncertainties and assumptions described under the sections titled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this prospectus. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. Except as required by applicable law, we undertake no obligation to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. You should, however, review the factors and risks we describe in the reports we will file from time to time with the SEC after the date of this prospectus. See the section titled “Where You Can Find More Information.”

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based on information available to us as of the date of this prospectus, and while we believe such information provides a reasonable basis for these statements, such information may be limited or incomplete. Our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and you are cautioned not to unduly rely on these statements.

MARKET, INDUSTRY AND OTHER DATA

We obtained the market, industry and statistical data in this prospectus from our own internal estimates and research as well as from industry and general publications and research, surveys and studies conducted by third parties. All of the market data used in this prospectus involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such data. While we believe that each of these studies and publications is reliable, the industry in which we operate is subject to a high degree of uncertainty and risk due to a variety of important factors, including those described in the section titled “Risk Factors.” These and other factors could cause results to differ materially from those expressed in the estimates made by third parties and by us.

USE OF PROCEEDS

We estimate that the net proceeds from our issuance and sale of 6,666,667 shares of our common stock in this offering will be approximately $70.1 million (or approximately $81.3 million if the underwriters exercise their option to purchase additional shares in full), based on the initial public offering price of $12.00 per share, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

The principal purposes of this offering are to increase our financial flexibility, create a public market for our common stock, and facilitate our future access to capital markets.

We intend to use the net proceeds from this offering, together with our existing cash, cash equivalents and short-term investments, as follows:

- approximately $74 million to $78 million to fund the continued development of TIDAL-01 in our two Phase 1 clinical trials for the treatment of breast cancer, colorectal cancer, uveal melanoma and other non-cutaneous and cutaneous melanomas, through initial clinical data update in mid-2024 and continued development into the second quarter of 2025;
- approximately $16 million to $21 million to advance our TIDAL-02 program through candidate declaration and TIDAL-01 and viral immunotherapy combination program through an investigational new drug application, or IND; and
- remaining proceeds, if any, for working capital and general corporate purposes.

We may also use a portion of the remaining net proceeds and our existing cash, cash equivalents and short-term investments, to in-license, acquire, or invest in complementary businesses, technologies, products, or assets. However, we have no current commitments or obligations to do so.

We believe that the net proceeds of this offering, together with our existing cash, cash equivalents and short-term investments will enable us to fund our operations into the second quarter of 2025. In particular, we expect that the net proceeds from this offering, together with our existing cash, cash equivalents and short-term investments, will allow us to fund the continued development of TIDAL-01 in our two Phase 1 clinical trials for the treatment of breast cancer, colorectal cancer, uveal melanoma and other non-cutaneous and cutaneous melanomas, and to advance our TIDAL-02 program and TIDAL-01 and viral immunotherapy combination program. We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we expect. This expected use of net proceeds from this offering and our existing cash, cash equivalents and short-term investments represents our intentions based upon our current plans

and business conditions, which could change in the future as our plans and business conditions evolve. Predicting the costs necessary to develop product candidates can be difficult and we anticipate that we will need additional funds to complete our clinical development of any of our product candidates. The amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including the progress of our development, the status of and results from clinical trials, as well as any collaborations that we may enter into with third parties for our product candidates, and any unforeseen cash needs.

Our management will have broad discretion in the application of the net proceeds from this offering, and investors will be relying on the judgment of our management regarding the application of those net proceeds. The timing and amount of our actual expenditures will be based on many factors, including cash flows from operations and the anticipated growth of our business. Pending these uses, we plan to invest these net proceeds in short-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the United States.

DIVIDEND POLICY

We have never declared or paid, and do not anticipate declaring or paying, in the foreseeable future, any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business. Any future determination related to our dividend policy will be made at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions, business prospects and other factors our board of directors may deem relevant.

CAPITALIZATION

The following table sets forth our cash, cash equivalents and short-term investments and capitalization as of March 31, 2023:

- on an actual basis;
- on a pro forma basis after giving effect to (i) the conversion of all outstanding shares of our convertible preferred stock into an aggregate of 12,493,879 shares of common stock and the related reclassification of the carrying value of our convertible preferred stock to permanent equity in connection with the closing of this offering and (ii) the filing and effectiveness of our amended and restated certificate of incorporation that will be in effect immediately following the closing of this offering; and
- on a pro forma as adjusted basis to reflect (i) the pro forma adjustments set forth above and (ii) our issuance and sale of 6,666,667 shares of common stock in this offering at the initial public offering price of $12.00 per share, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

You should read the information in this table together with our consolidated financial statements and related notes included elsewhere in this prospectus and the sections titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Description of Capital Stock.”

	As of March 31, 2023		
	Actual	Pro Forma	Pro Forma As Adjusted
	(in thousands, except share and per share data) (unaudited)		
Cash, cash equivalents and short-term investments	$ 63,969	$ 63,969	$ 134,060
Redeemable convertible preferred stock, $0.001 par value per share, 99,791,338 shares authorized, issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	$ 171,964	$ —	$ —
Stockholders’ (deficit) equity:			
Preferred stock, $0.001 par value per share; no shares authorized, issued or outstanding, actual; 10,000,000 shares authorized and no shares issued or outstanding, pro forma and pro forma as adjusted	—	—	—
Common stock, $0.001 par value; 147,892,358 shares authorized, 3,028,136 shares issued and outstanding, actual; 490,000,000 shares authorized, 15,522,015 shares issued and outstanding, pro forma; and 490,000,000 shares authorized, 22,188,682 shares issued and outstanding, pro forma as adjusted	3	16	22
Additional paid-in capital	21,556	193,507	263,592
Accumulated other comprehensive loss	(292)	(292)	(292)
Accumulated deficit	(121,490)	(121,490)	(121,490)
Total stockholders’ (deficit) equity	(100,223)	71,741	141,832
Total capitalization	$ 71,741	$ 71,741	$ 141,832

The outstanding share information in the table above is based on 15,522,015 shares of our common stock as of March 31, 2023, after giving effect to the conversion of all outstanding shares of our convertible preferred stock into 12,493,879 shares of our common stock in connection with the closing of this offering, and excludes:

- 2,495,301 shares of our common stock issuable upon the exercise of outstanding stock options as of March 31, 2023, with a weighted-average exercise price of $8.86 per share;
- 186,043 shares of our common stock issuable upon the exercise of outstanding stock options granted subsequent to March 31, 2023, with a weighted-average exercise price of $16.53 per share;
- 275,163 shares of our common stock reserved for future issuance to Moffitt contingent on the achievement of certain clinical and regulatory milestones pursuant to our Alliance Agreement with Moffitt;
- 2,722,887 shares of our common stock reserved for future issuance under our 2023 Plan, which became effective upon the execution of the underwriting agreement for this offering, as well as any automatic increases in the number of shares of common stock reserved for future issuance under this plan; and
- 222,287 shares of our common stock reserved for future issuance under our ESPP, which became effective upon the execution of the underwriting agreement for this offering, as well as any automatic increases in the number of shares of common stock reserved for future issuance under this plan.

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 initial public offering price per share and the pro forma as adjusted net tangible book value per share of our common stock after this offering.

As of March 31, 2023, we had a historical net tangible book value (deficit) of $(100.2) million, or $(33.10) per share of common stock. Our historical net tangible book value (deficit) per share represents total tangible assets less total liabilities and convertible preferred stock, which is not included within permanent equity, divided by the number of shares of our common stock outstanding as of March 31, 2023.

Our pro forma net tangible book value as of March 31, 2023, was $71.7 million, or $4.62 per share of our common stock. Pro forma net tangible book value represents the amount of our total tangible assets less our total liabilities, (i) the conversion of all outstanding shares of our convertible preferred stock into an aggregate of 12,493,879 shares of common stock and the related reclassification of the carrying value of our convertible preferred stock to permanent equity in connection with the closing of this offering and (ii) the filing and effectiveness of our amended and restated certificate of incorporation that will be in effect immediately following the closing of this offering. Pro forma net tangible book value per share represents pro forma net tangible book value divided by the total number of shares outstanding as of March 31, 2023, after giving effect to the pro forma adjustments described above.

After giving further effect to the sale of 6,666,667 shares of common stock in this offering at the initial public offering price of $12.00 per share, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of March 31, 2023 would have been approximately $141.8 million, or approximately $6.39 per share. This amount represents an immediate increase in pro forma net tangible book value of $1.77 per share to our existing stockholders and immediate dilution of approximately $5.61 per share to new investors in this offering. We determine dilution by subtracting the as pro forma adjusted net tangible book value per share after this offering from the amount of cash that a new investor paid for a share of common stock in this offering.

The following table illustrates this dilution:

Initial public offering price per share		$12.00
Historical net tangible book value (deficit) per share as of March 31, 2023	$(33.10)	
Increase per share attributable to the pro forma adjustments described above	37.72	
Pro forma net tangible book value per share as of March 31, 2023	4.62	
Increase per share attributable to this offering	1.77	
Pro forma as adjusted net tangible book value per share after this offering		$ 6.39
Dilution per share to new investors in this offering		$ 5.61

If the underwriters exercise their option to purchase an additional 1,000,000 shares of our common stock in full, the pro forma as adjusted net tangible book value of our common stock would increase to $6.60 per share, representing an immediate increase in the pro forma net tangible book value per share to existing stockholders of $1.98 per share and an immediate dilution of $5.40 per share to investors participating in this offering, in each case based on the initial public offering price of $12.00 per share.

The following table summarizes as of March 31, 2023 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 (i) paid to us by our existing stockholders and (ii) to be paid by investors purchasing our common stock in this offering at the initial public offering price of $12.00 per share before deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

	Shares Purchased		Total Consideration		Weighted-Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders	15,522,015	70.0%	$172,664,000	68.3%	$ 11.12
New investors	6,666,667	30.0%	$ 80,000,004	31.7%	$ 12.00
Total	22,188,682	100%	$252,664,004	100%	

The foregoing tables and calculations are based on 15,522,015 shares of our common stock as of March 31, 2023, after giving effect to the conversion of all outstanding shares of our convertible preferred stock into 12,493,879 shares of our common stock in connection with the closing of this offering, and excludes:

- 2,495,301 shares of our common stock issuable upon the exercise of outstanding stock options as of March 31, 2023, with a weighted-average exercise price of $8.86 per share;
- 186,043 shares of our common stock issuable upon the exercise of outstanding stock options granted subsequent to March 31, 2023, with a weighted-average exercise price of $16.53 per share;
- 275,163 shares of our common stock reserved for future issuance to Moffitt contingent on the achievement of certain clinical and regulatory milestones pursuant to our Alliance Agreement with Moffitt;
- 2,722,887 shares of our common stock reserved for future issuance under our 2023 Plan, which became effective upon the execution of the underwriting agreement for this offering, as well as any automatic increases in the number of shares of common stock reserved for future issuance under this plan; and
- 222,287 shares of our common stock reserved for future issuance under our ESPP, which became effective upon the execution of the underwriting agreement for this offering, as well as any automatic increases in the number of shares of common stock reserved for future issuance under this plan.

To the extent that any outstanding options are exercised or new options are issued under our stock-based compensation plans, or we issue additional shares of common stock in the future, there will be further dilution to investors participating in this offering. Additionally, pursuant to the Myst Merger Agreement, within 45 days of the closing of this offering, we will be obligated to pay the Myst Holders an aggregate amount equal to $3.0 million pursuant to the Myst Merger Agreement. Further, within 45 days of the achievement of the third milestone under the Myst Merger Agreement, we are obligated to pay the Myst Holder an aggregate amount equal to $20.0 million. At our election, we may pay either of these milestone considerations in cash or in shares of our common stock. If we elect to pay the Myst Holders either of these milestone considerations, if and when achieved, in the form of shares of our common stock, then our existing stockholders will experience further dilution.

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

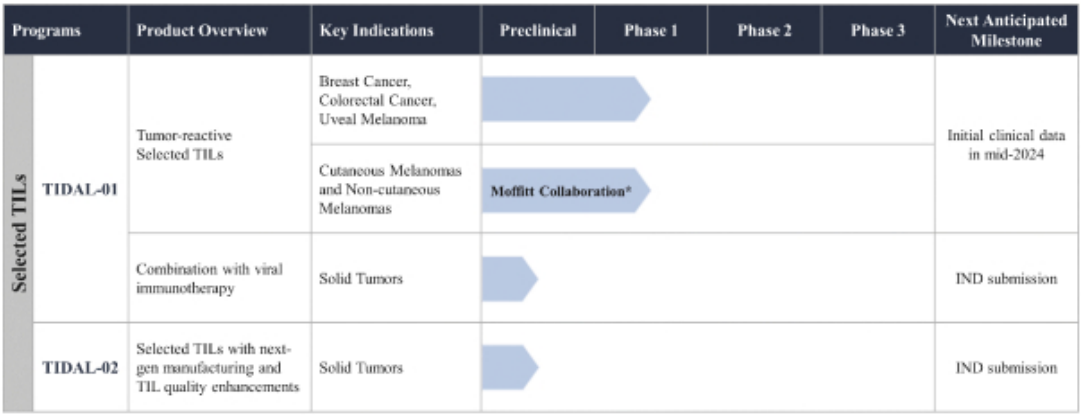
You should read the following discussion and analysis of our financial condition and results of operations together with the section titled "Summary Consolidated Financial Data" and our consolidated financial statements and related notes and the other financial information included elsewhere in this 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" section 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. You should carefully read the "Risk Factors" section of this prospectus to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see the section titled "Special Note Regarding Forward-Looking Statements."

Overview

We are a clinical stage biotechnology company focused on developing new medicines to treat and cure patients with solid tumors. Approved immunotherapies represent a significant advancement in the treatment of solid tumors, but many patients either do not respond or experience relapsed disease following an initial response. We believe the most significant challenge to creating curative immunotherapies in these patients is the low numbers of T cells that can recognize and attack the tumor, which we refer to as tumor-reactive T cells. To address this problem, we are pioneering a differentiated approach to tumor infiltrating lymphocytes, or TILs. We are developing next generation TIL therapies by selecting the most potent (meaning able to mediate an anti-tumor response) and tumor-reactive T cells, which we refer to as Selected TILs. Unlike other approaches that rely on standard "bulk TILs" that have demonstrated objective responses in clinical trials only in limited tumor types, we are developing our Selected TILs for potential treatment across the majority of solid tumors. We have initiated two Phase 1 clinical trials for TIDAL-01, including a multi-site trial for the treatment of breast cancer, colorectal cancer, and uveal melanoma, and an investigator sponsored trial with H. Lee Moffitt Cancer Center and Research Institute, Inc., or Moffitt, in both cutaneous and non-cutaneous melanomas. We intend to provide an initial clinical update across these two trials in mid-2024. We discuss the nature of this investigator-sponsored trial, including how this trial differs from a clinical trial sponsored by our company, as well as our roles and responsibilities in the trial, in more detail below. We are also advancing our preclinical pipeline including TIDAL-02, our next Selected TIL program, and TIDAL-01 in combination with viral immunotherapy. We define objective response as a patient experiencing a partial response or complete response to any given therapy.

We are developing next generation TIL therapies for the potential treatment of multiple solid tumors. There are no TIL therapies that have received FDA approval to date. To our knowledge, at present there are no therapies in clinical development that provide curative outcomes for the majority of patients in our chosen solid tumor indications. Our innovative Selected TIL approach focuses on selecting and expanding the most potent tumor-reactive T cells to overcome the limitations of bulk TILs. This approach expands upon work conducted in academia that demonstrated improved clinical responses for certain selected TILs in solid-tumor types where bulk TILs have not shown objective responses in clinical trials. We are leveraging this work to establish a standardized manufacturing process for large scale production of our Selected TILs.

We are applying our Selected TIL approach for potential treatment of a wide range of solid tumors. We are developing a broad pipeline aimed at improving outcomes for patients, as illustrated in the chart below.



* Investigator sponsored trial at Moffitt Cancer Center

We are advancing TIDAL-01, our lead Selected TIL product candidate, for the treatment of multiple solid tumor indications. TIDAL-01 utilizes an unbiased identification and functional screening process to isolate and selectively expand the greatest breadth of tumor-reactive TILs from the patient's tumor. Our TIDAL-01 production process is designed to deliver at least 10^9 cells and targets greater than 70% functional and potent tumor-reactive T cells. We have initiated two Phase 1 clinical trials for TIDAL-01, including a multi-site trial for the treatment of breast cancer, colorectal cancer, and uveal melanoma, and an investigator sponsored trial with Moffitt in both cutaneous and non-cutaneous melanomas.

Investigator sponsored trials are clinical trials where the investigator of the trial is also the "sponsor" of the trial for regulatory purposes. An "investigator" conducts clinical investigations and is the person under whose immediate direction the study drug is administered or dispensed to patients. A "sponsor" initiates and takes responsibility for a clinical investigation. A person who both initiates and conducts a clinical trial, and is responsible for all regulatory requirements, is designated as a "sponsor-investigator" by the FDA. Clinical investigators at academic medical centers who initiate clinical trials with a lawfully marketed drug to be used in a patient population or indication not within the official labeling often fit within this designation. In addition, as is the case with our investigator-sponsored trials, a company may provide a sponsor-investigator with supply of its unapproved product candidate and funding for the trial. Investigators who initiate and conduct such trials are responsible for obtaining an IND from the FDA and for ensuring compliance with the IND and associated regulatory requirements. As provided by the FDA's regulations, the sponsor of a clinical trial is responsible for, among other things, selecting qualified investigators, providing them with the information they need to conduct the trial properly, ensuring proper monitoring of the trial, ensuring that the trial is conducted in accordance with the protocols contained in the IND, maintaining an effective IND with respect to the trial, and ensuring that the FDA and all participating investigators are promptly informed of significant new adverse effects or risks with respect to the drug. In contrast, in a company-sponsored trial, the pharmaceutical company whose drug will be studied is the sponsor of the trial and, as such, is responsible for ensuring compliance with all regulatory requirements, including obtaining the IND.

Under our multi-site trial, we control all aspects of our trial including, but not limited to, study protocol development, patient selection and enrollment, regulatory interactions, data release, and manufacturing through our industrial contract development and manufacturing organization, or CDMO. Under the investigator sponsored trial, which is fully funded by us, Moffitt is solely responsible for regulatory interactions, trial conduct and manufacture of TIDAL-01 at the Moffitt Cancer Cell Therapy Facility, with input and support from us at Moffitt's discretion. Investigators at Moffitt are also solely responsible for the design of the trial and patient

selection and enrollment, where we remain in close contact with the investigators to provide our input if appropriate. Any data disclosures will be made in collaboration with us and any improvements to the TIDAL-01 manufacturing process are solely at our discretion. We intend to provide an initial clinical update across these two trials in mid-2024.

Our next Selected TIL program, TIDAL-02, is being designed to encompass a next generation streamlined manufacturing process for tumor-reactive T cells and additional modifications to enhance TIL quality and function (meaning the viability of the TILs and their ability to produce cytotoxic and immune activating cytokines). We believe that TIDAL-02 has the potential to address solid tumor indications that are distinct from and complementary to TIDAL-01. TIDAL-02 is currently in preclinical development.

We intend to evaluate the combination of TIDAL-01 with viral immunotherapy through two approaches: (1) treatment of the patient with viral immunotherapy prior to TIL extraction to optimize TIL harvest and broaden applicability to additional tumor types with low immune cell infiltration and (2) treatment of the patient with viral immunotherapy following treatment with TIDAL-01 to optimize TIL trafficking and infiltration into solid tumors and to support the anti-tumor functions of infiltrating immune cells. We are currently evaluating the optimal viral immunotherapy for combination with TIDAL-01 to advance into clinical development.

In December 2018, we completed a corporate reorganization pursuant to which Turnstone Biologics Inc. merged with and into Turnstone Biologics Corp., a newly formed Delaware corporation, as the successor company. As a result of this reorganization, we changed our domicile from the country of Canada to the State of Delaware. Our headquarters are located in San Diego, California and we operate as one segment. Since our inception, we have devoted substantially all of our efforts and financial resources to organizing and staffing our company, business planning, raising capital, discovering product candidates and securing related intellectual property rights and conducting research and development activities for our Selected TIL programs and product candidates. We do not have any products approved for sale and we have not generated any revenue from product sales and have incurred overall net losses since our inception through March 31, 2023. We have funded our operations primarily through the sale of our convertible preferred stock and revenue from certain of our collaboration agreements. Since our inception, we have raised an aggregate of approximately $172.0 million of gross proceeds from the issuance and sale of shares of our convertible preferred stock and $190.0 million in upfront, non-refundable collaboration revenue from the AbbVie Agreement and Takeda Agreement, each as defined below. As of December 31, 2022 and March 31, 2023, we had cash, cash equivalents and short-term investments of $82.1 million and $64.0 million, respectively.

We have incurred significant operating losses in the past, and we expect to continue to incur significant operating losses for the foreseeable future. Our net loss was $30.8 million for the year ended December 31, 2022. We had net income of $0.1 million and net loss of $12.6 million for the three months ended March 31, 2023 and 2022, respectively. As of December 31, 2022 and March 31, 2023, we had an accumulated deficit of $121.6 million and $121.5 million, respectively. Substantially all of our operating losses result from expenses incurred in our research and development programs and from general and administrative costs associated with our operations. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our current or future product candidates, and on our ability to enter into collaborations, strategic partnerships and alliances or marketing, distribution or licensing arrangements with third parties.

We expect to incur significant expenses and increasing operating losses for the foreseeable future as we continue the preclinical development, manufacturing and clinical development of, and seek regulatory approval for, our product candidates. In addition, we may incur expenses in connection with the in-license or acquisition of additional platform technologies and the development of any such product candidates. We also expect to incur additional costs associated with operating as a public company. Furthermore, our operating losses may fluctuate significantly from quarter to quarter and year to year due to timing of preclinical activities, clinical development and regulatory approval of our product candidates.

We plan to fund future operations and future capital funding needs through equity and debt financings, licensing transactions, and collaborations or strategic partnerships with other companies. We can provide no assurance that financing will be available in the amounts we need or on terms acceptable to us, if at all. If we enter into licensing transactions, collaborations, strategic partnerships or similar agreements 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 and may reduce the value of our common stock. If we are not able to secure adequate additional funding, we may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible, and suspend, delay or curtail our development programs. Any of these actions could materially harm our business.

Our innovative Selected TIL approach focuses on selecting and manufacturing the most potent tumor-reactive T cells to overcome the limitations of bulk TILs. This approach is grounded on work conducted in academia that has demonstrated improved clinical responses for selected TILs in solid tumor types where bulk TILs have shown limited to no objective responses in clinical trials. We are leveraging this work to establish a standardized manufacturing process for large scale production of our Selected TILs. We intend to establish in-house tumor sequencing capabilities, expedite manufacturing and shipping of peptides, and biopsy tumor prior to resection to enable earlier sequencing and peptide synthesis.

Macroeconomic and Geopolitical Trends

We continue to actively monitor the impact of various macroeconomic and geopolitical trends, such as high rates of inflation, supply chain disruptions and geopolitical instability, bank failures, and the COVID-19 pandemic on our business. To date, we have not experienced a material financial statement impact or business disruptions, including with our vendors or third parties, as a result of these negative macroeconomic or geopolitical trends. Our business has been, and may continue to be, impacted by the negative macroeconomic and geopolitical trends wherever we have clinical trial sites, contract manufacturing organizations, or CMOs, facilities or other business operations.

Global economic and business activities continue to face widespread uncertainties, and global credit and financial markets have experienced extreme volatility and disruptions in the past several years, including severely diminished liquidity and credit availability, rising inflation and monetary supply shifts, rising interest rates, labor shortages, declines in consumer confidence, declines in economic growth, increases in unemployment rates, recession risks, and uncertainty about economic and geopolitical stability. Moreover, negative macroeconomic conditions could adversely impact our ability to obtain financing in the future on terms acceptable to us, or at all. In addition, the geopolitical instability and related sanctions could continue to have significant ramifications on global financial markets, including volatility in the U.S. and global financial markets.

To date, the COVID-19 pandemic has not had a material adverse impact on our productivity or our business, and as of March 31, 2023, we have not identified any significant disruption or impairment of our assets due to the pandemic. However, as COVID-19 transitions from a pandemic to an endemic, we cannot predict the potential future impacts of COVID-19 on us and third parties with whom we conduct business. These impacts will depend on future developments that are highly uncertain and cannot be predicted at this time. Given these uncertainties, COVID-19 could impact our business operations and our ability to execute on our associated business strategies and initiatives, and adversely impact our results of operations and our financial condition in the future, and could disrupt the business of third parties with whom we do business. We will continue to closely monitor and evaluate the nature and extent of the impacts of COVID-19 on our business, financial condition, results of operations, and prospects.

Collaboration Agreements

Below is a summary of the key terms for certain of our collaboration agreements. For a more detailed description of our collaboration agreements, see the section titled “Business—Collaboration Agreements” and

Note 6 to our consolidated financial statements and Note 6 to our unaudited interim consolidated financial statements, each included elsewhere in this prospectus.

Moffitt Collaboration Agreements

Master Collaboration Agreement

In January 2021, we entered into an amended and restated master collaboration agreement, or the Moffitt Agreement, with Moffitt, to amend a then-existing master collaboration agreement from November 2019, as amended March 2020, between Moffitt and our now wholly-owned subsidiary, Myst Therapeutics LLC, with the intent to continue to work collaboratively in the research of cancer immunotherapies.

Moffitt granted us (1) a royalty-free, sublicensable, non-transferable, perpetual, non-exclusive license to use and practice certain inventions invented solely by Moffitt in the performance of a research plan or through use of any data generated thereunder, or Moffitt Inventions, (a) for internal, non-commercial research purposes outside the field of adoptive cell therapy and/or (b) to research, develop, make, use, sell, offer to sell, or import products and/or services in the field of adoptive cell therapy and (2) a royalty free, sublicensable, non-transferable, perpetual, non-exclusive license to use and practice certain inventions invented in performance of a research plan or through the use of Moffitt research materials, which are (i) specifically directed to the identity of melanoma-specific T cell receptors, (ii) invented during the collaboration term or within one year after the end of the collaboration term within the field of adoptive cell therapy, and (iii) invented solely by either parties' employees or by both parties' employees jointly, to research, develop, make, use, sell, offer to sell, or import products and/or services for cancer immunotherapy involving identifying relevant tumor reactive T cells from TILs.

Moffitt Alliance Agreement

In June 2022, we entered into a life science alliance agreement with Moffitt, or the Alliance Agreement, in order to further expand our relationship and support our existing agreements with Moffitt, or the Underlying Agreements. Pursuant to the Alliance Agreement, we will have priority access to Moffitt's scientific research, manufacturing, and clinical capabilities for the development of novel TIL therapies, including expedited clinical trial activation, enhanced patient screening and data sharing, access to Moffitt's cellular therapies research and development infrastructure, expanded molecular data sets and biospecimens for research, and allocated cGMP manufacturing capacity for our product candidates.

Under the Alliance Agreement, we are obligated to use commercially reasonable efforts to further develop TIL Products (as defined below), to manufacture TIL Products, to obtain regulatory approval for at least one TIL Product in the United States and to commercialize TIL Products in all countries in which regulatory approval for a TIL Product has been obtained. For purposes of the Alliance Agreement, TIL Product means any pharmaceutical, biopharmaceutical, or biotechnology TIL product that has been developed by us or Moffitt and is advanced into clinical development under an IND sponsored by Moffitt.

Pursuant to the Alliance Agreement, we have agreed to pay to Moffitt a total amount of at least $17.5 million, or the Alliance Funding Amount, for research, development and manufacturing related services that will be paid in five equal annual installments on June 1 of each year starting on June 1, 2023. However, the aggregate amounts we pay to Moffitt for all fees, costs, expenses and other payments pursuant to any Underlying Agreement with Moffitt entered into subsequent to February 7, 2022 may be credited against the Alliance Funding Amount. This reimbursement amount will be calculated annually at the conclusion of each payment period, and, to the extent our annual aggregate payments to Moffitt exceed the applicable annual installment amount, we will receive a reduction in the amount due for future installment payments based on a predetermined formula agreed to by the parties.

In connection with the execution of the Alliance Agreement, we issued Moffitt 91,721 shares of our common stock. As partial consideration under the Alliance Agreement, we also agreed to issue Moffitt an additional

366,884 shares of our common stock in the aggregate upon the satisfaction of certain clinical and regulatory milestones with respect to TIL Products. During the three months ended March 31, 2023, an additional 91,721 shares of our common stock were issued to Moffitt as a result of the achievement of the milestone related to the start of the Phase 1 clinical trial for a TIL Product. In addition, upon achievement of certain thresholds for aggregate net sales of all TIL Products, we are required to make tiered sales-based milestones payments to Moffitt of up to an aggregate of $50.0 million. With respect to each of the equity and sales milestones described above, TIL Products include any pharmaceutical, biopharmaceutical or biotechnology TIL product that is developed by us or Moffitt and is advanced into clinical development under an IND sponsored by Moffitt.

Components of Our Results of Operations

Revenue

Collaboration Revenue

We enter into collaboration arrangements that may include the receipt of payments for up-front fees, success-based milestones, option exercises, intellectual property rights, research services, product supplies, and royalties on any future sales of commercialized products that result from the collaborations.

AbbVie Biotechnology Ltd.

In September 2017, we entered into a research, option, and license agreement, or the AbbVie Agreement, with AbbVie Biotechnology Ltd., or AbbVie, for the development of up to three pharmaceutical product candidates, based on our engineered MG1 Maraba virus. In April 2021, AbbVie provided us written notice to terminate the AbbVie Agreement, in accordance with its termination for convenience rights. AbbVie did not provide a reason for termination of the AbbVie Agreement and, to our knowledge, AbbVie has not publicly disclosed the reasons for such termination. The AbbVie Agreement terminated in June 2021. One of the product candidates would carry the tumor-associated antigen MAGEA3, and the other two product candidates would carry a tumor-associated antigen selected by AbbVie, a tumor-associated immune agent selected by us or AbbVie, or both an antigen and immune agent. We were primarily responsible for funding the initial research and development activities for each product candidate, which consisted of the completion of two Phase 1/2 clinical trials for MG1-MAGEA3 and the research and preclinical development of the other two product candidates. Pursuant to the AbbVie Agreement, AbbVie paid us a nonrefundable up-front payment of $90.0 million.

The AbbVie Agreement accounted for 0% and 69% of our total collaboration revenue for the years ended December 31, 2022 and 2021, respectively.

The AbbVie Agreement accounted for 0% of our total collaboration revenue for the three months ended March 31, 2023 and March 31, 2022. We will not receive any additional collaboration revenue under the AbbVie Agreement in the future because this agreement has been terminated.

Takeda Pharmaceutical Company Limited

In November 2019, we entered into a discovery, collaboration and license agreement, or the Takeda Agreement, with Millennium Pharmaceuticals, Inc. (also known as Takeda Oncology), a wholly-owned subsidiary of Takeda Pharmaceutical Company Limited, or Takeda. Under the Takeda Agreement, Takeda paid us an upfront payment of $50.0 million and an additional upfront payment of $30.0 million for the option to license up to two selected discovery candidates, with additional consideration in the low to low-mid eight figures to be paid to us by Takeda for each exercise of such option.

The Takeda Agreement accounted for 100% and 31% of our total collaboration revenue for the years ended December 31, 2022 and 2021, respectively.

The Takeda Agreement accounted for 100% of our total collaboration revenue for the three months ended March 31, 2023 and March 31, 2022.

On June 13, 2022, Takeda provided us with six months' written notice to terminate the development program in accordance with its termination for convenience rights, with such termination being effective as of December 13, 2022. Upon the effective termination date of December 13, 2022, Takeda's co-exclusive license to TBio-6517 terminated and we are no longer obligated to pursue development of TBio-6517. On January 6, 2023, Takeda provided us with six months' written notice to terminate the remainder of the Takeda Agreement, in accordance with its termination for convenience rights, with such termination being effective as of July 6, 2023. Takeda has publicly stated that it terminated the Takeda Agreement for strategic reasons. As of March 31, 2023, we ceased all work under the Takeda Agreement and we have concluded that there are no remaining estimated services associated with the obligations under the Takeda Agreement as of the effective date of termination of the Takeda Agreement in its entirety. We will not receive any additional collaboration revenue under the Takeda Agreement in the future because this agreement has been terminated.

In determining the appropriate amount of revenue to be recognized as we fulfilled our obligations under our agreements, we performed the following steps: (1) identification of the promised goods or services in the contract; (2) determination of whether the promised goods or services are performance obligations, including whether they are distinct in the context of the contract; (3) measurement of the transaction price, including the constraint on variable consideration; (4) allocation of the transaction price to the performance obligations based on estimated selling prices; and (5) determining the pattern of recognition of revenue when we satisfy each performance obligation.

Pursuant to the Takeda Letter Agreement, Takeda has agreed to submit a non-binding indication of interest to participate in this offering by purchasing at the public offering price per share the number of shares of our common stock with an aggregate value of $8.0 million or such lesser amount as determined by us in our sole discretion, or the Takeda IPO Shares. Under the Takeda Agreement, Takeda's original equity commitment of up to $20.0 million was partially fulfilled by Takeda's purchase in June 2021 of 1,830,335 shares of our Series D preferred stock at a purchase price of $2.73174 per share for aggregate gross proceeds of approximately $5.0 million, and all of Takeda's remaining obligations under the Takeda Agreement expired upon the termination of the Takeda Agreement on July 6, 2023. If Takeda decides to participate in this offering pursuant to the Takeda Letter Agreement, then they must purchase our common stock in this offering at the public offering price, subject to compliance with applicable securities laws. If Takeda does not participate in this offering, the underwriters determine it is not advisable for Takeda to participate in this offering, or Takeda's participation in this offering is prohibited under U.S. federal securities laws or any other applicable laws, then, Takeda is obligated to purchase at the public offering price per share an aggregate number of shares of our common stock equal to the number of Takeda IPO Shares in a private placement contemporaneous with and conditioned on this offering. Takeda's agreement to participate in this offering or a concurrent private placement will expire on July 31, 2023.

In addition, if Takeda does not submit an indication of interest to participate in this offering, unless we determine otherwise, in our sole discretion, then we shall sell and Takeda shall purchase in a private placement effected substantially concurrent with this public offering such number of our common shares equal to the number of Takeda IPO Shares at the public offering price. The closing of this public offering is a condition precedent to the closing of the private placement.

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of external and internal costs incurred for our research and development activities, including adjusted development of our platform, our product discovery efforts and the development of our future product candidates. We expense research and development costs as incurred.

External costs include:

- clinical trial expenses, including costs of third-party CROs and costs of performing toxicity studies;
- expenses to acquire technologies to be used in research and development;
- manufacturing scale-up expenses and the cost of acquiring and manufacturing preclinical and clinical materials and developing manufacturing processes; and
- costs related to compliance with regulatory requirements.

Internal costs include:

- employee-related expenses, which include salaries, benefits and stock-based compensation for employees engaged in research and development functions; and
- facility-related and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities, depreciation and amortization expense and expenses related to other general support services and supplies.

Costs for external development activities are recognized based on an evaluation of the progress to completion of specific tasks using information provided to us by our vendors and our clinical investigative sites. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and are reflected in our consolidated financial statements as prepaid or accrued research and development expenses. Non-refundable advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses and expensed as the related goods are delivered or the services are performed.

The table below summarizes our research and development expenses incurred by major development program for the periods presented *(in thousands)*:

	Year Ended December 31,		Three Months Ended March 31,	
	2022	2021	2023	2022
RIVAL-01[(1)]	$ 32,078	$ 32,692	$ 644	$ 9,659
TIDAL-01	36,542	14,054	11,045	4,655
TIDAL-02	5,893	—	1,940	740
Other programs	12,190	8,008	2,039	3,647
Total research and development	$ 86,703	$ 54,754	$ 15,668	$ 18,701

(1) We pursued this development program pursuant to the Takeda Agreement. As the Takeda Agreement has been terminated, effective July 6, 2023, there will be no additional research and development expenses associated with this development program.

The successful development of our product candidates is highly uncertain. We plan to substantially increase our research and development expenses for the foreseeable future as we continue our existing clinical trials, initiate future clinical trials for our product candidates, continue to discover and develop additional product candidates, improve the efficiency and scalability of our manufacturing processes and supply chain and build our in-house process development, analytical and manufacturing capabilities. Therefore, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete the development and commercialization of any of our product candidates. We are also unable to predict when, if ever, material net cash inflows will commence from the sale of our current or any future product candidates, if

approved. This is due to the numerous risks and uncertainties associated with developing product candidates, including the uncertainty of:

- the scope, rate of progress and expenses of our planned clinical trials and other research and development activities;
- successful patient enrollment in, and the initiation and completion of, clinical trials, including the impact of patient discontinuations, the number and location of clinical sites, and our ability to manufacture Selected TILs efficiently;
- establishing an appropriate safety profile of our product candidates;
- whether our product candidates show safety and efficacy in our clinical trials;
- receipt of marketing approvals from applicable regulatory authorities;
- making arrangements with third-party manufacturers for the supply of materials to support our planned clinical trials and establishing commercial manufacturing capabilities for the potential manufacture of approved products, if any;
- obtaining, maintaining, protecting and enforcing patent and trade secret protection and regulatory exclusivity for our product candidates;
- commercializing product candidates, if and when approved, whether alone or in collaboration with others; and
- acceptable safety profile of the products following any regulatory approval.

Any changes in the outcome of any of these variables with respect to the development of our product candidates in preclinical and clinical development could mean a significant change in the costs and timing associated with the development of these product candidates. We may never succeed in achieving regulatory approval for any of our product candidates. We may obtain unexpected results from our clinical trials. We may elect to discontinue, delay or modify clinical trials of some product candidates or focus on others. For example, if the FDA or comparable foreign regulatory authority were to delay our planned clinical trials or require us to conduct pre-clinical or clinical trials beyond those that we currently expect or if we experience significant delays in enrollment in any of our planned clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development of that product candidate.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel costs, allocated expenses and other expenses for outside professional services, including legal, intellectual property, human resources, audit and accounting services. Personnel costs consist of salaries, bonuses, benefits and stock-based compensation.

We expect our general and administrative expenses will increase during the next few years to support our continued research and development activities of our product candidates and associated expenses with operating as a public company, including expenses related to compliance with the rules and regulations of the SEC and Nasdaq, insurance expenses, audit expenses, investor relations activities, Sarbanes-Oxley Act compliance expenses, increased costs related to the hiring of additional personnel and fees to outside consultants, lawyers and accountants, among other administrative expenses and professional services.

Other Income (Expense), Net

Other income (expense), net consists primarily of interest income earned on our short-term investments and foreign currency remeasurement gains and losses.

Results of Operations

Comparison of the Three Months Ended March 31, 2023 and 2022

The following tables set forth our results of operations for the three months ended March 31, 2023 and 2022 *(in thousands)*:

	Three Months Ended March 31,		
	2023	2022	Change ($)
Collaboration revenue	$19,306	$ 10,718	$ 8,588
Operating expenses:			
Research and development	15,668	18,701	(3,033)
General and administrative	4,032	4,698	(666)
Total operating expenses	19,700	23,399	(3,699)
Loss from operations	(394)	(12,681)	12,287
Other income (expense), net	380	85	295
Benefit (provision) for income taxes	82	(20)	102
Net income (loss)	$ 68	$(12,616)	$ 12,684

Collaboration Revenue

Collaboration revenue was $19.3 million and $10.7 million during the three months ended March 31, 2023 and 2022, respectively, an increase of $8.6 million, or 80.1%. The change was primarily due to the recognition of deferred revenue as a result of the termination of the Takeda Agreement.

Research and Development Expenses

The following table summarizes our research and development expenses for the three months ended March 31, 2023 and 2022 (*in thousands*):

	Three Months Ended March 31,	
	2023	2022
Pre-clinical	$ 2,988	$ 2,291
Manufacturing	5,697	10,976
Personnel related	4,778	4,615
Clinical and regulatory	2,205	819
Total research and development	$ 15,668	$ 18,701

Research and development expenses were $15.7 million and $18.7 million during the three months ended March 31, 2023 and 2022, respectively, a decrease of $3.0 million, or 16.2%. The decrease was due primarily to a decrease of $5.3 million in manufacturing expenses offset by increases of $0.7 million in preclinical research and development costs, $0.2 million in personnel-related costs, and $1.4 million in clinical and regulatory costs. Due to the termination of the Takeda Agreement and research and development activities

thereunder, we expect research and development expenses to continue to decline in the near term; however, we expect our research and development expenses to increase in the long term as we advance the development of our product candidates.

General and Administrative Expenses

General and administrative expenses were $4.0 million and $4.7 million during the three months ended March 31, 2023 and 2022, respectively, a decrease of $0.7 million, or 14.2%. The decrease was due primarily to a decrease of $1.6 million in professional services due to hiring finance staff and less expenses incurred on intellectual property due to the termination of activities under the Takeda Agreement offset by increases of $0.4 million in facility, office and other operating costs due to the new San Diego office lease and $0.5 million in personnel-related costs due to increased finance headcount. We anticipate that general and administrative expenses will continue to increase in the future due to an increase in expenses related to activities associated with operating as a public company.

Other Income (Expense), Net

Other income (expense), net was $0.4 million and $0.1 million during the three months ended March 31, 2023 and 2022, respectively, an increase of $0.3 million, or 300%. The increase was primarily related to an increase in interest income, net of $0.3 million.

Comparison of the Year Ended December 31, 2022 and 2021

The following tables set forth our results of operations during the years ended December 31, 2022 and 2021 *(in thousands)*:

	For the Year Ended December 31,		
	2022	2021	Change ($)
Collaboration revenue	$ 73,300	$101,293	$ (27,993)
Operating expenses:			
Research and development	86,703	54,754	31,949
General and administrative	18,223	13,546	4,677
Total operating expenses	104,926	68,300	36,626
Income (loss) from operations	(31,626)	32,993	(64,619)
Other income (expense), net	933	708	225
Provision for income taxes	(141)	(432)	(291)
Net income (loss)	$ (30,834)	$ 33,269	$ (64,103)

Collaboration Revenue

Collaboration revenue was $73.3 million and $101.3 million during the years ended December 31, 2022 and 2021, respectively, a decrease of $28.0 million, or 27.6%. Collaboration revenue of $0.0 million and $73.3 million, and $69.8 million and $31.5 million, was recorded during the years ended December 31, 2022 and 2021, respectively, for each of the AbbVie Agreement and Takeda Agreement, respectively. The change was primarily due to the recognition of deferred revenue as a result of the terminations of the AbbVie Agreement in 2021 and the Takeda Agreement in 2022.

Research and Development Expenses

The following table summarizes our research and development expenses during the years ended December 31, 2022 and 2021 *(in thousands)*:

	Year Ended December 31,	
	2022	2021
Pre-clinical research and development	$19,530	$ 8,269
Manufacturing	42,221	27,981
Personnel related	18,431	13,735
Clinical and regulatory	6,521	4,769
Total research and development	$86,703	$54,754

Research and development expenses were $86.7 million and $54.8 million during the years ended December 31, 2022 and 2021, respectively, an increase of $31.9 million, or 58.4%. The increase was due primarily to an increase of $11.3 million in preclinical research and development costs, an increase of $14.2 million in manufacturing expenses, an increase of $4.7 million in personnel-related costs, and an increase of $1.8 million in clinical and regulatory expenses. Based on stopping research and development activities on our RIVAL-01 program under the Takeda Agreement, we expect research and development expenses to decline in the near term; however, we expect our research and development expenses to increase in the long term as we advance the development of TIDAL-01.

General and Administrative Expenses

General and administrative expenses were $18.2 million and $13.5 million during the years ended December 31, 2022 and 2021, respectively, an increase of $4.7 million, or 34.5%. The increase was due primarily to increases of $0.7 million in professional service fees, $2.4 million in facility, office and other operating costs due to the new San Diego office lease and $1.6 million in personnel-related costs due to an increased headcount and stock-based compensation costs. We anticipate that general and administrative expenses will continue to increase in the future due to an increase in expenses related to activities associated with operating as a public company.

Other Income (Expense), Net

Other income (expense), net was $0.9 million and $0.7 million during the years ended December 31, 2022 and 2021, respectively, an increase of $0.2 million, or 31.8%. The increase was primarily related to an increase in interest income, net of $0.6 million, a gain on sale of assets in 2022 of $0.4 million and a decrease of $0.4 million in realized foreign exchange gains.

Liquidity and Capital Resources

Based on our expected operating losses and negative cash flows, we believe there is substantial doubt about our ability to continue as a going concern for 12 months after the date the unaudited interim consolidated financial statements for the three months ended March 31, 2023 included elsewhere in this prospectus were issued. If we cannot continue as a going concern, our stockholders may lose some or all of their investment in us. Our ability to continue as a going concern is dependent upon our ability to raise additional funding. We intend to raise additional capital through equity offerings, debt financings or other capital sources, including potential collaborations, licenses and other similar arrangements. However, we may not be able to secure additional financing in a timely manner or on favorable terms, if at all. Furthermore, if we issue equity securities to raise additional funds, our existing stockholders may experience dilution, and the new equity securities may have rights, preferences and privileges senior to those of our existing stockholders. If we raise additional funds

through collaboration, licensing or other similar arrangements, we may need to relinquish valuable rights to our potential products on terms that are not favorable to use. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may need to significantly delay, scale back or discontinue the development or future commercialization of one or more of our product candidates, if approved, or one or more of our other research and development initiatives and we may need to undertake additional workforce reductions or restructuring activities in the future. Any of the above events could adversely affect our business, results of operations and financial condition and cause the price of our common stock to decline.

Sources of Liquidity

In December 2018, we completed a corporate reorganization pursuant to which Turnstone Biologics Inc. merged with and into Turnstone Biologics Corp., a newly formed Delaware corporation, as the successor company. As a result of this reorganization, we changed our domicile from the country of Canada to the State of Delaware. Our headquarters are located in San Diego, California and we operate as one segment. Since our inception, we have devoted substantially all of our efforts and financial resources to organizing and staffing our company, business planning, raising capital, discovering product candidates and securing related intellectual property rights and conducting research and development activities for our Selected TIL programs and product candidates. We do not have any products approved for sale, we have not generated any revenue from product sales, and we have incurred overall net losses since our inception through March 31, 2023. We did not incur net losses for the year ended December 31, 2021 and for the three months ended March 31, 2023 as a result of collaboration revenue from the AbbVie Agreement and Takeda Agreement. We have funded our operations primarily through the sale of our convertible preferred stock and revenue from certain of our collaboration agreements. Since our inception, we have raised an aggregate of approximately $172.0 million of gross proceeds from the issuance and sale of shares of our convertible preferred stock and $190.0 million in upfront, non-refundable collaboration revenue. As of December 31, 2022 and March 31, 2023, we had cash, cash equivalents and short-term investments of $82.1 million and $64.0 million, respectively.

We have incurred significant operating losses in the past and expect to continue to incur significant operating losses for the foreseeable future. Our net loss was $30.8 million for the year ended December 31, 2022 and we had $33.3 million of net income for the year ended December 31, 2021. Our net income was $0.1 million and net loss was $12.6 million for the three months ended March 31, 2023 and 2022, respectively. As of December 31, 2022 and March 31, 2023, we had an accumulated deficit of $121.6 million and $121.5 million, respectively. Substantially all of our operating losses result from expenses incurred in our research and development programs and from general and administrative costs associated with our operations. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our current or future product candidates, and on our ability to enter into collaborations, strategic partnerships and alliances or marketing, distribution or licensing arrangements with third parties.

We expect that the net proceeds from this offering, together with our existing cash, cash equivalents and short-term investments, will enable us to fund our operating expenses and capital expenditure requirements into the second quarter of 2025. We have based this estimate on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect.

Funding Requirements

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we continue to advance our product candidates and programs through preclinical and clinical development. Furthermore, upon the completion of this offering, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs which could materially harm our business.

Our future capital requirements will depend on many factors, including:

- the costs of conducting clinical trials, including the clinical development of our TIDAL-01 product candidate;
- the progress of preclinical development and clinical trials of our current earlier-stage and future product candidates;
- the costs of manufacturing;
- the scope, progress, results and costs of discovery, preclinical development, laboratory testing and clinical trials for other potential product candidates we may develop, if any;
- the costs, timing and outcome of regulatory review of our product candidates;
- our ability to establish and maintain collaborations and partnerships on favorable terms, if at all;
- the achievement of milestones or occurrence of other developments that trigger payments under any collaboration agreements we might have at such time;
- the costs of preparing, filing and prosecuting patent applications, obtaining, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the cost of operating as a public company;
- the costs and timing of future commercialization activities, if any, including product sales, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- our ability to achieve sufficient market acceptance, adequate coverage and reimbursement from third-party payors and adequate market share; and
- the amount of revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval.

Identifying potential product candidates and conducting preclinical testing 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 and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.

As of December 31, 2022 and March 31, 2023, we had cash, cash equivalents and short-term investments of $82.1 million and $64.0 million, respectively. We believe that the anticipated net proceeds from this offering, together with our existing cash, cash equivalents and short-term investments, will enable us to fund our operating expenses and capital expenditure requirements into the second quarter of 2025. 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. We anticipate that we will require additional capital as we seek regulatory approval of our product candidates and if we choose to pursue in-licenses or acquisitions of other product candidates. If we need to raise additional capital to fund our operations, funding may not be available to us on acceptable terms, or at all. If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of, or suspend one

or more of our preclinical studies, clinical trials, research and development programs, or commercialization efforts. If we receive regulatory approval for our current or future product candidates, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution, depending on where we choose to commercialize.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interests may be diluted, and the terms of these securities may include liquidation or other preferences that could adversely affect your rights as a common stockholder. Debt financing, if available, may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, that could adversely impact our ability to conduct our business.

If we raise funds through collaborations, strategic alliances 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 to grant licenses on terms that may not be favorable to us. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may need to significantly delay, scale back or discontinue the development or future commercialization of one or more of our product candidates, if approved, or one or more of our other research and development initiatives and we may need to undertake additional workforce reductions or restructuring activities in the future. Any of the above events could adversely affect our business, results of operations and financial condition and cause the price of our common stock to decline.

Cash Flows

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

	Year Ended December 31,		Three Months Ended March 31,	
	2022	2021	2023	2022
Cash used in operating activities	$(71,062)	$(45,629)	(17,170)	$(16,455)
Cash provided by (used in) investing activities	(14,932)	(3,348)	16,500	(718)
Cash provided by (used in) financing activities	(2,656)	79,954	(815)	10
Net increase (decrease) in cash, cash equivalents and restricted cash	$(88,650)	$ 30,977	$ (1,485)	$(17,163)

Cash Flows from Operating Activities

Cash used in operating activities for the three months ended March 31, 2023 was $17.2 million, primarily due to the decrease in our net operating assets and liabilities of $19.3 million, which included changes in deferred revenue of $19.3 million, accretion of the premium on short-term investments of $0.3 million and partially offset by changes in stock-based compensation of $1.0 million, depreciation and amortization expense of $0.7 million, change in the fair value of contingent consideration liabilities of $0.6 million and net income of $0.1 million.

Cash used in operating activities for the three months ended March 31, 2022 was $16.5 million, primarily due to our net loss of $12.6 million and change in our net operating assets and liabilities of $6.0 million which were partially offset by changes in stock-based compensation of $1.0 million, depreciation and amortization expense of $0.7 million, and change in the fair value of contingent consideration liabilities of $0.4 million.

Cash used in operating activities for the year ended December 31, 2022 was $71.1 million, primarily due to our net loss of $30.8 million and decrease in our net operating assets and liabilities of $58.0 million, which

included changes in deferred revenue of $53.1 million, partially offset by changes in stock-based compensation and Moffitt performance awards of $6.4 million, depreciation and amortization expense of $3.9 million and change in the fair value of contingent consideration liabilities of $7.0 million.

Cash used in operating activities for the year ended December 31, 2021 was $45.6 million, primarily due to the decrease in our net operating assets and liabilities of $85.8 million which was partially offset by our net income of $33.3 million, stock-based compensation of $2.6 million, change in fair value of contingent consideration liability of $1.7 million and depreciation and amortization expense of $1.4 million.

Cash Flows from Investing Activities

Cash provided by investing activities for the three months ended March 31, 2023 was $16.5 million, due primarily to the maturities of $17.3 million of short-term investments, $0.1 million of proceeds from the sale of property and equipment, and $0.9 million in purchases of property and equipment.

Cash used in investing activities for the three months ended March 31, 2022 was $0.7 million, due primarily to the purchase of short-term investments of $13.1 million and $0.6 million in purchases of property and equipment offset by the maturities of short-term investments of $13.0 million.

Cash used in investing activities for the year ended December 31, 2022 was $14.9 million, due primarily to the maturities of $49.8 million of short-term investments, the purchase of short-term investments of $59.5 million, and $5.2 million in purchases of property and equipment.

Cash used in investing activities for the year ended December 31, 2021 was $3.3 million, due primarily to the maturities of $41.4 million of short-term investments, the purchase of short-term investments of $41.4 million, and $3.4 million in purchases of property and equipment.

Cash Flows from Financing Activities

Net cash used in financing activities for the three months ended March 31, 2023 was $0.8 million, due primarily to the $0.9 million cash payment of contingent consideration related to Myst's achievement of the second milestone under the Myst Merger Agreement due to the acceptance by the FDA of an IND filed by, on behalf of or for the benefit of us.

Net cash provided by financing activities for the three months ended March 31, 2022 was $0.0 million.

Net cash used in financing activities for the year ended December 31, 2022 was $2.7 million, due primarily to the $0.2 million received from the exercise of stock options and $2.8 million payment of contingent consideration related to Myst's achievement of the second milestone under the Myst Merger Agreement due to the acceptance by the FDA of an IND filed by, on behalf of or for the benefit of us.

Net cash provided by financing activities for the year ended December 31, 2021 was $80.0 million, due primarily to the $79.6 million net proceeds from the sale and issuance of Series D preferred stock and the $0.3 million received from the exercise of stock options.

Contractual Obligations and Commitments

We enter into contracts in the normal course of business with CROs and CMOs for clinical trials, preclinical research studies and testing, manufacturing and other services and products for operating purposes. These contracts provide for termination at the request of either party with less than one year notice, and therefore we believe that our non-cancelable obligations under these agreements are not material. We additionally have contractual obligations for our operating leases for our corporate headquarters and office and laboratory spaces.

These obligations are further described in Note 11 to our consolidated financial statements and Note 11 to our unaudited interim consolidated financial statements, each included elsewhere in this prospectus. We are also party to certain collaboration and license agreements, which contain a number of contractual obligations. Those contractual obligations may entitle us to receive, or may obligate us to make, certain payments. The amount and timing of those payments are unknown or uncertain as we are unable to estimate the timing or likelihood of the events that will obligate those payments.

We have milestones, royalties, and/or other payments due to third parties under our existing license and collaboration agreements. See the section titled "Business—Collaboration Agreements" and Note 6 to our audited consolidated financial statements and Note 6 to our unaudited interim consolidated financial statements, each included elsewhere in this prospectus. We could not estimate when such payments will be due and none of these events were probable to occur as of December 31, 2022 and March 31, 2023, respectively.

Critical Accounting Polices and Estimates

The preparation of our financial statements and related disclosures in conformity with generally accepted accounting principles in the United States and our discussion and analysis of our financial condition and operating results require us to make judgments, assumptions and estimates that affect the amounts reported in our consolidated financial statements and accompanying notes. Our significant accounting policies and methods used in preparation of our consolidated financial statements are described in Note 2 to our audited consolidated financial statements and Note 2 to our unaudited interim consolidated financial statements, each included elsewhere in this prospectus. We base our estimates on historical experience and on various other assumptions we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates, and such differences may be material.

We believe that the critical accounting policies and estimates discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving our judgments and estimates.

Revenue Recognition

We entered into collaboration arrangements that may include the receipt of payments for up-front license fees, success-based milestone payments, full time equivalent based payments for research services, and royalties on any future sales of commercialized products that result from the collaborations.

Effective January 1, 2017, we adopted the provisions of ASC Topic 606, *Revenue from Contacts with Customers*, or ASC 606. Under ASC 606, an entity recognizes revenue when our customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects 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 contract(s) with the customer, (ii) identification of the promised goods or services in the contract and determination of whether the promised goods or services are performance obligations, (iii) measurement of the transaction price, (iv) allocation of the transaction price to the performance obligations, and (v) recognition of revenue when (or as) we satisfy each performance obligation. We only apply the five-step model to contracts when it is probable that the entity will collect consideration it is entitled to in exchange for the goods or services it transfers to the customer.

We account for a contract with a customer that is within the scope of ASC 606 when all of the following criteria are met: (i) the arrangement has been approved by the parties and the parties are committed to perform their respective obligations, (ii) each party's rights regarding the goods or services to be transferred can be identified, (iii) the payment terms for the goods and services to be transferred can be identified, (iv) the

arrangement has commercial substance and (v) collection of substantially all of the consideration to which we will be entitled in exchange for the goods or services that will be transferred to the customer is probable.

We estimate the transaction price based on the amount of consideration that we expect for transferring the promised goods or services in the contract. The consideration may include both fixed consideration and variable consideration. At the inception of each arrangement that includes variable consideration, we evaluate the amount of the potential payments and the likelihood that the payments will be received. We utilize either the most likely amount method or expected value method to estimate the transaction price based on which method better predicts the amount of consideration expected to be received. If it is probable that a significant revenue reversal would not occur, the variable consideration is included in the transaction price.

For arrangements that include development and regulatory milestone payments, we evaluate 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 revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within our control or the licensee's control, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. At the end of each reporting period, we re-evaluate the probability of achievement of such milestones and any related constraint, and if necessary, adjusts the estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect collaboration revenue and net income (loss) in the period of adjustment.

For sales-based royalties, including milestone payments based on the level of sales, we determine whether the sole or predominant item to which the royalties relate is a license. When the license is the sole or predominant item to which the sales-based royalty relates, we recognize revenue at the later of: (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

We allocate the transaction price based on the estimated standalone selling price. We must develop assumptions that require judgment to determine the standalone selling price for each performance obligation identified in the contract. We utilize key assumptions to determine the standalone selling price, which may include other comparable transactions, pricing considered in negotiating the transaction and the estimated costs. Certain variable consideration is allocated specifically to one or more performance obligations in a contract when the terms of the variable consideration related to the satisfaction of the performance obligation and the resulting amounts allocated to each performance obligation are consistent with the amounts we would expect to receive for each performance obligation.

For performance obligations, which consist of licenses and other promises, we utilize judgment to assess the nature of the combined performance obligation in order to determine whether the combined performance obligation is satisfied over time or at a point in time. We determine the appropriate method of measuring progress of combined performance obligations satisfied over time for purposes of recognizing revenue determined on a contract by contract basis. We evaluate the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition. If the license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we will recognize revenue from non-refundable, up-front fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license.

We receive payments from customers based on billing schedules established in each contract. Up-front payments and fees are recorded as deferred revenue upon receipt or when due until we perform our obligations under these arrangements. Amounts are recorded as accounts receivable when our right to consideration is unconditional.

Stock-Based Compensation

We measure the cost of employee, nonemployee and director services received in exchange for an award of equity instruments based on the fair value of the award on the date of grant and recognizes the related expense over the period during which the employee, nonemployee or director is required to provide service in exchange for the award on a straight-line basis.

We estimate the fair value of each award on the date of grant using the Black-Scholes option -pricing model. This model requires the use of highly subject assumptions to determine the fair value of each stock-based award, including:

- *Fair value of common stock*. See the subsection titled "—Determination of the Fair Value of Common Stock" below.
- *Expected term*. The expected term represents the period that the stock-based awards are expected to be outstanding. The expected term for our stock options was calculated based on the weighted-average vesting term of the awards and the contract period, or simplified method.
- *Expected volatility*. Since we are not yet a public company and do not have any trading history for our common stock, the expected volatility was estimated based on the average historical volatilities of common stock of comparable publicly traded entities over a period equal to the expected term of the stock option grants. The comparable companies were chosen based on their size, stage of their life cycle or area of specialty. We will continue to apply this process until enough historical information regarding the volatility of our stock price becomes available.
- *Risk-free interest rate*. The risk-free interest rate is based on a treasury instrument whose term is consistent with the expected term of the stock options.
- *Expected dividend yield*. We have never paid dividends on our common stock and have no plans to pay dividends on our common stock. Therefore, we used an expected dividend yield of zero.

The Black-Scholes option pricing model requires inputs based on certain subjective assumptions, including (a) the expected stock price volatility, (b) the expected term of the award, (c) the risk-free interest rate and (d) expected dividends. Due to the lack of a public market for our common stock and lack of company- specific historical and implied volatility data, we have based our computation of expected volatility on the historical volatility of a representative group of public companies with similar characteristics to us, including stage of product development and life science industry focus. The historical volatility is calculated based on a period of time commensurate with the expected term. We use the simplified method as prescribed by the SEC Staff Accounting Bulletin No. 107, *Share-Based Payment*, to calculate the expected term for options granted to our employees as it does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. The expected term is applied to the stock option grant group as a whole, as we do not expect substantially different exercise or post-vesting termination behavior among our employee population. The risk-free interest rate is based on a treasury instrument whose term is consistent with the expected term of the stock options. The expected dividend yield is assumed to be zero as we have never paid dividends and has no current plans to pay any dividends on our common stock.

See Note 2 to our audited consolidated financial statements and Note 2 to our unaudited interim consolidated financial statements, each included elsewhere in this prospectus, for information concerning certain of the specific assumptions we used in applying the Black-Scholes option pricing model to determine the estimated fair value of our stock options granted in the periods presented.

As of December 31, 2022 and March 31, 2023, there was $8.9 million and $7.7 million of total unrecognized stock-based compensation expense related to our granted options, which we expect to recognize over a remaining weighted-average period of 2.7 years and 2.5 years, respectively.

The intrinsic value of all outstanding stock options as of March 31, 2023 was approximately $7.8 million, based on the initial public offering price of $12.00 per share, of which approximately $4.6 million related to vested stock options, and approximately $3.2 million related to unvested stock options.

Determination of the Fair Value of Common Stock

There are significant judgments and estimates inherent in the determination of the fair value of our common stock. These estimates and assumptions include a number of objective and subjective factors, including external market conditions, the prices at which we sold shares of our convertible preferred stock, the superior rights and preferences of securities senior to our common stock at the time of, and the likelihood of, achieving a liquidity event, such as an initial public offering or sale of the company.

As there has been no public market for our common stock prior to this offering, the estimated fair value of our common stock underlying our stock-based awards has been determined by our board of directors as of each option grant date 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*, or the Practice Aid. In valuing our common stock, the equity value of the business was determined using the backsolve method, a form of the subject company transaction method, wherein the equity value for a privately held company is derived from a recent transaction in our securities. The value is then allocated using the hybrid method allocation methodology. For grants made prior to September 30, 2018, in accordance with the Practice Aid, we determined the option pricing method, or OPM, was the most appropriate method for determining the fair value of our common stock based on our stage of development and other relevant factors. For grants made subsequent to September 30, 2018, in accordance with Practice Aid, we used a hybrid method, which is a hybrid between the OPM and the probability-weighted expected return method, or PWERM. The hybrid method is a combination of the PWERM and OPM. The OPM allocates the overall company value to the various share classes based on differences in liquidation preferences, participation rights, dividend policy and conversion rights, using a series of call options. The call right is valued using a Black-Scholes option pricing model. The PWERM employs additional information not used in the OPM, including various market approach calculations depending upon the likelihood of various discrete future liquidity scenarios, such as an initial public offering or sale of the company, as well as the probability of remaining a private company. In a hybrid method, various exit scenarios are analyzed. A discount for lack of marketability of our common stock is then applied to arrive at an indication of value for the common stock.

In addition to considering the results of these third-party valuations, we considered various objective and subjective factors to determine the fair value of our common stock as of each grant date, which may be a date later than the most recent third-party valuation date, including:

- the prices of our convertible preferred stock sold to outside investors in arm's length transactions, and the rights, preferences and privileges of our convertible preferred stock as compared to those of our common stock, including the liquidation and redemption preferences of our convertible preferred stock;
- the progress of our research and development efforts, including the status of preclinical studies and ongoing and planned clinical trials for our product candidates and progress of our development and manufacturing processes;
- our stage of development and our business strategy, and material risks related to our business;
- the hiring of key personnel and management;

- external market conditions affecting the biotechnology industry, and trends within the biotechnology industry;
- our financial position, including cash on hand, and our historical and forecasted performance and results of operations;
- the lack of an active public market for our common stock and our convertible preferred stock;
- the likelihood of achieving a liquidity event for the holders of our common stock, such as an initial public offering, or a sale of our company, given prevailing market conditions;
- the achievement of enterprise milestones, including entering into collaboration and license agreements;
- the analysis of initial public offerings and the market performance of similar companies in the biotechnology industry; and
- the economy in general.

We also performed a retrospective review of common stock fair value when preparing for our financial statements audits and considered the amount of time between the independent third-party valuation dates and the grant dates. We performed an interpolation of the fair value between the two valuation dates if we concluded that a significant change in valuation had occurred between the previous valuation and the grant date due to significant business or market events. The incremental stock-based compensation expense recorded as a result of the retrospective review was insignificant.

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 used significantly different estimates and assumptions, our stock-based compensation expense could be materially different.

Following the completion of this offering, the fair value of our common stock will be determined based on the quoted market price of our common stock. In connection with this offering, all outstanding shares of our convertible preferred stock will be converted into shares of our common stock.

Contingent Consideration

Consideration paid related to the Myst Merger Agreement may include potential future payments that are contingent upon our achieving certain milestones in the future. Contingent consideration liabilities are measured at their estimated fair value as of the date of the consolidated balance sheets using a probability-based income approach based on the monetary value of the milestone payment discounted for the likelihood of achieving the milestone and a present value factor based on the timing of when the milestone is expected to be achieved.

Contingent consideration liabilities expected to be settled within 12 months after the balance sheet date are presented in current liabilities, with the non-current portion recorded under other liabilities, noncurrent in the consolidated balance sheets, each included elsewhere in this prospectus. Changes in the fair value of the contingent consideration are recorded as research and development expenses in the consolidated statement of operations, each included elsewhere in this prospectus.

Accounting Pronouncements Recently Adopted

See Note 2 to our audited consolidated financial statements and Note 2 to our unaudited interim consolidated financial statements, each included elsewhere in this prospectus, for a description of recent accounting pronouncements applicable to our financial statements.

Quantitative and Qualitative Disclosures about Market Risk

Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and interest rates. We are exposed to market risks in the ordinary course of our business. We currently have no outstanding debt or related interest rate risk. Our primary exposure to market risk is related to changes in foreign currency exchange rates, mainly relating to Turnstone Canada. In addition, we contract with certain vendors that are located in Europe and Australia, and the payments under such contracts are denominated in foreign currencies. We are subject to fluctuations in foreign currency rates in connection with these agreements. We do not currently hedge our foreign currency exchange rate risk. As of December 31, 2022 and March 31, 2023, our liabilities denominated in foreign currencies were not material. Accordingly, we do not believe a 10% increase or decrease in current exchange rates would have a material effect on our financial results.

Emerging Growth Company and Smaller Reporting Company Status

The JOBS Act permits an "emerging growth company" such as us to take advantage of reduced reporting requirements that are otherwise applicable to public companies and also 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 to not "opt out" of this provision and, as a result, we will adopt new or revised accounting standards at the time private companies adopt the new or revised accounting 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 will remain an emerging growth company until the earliest of (i) the last day of the fiscal year following the fifth anniversary of the completion of this offering, (ii) the last day of the fiscal year in which we have total annual gross revenues of $1.235 billion or more, (iii) the date on which we have issued more than $1.0 billion in non-convertible debt during the previous rolling three-year period or (iv) the date on which we are deemed to be a large accelerated filer under the Exchange Act.

We are also a "smaller reporting company" as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our ordinary shares held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and our ordinary shares held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

BUSINESS

We are a clinical stage biotechnology company focused on developing new medicines to treat and cure patients with solid tumors. Approved immunotherapies represent a significant advancement in the treatment of solid tumors, but many patients either do not respond or experience relapsed disease following an initial response. We believe the most significant challenge to creating curative immunotherapies in these patients is the low numbers of T cells that can recognize and attack the tumor, which we refer to as tumor-reactive T cells. To address this problem, we are pioneering a differentiated approach to tumor infiltrating lymphocytes, or TILs. We are developing next generation TIL therapies by selecting the most potent (meaning able to mediate an anti-tumor response) and tumor-reactive T cells, which we refer to as Selected TILs. Unlike other approaches that rely on standard "bulk TILs" that have demonstrated objective responses in clinical trials only in limited tumor types, we are developing our Selected TILs for potential treatment across the majority of solid tumors. We have initiated two Phase 1 clinical trials for TIDAL-01, including a multi-site trial for the treatment of breast cancer, colorectal cancer, and uveal melanoma, and an investigator sponsored trial with H. Lee Moffitt Cancer Center and Research Institute, Inc., or Moffitt, in both cutaneous and non-cutaneous melanomas. We discuss the nature of this investigator-sponsored trial, including how this trial differs from a clinical trial sponsored by our company, as well as our roles and responsibilities in the trial, in more detail below. We intend to provide an initial clinical update across these two trials in mid-2024. We are also actively advancing our preclinical pipeline programs including TIDAL-02, our next Selected TIL program, and our TIDAL-01 and viral immunotherapy combination program. We define objective response as a patient experiencing a partial response or complete response to any given therapy.

Solid tumors present a major burden to society, with high mortality and poor outcomes associated with more advanced disease. Several key factors, such as tumor heterogeneity (meaning differences in the characteristics, including variable tumor antigen expression, between cancer cells within a patient's tumor, between tumors within the same patient and/or between different patients' tumor(s)) and challenging tumor microenvironments, have made treatment of solid tumors more difficult than treatment of hematologic cancers. Immunotherapies that activate the immune system to enhance and/or create anti-tumor immune responses, such as immune checkpoint inhibitors, or ICIs, have improved outcomes for some patients. However, more than 85% of cancer patients fail to respond to ICI therapy. The effectiveness of ICIs is heavily dependent on the presence of tumor-reactive T cells that ICIs can reinvigorate, and many patients lack a sufficient number of T cells that recognize the target tumor. Therefore, we believe new treatments that can expand and enhance the patient's tumor-reactive T cells are needed.

TILs are a type of cell therapy that harness the patient's own immune cells to target their own tumors. TIL therapy involves the isolation of lymphocytes from the patient's tumor, expansion of the isolated cells outside the body, and then infusion of the cells back into the patient. TILs have the ability to penetrate, recognize, and kill cancer cells and offer potential to treat or cure solid tumors. Because TILs include an expansive breadth of lymphocytes that are specific to the patient's tumor antigens, we believe they have the potential to overcome tumor heterogeneity which often presents a significant challenge for other therapies. Clinical trials with standard "bulk TILs," the first generation of TIL therapy that involves isolation and expansion of all of the TILs in the tumor sample, have shown objective responses in clinical trials in limited solid tumor types.

To date, several hundred patients in the United States have received bulk TIL therapies, with the greatest success observed in metastatic melanoma. In metastatic melanoma patients refractory to ICI therapy, specifically, PD-(L)1 treatments (meaning monoclonal antibodies targeting the immune checkpoint PD-1), bulk TIL monotherapy has yielded objective response rates (meaning the percentage of patients experiencing a partial response or complete response in any given study) of approximately 30% to 50%, with complete response rates (percentage of patients with complete eradication of measurable disease in the patient and no new lesions) ranging from approximately 5% up to 20%. If a complete response lasts the lifespan of a patient it would be considered as a cure – in general clinical practice patients are referred to as "cured" if they remain in complete response for greater than five years as the probability of their disease recurrence is low. Beyond metastatic melanoma, bulk TIL therapy has demonstrated therapeutic potential in a limited number of solid tumors,

including squamous cell carcinoma of the head and neck, cervical cancer, and non-small cell lung cancer. We believe that the activity of TILs is driven by the subset of tumor-reactive T cells, and that the key limitation for bulk TILs is the small number and proportion of tumor-reactive T cells that make up the bulk TIL product (reported median less than 3%, *Lowery et al., 2022*). We believe increasing the proportion and diversity of tumor-reactive T cells in a TIL product can expand the potential utility of TILs, if approved, to a greater breadth of tumor types, where bulk TILs have shown limited to no objective responses in clinical trials to date.

Our Solution: Selected TILs

We are developing next generation TIL therapies for the potential treatment of multiple solid tumors. There are no TIL therapies that have received FDA approval to date. To our knowledge, at present there are no therapies in clinical development that provide curative outcomes for the majority of patients in our chosen solid tumor indications. Our innovative Selected TIL approach focuses on selecting and expanding the most potent tumor-reactive T cells to overcome the limitations of bulk TILs. This approach expands upon work conducted in academia that demonstrated improved clinical responses for certain selected TILs in solid-tumor types where bulk TILs have shown limited to no objective responses in clinical trials to date. We are leveraging this work to establish a standardized manufacturing process for large scale production of our Selected TILs.

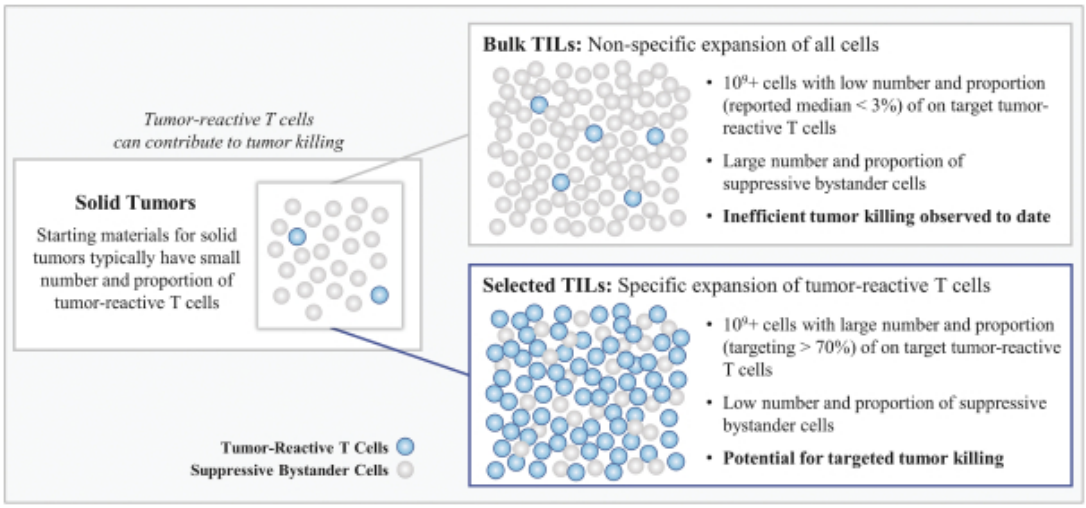
Our Selected TIL approach employs the following foundational principles with the goal of yielding the greatest number and proportion of tumor-reactive T cells in our TIL product candidates:

(1) *Unbiased identification of patient-specific tumor antigens:* We seek to identify the most comprehensive set of patient-specific tumor antigens. We use an unbiased identification process that aims to find and capture the greatest diversity of antigens with the potential to drive the most robust T cell response. Our proprietary approach is unlike other TIL products that are biased toward a specific subset or class of antigen(s), which may miss relevant tumor antigens or focus on the wrong targets.

(2) *Selection of greatest breadth of tumor-reactive T cells from patient extracted TILs:* Our goal is to capture and isolate the greatest number and proportion of a patient's tumor-reactive T cells that have the potential to attack and destroy heterogeneous solid tumors. We aim to select the greatest diversity of T cells by using a function-based screening process that confirms reactivity to the identified patient-specific tumor antigens rather than relying on a bioinformatics-based prediction algorithm that may not be truly predictive.

(3) *Expansion of tumor-reactive T cells and removal of non-tumor-reactive bystander cells:* We expand our selected tumor-reactive TIL population to magnitudes consistent with bulk TIL products and actively remove unnecessary bystander cells. This selective expansion resulted in a substantially higher proportion of tumor-reactive T cells in the final product in comparison to the relatively infrequent tumor-reactive T cells that are routinely found in bulk TIL. Based on our non-clinical studies across multiple tumor samples to date, we have been able to achieve tumor-reactive T cell frequencies in our Selected TIL drug product of up to 62%, with a median frequency of 23%. With ongoing continuous process improvements as part of our manufacturing strategy we are targeting >70% tumor-reactive T cells in our drug product as we advance clinical development.

The potential advantages of Selected TILs over bulk TILs are depicted in the figure below.



The Selected TILs approach described above is inherently designed to select for and characterize the active TIL product—the tumor-reactive T cells. Bulk TIL approaches do not select for the active TIL product and have consequently faced challenges in product characterization and potency assay development. We define potency as the specific ability or capacity of the product, as indicated by appropriate laboratory tests or by adequately controlled clinical data obtained through the administration of the product in the manner intended, to effect a given result. We believe that our Selected TIL approach has the potential to facilitate the development of potency release assays to support regulatory requirements and avoid the characterization challenges of bulk TILs.

Supporting Clinical Evidence

We believe the growing body of prospective and translational clinical data in the TIL field supports the potential of our Selected TIL approach. Third party studies have demonstrated that the anti-tumor activity of bulk TILs is driven by a small subset of tumor-reactive T cells in the bulk TIL product. Furthermore, clinical studies in academic centers utilizing rudimentary selection strategies for tumor-reactive T cells have reported responses including tumor regressions in a single patient bile duct study (*Tran et. al., 2014*) and a single patient colorectal cancer study (*Tran et. al., 2016*), one complete response and two partial responses out of six patients in a breast cancer study (*Zacharachis, et.al 2022*), and two complete responses and one partial response out of seven patients who received a TIL product with confirmed tumor reactivity, in a non-small cell lung cancer study (*Creelan et. al., 2021*). We define partial response as a patient experiencing a reduction in tumor size or volume as defined by the applicable standard, e.g. response evaluation criteria in solid tumors or RECIST, and no new lesions. A partial response does not indicate that a patient is cured of their disease.

Building a Product Pipeline to Further Enhance the Quality and Function of Selected TILs

Our Selected TIL approach sets us apart from others in the industry that are utilizing bulk TILs, including newer bulk TIL approaches that introduce genetic modifications and culture media additives to enhance TIL quality and function. We believe that without the optimal starting population of tumor-reactive T cells, further enhancements or modifications to bulk TILs are unlikely to succeed in extending their potential utility beyond the limited tumor types where bulk TILs have already shown objective responses in clinical trials. We are also expanding our product pipeline by making additional modifications to our proprietary Selected TILs and deploying them in differentiated combination strategies to further enhance TIL quality and function.

Modifications to Enhance TIL Quality

We are developing pipeline programs where we are evaluating enhanced culture conditions during the TIL production process to maintain and further improve TIL quality *ex vivo*. These enhanced culture conditions are designed to incorporate a mix of cytokines with the potential to rejuvenate dysfunctional and/or exhausted T cells.

Additionally, we plan to introduce functional genetic modifications into our pipeline programs that may drive potential for more sustained TIL quality and persistence, or ability of the TILs to survive and proliferate, *in vivo*. These gene edits will be designed to modify the tumor-reactive T cells to proliferate while resisting exhaustion post infusion, minimize their dependence on exogenous IL-2 for *in vivo* proliferation, and maintain their potential to kill tumors in suppressive tumor microenvironments. We are currently evaluating and prioritizing clinically informed targets for these genetic modifications.

Virus Combinations

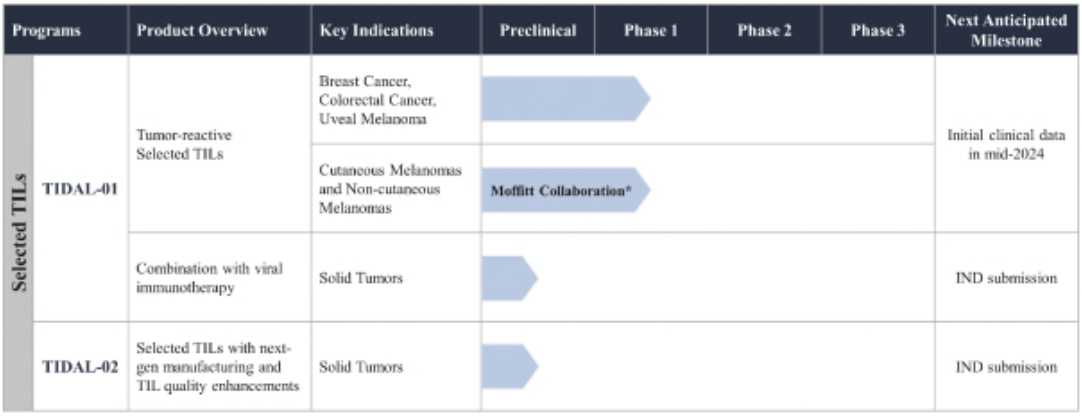
Viral immunotherapy is a therapeutic modality with widespread potential to drive and modulate immune responses to solid tumors. Many viruses have inherent oncolytic activity that can be modulated through genetic engineering. These viruses preferentially infect, replicate within, and kill malignant tumor cells, and can induce broad immune responses. Viral immunotherapies are designed to convert immunologically unresponsive "cold" tumor microenvironments to more reactive "hot" tumor microenvironments and thereby enhance the activity of other immunotherapies.

We are strongly positioned to combine our Selected TIL products with our proprietary viral immunotherapies utilizing two distinct approaches:

- viral immunotherapy pre-treatment (prior to TIL extraction): optimize TIL harvest and broaden access to indications that are currently less amenable to generating effective TIL products; and
- viral immunotherapy post-treatment (following delivery of the TIL product): optimize TIL trafficking and function and further increase the activity of our TIL therapies, if approved.

Our Pipeline

We are applying our Selected TIL approach for the potential treatment of a wide range of solid tumors. We are developing a broad pipeline aimed at improving outcomes for patients, as illustrated in the chart below.



* Investigator sponsored trial at Moffitt Cancer Center

We are advancing TIDAL-01, our lead Selected TIL product candidate, for the treatment of multiple solid tumor indications. TIDAL-01 utilizes an unbiased identification and functional screening process to isolate and selectively expand the greatest breadth of tumor-reactive TILs from the patient's tumor. Our TIDAL-01 production process is designed to deliver at least 10^9 cells and targets greater than 70% functional and potent tumor-reactive T cells. We have initiated two Phase 1 clinical trials for TIDAL-01, including a multi-site trial for the treatment of breast cancer, colorectal cancer, and uveal melanoma, and an investigator sponsored trial with Moffitt in both cutaneous and non-cutaneous melanomas. Under our multi-site trial, we control all aspects of our trial including, but not limited to, study protocol development, patient selection and enrollment, regulatory interactions, data release, and manufacturing through our CDMO. Under the investigator sponsored trial, which is fully funded by us, Moffitt is solely responsible for regulatory interactions, trial conduct and manufacture of TIDAL-01 at the Moffitt Cancer Cell Therapy Facility, with input and support from us at Moffitt's discretion. Investigators at Moffitt are also solely responsible for the design of the trial and patient selection and enrollment, where we remain in close contact with the investigators to provide our input if appropriate. Any data disclosures will be made in collaboration with us and any improvements to the TIDAL-01 manufacturing process are solely at our discretion. We intend to provide an initial clinical update across these two trials in mid-2024.

Our next Selected TIL program, TIDAL-02, is being designed to encompass a next generation streamlined manufacturing process for tumor-reactive T cells and additional modifications to enhance TIL quality and function. We believe that TIDAL-02 has the potential to address the medical need in solid tumor indications that are distinct from and complementary to TIDAL-01. TIDAL-02 is currently in preclinical development.

We intend to evaluate the combination of TIDAL-01 with viral immunotherapy through two approaches: (1) treatment of the patient with viral immunotherapy prior to TIL extraction to optimize TIL harvest and broaden applicability to additional tumor types with low immune cell infiltration and (2) treatment of the patient with viral immunotherapy following treatment with TIDAL-01 to optimize TIL trafficking and infiltration into solid tumors and to support the anti-tumor functions of infiltrating immune cells. We are currently evaluating the optimal viral immunotherapy for combination with TIDAL-01 to advance into clinical development.

Our History and Team

We were founded in 2015 with the goal of developing medicines to treat and cure patients with solid tumors. Our initial scientific and technological focus was built around developing novel oncolytic viral immunotherapies. In late 2020, we acquired an innovative TIL platform and capabilities to expand our portfolio of cancer immunotherapies. Our TIL-based technology now represents the foundational therapeutic modality driving our current pipeline, though we continue to explore the synergistic potential of combining these two technologies in the pursuit of our mission.

We have assembled a team with extensive experience in complex biologics, drug discovery and development, manufacturing, and business and commercial product development.

We are led by our Chief Executive Officer, Sammy Farah, M.B.A, Ph.D., who has 20 years of scientific, business, and executive management experience in the biotechnology industry at Synthetic Genomics, Immune Design, Versant Ventures, and Merck.

Our experienced research and clinical development team brings a strong track record of advancing assets through clinical development and delivering products to the market. Our research organization is led by our Chief Scientific Officer, Stewart Abbot, Ph.D., who brings over 20 years of research and development experience in cell-based and immune-oncology products from Adicet, Fate, Celgene and GE Healthcare. Our clinical development and regulatory organization is led by our interim Chief Medical Officer, Michael Burgess, MBChB, Ph.D., who has more than 20 years of experience building research and development teams and leading strategy and execution of clinical development at SpringWorks Therapeutics, Bristol-Myers Squibb, Roche, and Eli Lilly.

Our chemistry, manufacturing, and control, or CMC, expertise and strategy is anchored in our in-house technical operations team with deep experience across bioprocess, analytical, and formulation development for complex biologics, with a proven track-record of enabling scalable, robust, and industrialized clinical and commercial manufacturing processes and supply chains. Vijay Chiruvolu, Ph.D., our interim Chief Technology Officer who leads our technical operations organization, holds over 27 years of relevant industry experience in process development, manufacturing, supply chain, and quality at Instil Bio, Kite Pharma/Gilead Sciences, Scios, Avigen, Hoffmann-La Roche, Johnson & Johnson, and Amgen, and was responsible for the manufacturing and process teams that worked towards regulatory approval of two cell therapy products, Yescarta and Tecartus.

We believe that actively exploring and forming the right partnerships to drive innovation and enhance our pipeline is core to our strategy and growth. We have assembled a team with sophisticated business development expertise and capital formation experience to drive deal making and transactional activities. Our Chief Business Officer, Saryah Azmat, brings over 10 years of experience in biopharmaceutical business development, corporate strategy and capital formation at Bristol Myers Squibb and Putnam Associates. Our Chief Legal Officer, P. Joseph Campisi, Jr., Esq., holds over 30 years of experience in mergers and acquisitions, collaborations, and securities offerings and corporate governance at Scorpion, Bristol Myers Squibb, and Pillsbury Winthrop; and Venkat Ramanan, Ph.D., our Chief Financial Officer, holds over 20 years of experience in biopharmaceutical finance and operations at Seagen, Gilead, and Amgen.

Since our inception, we have raised $362.0 million in capital, including approximately $172.0 million from preferred stock financings and $190.0 million in non-dilutive payments from strategic partnerships. We are supported by a syndicate that includes entities affiliated with Versant Venture Management, LLC, OrbiMed Private Investments VI, LP, entities affiliated with F-Prime Capital and entities affiliated with FACIT Inc., or FACIT. Prospective investors should not rely on the investment decisions of our existing investors, as these investors may have different risk tolerances and have received their shares in prior offerings at prices lower than the price offered to the public in this offering. See the section titled “Certain Relationships and Related Party Transactions” for more information.

Our Strategy

Our mission is to develop new medicines to treat and cure patients with solid tumors using our next generation TIL therapy approach. We intend to achieve our mission by implementing the following strategies.

- ***Advance our lead Selected TIL product candidate, TIDAL-01, for the treatment of solid tumors***. We are developing TIDAL-01 for the potential treatment of a broad range of solid tumor types and we are pursuing a clinical development strategy designed to demonstrate benefit in multiple indications. We have initiated a Phase 1b clinical trial that will evaluate TIDAL-01 in solid tumors where the benefit of bulk TILs has not been established, including breast cancer, colorectal cancer, and uveal melanoma. Additionally, we have also initiated our investigator sponsored Phase 1 clinical trial in collaboration with Moffitt that will evaluate TIDAL-01 in multiple types of melanoma including cutaneous melanomas, an indication where bulk TILs have shown objective responses in clinical trials. We are very early in our development efforts, and as we make progress, if we obtain positive results of sufficient magnitude from one or both trials, we intend to discuss, receive guidance and the appropriate acceptance from the relevant regulatory agency(ies) to determine if we will be advancing TIDAL-01 into pivotal trials, which are trials that are intended to secure regulatory approval for a product candidate.

- ***Develop TIDAL-02 and continue to build our pipeline of additional Selected TIL programs.*** We are expanding our portfolio by making modifications to our Selected TILs to streamline manufacturing and further enhance the quality and function of Selected TILs. This strategy is exemplified by our second Selected TIL program, TIDAL-02. This program is intended to employ a next generation rapid selection process, culture enhancements to improve and maintain TIL quality

ex vivo, and/or functional gene edits to ensure durable enhancements to TIL quality and persistence *in vivo*, while minimizing dependance on exogenous IL-2 for *in vivo* proliferation. We intend to advance TIDAL-02 towards the clinic for the treatment of solid tumor indications that are distinct from and complementary to TIDAL-01, with the goal of moving into earlier lines of therapy. In addition to TIDAL-02, we have ongoing research efforts to further expand our pipeline of Selected TIL programs.

- ***Leverage viral immunotherapies to further increase the activity of Selected TILs, if approved, across multiple solid tumors.*** Given our oncolytic virus expertise and our proprietary viral immunotherapies, we believe we are strongly positioned to be a leading company in using viral immunotherapy to further increase the activity of our TIL therapies, if approved. We plan to advance our TIDAL-01 and viral immunotherapy combination strategy to further expand the breadth and depth of response of our Selected TILs across multiple solid tumors. We also plan to explore additional Selected TIL and viral immunotherapy combinations.

- ***Commercialize and improve patient access to Selected TIL therapy through our CMC development expertise and manufacturing capabilities.*** We are expanding our in-house cell therapy process and analytical development capacity and capability, and in parallel assembling a network of external manufacturing and supply chain partners. We have designed a robust analytical characterization program to complement clinical development, support regulatory requirements and enable access to our Selected TILs for a broad range of patients with solid tumors. Our intent is that all early-clinical stage Selected TIL product candidates are built upon a CMC foundation with clear line-of-sight to commercial viability, sequenced and staged appropriately with clinical progress.

- ***Support existing and opportunistically explore future strategic partnerships and collaborations to maximize the potential of our programs.*** We are leveraging relationships with three academic collaborators, including a strategic partnership with Moffitt, and collaborations with the National Cancer Institute, or NCI, and Centre hospitalier de l'Université de Montreal, or CHUM, to help support development of our Selected TIL approach and pipeline. Our academic relationships are designed to enable us to tap into the deep expertise within these leading institutes that have decades of research and clinical experience in developing TIL therapies. We plan to continue to explore opportunistic collaborations with both academic and industry partners to extend our reach and maximize the potential of our programs.

Background on Solid Tumors and TILs

Solid Tumors: A Medical Need in Cancer

Solid tumors contribute a massive burden to society, with high mortality and poor outcomes associated with more advanced disease. In the United States, there are over 1.6 million new solid tumor cases per year, representing approximately 90% of all cancers. Furthermore, solid tumors result in over 500,000 U.S. deaths per year. Several key factors such as tumor heterogeneity, as well as challenging tumor microenvironments, have made solid tumors very difficult to treat. Despite advances in the oncology treatment landscape, solid tumors continue to result in low rates of long-term survival in the United States. When tumors become refractory to early lines of treatment, options for further therapy are currently limited to alternate forms of chemotherapy, clinical trials of agents in development or palliative care. Each of these alternatives presents a low likelihood of cure, while generally exposing patients to safety and tolerability concerns. Once the cancer metastasizes, mortality exceeds 90%.

Overview of Current Cancer Immunotherapies and Limitations

Immuno-oncology is an evolving field of cancer therapy that is designed to harness the power of the body's own immune system to prevent, control, and eliminate cancer. Immuno-oncology therapies activate the

immune system to enhance and/or create anti-cancer immune responses, as well as to overcome immunosuppressive mechanisms that cancer cells have developed. FDA approval of several immunotherapies has firmly established the role of this modality in the fight against cancer. A few of the leading immunotherapies include ICIs and adoptive cell therapy, or ACT.

Immune Checkpoint Inhibitors

The development of ICIs represented a breakthrough for the treatment of various cancers. Immune checkpoints act as gatekeepers of immune responses, down-regulating T cell activity to prevent the destruction of healthy cells. However, cancer cells can also express these checkpoints to evade the immune system. Immune checkpoints have become the focus of numerous therapies that seek to block the activation of inhibitory immunoreceptors and reinvigorate antitumor function of immune cells. Monoclonal antibodies targeting immune checkpoints such as CTLA-4, PD-(L)1, and LAG-3 can restore antitumor immunity, thus reversing immune evasion and promoting tumor cell death. These therapies have found robust commercial success, with approximately $40.0 billion in worldwide sales in 2022. However, they have only incrementally improved broader patient outcomes, with less than 15% of all cancer patients responding to ICI therapy. The effectiveness of ICIs is heavily dependent on the presence of tumor-reactive T cells for this treatment to reinvigorate, and many patients lack enough T cells that recognize the target tumor. Furthermore, ICIs can promote systemic activation of self-reactive T cells resulting in immune-related adverse events.

Adoptive Cell Therapies

ACTs are immunotherapies that directly harness immune cells as the therapeutic modality. These immune cells, often T cells, are isolated from the patient or healthy donors, expanded, and sometimes engineered *ex vivo*, and then transferred into the patient. These processes allow for the expansion of T cells away from the immunosuppressive nature of the tumor microenvironment. While checkpoint inhibitors seek to re-activate the endogenous immune response, ACTs introduce immune cells into the body to attack target cancer cells. Most of the activity in ACTs has focused on ways to provide the requisite specificity of the T cells to cancer: identifying tumor-associated targets, evaluating their frequency on cancers versus healthy tissues, and evaluating the best ways to traffic T cells to them and attack the cancer. Three of the key ACT modalities utilizing T cells, that have been evaluated for the treatment of cancer include CAR-T, TCR-T, and TILs.

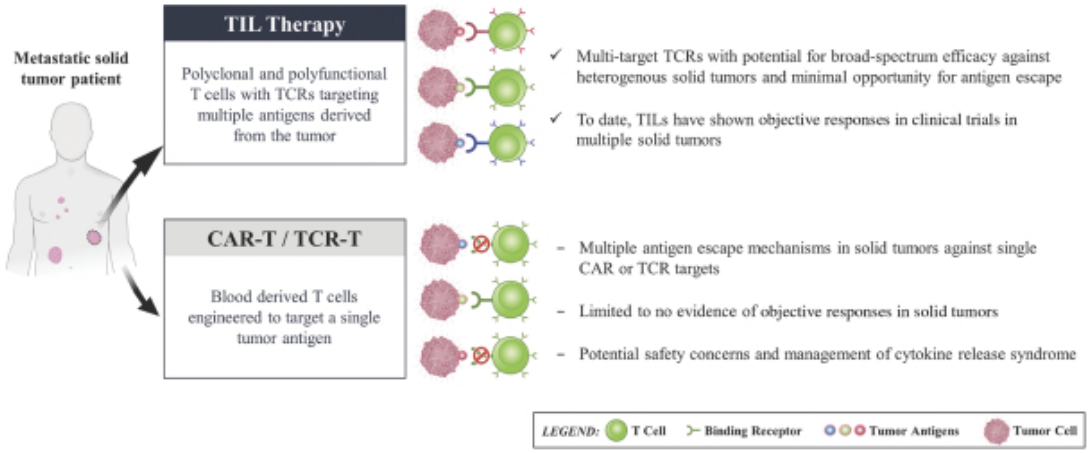
- *CAR-T*: CAR-T therapies are T cells extracted from blood that have been genetically engineered to express artificial cell surface receptors known as chimeric antigen receptors, or CARs. CARs are comprised of an extracellular binding domain specific to a surface molecule on tumor cells and an intracellular activation domain that turns the T cells “on” to kill tumor cells when the CAR binds to the tumor cell target. While patient-derived, or autologous, CAR-T therapies have been approved and have demonstrated responses in hematological cancers, they have resulted in significant off-tumor effects and limited to no objective responses in clinical trials in solid tumors. CAR-T therapies face a number of challenges in solid tumor settings, including lack of cell surface molecules that can be safely targeted, an inability to recognize intracellular tumor-specific proteins, and tumor antigen heterogeneity. Furthermore, the potent immune activation responsible for the success of CAR-Ts also drives the potential for life-threatening toxicity of cytokine release syndrome.

- *TCR-T*: TCR-T therapies are T cells extracted from blood that have been genetically engineered to express T cell receptors, or TCRs, that bind specific fragments of proteins presented by the human leukocyte antigen, or HLA, complexes on the surface of target cells. TCR-T therapies are engineered with a cloned TCR that directs the T cells to recognize peptides that arise from the tumor’s mutated proteins or an aberrant or overexpressed self-protein. Unlike CAR-T therapies, TCR-T therapies have the potential to target intracellular proteins preferentially expressed by cancer cells. While there has been some limited clinical success in solid tumors, the HLA-dependent mechanism of TCR-Ts requires careful tissue matching between the transgenic

TCR and the patient or the expression of engineered TCRs in the patient's own cells, thus restricting the addressable patient population. In addition, the targeted antigen may not be expressed uniformly across the tumor cells, and this heterogeneity can lead to ineffective targeting of the tumor, tumor escape and treatment-resistant tumor growth.

- *TILs:* TIL therapies are a type of ACT whereby lymphocytes including T cells are extracted from the patient's tumor, expanded outside the body, and then infused back into the patient. TILs contain T cells with a diverse set of TCRs and are polyclonal, meaning they recognize multiple different antigens, and polyfunctional, meaning that they have multiple effector functions. Due to these features, TILs have the potential to penetrate tumors and recognize and kill cancer cells and offer potential as a therapeutic for the treatment of solid tumors. To date, TILs have shown objective responses in clinical trials in solid tumors.

We believe that TILs have the potential to address the challenges of solid tumor recognition and heterogeneity in ways that CAR-Ts and TCR-Ts cannot, as illustrated in the figure below.



Responses Observed with Bulk TILs in Clinical Trials

Patient-specific TIL-based investigational therapies have been studied and developed for the treatment of solid tumors for over three decades. Pioneering work led by Dr. Steven A. Rosenberg, M.D., Ph.D., at NCI, first demonstrated objective responses in clinical trials of TILs in the treatment of melanoma. Most of the early work in TILs was focused on the development of an ACT using "bulk TILs," whereby all TILs extracted from a patient's tumor are isolated, expanded *ex vivo* and then reinfused into the patient.

Over the years, several hundred patients in the United States have received bulk TIL therapies across academia and industry sponsored clinical studies. In metastatic melanoma patients refractory to PD-(L)1 treatments, bulk TIL monotherapy has yielded objective response rates, or ORR, of approximately 30% to 50%, with complete response rates, or CRs, ranging from approximately 5% up to 20%. If a complete response lasts the lifespan of a patient it would be considered as a cure – in general clinical practice patients are referred to as "cured" if they remain in complete response for greater than five years as the probability of their disease recurrence is low. Beyond metastatic melanoma, bulk TIL therapy has demonstrated early therapeutic potential in a limited number of solid tumors including squamous cell carcinoma of the head and neck, cervical cancer, and non-small cell lung cancer. To date, clinical trials of bulk TIL products have trended toward achieving their greatest success in cancers with a high number of mutations, also typically referred to as high tumor mutational burden, or TMB.

Limitations of Bulk TILs

The body of data spanning decades of research and clinical development in TILs has shed light on what we believe is the key feature that has made TILs successful to date, and also what has limited the success of bulk TILs to a subset of high TMB solid tumor indications. The therapeutic potential in any TIL product is driven by the "tumor-reactive T cells" that are characterized by recognition of tumor-specific antigens. Tumor-reactive T cells are polyclonal and polyfunctional populations of cells that can comprehensively recognize and kill a diverse population of heterogenous tumor cells unique to each patient.

We believe the key limitation of bulk TILs is the small subset of tumor-reactive T cells that exist in most bulk TIL products. Bulk TILs are routinely dosed at 10^9 cells or more, with tumor-reactive T cells representing reported median values of less than 3% *(Lowery et al., 2022)* of the total number of cells infused back into the patient. The tumor-reactive T cells included in bulk TIL products may be sufficient to drive utility in some patients with high TMB tumors. However, the fewer the number of mutations in the initial tumor material used to generate the bulk TIL product, the lower the number and proportion of tumor-reactive T cells included in a bulk TIL product, and consequently the lower the activity observed. In fact, across more than 50 patients with epithelial malignancies and low TMB tumors studied at the National Cancer Institute, or NCI, bulk TILs have demonstrated limited to no objective responses in clinical trials.

We believe the limitations described above highlight the need for the next generation of TIL therapy to selectively expand the necessary population of tumor-reactive T cells to maximize the benefit of TILs across a greater breadth of solid tumors. We believe that a greater population of tumor-reactive T cells delivered to a patient in a TIL product can to expand the potential utility of TILs, if approved, to multiple solid tumor types.

Our Solution: Selected TILs

We are developing next generation TIL therapies for the potential treatment of multiple solid tumors. There are no TIL therapies that have received FDA approval to date and at present, no therapies in clinical development for our chosen solid tumor indications have demonstrated consistent curative outcomes for patients. Our innovative Selected TIL approach focuses on selecting and expanding the most potent tumor-reactive T cells to overcome the limitations of bulk TILs. This approach is grounded in work conducted in academia that has demonstrated improved clinical responses for selected TILs in solid tumor types where bulk TILs have not shown objective responses in clinical trials. We are leveraging this work to establish a standardized manufacturing process for large scale production of our Selected TILs.

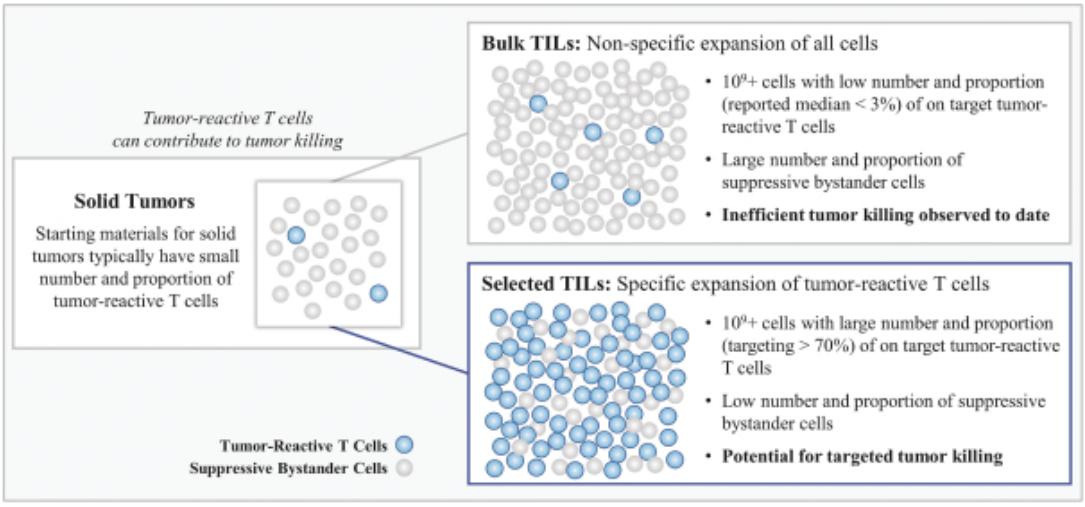
We are developing Selected TILs based on foundational principles with the goal of yielding the greatest number and proportion of tumor-reactive T cells in our TIL product candidates. We are developing TIL therapies for the potential treatment of a broad range of solid tumor types by employing the following principles:

(1) ***Unbiased identification of patient-specific tumor antigens****:* We seek to identify the most comprehensive set of patient-specific tumor antigens. We use an unbiased identification process that aims to find and capture the greatest diversity of antigens with the potential to drive the most robust T cell response, unlike other TIL products that are biased toward a specific subset or class of antigen(s), which may miss relevant tumor antigens or focus on the wrong targets.

(2) ***Selection of greatest breadth of tumor-reactive T cells from patient extracted TILs****:* Our goal is to capture and isolate the greatest number and proportion of a patient's tumor-reactive T cells that have the potential to attack and destroy heterogeneous solid tumors. We aim to select the greatest diversity of T cells, by using a functional-based screening process that confirms reactivity to the identified patient-specific tumor antigens rather than relying on a bioinformatics-based prediction algorithm that may not be truly predictive. Importantly, we seek to select for both CD8+ T cells, which can directly kill tumor cells, and CD4+ T cells, which stimulate and recruit other immune cells to tumor sites; studies have shown that the presence of both types of T cells is important for effective tumor control.

(3) ***Expansion of all tumor-reactive T cells and removal of all non-tumor-reactive bystander cells****:* We expand our selected tumor-reactive TIL population to magnitudes consistent with bulk TIL products and actively remove unnecessary bystander cells. This selective expansion has resulted in a substantially higher proportion of tumor-reactive T cells in the final product in comparison to the relatively infrequent tumor-reactive T cells that are routinely found in bulk TIL. Based on our non-clinical studies across multiple tumor samples to date, we have been able to achieve tumor-reactive T cell frequencies in our selected TIL drug product of up to 62%, with a median frequency of 23%. With ongoing continuous process improvements as part of our manufacturing strategy we are targeting >70% tumor-reactive T cells in our drug product as we advance clinical development.

The potential advantages of Selected TILs over bulk TILs are depicted in the figure below.

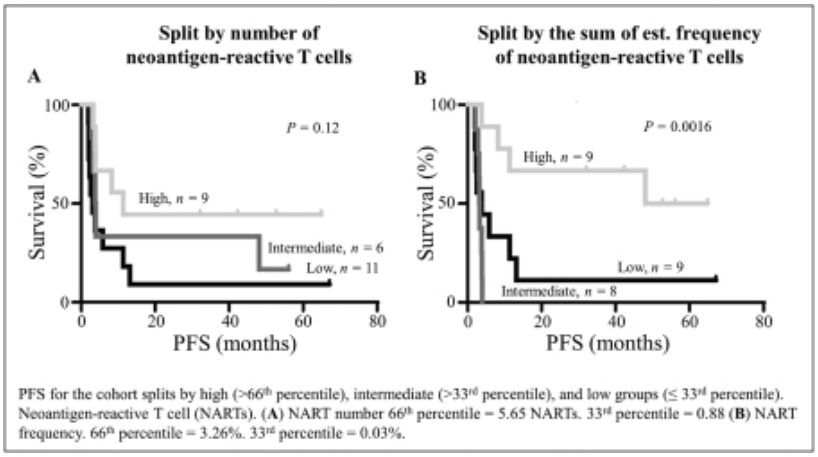


The approach described above is inherently designed to select for and characterize the active TIL product, *i.e.*, the tumor-reactive T cells. Bulk TIL approaches do not select for the active TIL product and have consequently faced challenges in product characterization and potency assay development. We believe that our Selected TIL approach will facilitate the development of potency release assays to support regulatory requirements and avoid the characterization challenges of bulk TILs.

Supporting Clinical Evidence

We believe the growing body of prospective and translational clinical data in the TIL field supports the potential of our Selected TIL approach.

A study by Kristensen *et al.* in 2022 reviewed data from 26 metastatic melanoma patients who were treated with TILs and evaluated the correlation between the number and frequency of tumor-reactive T cells in the TIL product and the level of progression-free survival, or PFS, observed. Progression-free survival is the length of time during and after the treatment of the patient's cancer, that a patient lives with their cancer but it does not get worse. PFS does not indicate that a patient is cured of their disease. As demonstrated in the figure below, patients that received TIL products with a high frequency of tumor-reactive T cells, more specifically referenced as neoantigen-reactive T cells in this study, experienced longer periods of PFS. Comparatively, patients receiving TIL products virtually devoid of tumor-reactive antigen recognition experienced rapid disease progression following TIL treatment.



PFS for the cohort splits by high (>66th percentile), intermediate (>33rd percentile), and low groups (≤ 33rd percentile). Neoantigen-reactive T cell (NARTs). (**A**) NART number 66th percentile = 5.65 NARTs. 33rd percentile = 0.88 (**B**) NART frequency. 66th percentile = 3.26%. 33rd percentile = 0.03%.

The key challenge for bulk TILs is that there is a limited number and breadth of these tumor-reactive T cells, which constrains the potential for bulk TILs to drive higher objective response rates in patients (vs. the objective response rates that have been observed in clinical trials to date). As a result, academic researchers have explored the potential of selecting or enriching for tumor-reactive T cells within the bulk TILs as a potential therapy for cancers where bulk TILs have not shown high objective response rates in clinical trials, including lung, breast, colorectal, and bile duct cancers.

Early academic selection and enrichment strategies typically utilized fragment-based selection and expansion approaches. Following harvest and dissection of the tumor, small numbers of tumor fragments were placed into separate multi-well tissue culture dishes and cultured with the tumor or manufactured antigens. TIL populations that were activated by exposure to tumor antigens in culture would then be identified based on cytokine expression and/or T cell activation marker expression, and only those activated TIL populations would be expanded for use in the final product.

A variation of this TIL selection approach demonstrated preliminary outcomes in non-small cell lung cancer in a study reported by Creelan *et al.* in 2021. Approximately 54% of the patients evaluable for clinical response in this study received TILs with confirmed tumor-reactivity, whereas the remainder received TIL products with no confirmed tumor-reactive T cells, which we believe demonstrates the crude and inconsistent nature of the academic manufacturing process. However, of the patients that received a TIL product with tumor-reactive T cells, 43% experienced a partial response, or PR, or CR, whereas all of the patients that received TILs without confirmed tumor-reactive T cells experienced disease progression, as shown in the table below. We believe this study highlights the potential of selected TILs to generate positive outcomes in a challenging tumor indication, even with a rudimentary selection process.

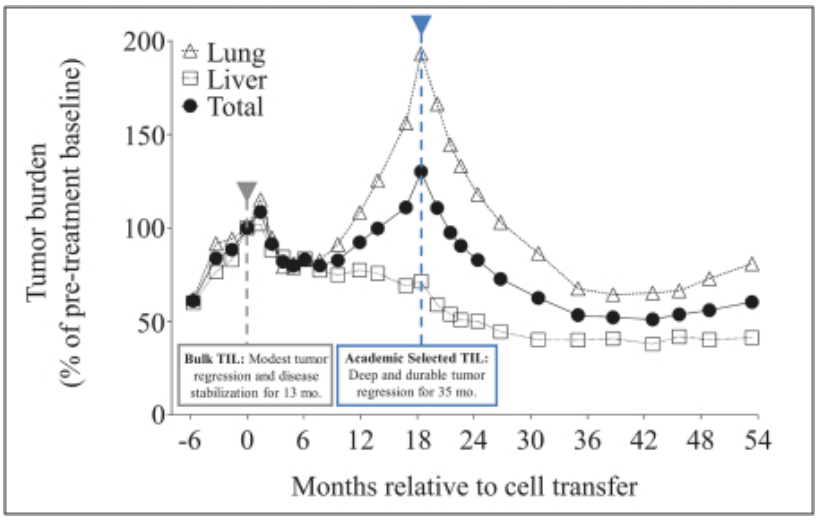
	Patients that received a TIL product ***with confirmed*** tumor-specific reactivity	Patients that received a TIL product ***with no confirmed*** tumor-specific reactivity
N*	7 (54%)	6 (46%)
N with confirmed ORR (%)	3 of 7 (43%)	0 of 6 (0%)
N with confirmed CR (%)	2 of 7 (29%)	0 of 6 (0%)

**only includes patients evaluable for clinical response (N=13)*

In clinical trials, TIL products enriched for tumor-reactive T cells using early selection strategies have also led to cancer regressions in difficult to treat epithelial malignancies including metastatic breast cancer, or mBrCa. Zacharakis *et al.*, in 2022 demonstrated that these TILs mediate regression in patients with breast cancer refractory to standard treatments. Three of six patients with mBrCa treated with infusion of tumor-reactive TILs developed objective cancer regression, and one CR was observed to be durable for more than 5.5 years.

This trial also highlighted the importance of different T cell populations in the TIL product. CD4+ T cells appeared to be the predominant population in the mBrCa TILs that demonstrated tumor reactivity. We believe this result suggests that successful selection strategies should include both CD8+ and CD4+ cells in the final TIL product.

Additional single patient academic studies in colorectal cancer in 2016 and bile duct cancer in 2014 conducted by Tran *et al.* utilizing early TIL selection strategies also have yielded responses. Notably, the bile duct patient was originally treated with bulk TILs that initially resulted in some tumor reduction, although the patient subsequently progressed. This patient was further treated with selected TILs at a point when the patient had higher disease burden and demonstrated a tumor regression that was durable for 35 months as shown in the graphic below.



The selection processes of the studies above differ from our Selected TIL approach due to a crude enrichment of tumor-reactive T cells through small pools of tumor fragments. These processes only partially enriched the drug products for tumor-reactive T cells and allowed carry over of bystander cells into the drug products. In contrast, our method of physical single cell sorting is designed to ensure selection of all tumor-specific antigen-reactive T cells and also facilitates efficient removal of bystander cells.

Building a Product Pipeline to Further Enhance the Quality and Function of Selected TILs

We believe our Selected TIL approach sets us apart from others in the industry that are utilizing bulk TILs, including newer bulk TIL approaches that introduce gene edits and culture media additives to enhance TIL quality and function. We believe that without the optimal starting population of tumor-reactive T cells, further enhancements or modifications to bulk TILs are unlikely to succeed in extending their potential utility beyond the limited tumor types where bulk TILs have already shown objective responses in clinical trials. We are also extending our product pipeline by making additional modifications to our proprietary Selected TILs and deploying them in differentiated combination strategies to further enhance TIL quality and function.

Modifications to Enhance TIL Quality

We are developing pipeline programs where we are evaluating enhanced culture conditions during the TIL production process to maintain and further improve TIL quality *ex vivo*. These enhanced culture conditions are designed to incorporate a mix of cytokines with the potential to rejuvenate dysfunctional and/or exhausted T cells.

Additionally, we plan to introduce functional genetic modifications into our pipeline programs that may drive potential for more sustained TIL quality and persistence *in vivo*. These gene edits will be designed to modify the tumor-reactive T cells to proliferate while resisting exhaustion post infusion, minimize their dependance on exogenous IL-2 for *in vivo* proliferation, and maintain their potential to kill tumors in suppressive tumor microenvironments. We are currently evaluating and prioritizing clinically informed targets for these genetic modifications.

Virus Combinations

Viral immunotherapy is a therapeutic modality with widespread potential to drive and modulate immune responses to tumors. The potential of viral immunotherapy has been validated by the FDA-approval of Talimogene laherparepvec for the treatment of metastatic melanoma. Many viruses have inherent oncolytic activity that can be modulated through genetic engineering. These viruses are characterized by the unique features of preferentially infecting, replicating within, and killing malignant tumor cells, as well as activating the immune response. Viral immunotherapies are designed to convert immunologically unresponsive “cold” tumor microenvironments to more reactive “hot” tumor microenvironments and thereby enhance the activity of immunotherapies including ICIs and ACTs, such as TIL therapies.

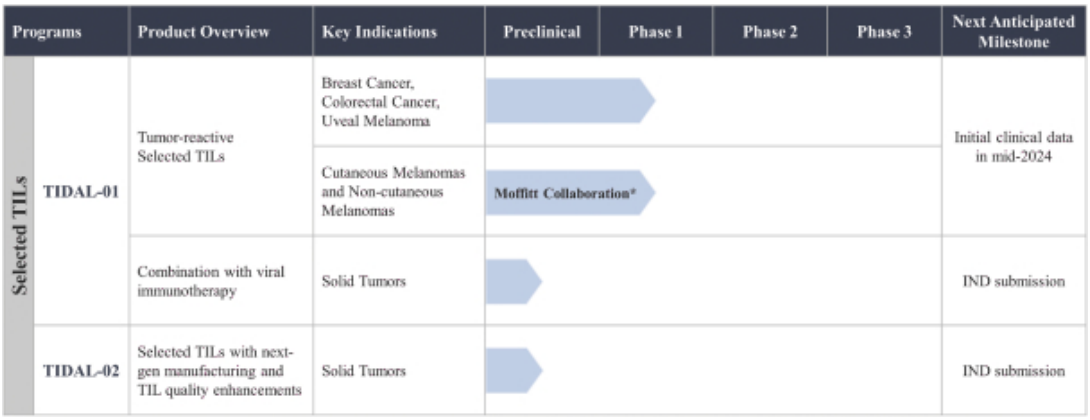
We believe we are strongly positioned to combine our Selected TIL product candidates with our proprietary viral immunotherapies utilizing two distinct approaches:

- *Viral immunotherapy pre-treatment (prior to TIL extraction) to optimize TIL harvest and broaden access to indications less amenable to TIL therapy*: Pre-treating the patient with a viral immunotherapy has the potential to disrupt the tumor and expose new antigens to the immune system thus driving a larger and more diverse population of tumor-reactive T cells. In addition, viruses elicit systemic cytokine production that can traffic T cells to the site of the tumor. We believe treatment with our viral immunotherapies could enable a superior TIL harvest, in quality, quantity and breadth of TILs. We plan to target this approach specifically to patients and indications for which the TIL yield is typically low, often leading to failure in generating sufficient TIL therapy for the patient.

- *Viral immunotherapy post-treatment (following delivery of the TIL product) to optimize TIL trafficking and function to further increase the activity of our TIL therapies*: Viral immunotherapy utilizes multi-mechanistic approaches to reprogram the immunosuppressive tumor microenvironment (*i.e.*, turn a "cold" tumor "hot") that can potentiate TIL infiltration, function, and proliferation within the tumor. In addition, virus at the tumor site is designed to serve as a beacon to call TILs to the site of the tumor. We believe treating the patient with viral immunotherapy following TIL infusion into the patient has the potential to further increase the activity of our TIL therapies, if approved, across several challenging solid tumors.

Our Pipeline

We are applying our Selected TIL approach for the potential treatment of a wide range of solid tumors. We are developing a broad pipeline aimed at improving outcomes for patients with cancers, as illustrated in the chart below.



* Investigator sponsored trial at Moffitt Cancer Center

- ***TIDAL-01****:* Our lead Selected TIL product candidate utilizes an unbiased identification and functional screening process to isolate and selectively expand the greatest breadth of tumor-reactive T cells extracted from the patient's tumor. We have initiated two Phase 1 clinical trials for TIDAL-01, including a multi-site trial for the treatment of breast cancer, colorectal cancer, and uveal melanoma, and investigator sponsored trial with Moffitt, in both cutaneous and non-cutaneous melanomas.

  Investigator sponsored trials are clinical trials where the investigator of the trial is also the "sponsor" of the trial for regulatory purposes. An "investigator" conducts clinical investigations and is the person under whose immediate direction the study drug is administered or dispensed to patients. A "sponsor" initiates and takes responsibility for a clinical investigation. A person who both initiates and conducts a clinical trial, and is responsible for all regulatory requirements, is designated as a "sponsor-investigator" by the FDA. Clinical investigators at academic medical centers who initiate clinical trials with a lawfully marketed drug to be used in a patient population or indication not within the official labeling often fit within this designation. In addition, as is the case with our investigator-sponsored trials, a company may provide a sponsor-investigator with supply of its unapproved product candidate and funding for the trial. Investigators who initiate and conduct such trials are responsible for obtaining an IND from the FDA and for ensuring compliance with the IND and associated regulatory requirements. As provided by the FDA's regulations, the sponsor of a clinical trial is responsible for, among other things, selecting qualified investigators, providing them with the information they need to conduct the trial properly, ensuring proper

monitoring of the trial, ensuring that the trial is conducted in accordance with the protocols contained in the IND, maintaining an effective IND with respect to the trial, and ensuring that the FDA and all participating investigators are promptly informed of significant new adverse effects or risks with respect to the drug. In contrast, in a company-sponsored trial, the pharmaceutical company whose drug will be studied is the sponsor of the trial and, as such, is responsible for ensuring compliance with all regulatory requirements, including obtaining the IND.

Under our multi-site trial, we control all aspects of our trial including, but not limited to, study protocol development, patient selection and enrollment, regulatory interactions, data release, and manufacturing through our industrial contract development and manufacturing organization, or CDMO. Under the investigator sponsored trial, which is fully funded by us, Moffitt is solely responsible for regulatory interactions, trial conduct and manufacture of TIDAL-01 at the Moffitt Cancer Cell Therapy Facility, with input and support from us at Moffitt's discretion. Investigators at Moffitt are also solely responsible for the design of the trial and patient selection and enrollment, where we remain in close contact with the investigators to provide our input if appropriate. Any data disclosures will be made in collaboration with us and any improvements to the TIDAL-01 manufacturing process are solely at our discretion. We intend to provide an initial clinical update across these two trials in mid-2024.

- ***TIDAL-02****:* Our next generation Selected TIL program encompasses a streamlined manufacturing process designed for selecting tumor-reactive T cells, with additional modifications to enhance TIL quality and function. TIDAL-02 is currently in preclinical development.

- ***Selected TIL and viral immunotherapy****:* Our combination strategies are designed to improve TIL harvest and overcome the immunosuppressive tumor microenvironment for better trafficking and expansion of TILs *in vivo.* We are currently evaluating the optimal viral immunotherapy for combination with TIDAL-01 to advance into clinical development.

TIDAL-01

Overview

TIDAL-01 is our lead Selected TIL product candidate that we are advancing in multiple solid tumor indications. TIDAL-01 utilizes an unbiased identification and functional screening process to isolate and selectively expand the most comprehensive set of tumor-reactive TILs from the patient's tumor. Our TIDAL-01 production process is designed to deliver at least 10^9 cells and targets greater than 70% functional and potent tumor-reactive T cells.

We have initiated a multi-site Phase 1b clinical trial for TIDAL-01 in patients with solid tumors such as breast cancer, colorectal cancer, and uveal melanoma, which are indications where bulk TILs have not historically shown objective responses in clinical trials. Additionally, we have also initiated our investigator sponsored Phase 1 clinical trial in collaboration with Moffitt that will evaluate TIDAL-01 in multiple types of melanoma including cutaneous melanomas, an indication where bulk TILs have shown objective responses in clinical trials. We are very early in our development efforts, and as we make progress, if we obtain positive results of sufficient magnitude from one or both trials, we intend to discuss, receive guidance and the appropriate acceptance from the relevant regulatory agency(ies) to determine if we will be advancing TIDAL-01 into pivotal trials, which are trials that are intended to secure regulatory approval for a product candidate. We plan to provide an initial clinical update on the TIDAL-01 program in mid-2024.

Background on Breast Cancer, Colorectal Cancer, Uveal Melanoma, and Cutaneous Melanoma

Breast cancer: Breast cancer makes up approximately 15% and 13.3% of all new cancer cases in the United States and Europe, respectively. About one in eight U.S. women and one in 11 European women will

develop invasive breast cancer over the course of her lifetime. In 2020, the United States and European Union saw an estimated 279,000 and 350,000 new cases as well as over 42,000 and 90,000 deaths, respectively. Nearly 30% of women diagnosed with early-stage breast cancer will eventually develop metastatic disease. Breast cancer is the second leading cause of cancer death in women in the United States, only trailing lung cancer. In recent years, improvements in early diagnosis and treatment have improved survival rates by approximately 1% per year, but the five-year survival rate for women with metastatic breast cancer is 30%. Treatment options and recommendations depend on several factors, including the tumor's subtype, stage, genomic markers, the patient's age, and presence of known mutations in inherited breast cancer genes, but may include surgery, radiation therapy, chemotherapy, hormonal therapy, targeted therapy, and immunotherapy.

Colorectal cancer, or CRC: CRC is the fourth most commonly diagnosed cancer and ranks second in terms of mortality in the United States. In 2020 in the United States and Europe, there were estimated to be more than 145,000 and 341,000 cases as well as over 50,000 and 150,000 deaths from CRC, respectively. Of these cases, approximately 80% of patients are characterized as microsatellite stable, or MSS as opposed to the approximately 15% which are microsatellite instable, or MSI. Whereas the microsatellite instability-high, or MSI-H, phenotype confers good prognosis and greater response to immunotherapy in CRC, MSS tumors are generally considered 'cold' tumors and are less responsive to immunotherapies, with anti-PD-(L)1 therapy demonstrating nearly no effect. The five-year survival rate for all colorectal cancer is approximately 65% and drops below 20% if the cancer has metastasized. Treatment options for CRC include surgery, radiation therapy, chemotherapy, targeted therapy, and immunotherapy.

Uveal melanoma: Uveal melanoma is a rare and aggressive form of melanoma that affects the eye. It is the most common primary intraocular malignancy in adults, and up to 50% of people with uveal melanoma will eventually develop metastatic disease, usually involving the liver and less frequently lung, bone, and other organs. Epidemiology of uveal melanoma varies by region and ethnicity. In the United States and Europe, it is estimated that there are approximately 4,000 to 5,000 new cases of primary uveal melanoma per annum. About 5% of patients present with metastatic disease, and up to 50% will eventually develop metastatic disease. Treatment generally involves surgery if metastases are not present and radiation therapy. In cases where uveal melanoma is constrained to the eye, five-year survival rates are about 85%, but if the disease spreads to other organs, the five-year survival rate is 15%. While there is one FDA-approved drug for the treatment of unresectable or metastatic uveal melanoma, there remains a medical need due to a number of factors including only a subset of patients being eligible for treatment by the approved product. Other potential treatment options include anti-PD-(L)1 or anti-CTLA-4 checkpoint inhibitors, chemotherapy, and kinase inhibitors.

Cutaneous melanoma: Cutaneous melanoma, or melanoma of the skin, is the most common form of melanoma. In the United States and Europe, there are approximately 97,000 and 106,000 new cases of cutaneous melanoma and approximately 8,000 and 16,000 deaths, respectively, per year. Melanoma is unique compared to non-melanoma skin cancers in that it tends to spread locally, regionally, and distantly. Metastatic spread risk is high in melanoma patients, with approximately 5% of melanoma cases being metastatic at diagnosis, and most often involves skin and subcutaneous tissues, lungs, liver, bones and brain. Surgery is the main treatment option for most melanomas and usually cures localized invasive melanoma. For melanomas that have metastasized to other areas of the body or organs that cannot be surgically removed, radiation, checkpoint inhibitor therapy (anti-PD-(L)1 with or without anti-CTLA-4), targeted therapy or chemotherapy are the most common treatment options, with a five-year survival rate of 15% to 20%.

Our Solution: TIDAL-01

TIDAL-01 is a Selected TIL product candidate that utilizes an unbiased identification and functional screening process designed to isolate and selectively expand the greatest breadth of tumor-reactive TILs from the patient's tumor. We are developing TIDAL-01 for the potential treatment of a broad range of solid tumor types.

We have developed consistent and scalable current good manufacturing practice, or cGMP manufacturing for TIDAL-01 designed to deliver a potent tumor-reactive T cell product. The manufacture of

each TIDAL-01 product is initiated by harvesting the patient's tumor samples through surgical resection and collecting monocytes from the blood through apheresis. The three key processes steps to manufacture TIDAL-01 are isolation, selection, and expansion:

- *Isolation:* Tumor samples are shipped to a centralized manufacturing facility where the tumor is dissected into small fragments and cultured with cytokines. TILs are then isolated from the tumor fragments and incubated to generate a sufficient population of cells to perform the selection process.

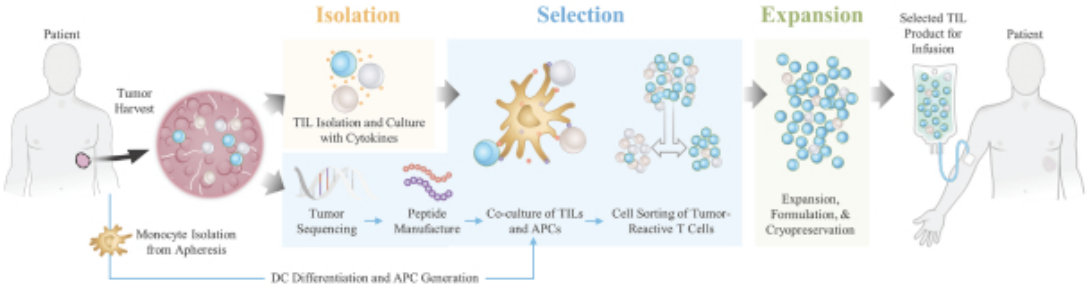
- *Selection:* The patient's tumor sample is sequenced and mutations that are specific to the tumor are identified based on comparisons to the patient's healthy tissue. These mutant sequences are used to generate more than 190 unique peptides that represent potential tumor antigens. We believe that this number of peptides can cover the full set of tumor antigens found in low TMB tumors. In the case of high TMB tumors where more than 200 antigens have been identified, we use our in-house bioinformatics capabilities to prioritize the most immunogenic antigens for peptide generation.

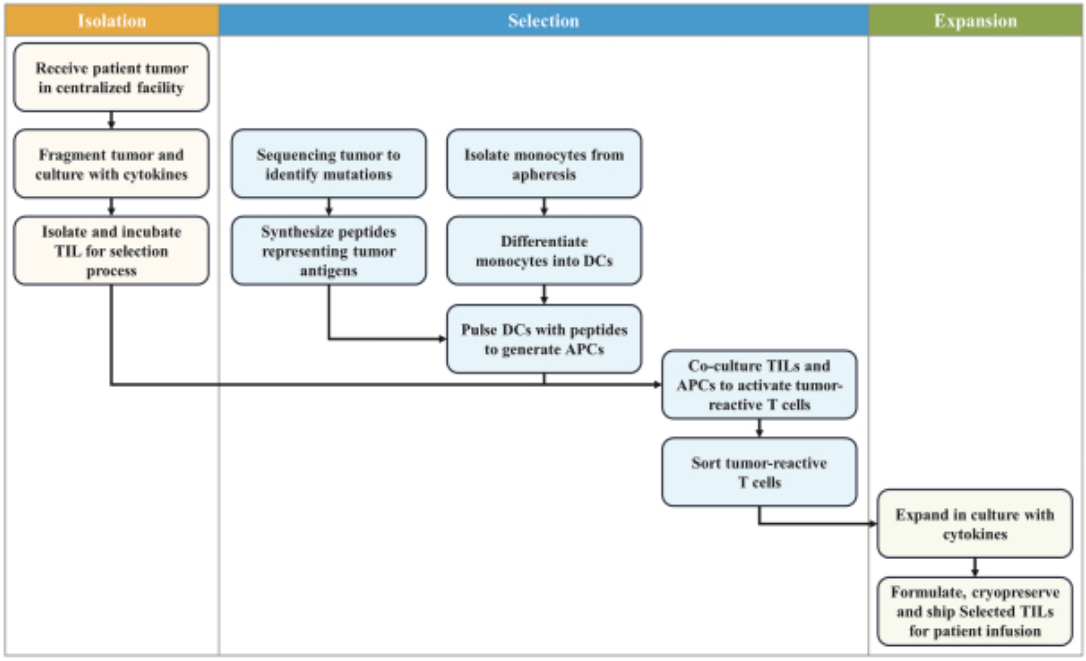
  In parallel, monocytes from the apheresis product are differentiated into dendritic cells, or DCs. The synthesized peptides are incubated with the DCs, which process and present the antigens to become antigen-presenting cells, or APCs.

  In order to identify tumor-reactive T cells within the isolated TILs, we utilize a functional screening process leveraging these APCs. The isolated TILs are co-cultured with APCs and only the tumor-reactive T cells that recognize the antigens on the APCs become activated. These activated tumor-reactive T cells are then physically sorted from the cells that are not tumor-reactive on the basis of well-established activation markers. This process is designed to generate Selected TILs that capture the greatest breadth of tumor-reactive T cells and remove potentially detrimental bystander cells.

- *Expansion:* These Selected TILs are expanded in culture with cytokines to a target of 10^9 or more cells, which we believe represent a therapeutically relevant dose. The cells are then formulated, cryopreserved, and shipped to the clinical site for patient administration.

These three processes steps are depicted in the schematic and associated process flow chart below:





Our process is designed to result in a Selected TIL therapy targeting at least 10^9 cells with the following product attributes:

- Targets greater than 70% tumor-reactive T cells
- Polyclonal and polyfunctional mix of CD4+ and CD8+ cells
- Potential to target a large breadth of antigens specific to each individual patient
- Potential to stimulate broad immunological responses
- Clearly defined potency parameters

Manufacturing, Process Development, and Analytical Characterization

To date, we have completed multiple manufacturing runs that meet clinical specifications to establish readiness for clinical manufacturing. All completed runs successfully demonstrated consistency and reproducibility of desired yield, distribution of CD8+ and CD4+ T cells, and anticipated preliminary potency parameters of the TIDAL-01 product at good current manufacturing practice, or cGMP scale.

Manufacturing of TIDAL-01, from the collection of patient samples to the infusion of the drug product into the patient, currently takes around eight weeks. We have ongoing in-house process development efforts focused on reducing manufacturing time to approximately four weeks by optimizing critical steps in manufacturing, supply chain and logistics. Some improvements include establishing in-house tumor sequencing capabilities, expediting synthesis and shipping of peptides and reducing the duration of the expansion process. Most of our efforts to reduce manufacturing time are well underway and we expect to have the key improvements fully implemented prior to the initiation of any pivotal trials.

Our TIDAL-01 process is inherently designed to select for and characterize the tumor-reactive T cells that provides the tools to measure tumor specific potency and facilitate the development of potency release assays to support regulatory requirements and avoid the characterization challenges of bulk TILs. We have implemented a comprehensive sample retention strategy for the final TIL product manufactured per patient as well as critical raw materials and process intermediates to facilitate a robust analytical characterization program, with a variety of functional and phenotypic assays deployed for potency assessment.

TIDAL-01 is currently deployed at two primary manufacturers for the isolation, selection, and expansion steps: the Moffitt Cancer Center Cell Therapy Facility and an industrial contract development and manufacturing organization, or CDMO. We believe that continuing to maintain full control of our manufacturing network and supply chain, across our overall pipeline, is central to our success and a core component of our strategy. As TIDAL-01 progresses in clinical development, we expect to continue to form and expand strategic external partnerships across all facets of our manufacturing and supply chain. If we demonstrate clinical success of TIDAL-01, we intend to explore both the design, engineering, construction, commissioning, and operation of a fully integrated commercial manufacturing supply chain, as well as external strategic partnerships that are favorable to us and satisfy anticipated manufacturing demand.

Strategic Alliance and Collaboration with Moffitt Cancer Center

We have entered into a strategic alliance with Moffitt, an academic leader in the TIL field to leverage their expertise for advancement of TIDAL-01 into the clinic. Moffitt has significant experience in conducting cell therapy clinical trials, and specialized expertise in treating patients with TIL therapies. Moffitt has on-site cGMP facility for clinical manufacturing of TIL products and laboratories which provides them with research and translational support. We have partnered with Moffitt to open the TIDAL-01 IND for an investigator sponsored trial for the treatment of cutaneous and non-cutaneous melanomas. Under the strategic alliance, Moffitt will provide us support for clinical site activation and patient recruitment. Additionally, Moffitt will support the ongoing trial with dedicated cleanroom capacity and manufacturing priority at their on-site cGMP facility for TIDAL-01 production. In parallel, we are also working with Moffitt on our dedicated pre-clinical research studies supporting the use of our Selected TILs in solid tumor types, including breast and gastrointestinal cancers.

Nonclinical Studies

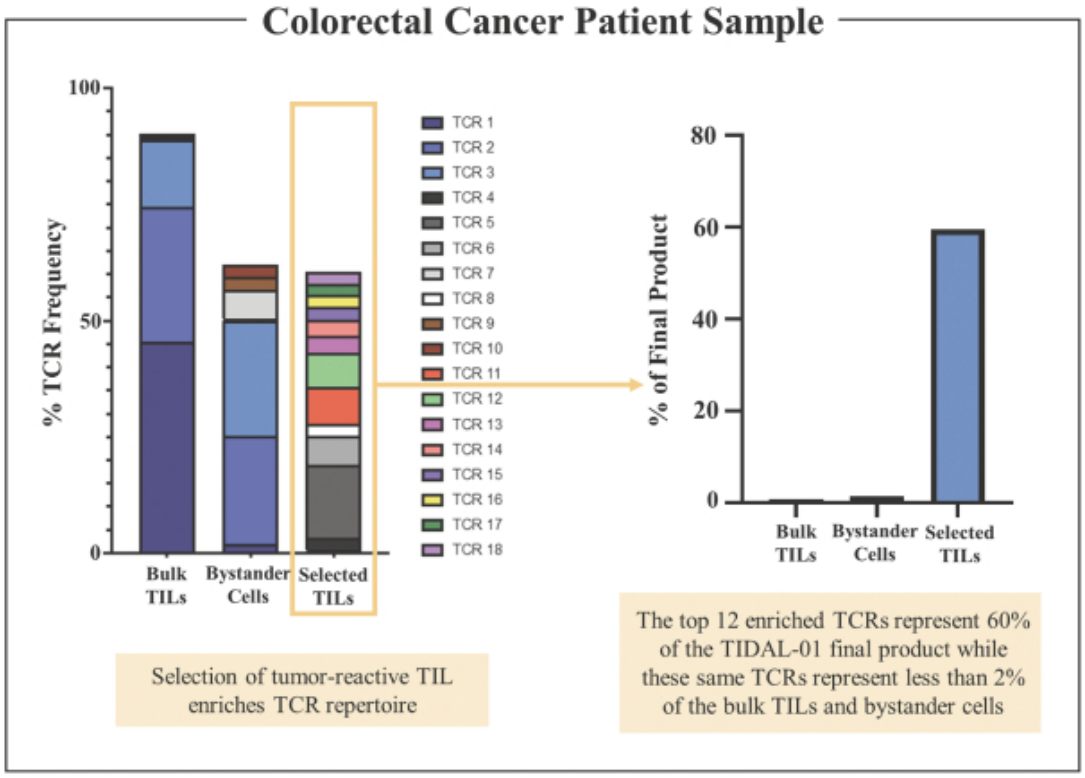
In order to evaluate the therapeutic potential of TIDAL-01, we conducted a series of nonclinical studies using Selected TILs generated with our TIDAL-01 process from patients with various solid tumor types. Substantial variability in our nonclinical study results were observed based upon heterogeneity of individual tumor samples, which can impact the magnitude of effects of the TIDAL-01 process. We provide sample data below that represents the directional effects of the TIDAL-01 process in each of these studies.

1. Consistent enrichment of tumor-reactive T cells targeting multiple relevant patient-specific tumor antigens

TIDAL-01 is designed to select for T cells that are specifically reactive to the patient's tumors. Using TILs generated from patients with multiple solid tumor types employing the TIDAL-01 process, we evaluated the T cell receptor, or TCR, repertoire of the TILs using next-generation sequencing before and after the selection step of our process. We then evaluated the frequency of T cells in the samples that recognized patient-specific tumor antigens. We consistently observed that Selected TILs displayed an enriched TCR repertoire and increased T-cell reactivity toward patient-specific tumor antigens relative to the bulk TIL comparator.

To further evaluate enrichment of tumor-reactive T cells, we compared the frequencies of TCRs in TIDAL-01 versus bulk TILs in 10 tumor samples. The data shown below has been generated from a colorectal cancer patient. The left side of the figure below shows the frequency of the top approximately 20 most abundant TCRs in the bulk TIL sample, the TIDAL-01 Selected TIL sample, and the non-tumor-reactive bystander cells

removed during the TIDAL-01 Selection process. This study demonstrated that relatively few TCRs predominated in bulk TIL products, and that those abundant TCRs were non- tumor-reactive, as evidenced by overlap of the predominant TCRs in the bulk TIL with the bystander cell TCRs. Conversely, our Selected TILs displayed a more diverse and less biased TCR repertoire, which we anticipate will enable the Selected TILs to target a large breadth of patient-specific tumor antigens. The TIDAL-01 selection process enriched tumor-reactive T cells by approximately 30-fold in comparison to frequencies present in bulk TIL.



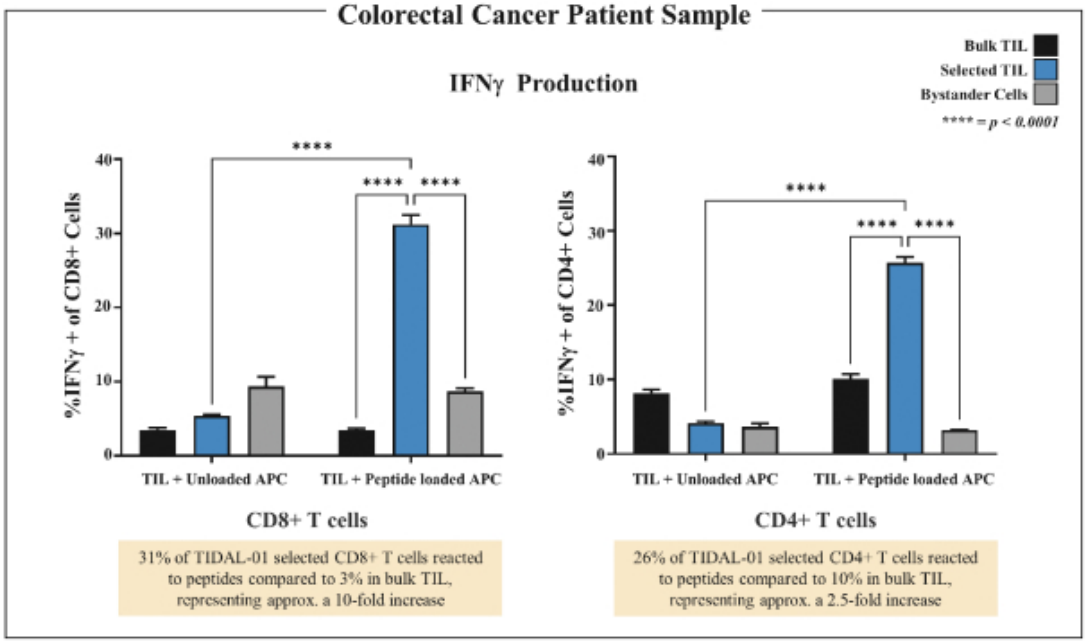
Across all the samples where we conducted this assessment, in comparison to frequencies present in bulk TIL, the TIDAL-01 process enriched tumor-reactive T cells by a range of 1.5 to 43-fold, with an average of approximately 11-fold increase.

2. Selection and enrichment of therapeutically relevant quantities of both CD4+ and CD8+ tumor-reactive T cells

In order to further evaluate the tumor-reactive T cell population in TIDAL-01, we conducted flow cytometry studies using Selected TILs and bulk TILs from the same colorectal cancer patient. The purpose of this study was to compare the percentage of tumor-reactive CD4+ and CD8+ T cells resulting from these processes.

Representative cytokine staining data is depicted in the figure below. The frequency of tumor-reactive T cells in each sample is depicted by the percentage of cells that express interferon gamma, or IFNg, in response to tumor antigens presented by “peptide loaded APC”. For the Selected TILs, bulk TILs, and bystander cells, we measured tumor-reactive CD4+ and CD8+ T cells after incubating the TIL samples with APCs displaying patient-specific tumor antigens and with APCs without patient-specific tumor antigens. As shown below,

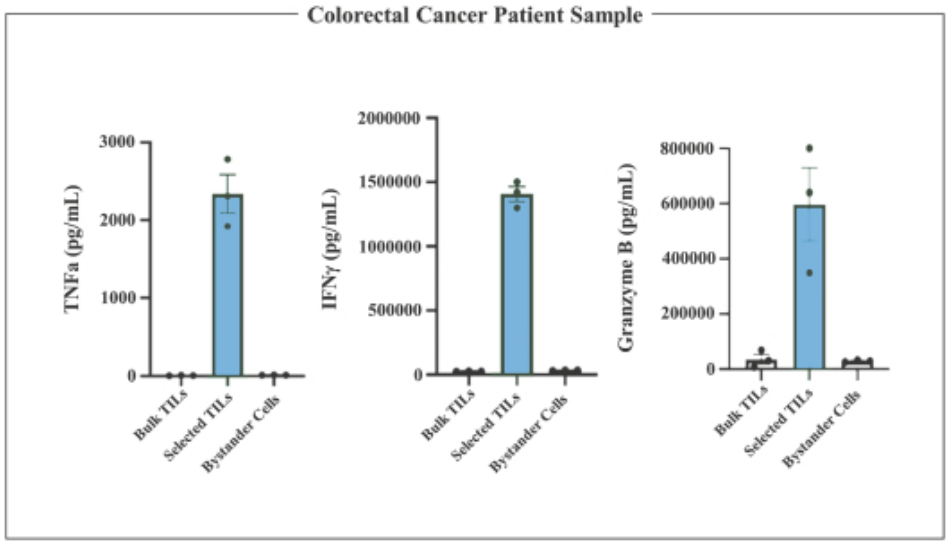
Selected TILs generated by TIDAL-01 contained far higher frequencies of tumor-reactive CD4+ and CD8+ T cells relative to bulk TILs.



This study was conducted using Selected TILs and bulk TILs generated from 6 tumor samples, and the frequencies of tumor-reactive CD4+ and CD8+ T cells in Selected TILs relative to bulk TILs ranged from a 1.5 to an approximately 10-fold increase, with an average of approximately 3-fold increase for both cell types.

3. Polyfunctional anti-tumor activity of Selected TIL products

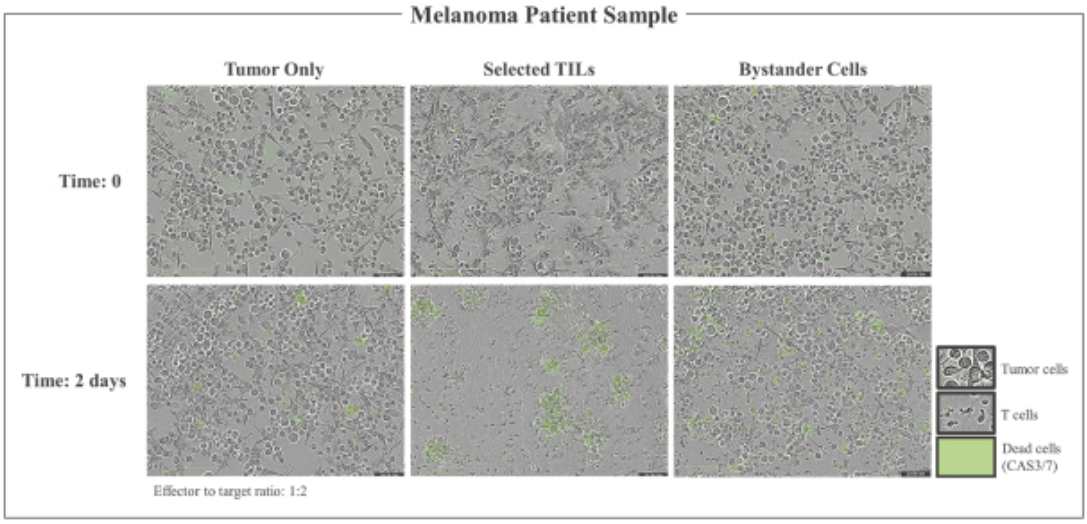
We compared the potency of Selected TILs and bulk TILs from the same patients across 13 solid tumor samples by measuring the expression of key indicators following exposure to patient-specific tumor antigens. The expression of IFNg and tumor necrosis factor α, or TNFα, in response to patient-specific tumor antigens indicates the potential of TILs to orchestrate broad anti-tumor immunological responses, and the expression of granzyme B indicates the potential of TILs to kill nearby tumor cells. The figure below depicts results from a colorectal cancer patient comparing the expression of these potency indicators as measured by enzyme-linked immunosorbent assay for the bulk TILs, the TIDAL-01 Selected TILs, and the non-tumor-reactive bystander cells removed during the TIDAL-01 Selection process. The columns highlighted in blue indicate that our Selected TILs displayed several orders of magnitude higher levels of potency indicators when compared to bulk TILs or bystander cells for a colorectal cancer patient sample. Additionally, the responses of bulk TIL resembled those of bystander cells, suggesting the predominance of bystander cells in the bulk TIL population.



Across all the samples from which we conducted this assessment, for IFNg, the fold increase between the TIDAL-01 Selected TILs and the bulk TILs ranged between 2 to 86-fold, with an average increase of approximately 27 fold; for TNFα the fold increase between the TIDAL-01 Selected TILs and the bulk TIL ranged between 1.6 to 95-fold with an average increase of approximately 25-fold; and for granzyme B the fold increase between the TIDAL-01 Selected TILs and the bulk TIL ranged between 1.5 to 33-fold with an average increase of approximately 9 fold.

4. Tumor-killing activity of Selected TIL products

In order to evaluate the antitumor activity of TIDAL-01, we compared the impact of Selected TILs and bystander cells from the same patient on tumor cells derived from that patient. Selected TILs and bystander cells were mixed with patient-derived tumor cells for 48 hours. The cell populations were analyzed by video microscopy, and image analysis algorithms were used to assess the number of dead and alive tumor cells at regular intervals. Selected TILs displayed a higher capacity to kill tumor cells relative to bystander cells as depicted in the figure below for a melanoma patient sample. Given the considerable technical challenges in maintaining patient-derived tumors as disaggregated single cell cultures that maintain tumor-reactive antigen expression, we have successfully completed this study only using the single melanoma patient sample depicted below.



5. Functionally competent T cells in the final product

To ensure that TIDAL-01 is comprised of functionally competent T cells, we conducted an immunophenotypic analysis of Selected TILs following the TIDAL-01 Expansion process. Multiparameter flow cytometry was used to quantify the expression of key indicators of functionality, including markers for T cell exhaustion (PD-1, TIM-3 and LAG-3) and T stem central memory, or Tscm (CD45RA+, CCR7+ and CD27+).

In a single sample that was assessed for overlapping expression of PD-1, TIM-3 and LAG-3, TIDAL-01 showed low (2%) and predominantly non-overlapping expression of PD-1, TIM-3 and LAG-3, indicating a lack of functional exhaustion in the final drug product. Additionally, in 3 tumor samples that were assessed for overlapping PD-1 and TIGIT expression representative of exhaustion, only 0.7% - 11% of the drug product demonstrated overlapping expression of the two markers.

In a single sample that was assessed, TIDAL-01 also demonstrated a relatively high frequency of cells co-expressing CD45RA+, CCR7+, and CD27+, indicating the presence of a Tscm subset. The frequency of long-lived T cells displaying markers associated with Tscm populations has been associated with enhanced outcomes in response to T cell immunotherapy (Ren, Cao & Wang 2021), and there is clinical evidence of a highly significant association between the likelihood of having a complete response and the infusion of TIL containing CD8+ CD27+ cells (Rosenberg et al., 2011).

Clinical Development Strategy

Our clinical strategy is designed to evaluate the activity of TIDAL-01 in multiple solid tumor indications. We seek to: (i) generate clinical data through a multi-site trial in indications where objective

responses for bulk TILs have not been demonstrated in clinical trials and (ii) determine the clinical activity of TIDAL-01 in indications where bulk TILs have previously shown objective response rates in clinical trials, through an investigator-initiated trial.

Multisite solid tumor clinical trial: We have initiated a multicenter Phase 1 trial evaluating TIDAL-01 for the treatment of patients with breast cancer, colorectal cancer and uveal melanoma. These tumor types are generally characterized by a low TMB, and have not historically benefitted from bulk TIL therapy. Given the limited treatment options in these indications, the historically low response rates, and our belief in the therapeutic potential of Selected TILs in challenging solid tumors, we are developing TIDAL-01 for the potential treatment of these indications. We are initially targeting enrollment of 40 to 60 patients across the three indications with the following criteria:

- Patients with unresectable or metastatic breast cancer who have relapsed on at least one prior treatment for metastatic disease including guideline directed targeted therapy for eligible subtypes.

- Patients with unresectable or metastatic colorectal cancer including both MSS and MSI subtypes. MSS-colorectal cancer patients must have received a prior regimen containing at least oxaliplatin or irinotecan. MSI-colorectal cancer patients must have failed or progressed on a prior regimen with anti-PD-(L)1 therapy.

- Patients with uveal melanoma that have only received local-regional or adjuvant therapy if systemic treatments are contra-indicated or unavailable.

Melanoma-focused clinical trial at Moffitt Cancer Center: We have initiated an investigator sponsored Phase 1 clinical trial for TIDAL-01 in collaboration with Moffitt, Investigator sponsored trials are clinical trials where the investigator of the trial is also the “sponsor” of the trial for regulatory purposes. An “investigator” conducts clinical investigations and is the person under whose immediate direction the study drug is administered or dispensed to patients. A “sponsor” initiates and takes responsibility for a clinical investigation. A person who both initiates and conducts a clinical trial, and is responsible for all regulatory requirements, is designated as a “sponsor-investigator” by the FDA. Clinical investigators at academic medical centers who initiate clinical trials with a lawfully marketed drug to be used in a patient population or indication not within the official labeling often fit within this designation. In addition, as is the case with our investigator-sponsored trials, a company may provide a sponsor-investigator with supply of its unapproved product candidate and funding for the trial. Investigators who initiate and conduct such trials are responsible for obtaining an IND from the FDA and for ensuring compliance with the IND and associated regulatory requirements. As provided by the FDA’s regulations, the sponsor of a clinical trial is responsible for, among other things, selecting qualified investigators, providing them with the information they need to conduct the trial properly, ensuring proper monitoring of the trial, ensuring that the trial is conducted in accordance with the protocols contained in the IND, maintaining an effective IND with respect to the trial, and ensuring that the FDA and all participating investigators are promptly informed of significant new adverse effects or risks with respect to the drug. In contrast, in a company-sponsored trial, the pharmaceutical company whose drug will be studied is the sponsor of the trial and, as such, is responsible for ensuring compliance with all regulatory requirements, including obtaining the IND.

Under our multi-site trial, we control all aspects of our trial including, but not limited to, study protocol development, patient selection and enrollment, regulatory interactions, data release, and manufacturing through our CDMO. Under the investigator sponsored trial, which is fully funded by us, Moffitt is solely responsible for regulatory interactions, trial conduct and manufacture of TIDAL-01 at the Moffitt Cancer Cell Therapy Facility, with input and support from us at Moffitt's discretion. Investigators at Moffitt are also solely responsible for the design of the trial and patient selection and enrollment, where we remain in close contact with the investigators to provide our input if appropriate. Any data disclosures will be made in collaboration with us and any improvements to the TIDAL-01 manufacturing process are solely at our discretion. In this trial we are targeting enrollment of approximately 25 patients across three cohorts including:

- Patients with cutaneous (non-acral) melanoma having failed prior anti-PD-(L)1, anti-CTLA-4, and BRAF+/- MEK inhibitor if BRAF V600 mutant.

- Patients with acral, mucosal, or uveal melanoma having failed prior standard of care in the opinion of the investigator.

- Patients with melanoma (cutaneous, mucosal, or uveal) undergoing therapeutic resection whose tissue samples were collected and banked and who have a high likelihood of recurrence or progression within two years. TIDAL-01 product will only be generated and administered to these patients at time of recurrence.

All patients across our trials will undergo surgery to remove a small amount of their tumor to initiate the manufacturing process. The patient-specific TIDAL-01 product candidate will be manufactured and sent back to the clinical site, and patients will be treated with a conditioning regimen that includes lymphodepleting chemotherapy prior to treatment with TIDAL-01 and treatment with IL-2 following TIDAL-01 infusion, to support further proliferation of TIDAL-01 *in vivo*. Both lymphodepleting chemotherapy and treatment with IL-2 are standard for bulk TIL therapies.

In our multi-site solid tumor trial, patients will also be receiving pembrolizumab as their anti-PD-(L)1 treatment two weeks after the TIDAL-01 infusion. Combination with anti-PD-(L)1 has the potential to enhance and prolong the activity of TIDAL-01 by minimizing PD-1 driven T cell exhaustion in indications where anti-PD-(L)1 monotherapy has demonstrated little to no objective responses in clinical trials. Pembrolizumab will be dosed every three weeks until confirmed progressive disease or CR. Additionally as part of our multi-site solid tumor trial we are also exploring the inclusion of low dose radiation therapy, or LDRT as part of the conditioning regimen with the first dose of LDRT administered immediately prior to the TIDAL-01 infusion and the second dose administered following IL-2 treatment, prior to initiating pembrolizumab. Inclusion of LDRT as part of the conditioning regimen, has the potential to enhance T cell penetration into the tumor and reduce the inhibitory tumor stroma microenvironment to further potentiate the depth of response to TIDAL-01. Lastly, we are also exploring expansion into additional indications including non-small cell lung cancer and head and neck squamous cell carcinoma.

The primary endpoint of both trials will be safety and tolerability of TIDAL-01, with secondary endpoints focusing on efficacy based on measures including ORR and durability of response. Additionally, TIDAL-01 clinical translational studies will include investigational endpoints, including TCR sequencing and detailed T cell subset immunophenotyping, that are designed to define the pharmacokinetic profile of the selected TIL drug products together with key aspects of pharmacodynamic profiles. These data will be correlated with clinical outcomes to enable future refinement of clinical dosing regimens and, in combination with drug product characterization data collected during manufacture, support the validation of mechanistically relevant potency release endpoints. We intend to provide an initial clinical update across these two trials in mid-2024.

TIDAL-02

Overview

TIDAL-02 is our next Selected TIL program where we are developing a next generation streamlined manufacturing process designed for selecting tumor-reactive T cells and additional modifications to enhance TIL quality and function. We believe that streamlined manufacturing has the potential to provide commercial advantages, as well as enable access to solid tumor indications where patients may progress rapidly. The TIDAL-02 manufacturing process targets less than three weeks of production time and will seek to employ a direct selection process step that utilizes our proprietary combination of selection markers to select for the greatest breadth of tumor-reactive T cells without requiring sequencing or peptide generation. Additionally, we believe that enhancing quality, function, and phenotype of T cells has the potential to drive additional activity in solid tumors. To enhance Selected TIL quality and function, we are assessing two key strategies: (i) culture enhancements to improve and maintain quality and function of the Selected TILs during *ex vivo* cell expansion and (ii) evaluation of functional genetic modifications of the Selected TILs to ensure durable enhancements to TIL quality and persistence *in vivo*. We believe that TIDAL-02 has the potential to address the medical need in solid tumor indications that are distinct but complementary to TIDAL-01, with the goal of moving into earlier lines of therapy. TIDAL-02 is currently in preclinical development.

TIDAL-02 Process Parameters

We are currently assessing three key process parameters to guide development of our TIDAL-02 product candidate that will be advanced into IND enabling studies. These three process parameters include: direct selection, gene editing, and enhanced isolation and expansion, as described below.

- *Direct Selection*: Our direct selection process for TIDAL-02 will seek to utilize our proprietary combination of clinically defined selection markers to select for the greatest breadth of tumor-reactive T cells directly from the TIL population generated in the enhanced isolation process (see below). These selection markers are intended to be indication agonistic and have the potential to recognize cell surface receptors that are present only on the surface of tumor-reactive T cells. We will then physically sort the tumor-reactive T cells from the bystander cells that are not tumor-reactive, on the basis of these selection markers. Our ongoing collaboration with Dr. Simon Turcotte at CHUM is enabling us to screen and evaluate the application of our proprietary mix of direct selection markers across a broad range of solid tumors.

- *Gene Editing*: We are assessing and prioritizing clinically informed targets for functional genetic modifications that we believe have the potential to drive durable TIL quality and persistence *in vivo*. These gene edits will be designed to modify the tumor-reactive T cells to proliferate while resisting exhaustion post infusion, minimize their dependance on exogenous IL-2 for *in vivo* proliferation, and maintain their potential to kill tumors in suppressive tumor microenvironments. We plan to introduce these genetic modifications into our sorted population of directly selected TILs.

- *Enhanced Isolation and Expansion*: We are developing a set of culture media supplements to enhance our isolation and/or expansion steps. These supplements incorporate a mix of cytokines with the potential to rejuvenate dysfunctional and/or exhausted T cells. We aim to use these enhancements to improve and maintain TIL quality and function in culture to deliver a high-quality infusion product.

Selected TIL and Viral Immunotherapy

Overview

We believe that we are strongly positioned to be a leader in leveraging viral immunotherapy to further increase the activity of our TIL therapies, if approved. Viruses are naturally adept at reprogramming the TME, and we believe that our proprietary viral immunotherapies can be tailored to drive the best combination approach for TILs.

We are initially evaluating viral immunotherapies in combination with our lead Selected TIL product candidate, TIDAL-01, via two approaches: (i) administration of virus prior to TIL extraction to optimize TIL harvest and broaden applicability to additional tumor types with low immune cell infiltration, and (ii) administration of virus following treatment with TIDAL-01 to optimize TIL trafficking and infiltration into solid tumors and to support the anti-tumor functions of infiltrating immune cells. We are currently evaluating the optimal viral immunotherapy for combination with TIDAL-01 to advance into clinical development.

Selected TIL and Viral Immunotherapy Combination Strategies

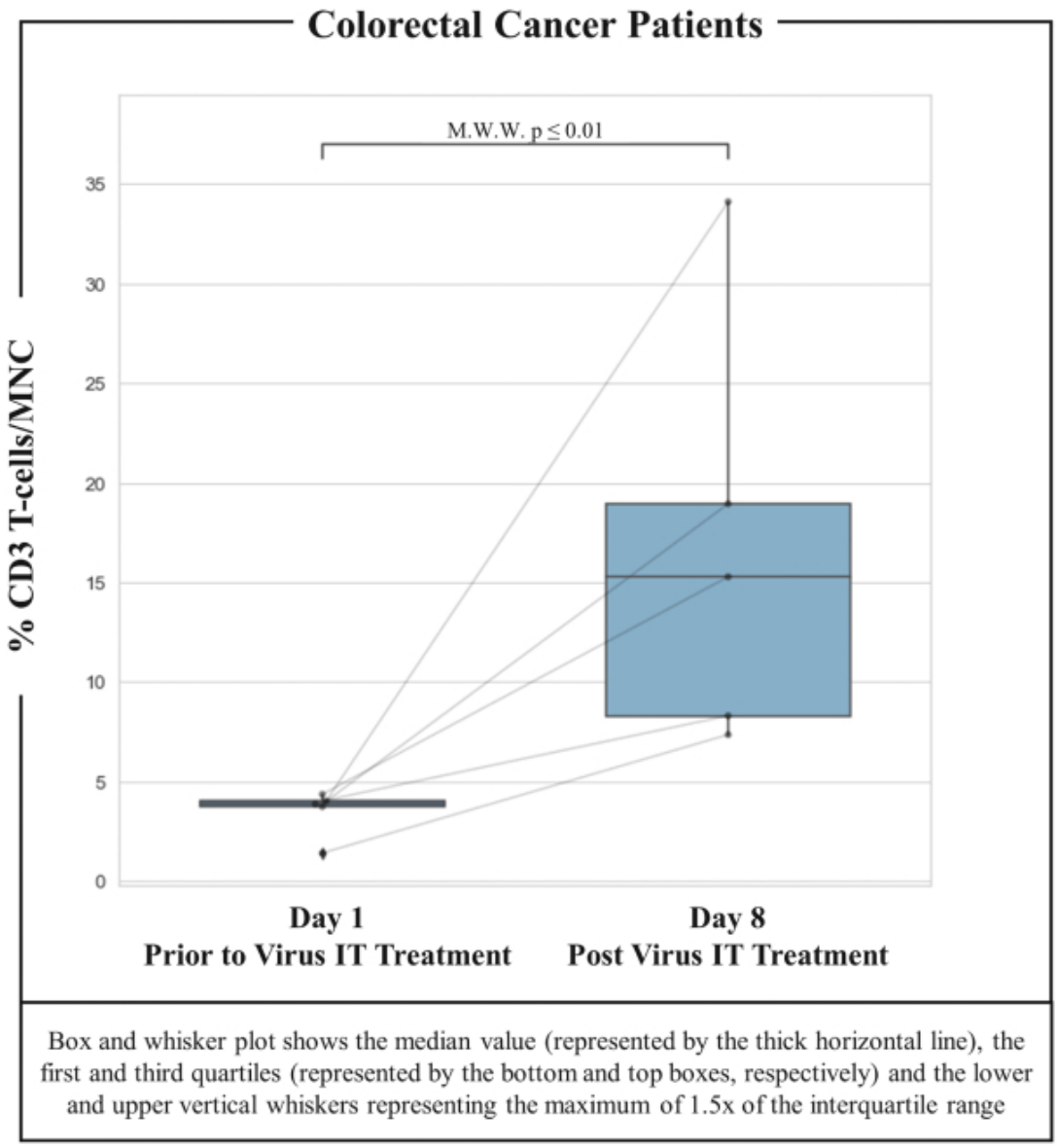
- *TIDAL-01 + Virus Pre-treatment:* We believe that treating patients with virus, prior to surgical resection of the tumor sample, has the potential to drive a superior TIL harvest that can result in a more potent TIDAL-01 product for the patient. Intra-tumoral, or IT, administration of virus into the tumor site targeted for TIL resection has the potential to disrupt the tumor cells via oncolytic killing and expose new antigens to the immune system thus driving a larger and more diverse population of tumor-reactive T cells into the tumor bed. We believe that pre-treatment of a patient with virus will enable a superior TIL harvest, with the potential to increase the quality, quantity, and breadth of TILs. We plan to target this approach specifically to patients for whom and indications for which the TIL yield is typically low, often leading to failure in generating a therapeutic product for the patient.

- *TIDAL-01 + Virus Post-treatment:* Viral immunotherapy has the potential to reprogram the immunosuppressive tumor microenvironment (*e.g.*, turn a ‘cold’ tumor ‘hot’) potentiating TIL infiltration, function, and proliferation within the tumor. In addition, the presence of virus at the tumor site can serve as a beacon to call TILs to the site of the tumor. Treating the patient with virus following TIDAL-01 has the potential to increase the activity of TIDAL-01 treatment, if approved, across several challenging solid tumors. We believe this combination strategy has the potential for improved patient outcomes in indications with highly suppressive TMEs that typically are resistant to immune mediated treatment regimens.

Clinical Evidence Supporting Viral Immunotherapy Combination

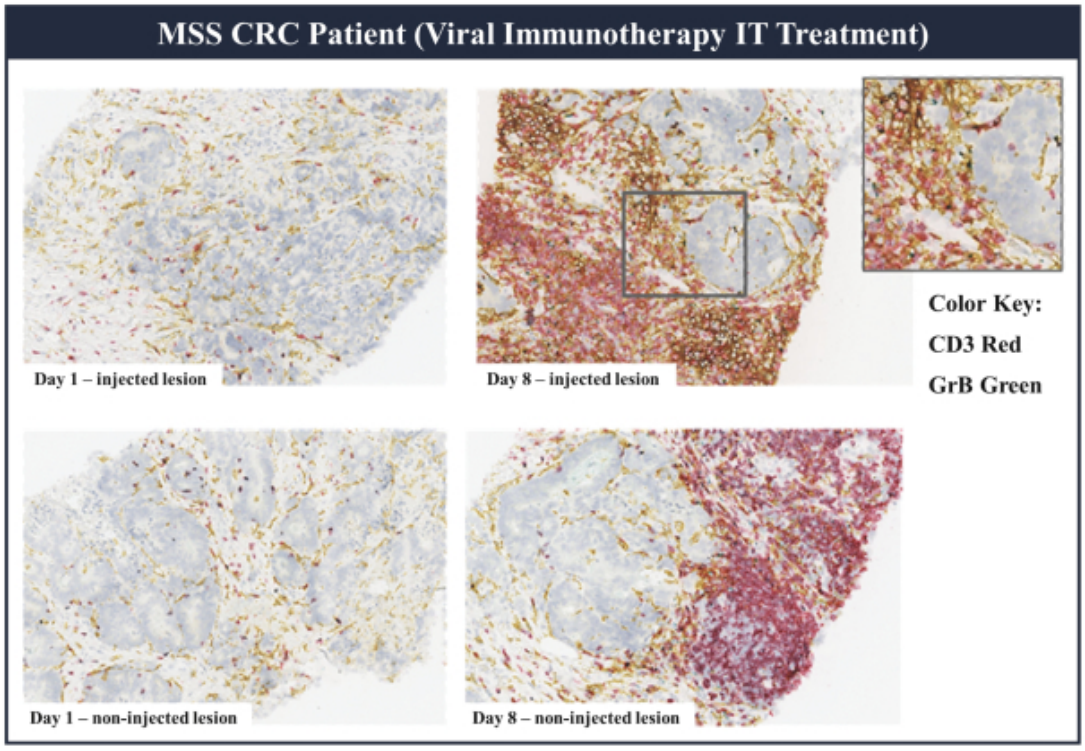
In our clinical experience with viral immunotherapy, we have observed that viruses improved immune cell infiltration of the tumor and were well tolerated. Based on clinical experience with one of our proprietary viral immunotherapies, we have seen preliminary translational data supporting the biological rationale for combination of our Selected TILs with viral immunotherapies.

We conducted a clinical study with one of our proprietary viral immunotherapies between 2020 and 2022 where we enrolled and treated 18 patients in a dose escalation study for intra-tumoral delivery of our virus across multiple tumor types. Five of these 18 patients in the study had colorectal cancer and the graph below shows comparative translational data for all five colorectal cancer patients from this clinical trial. When comparing the paired tumor biopsies prior to and seven days following IT administration of our virus, we have observed increased T cell infiltration in the injected lesion across multiple colorectal cancer patients as evidenced in the graph below.



Serious adverse events in the trial included the following: two incidences of each of abdominal pain and pyrexia (meaning fever or an increase in body temperature above normal range), and one incident of each of sinus tachycardia (meaning an increase in heart rate with a normal rhythm while at rest), inappropriate antidiuretic hormone secretion (secretion of anti-diuretic hormone, a hormone that retains water in order to maintain appropriate water and salt balance via the kidney, outside of regular physiological release from the pituitary gland), ascites (meaning buildup of fluid in the abdomen), colitis (meaning inflammation of the colon), nausea, chills, systemic inflammatory response syndrome, cholecystitis (meaning inflammation of the gallbladder), enterocolitis infection (inflammation of small or large intestine as a result of infection by a pathogen), hyponatraemia (meaning abnormally low levels of sodium in the blood), dizziness, hypoaesthesia (meaning reduced sense of touch or sensation, or a partial loss of sensitivity to sensory stimuli), monoparesis

(meaning partial loss of voluntary motor function in a single limb), acute respiratory failure, cough and haemorrhagic shock (meaning loss of blood or other fluid reducing the capacity of the heart unable to pump sufficient blood to the body). We have also observed that our proprietary viruses turned "cold" tumors "hot" by driving T cells into tumors that were immunologically cold due to highly suppressive TMEs. This was exemplified by immunohistochemical evidence of increased CD3+ cells with a cytotoxic phenotype (granzyme B expression) in a MSS-colorectal cancer patient in both injected and non-injected tumors following IT administration of one of our proprietary viral immunotherapies.



We believe that these data suggest that our viral immunotherapies have the potential to increase the number of intra-tumoral T cells across multiple solid tumor types, including tumors with an immunosuppressive TME and provides support for both pre- and post-treatment combination approaches with our Selected TIL pipeline programs.

Translational Assessment and Development Strategy

We are collaborating with the NCI to evaluate the generation of tumor-reactive T cells, which form the basis of our Selected TILs, from clinical tissue samples obtained from patients treated with our proprietary viral immunotherapies. NCI investigators are using NCI-developed methods and proprietary in vitro techniques to study lymphocytes derived from these patients, characterize their TCR specificity, and evaluate their persistence. We and the NCI plan to jointly analyze data and exchange information and expertise to advance the development of oncolytic viruses as a method for the generation of Selected TILs.

We are currently evaluating the optimal viral immunotherapy for combination with TIDAL-01 to advance into clinical development.

Manufacturing

We have established both internal and external technical operations, manufacturing, quality, and supply chain capabilities that support our pre-clinical and clinical assets. We have fully operational TIL cell therapy process and analytical development operations at our facility in San Diego, California. The site is approximately 20,000 square feet, and we have assembled an experienced team of cell therapy CMC experts. Our team of experts has completed technology transfer of TIDAL-01 to our U.S.-based CDMO, Charles River Laboratories, and our manufacturing sciences group is fully enabled to support development efforts across our Selected TIL pipeline. As of March 31, 2023, our technical operations team is composed of 38 employees spanning expertise across core CMC functional areas, including upstream and downstream process development, bioanalytical sciences, formulation, process scale-up, technology transfer, quality control, manufacturing operations, packaging, distribution, and supply chain.

To support our TIDAL product candidate and pipeline programs, we have formed deep partnerships across a global network of CDMOs that specialize in bioprocess development, testing, cGMP manufacturing, formulation and filling, packaging, controlled temperature storage, and distribution. For TIDAL-01, this includes a close partnership with the Cell Therapy Facility at Moffitt Cancer Center, responsible for cGMP manufacturing, testing, release, and distribution of Selected TIL to the clinical investigators at Moffitt under our investigator sponsored clinical trial. We have separate partnerships, fully controlled and supervised by us, for the sequencing and peptide manufacturing portions of the TIDAL-01 manufacturing process. In parallel, we have completed a technology transfer of the TIDAL-01 Selected TIL manufacturing process to a U.S.-based CDMO. We intend for this to be our primary cGMP manufacturing partner for clinical supplies for TIDAL-01, to serve multiple clinical sites, independent and complimentary to our partnership with Moffitt. In addition to this core TIL cell therapy manufacturing network, we have a network of contract testing partners to fully enable our quality control and analytical release testing program, for our TIDAL pipeline that is managed by our internal quality control team. Except for the Moffitt sponsored TIDAL-01 clinical trial, all clinical trial materials for use in clinical trials are released, stored, and managed under our quality systems.

As clinical trial development progresses forward, technical operations will scale in a complimentary approach, exploring both internal capabilities as well as deepening and expanding external relationships to ensure we remain in full control of our CMC development, through commercialization.

Commercialization

We do not currently have a commercial organization for the marketing, sales, and distribution of products. We are advancing our clinical product candidate and pipeline programs for the treatment of patients with solid tumors, most of whom are treated in specialized treatment centers or hospitals.

We plan to build our global commercialization capabilities internally over time such that we are able to commercialize any product candidate for which we may obtain regulatory approval. While we hold global rights to our product candidates, we may selectively pursue strategic collaborations with third parties in order to maximize the commercial potential of our product candidates.

Competition

The biotechnology and pharmaceutical industries are characterized by the rapid evolution of technologies and understanding of disease etiology, significant investment, and a strong emphasis on intellectual property. While we believe that our differentiated scientific expertise in the field of cancer immunotherapy provides us with competitive advantages, we face potential competition from multiple sources, including major pharmaceutical, specialty pharmaceutical and existing or emerging biotechnology companies, as well as from academic institutions, governmental agencies, and public and private research institutions. We anticipate that we will face intense and increasing competition as new drugs and therapies enter the market and advanced technologies become available.

Many of our competitors, either alone or with their strategic collaborators, have substantially greater financial, technical, and human resources than we do. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. These entities also compete with us in recruiting and retaining qualified scientific, manufacturing, and management personnel and establishing clinical trial sites and patient enrollment in clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. As a result, our competitors may discover, develop, license, or commercialize products before or more successfully than we do.

We face competition from segments of the pharmaceutical, biotechnology, and other related markets that pursue the development of TIL or other cell therapies for the treatment of solid tumors. Companies that are developing TIL therapies include Iovance Biotherapeutics, Inc., Achilles Therapeutics plc, Instil Bio, Inc., Intima Bioscience, Inc., KSQ Therapeutics, Inc., Lyell Immunopharma, Inc., Obsidian Therapeutics, Inc, and others. In addition, we may face competition from companies focused on CAR-T and TCR-T cell therapies for solid tumors, such as Adaptimmune Therapeutics PLC, Adicet Bio, Inc., Alaunos Therapeutics, Inc., Atara Biotherapeutics, Inc., and Immatics N.V. Other privately held biotechnology companies are evaluating neoantigen directed T cell approaches. We cannot predict whether new types of immunotherapies including novel checkpoint inhibitors may be enhanced and show greater efficacy, and we may have direct and substantial competition from such immunotherapies in the future. In addition, there are companies utilizing other cell-based approaches that may be competitive to our product candidates. More effective small molecules, cancer vaccines and other approaches may be developed and used as first line or second line treatments, which would reduce the opportunity for our Selected TIL therapies. 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 methods. 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 TIL product 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 TIL products 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 TIL 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 with a more favorable label than our TIL product 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.

Myst Merger Agreement

In December 2020, we entered into the Myst Merger Agreement, by and among our company, Flatiron Merger Sub I, Inc., or Merger Sub, Flatiron Merger Sub II, LLC, or Merger LLC, a direct, wholly-owned subsidiary of ours, Myst Therapeutics, Inc., or Myst, and Timothy Langer, the sole common stockholder of Myst, or Langer. Pursuant to the Myst Merger Agreement, the business combination, or the Merger, was effected in two steps. The first step was the merger of Merger Sub with and into Myst. The second step was the merger of Myst with and into Merger LLC. The Merger closed on December 14, 2020 and the effective date of the Merger was January 20, 2021. As a result of the Merger, the separate existences of Merger Sub and Myst ceased, and Merger LLC became our wholly-owned subsidiary.

Pursuant to the Myst Merger Agreement, on December 15, 2020, we paid the former equity holders of Myst, or the Myst Holders, a one-time up-front payment of $9.0 million in cash. We paid an additional cash consideration of $1.0 million to the Myst Holders on June 14, 2022. We also issued Langer 725,920 shares of our common stock. Of these shares, 362,960 shares of our common stock were issued upon the closing of the Merger and the remaining 362,960 shares were held in escrow with 25% vesting in December of each year that Langer remains our employee. As of December 31, 2022, Langer is still employed by our company and 181,480 shares of our common stock have vested and been released from escrow, with the remaining 181,480 shares of our common stock to be released in equal annual installments over the next two years based on his continued employment.

In addition, under the Myst Merger Agreement, each Myst Holder is entitled to receive certain payments as consideration based on the achievement by us of three predefined milestones. The initial milestone is the closing of an initial public offering, which will be triggered by the closing of this offering, the second milestone is the first acceptance by the FDA of an IND filed by, on behalf of or for the benefit of us, or the our sublicensees for a product being developed by or on behalf of us or our sublicensees that is claimed as a product or method of making or using the product by a pending or issued Myst patent claim existing at the time of such acceptance, and the third milestone is the occurrence of the earlier of (i) the commencement of the first registration study for a product being developed by, on behalf of or for the benefit of us or our sublicensees that is claimed as a product or a method of making or using the product by an issued Myst patent claim existing as of the time of such commencement or (ii) the issuance of a Myst patent claim that claims a product or method of making or using the product then being developed by, on behalf of or for the benefit of us or our sublicensees, that is or was the subject of a registration study that has or had commenced. The milestones are not contingent on one another, and the milestones do not need to be achieved in any specific order.

Within 45 days of the achievement of the initial milestone, which the closing of this offering triggers, we are obligated to pay the Myst Holders an aggregate amount equal to $3.0 million. At our election, we may pay this consideration in cash or in shares of our common stock. The fair market value of our common stock measured after this offering, is the volume weighted-average closing price of our common stock on Nasdaq for the consecutive 20 trading day period ending on the last trading day on or prior to the date on which the milestone was earned pursuant to the Myst Merger Agreement. If we elect to pay the Myst Holders this consideration in the form of shares of our common stock, then our existing stockholders will experience further dilution.

Within 45 days of the achievement of the second milestone, we are obligated to pay the Myst Holders an aggregate amount equal to $10.0 million. At our election, we may pay this consideration in cash or in shares of our common stock. In May 2022, this $10.0 million milestone was achieved, and we elected to pay $5.0 million in shares of our common stock and $5.0 million in cash. We entered into a letter agreement dated July 25, 2022 with the former equityholders of Myst regarding the $10.0 million milestone payment that became due and owing to the Myst Holders, in which we agreed to pay to the former optionholders of Myst on or before July 28, 2022 $0.6 million in cash, with the remaining $9.4 million payable to Langer as follows: (i) on or before July 28, 2022, $2.2 million in cash, (ii) on or before July 31, 2022, $5.0 million in shares of our common stock and (iii) on or before January 10, 2023, $2.2 million in cash. On June 8, 2022, we issued Langer 212,203 shares of our common stock to settle the $5.0 million obligation payable in common stock. We then paid the Myst Holders $2.8 million in July 2022, with $2.2 million paid to Langer and $0.6 million paid to the remaining Myst Holders, and the remaining $2.2 million was paid to Langer in January 2023.

Within 45 days of the achievement of the third milestone, we are obligated to pay the Myst Holder an aggregate amount equal to $20.0 million. At our election, we may pay this consideration in cash or in shares of our common stock. If we elect to pay the Myst Holders this consideration in the form of shares of our common stock, then our existing stockholders will experience further dilution.

Pursuant to the Myst Merger Agreement, we had agreed to use commercially reasonable efforts to (i) cause a registration statement covering the sale on a continuous basis of the shares of our common stock to be

declared effective as soon as reasonably practicable after filing such registration statement or (ii) register the resale of such shares of our common stock under an existing registration statement without amendment. Langer has waived his registration rights in connection with this offering.

Collaboration Agreements

Moffitt Collaboration Agreements

Master Collaboration Agreement

In January 2021, we entered into an amended and restated master collaboration agreement, or the Moffitt Agreement, with Moffitt, to amend a then-existing master collaboration agreement from November 2019, as amended March 2020, between Moffitt and our now wholly-owned subsidiary, Myst Therapeutics LLC, with the intent to continue to work collaboratively in the research of cancer immunotherapies.

Each party granted the other party a right to use its research materials for performance of the research plans agreed to by the parties, or Research Plans. Each party granted the other party a non-exclusive, worldwide, sublicensable, perpetual, irrevocable, royalty-free license under all inventions invented in performance of a Research Plan and invented jointly by us and Moffitt, or Joint Inventions (with certain exclusions) to make, use, sell, offer for sale, import products and services and/or otherwise practice such inventions.

We granted Moffitt a royalty free, non-sublicensable, non-transferable, perpetual, non-exclusive license to use and practice certain inventions invented solely by us in the performance of a Research Plan for its internal non-commercial research purposes.

Moffitt granted us (i) a royalty-free, sublicensable, non-transferable, perpetual, non-exclusive license to use and practice certain inventions invented solely by Moffitt in the performance of a Research Plan, or Moffitt Inventions, (a) for internal, non-commercial research purposes outside the field of ACT and/or (b) to research, develop, make, use, sell, offer to sell, or import products and/or services in the field of ACT and (ii) a royalty free, sublicensable, non-transferable, perpetual, non-exclusive license to use and practice certain inventions invented in performance of a Research Plan or through the use of specified Moffitt research materials.

Moffitt granted us an option to obtain, with terms to be negotiated in good faith under commercially reasonable terms, a royalty-bearing, sublicensable exclusive license in the Moffitt Inventions, the TCR Inventions, and/or Moffitt's interest in Joint Inventions. We can exercise this option at any time within six months after Moffitt informs us of any new invention, and upon our exercise, the parties will have a period of six months to negotiate the terms of such exclusive license.

The Moffitt Agreement will expire upon the later of (i) four years from the effective date of the Moffitt Agreement or (ii) the termination or expiration of all Research Plans in effect under the Moffitt Agreement, unless extended upon mutual written agreement of the parties. Either party may terminate the Moffitt Agreement for cause upon any uncured breach by the other party or upon the insolvency of the other party.

Moffitt Alliance Agreement

In June 2022, we entered into a life science alliance agreement with Moffitt, or the Alliance Agreement, in order to further expand our relationship and support our existing agreements with Moffitt, or the Underlying Agreements. Pursuant to the Alliance Agreement, we will have priority access to Moffitt's scientific research, manufacturing, and clinical capabilities for the development of novel TIL therapies, including expedited clinical trial activation, enhanced patient screening and data sharing, access to Moffitt's cellular therapies research and development infrastructure, expanded molecular data sets and biospecimens for research, and allocated cGMP manufacturing capacity for our product candidates.

Under the Alliance Agreement, we are obligated to use commercially reasonable efforts to further develop TIL Products (as defined below), to manufacture TIL Products, to obtain regulatory approval for at least one TIL Product in the United States and to commercialize TIL Products in all countries in which regulatory approval for a TIL Product has been obtained. For purposes of the Alliance Agreement, TIL Product means any pharmaceutical, biopharmaceutical, or biotechnology TIL product that has been developed by us or Moffitt and is advanced into clinical development under an IND sponsored by Moffitt.

Pursuant to the Alliance Agreement, we have agreed to pay to Moffitt a total amount of at least $17.5 million, the Alliance Funding Amount, for research, development and manufacturing related services that will be paid in five equal annual installments on June 1st of each year starting on June 1, 2023. However, the aggregate amount we pay to Moffitt for all fees, costs, expenses and other payments pursuant to any Underlying Agreement with Moffitt entered into subsequent to February 7, 2022 may be credited against the Alliance Funding Amount. This reimbursement amount will be calculated annually at the conclusion of each payment period, and, to the extent our annual aggregate payments to Moffitt exceed the applicable annual installment amount, we will receive a reduction in the amount due for future installment payments based on a predetermined formula agreed to by the parties.

In connection with the execution of the Alliance Agreement, we issued Moffitt 91,721 shares of our common stock. As partial consideration under the Alliance Agreement, we also agreed to issue Moffitt an additional 366,884 shares of our common stock in the aggregate upon the satisfaction of certain clinical and regulatory milestones with respect to TIL Products. During the three months ended March 31, 2023, an additional 91,721 shares of common stock were issued to Moffitt as a result of the achievement of the milestone related to the start of the Phase 1 clinical trial for a TIL Product. In addition, upon achievement of certain thresholds for aggregate net sales of all TIL Products, we are required to make tiered sales-based milestones payments to Moffitt of up to an aggregate of $50.0 million. With respect to each of the equity and sales milestones described above, TIL Products include any pharmaceutical, biopharmaceutical or biotechnology TIL product that is developed by us or Moffitt and is advanced into clinical development under an IND sponsored by Moffitt.

Unless earlier terminated, the Alliance Agreement will remain in effect for a term of five years and may be extended for additional periods upon the mutual written consent of both parties. Either party may terminate the Alliance Agreement in the event of (i) the other party's material breach of the Alliance Agreement that remains uncured after ninety days of receiving written notice of such breach (or in the case of breach of payment obligations, within ten days), (ii) the other party's insolvency and (iii) a pandemic event resulting in government lockdowns or orders that legally compel such party to cease operations or that result in material disruptions in the available workforce and prevents such party from performing its contractual obligations for a period of more than six months. At any time after June 1, 2025, either party may terminate the Alliance Agreement without cause upon sixty days prior written notice to the other party, or a Termination for Convenience. Upon a Termination for Convenience, the terminating party shall pay to the other party a termination fee in an amount equal to a low double digit percentage of the then remaining Alliance Funding Amount. Termination or expiry of one or more Underlying Agreements does not affect the term of the Alliance Agreement, which will continue to apply to the remaining ongoing Underlying Agreements.

Intellectual Property

Our commercial success may depend in part on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions, improvements and know-how related to our business; defend and enforce our patents and other intellectual property; preserve the confidentiality of our trade secrets; and operate without infringing or otherwise violating the valid enforceable patents and proprietary rights of third parties. Our ability to stop third parties from making, using, selling, offering to sell or importing our products and methods may depend on the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. With respect to both licensed and company-owned intellectual property, we cannot be sure that patents will be granted with respect to any of our pending patent applications or

with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our commercial products and methods of manufacturing the same. We may rely, in some circumstances, on trade secrets to protect our technology. However, trade secrets can be difficult to protect. See “Risk Factors—Risks Related to Our Intellectual Property.”

We actively seek to protect our proprietary technology, inventions, and other intellectual property that is commercially important to the development of our business by a variety of means, such as seeking, maintaining, and defending patent rights, whether developed internally or licensed from third parties. We also may rely on trade secrets and know-how relating to our proprietary technology platform, on continuing technological innovation and on in-licensing opportunities to develop, strengthen and maintain the strength of our position in the field of cell therapy that may be important for the development of our business. We may also seek patent protection or rely upon trade secret rights to protect other technologies that may be used to discover and validate targets, as well as to manufacture and develop novel cell or viral therapy products. Additional regulatory protection may also be afforded through data exclusivity, market exclusivity and patent term extensions where available.

As of May 2, 2023, we own or exclusively license 14 issued U.S. patents and 96 issued foreign patents in Australia, Austria, Belgium, Brazil, Canada, China, France, Germany, Great Britain, Hong Kong, India, Ireland, Israel, Italy, Japan, Lebanon, Luxembourg, Mexico, Netherlands, Russia, and Spain. We currently own or exclusively license 13 pending U.S. patent applications, eight U.S. provisional applications, and 121 pending foreign patent applications in Algeria, Argentina, Australia, Brazil, Canada, Chile, China, Colombia, Egypt, Europe, Gulf Coast Cooperation, Hong Kong, India, Israel, Japan, Korea, Malaysia, Mexico, New Zealand, Peru, Philippines, Singapore, South Africa, Thailand, Ukraine and Vietnam.

TIL Therapy, Including TIDAL-01

We own four patent families related to TIL therapy that are filed worldwide. The first TIL-001, includes 12 patent applications pending in Australia, Brazil, Canada, China, Europe, Hong Kong, India, Israel, Korea, Mexico, New Zealand and the United States. The TIL-001 patent applications are directed to a processing method for producing autologous T cells for the treatment of cancer and resulting cell therapy compositions, which, if issued, are expected to expire in 2040, without taking into account any possible patent term adjustment or extension and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

The second family, TIL-002, includes 13 patent applications pending in Australia, Brazil, Canada, China, Europe, Hong Kong, India, Israel, Japan, Korea, Mexico, New Zealand and the United States. The TIL-002 patent applications are related to further aspects of processes for producing a TIL therapy and related compositions and methods, and patents that issue from this family, if any, are expected to expire in 2040, without taking into account any possible patent term adjustment or extension and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

The third family, TIL-003, includes 10 patent applications pending in Australia, Canada, China, Europe, Hong Kong, Israel, Japan, Korea, New Zealand and the United States. The TIL-003 patent applications are directed to methods of producing tumor-reactive T cell compositions using modulatory agents, and patents that issue from this family are expected to expire in 2040, without taking into account any possible patent term adjustment or extension and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

The fourth family, TIL-004, includes 12 patent applications pending in Australia, Brazil, Canada, China, Europe, Israel, India, Japan, Korea, Mexico, New Zealand and the United States. The TIL-004 patent applications are directed to methods for ex vivo enrichment and expansion of tumor-reactive T cells and related compositions, and any patents that issue from this family are expected to expire in 2041, without taking into

account any possible patent term adjustment or extension and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

We own four provisional application families, in which, if patents from applications claiming priority to these provisional applications issue, the patents are expected to expire in 2043 or 2044, without taking into account any possible patent term adjustment or extension and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees. One provisional application family is directed to methods of producing tumor-reactive T cell compositions using multi-specific binding agents. We have two provisional application families directed to particular TIL compositions and related methods, and a further provisional application family directed to combination of TILS and viral immunotherapy.

Orthopox/Vaccinia Viral Therapy

We own or exclusively license four patent families and one provisional application family directed to oncolytic orthopox, e.g., vaccinia, modified viral compositions that may contain transgenes that encode therapeutic payloads, and methods of using and making such viral compositions.

The first family, SKV-001, is licensed from Ottawa Hospital Research Institute, and includes 11 patent applications pending in Australia, Brazil, Canada, China, Europe, India, Israel, Japan, Korea, Mexico and the United States. Pending SKV-001 claims include claims directed to particular modified vaccinia backbone compositions, including modified vaccinia compositions that express one or more transgenes, and methods of using the viral compositions for the treatment of various cancers. Patents that may issue from this family are expected to expire in 2039, without taking into account any possible patent term adjustment or extension and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

The second patent family, SKV-002, is co-owned with Ottawa Hospital Research Institute, and includes 15 patent applications pending in Australia, Brazil, Canada, China, Europe, Hong Kong, India, Israel, Japan, Korea, Mexico, Singapore, Thailand, Ukraine and the United States. The pending SKV-002 claims include claims directed to modified orthopoxvirus, e.g., vaccinia, compositions, including modified orthopoxvirus compositions that express particular transgenes, and methods for using the compositions for the treatment of various cancers. Patents that may issue from this family are expected to expire in 2039, without taking into account any possible patent term adjustment or extension and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

The third patent family and fourth patent families, SKV-003PC1 and SKV-003PC2, are co-owned with Ottawa Hospital Research Institute and have claimed directed to compositions of a particular modified vaccinia virus that expresses particular transgenes, and methods of using the modified vaccinia viruses for treatment of cancers. The SKV-003PC1 family contains 24 patent applications pending in Algeria, Argentina, Australia, Canada, Chile, China, Colombia, Egypt, Europe, Gulf Cooperation Council, Hong Kong, Israel, Japan, Korea, Malaysia, Mexico, New Zealand Peru, Philippines, Singapore, South Africa, Thailand, United State and Vietnam, and one issued patent in Lebanon. The SKV-003PC2 family contains 11 patent applications pending in Australia, Canada, China, Europe, Hong Kong, Israel, Japan, Korea, Mexico, New Zealand and the United States. Patents that may issue from the SKV-003PC1 or SKV-003PC2 families are expected to expire in 2039, without taking into account any possible patent term adjustment or extension and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

We also own a provisional application family, in which, if patents from applications claiming priority to these provisional applications issue, the patents are expected to expire in 2044, without taking into account any possible patent term adjustment or extension and assuming payment of all appropriate maintenance renewal, annuity or other governmental fees. The provisional application family is directed to compositions of a recombinant vaccinia virus encoding a particular Natural Killer cell and T lymphocyte inhibitor.

Additional Miscellaneous Virus IP

The first family, TBI-001, is licensed and includes 28 granted patents, in particular, two granted patents in each of Austria, Belgium, Canada, China, France, Germany, Great Britain, Ireland, Italy, Japan, Luxembourg the Netherlands, Spain and the United States. One patent application is pending in the US. Granted TBI-001 patent claims include claims directed to particular recombinant rhabdovirus compositions and uses thereof for treatment of cancer. Patents that have issued or may issue from this family are expected to expire in 2027, without taking into account any possible patent term adjustment or extension and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

The second family, TBI-002, is licensed and includes 12 granted patents, in particular, two United States patents and one granted patent in each of Austria, Belgium, China, France, Germany, Great Britain, Ireland, Italy, Luxemburg, the Netherlands and Spain. One patent application is pending in Canada. Granted TBI-002 patent claims include claims directed to methods of using particular recombinant rhabdovirus vectors that express a tumor antigen for treatment of cancer, and kits that comprise such vectors. Patents that have issued or may issue from this family are expected to expire in 2030, without taking into account any possible patent term adjustment or extension and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

The third family, TBI-003, is licensed and includes 25 granted patents, in particular, two granted patents in each of Australia, Brazil, Israel, Japan, Mexico and the United States and one granted patent in each of Austria, Belgium, Canada, China, France, Germany, Great Britain, India, Ireland, Italy, Luxemburg, the Netherlands and Spain. Granted TBI-003 patent claims include claims directed to particular attenuated rhabdovirus compositions, and particular oncolytic rhabdovirus compositions, and uses thereof for killing hyperproliferative cells and treatment of cancer. Patents that issued from this family are expected to expire in 2030, without taking into account any possible patent term adjustment or extension and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

The fourth family, TBI-004, is licensed and includes 5 granted patents, in particular, one granted patent in each of France, Germany, Great Britain, Japan and the United States. Granted TBI-004 patent claims include claims directed to methods of inducing an immunogenic response utilizing a viral particle encoding particular rhabdovirus proteins. Patents that issued from this family are expected to expire in 2032, without taking into account any possible patent term adjustment or extension and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

The seventh family, TBI-007, is licensed and includes 5 granted patents, in particular, one granted patent in each of France, Germany, Great Britain, Hong Kong and the United States. Granted TBI-007 patent claims include claims directed to methods of inducing a contemporaneous synergistic oncolytic virus infection of a cancer cell utilizing particular pairs of oncolytic viruses wherein one virus expresses an interferon (IFN) binding protein and the second virus is unable to block IFN gene expression. Patents that issued from this family are expected to expire in 2029, without taking into account any possible patent term adjustment or extension and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

The eighth family, TBI-009, is licensed and includes 5 granted patents, in particular, two granted United States patents and one granted patent in each of France, Germany and Great Britain. Granted TBI-009 patent claims include claims directed to compositions of an oncolytic virus encoding an FGF2 protein and a Type 1 interferon scavenger. Patents that issued from this family are expected to expire in 2034, without taking into account any possible patent term adjustment or extension and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

The tenth family, TBI-017, is licensed. Patent applications are pending in Canada, China, Europe, Hong Kong, Japan and the United States. Pending TBI-017 patent claims include claims directed to vaccine compositions comprising peptide antigens and oncolytic virus adjuvants, and methods of using the compositions

to induce an immune response. Patents that may issue from this family are expected to expire in 2039, without taking into account any possible patent term adjustment or extension and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

We have licensed one patent family covering a method of treating cancer by combining adoptive cell therapy (ACT) and an oncolytic virus vaccine. The patent family includes six granted patents, in particular, one granted patent in each of France, Germany, Great Britain, Ireland, the Netherlands and the United States. The issued patent claims include claims directed to combination therapies, methods of treating cancer and methods of producing a population of cells. Patent applications are pending in Canada, China, Europe, Hong Kong and the United states. Any patents issuing from this family are expected to expire in 2037, without taking into account any possible patent term adjustment or extension and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

Government Regulation and Product Approval

Government authorities in the United States (at the federal, state and local level) and in other countries extensively regulate, among other things, the research, development, testing, manufacturing, quality control, safety, effectiveness, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of biopharmaceutical products such as those we are developing.

Our product candidates must be approved by the FDA before they may be legally marketed in the United States and by the appropriate foreign regulatory authority before they may be legally marketed in foreign countries. Generally, our activities in other countries will be subject to regulation that is similar in nature and scope as that imposed in the United States, although there can be important differences. Additionally, some significant aspects of regulation in the European Union are addressed in a centralized way, but country-specific regulation remains essential in many respects. The process for obtaining regulatory approvals and the subsequent compliance with federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

U.S. Product Development Process

In the United States, the FDA regulates biological products, or biologics, under the Federal Food, Drug and Cosmetic Act, or FDCA, the Public Health Service Act, or PHSA, and their implementing regulations. The process required by the FDA before a biological product may be marketed in the United States generally involves the following:

- completion of nonclinical laboratory tests and animal studies according to good laboratory practices, requirements, or GLPs, and applicable requirements for the humane use of laboratory animals or other applicable regulations;
- submission to the FDA of an investigational new drug application, or IND, which must become effective before human clinical trials may begin;
- approval by an independent Institutional Review Board or ethics committee at each clinical site before the trial is commenced;
- performance of adequate and well-controlled human clinical trials according to the FDA's regulations commonly referred to as GCPs and any additional requirements for the protection of human research patients and their health information, to establish the safety, purity and potency (or efficacy) of the proposed biological product for its intended use;
- submission to the FDA of a biologics license application, or BLA, seeking marketing approval that includes substantial evidence of safety, purity, and potency from results of nonclinical testing and clinical trials;

- 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 Advisory Committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the biological product is produced to assess compliance with current good manufacturing practice requirements, or cGMPs, to assure that the facilities, methods and controls are adequate to preserve the biological product's identity, strength, quality and purity;
- potential FDA audit of the nonclinical study and clinical trial sites that generated the data in support of the BLA; and
- FDA review and approval of the BLA.

Before testing any biological product candidate, including our product candidates, in humans, the product candidate enters the preclinical testing stage. Preclinical tests, also referred to as nonclinical studies, include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the product candidate. The conduct of the preclinical tests must comply with federal regulations and requirements including GLPs. The clinical trial sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. Some preclinical testing may continue even after the IND is submitted. 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 raises safety concerns or questions regarding the proposed clinical trials and places the trial on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a biological product candidate at any time before or during clinical trials due to safety concerns or non-compliance. If the FDA imposes a clinical hold, trials may not recommence without FDA authorization and then only under terms authorized by the FDA.

In addition to the submission of an IND to the FDA before initiation of a clinical trial in the United States, certain human clinical trials involving recombinant or synthetic nucleic acid molecules are subject to oversight at the local level as set forth in the National Institutes of Health Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, or NIH Guidelines. Specifically, under the NIH Guidelines, supervision of human gene transfer trials includes evaluation and assessment by an Institutional Biosafety Committee, or 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, companies and other institutions not otherwise subject to the NIH Guidelines may voluntarily follow them.

Clinical trials involve the administration of the biological product candidate to patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety, including stopping rules that assure a clinical trial will be stopped if certain adverse events should occur. Each protocol and any amendments to the protocol must be submitted to the FDA as part of the IND. Clinical trials must be conducted and monitored in accordance with the FDA's regulations comprising the GCP requirements, including the requirement that all subjects provide informed consent. Further, each clinical trial must be reviewed and approved by an independent IRB at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable

in relation to anticipated benefits. The IRB also approves the form and content of the informed consent that must be signed by each clinical trial subject or his or her legal representative and must monitor the clinical trial 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.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1. The biological product is initially introduced into healthy human subjects or patients with the target disease or condition and tested for safety. 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 biological product is evaluated in a limited patient population with a specified disease or condition to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for the specific targeted diseases or condition and to determine dosage tolerance, optimal dosage and dosing schedule. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.

- Phase 3. Clinical trials are undertaken to further evaluate dosage, clinical efficacy, potency, and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk to benefit ratio of the product and provide an adequate basis for product approval.

- Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up. During all phases of clinical development, regulatory authorities require extensive monitoring and auditing of all clinical activities, clinical data, and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA, and the investigators for serious and unexpected adverse events, findings from other studies suggesting a significant risk to humans exposed to the same or similar product, findings from, animal or in vitro testing suggesting a significant risk to humans, and any clinically important increased incidence of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor’s initial receipt of the information. In addition, during the development of a new biological product, sponsors are given opportunities to meet with the FDA at certain points, including prior to submission of an IND, at the end of Phase 2, and before a BLA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and the FDA to reach alignment on the next phase of development. Sponsors typically use the meetings at the end of the Phase 2 trial to discuss Phase 2 clinical results and present plans for the pivotal Phase 3 clinical trials that they believe will support approval of the product candidate.

Concurrently with clinical trials, companies usually complete additional studies and must also develop additional information about the physical characteristics of the biological product as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. To help reduce the risk of the introduction of adventitious agents with use of biological products, the PHSA emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the sponsor must develop methods for testing the identity, strength, quality, potency and purity of the final biological product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the biological product candidate does not undergo unacceptable deterioration over its shelf life.

U.S. Review and Approval Processes

After the completion of clinical trials all required testing of a biological product in accordance with all applicable regulatory requirements, the results of product development, preclinical studies and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product candidate for one or more indications. FDA approval of a BLA must be obtained before commercial marketing of the biological product. The BLA submission must include results of all relevant data available from 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. Data can come from company sponsored clinical studies intended to test the safety and effectiveness of a use of the product candidate, or from a number of alternative sources, including studies initiated by independent investigators.

Under the Prescription Drug User Fee Act, as amended, or PDUFA, each BLA must be accompanied by a significant user fee. The FDA adjusts the PDUFA user fees on an annual basis. PDUFA also imposes an annual program fee for biological products. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

Within 60 days following submission of the application, the FDA reviews a BLA submitted to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA's goal is to review standard applications within ten months after the filing date, 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 may also be extended by FDA requests for additional information or clarification. The FDA reviews the BLA to determine, among other things, whether the proposed product is safe, pure and potent for the proposed indication, and the facility in which it is manufactured, processed, packed or held meets standards designed to assure and preserve the product's identity, safety, strength, quality, potency and purity. The FDA may refer applications for novel biological products or biological products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving a BLA, the FDA will generally inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure that the clinical trials were conducted in compliance with IND trial requirements and GCP

requirements. To assure cGMP and GCP compliance, an applicant must incur significant expenditure of time, money and effort in the areas of training, record keeping, production, and quality control.

Notwithstanding the submission of relevant data and information, the FDA may ultimately decide that the BLA does not satisfy its regulatory criteria for approval and deny approval. If the agency decides not to approve the BLA in its present form, the FDA will issue a complete response letter that describes all of the specific deficiencies in the BLA identified by the FDA, 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. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application.

If a product receives regulatory approval, the approval may be limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. 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 candidate and to enable patients to have continued access 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. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a risk management plan, or otherwise limit the scope of any approval. In addition, the FDA may require post marketing clinical trials, sometimes referred to as Phase 4 clinical trials, designed to further assess a biological product's safety and effectiveness, and testing and surveillance programs to monitor the safety of approved products that have been commercialized, and may further limit marketing of the product based on the results of these post-marketing studies.

In addition, under the Pediatric Research Equity Act, or PREA, a BLA or supplement to a BLA must contain data to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers. Unless otherwise required by regulation, PREA does not apply to any product for an indication for which orphan designation has been granted. However, if only one indication for a product has orphan designation, a pediatric assessment may still be required for any applications to market that same product for the non-orphan indication(s).

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 generally 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 and 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 or condition 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 full BLA, to market the same biologic for the same disease or condition 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 user fee.

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

Expedited Development and Review Programs

The FDA has a fast track designation program that 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. As part of the fast track program, 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, the FDA agrees to accept 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.

Any product, submitted to the FDA for approval, including a product with a fast track designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. A product is eligible for priority review if the product candidate is designed to treat a serious or life-threatening disease or condition, and if approved, would provide a significant improvement in safety or effectiveness compared to available alternatives for such disease or condition. The FDA will attempt to direct additional resources to the evaluation of an application for a new product designated for priority review in an effort to facilitate the review. For original BLAs, 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 (as compared to ten months under standard review).

Additionally, a product may be eligible for accelerated approval. 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 approval, the FDA may require that a sponsor of a drug or biological product receiving accelerated approval 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 addition, the FDA may grant breakthrough therapy designation to a product candidate for its indication under study. Breakthrough therapy designation is intended to expedite the development and review of products that are intended to treat serious or life-threatening conditions and that preliminary clinical evidence demonstrates that the product candidate, alone or in combination with other drugs and biologics, shows substantial improvement over currently available therapy on one or more clinically significant endpoints, such as

substantial treatment effects observed early in clinical development. If the FDA grants a breakthrough therapy designation, it may take actions appropriate to expedite the development and review of the application, which may include holding meetings with the sponsor and the review team throughout the development of the therapy; providing timely advice to, and interactive communication with, the sponsor regarding the development of the product candidate to ensure that the development program to gather the nonclinical and clinical data necessary for approval is as efficient as practicable; involving senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review; assigning a cross-disciplinary project lead for the FDA review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor; and considering alternative clinical trial designs when scientifically appropriate, which may result in smaller trials or more efficient trials that require less time to complete and may minimize the number of patients exposed to a potentially less efficacious treatment. Breakthrough therapy designation comes with all of the benefits of fast track designation, which means that the sponsor may file sections of the BLA for review on a rolling basis if certain conditions are satisfied, including an agreement with FDA on the proposed schedule for submission of portions of the application and the payment of applicable user fees before the FDA may initiate a review. The breakthrough therapy designation is a distinct status from both accelerated approval and priority review, which can also be granted to the same product if relevant criteria are met.

The FDA may also designate a product candidate as a regenerative medicine advanced therapy, or RMAT. The RMAT designation is intended to facilitate an efficient development program for, and expedited review of, any product candidate that meets the following criteria: (i) the product candidate 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; (ii) the product candidate is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and (iii) preliminary clinical evidence indicates that the product candidate has the potential to address unmet medical needs for such a disease or condition. 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 of BLAs. Cell therapy candidates 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, as appropriate. RMAT-designated cell therapy candidates that receive accelerated approval may, as appropriate, fulfill their post-approval requirements through the completion of clinical studies, patient registries, or through submission of other sources of real world evidence (such as electronic health records), through the collection of larger confirmatory data sets, or via post-approval monitoring of all patients treated with such therapy prior to approval of the therapy.

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

Post-Approval Requirements

Biological products 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, providing the FDA with updated safety and efficacy information, product sampling and distribution, and advertising and promotion of the product.

In addition, quality control and manufacturing procedures must continue to conform to applicable manufacturing requirements after approval to ensure the long-term stability of the product. cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of

records and documentation and the obligation to investigate and correct any deviations from cGMPs. Manufacturers and other entities involved in the manufacture and distribution of approved products 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 cGMPs and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved BLA, including, among other things, recall or withdrawal of the product from the market. In addition, changes to the manufacturing process are strictly regulated, and depending on the significance of the change, may require prior FDA approval before being implemented. Other types of changes to the approved product, such as adding new indications and claims, are also subject to further FDA review and approval.

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 label 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. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters, or untitled letters;
- clinical holds on clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal 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 that are in accordance with the provisions of the approved label. The FDA and other authorities 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 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 a manufacturer's communications on the subject of off-label use of their products.

U.S. Marketing Exclusivity

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, amended the PHSA to authorize the FDA to approve similar versions of innovative biologics, commonly known as biosimilars. Biosimilarity, which requires that the biological product be highly similar to the reference product notwithstanding minor differences in clinically inactive components and 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 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.

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.

Pediatric exclusivity is another type of regulatory 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 trial in accordance with an FDA-issued "Written Request" for such a trial.

Other U.S. Healthcare Laws and Compliance Requirements

In the United States, our current and future operations are subject to regulation by various federal, state and local authorities in addition to the FDA, including but not limited to, the Centers for Medicare & Medicaid Services, or CMS, other divisions of the U.S. Department of Health and Human Services, or HHS, (e.g., the Office of Inspector General, Office for Civil Rights and the Health Resources and Service Administration), the U.S. Department of Justice, or DOJ, and individual U.S. Attorney offices within the DOJ, and state and local governments. For example, our business practices, including our clinical research program and any future sales, marketing and scientific/educational grant programs may be required to comply with the anti-fraud and abuse provisions of the Social Security Act, the false claims laws, transparency requirements, 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. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Rather, if "one purpose" of the remuneration is to induce referrals, the federal Anti-Kickback Statute is violated. The federal Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. 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 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 may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor.

The civil monetary penalties statute imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to, among others, a federal healthcare program that the person knows or should know is for a medical or other item or service that was not provided as claimed or is false or fraudulent.

The federal false claims laws, including the federal False Claims Act, or FCA, impose significant penalties and 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 government, including federal healthcare programs such as 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. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes “any request or demand” for money or property presented to the U.S. government. 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. In addition, a claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA.

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, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

Additionally, the federal Physician Payments Sunshine Act, or the Sunshine Act, 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 information related to certain payments or other transfers of value made or distributed to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (such as physician assistants and nurse practitioners), and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually to CMS certain ownership and investment interests held by physicians and their immediate family members. Failure to report accurately could result in penalties. In addition, many states also govern the reporting of payments or other transfers of value, many 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.

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. 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.

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 significant 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 requirements and/or oversight if we become subject to a corporate integrity agreement or similar 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 obtain regulatory approval. In the United States and markets in other countries, 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.

The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price of a product or for establishing the reimbursement rate that such a payor will pay for the product. Third-party payors may limit coverage to specific products on an approved list, or also known as a formulary, which might not include all of the FDA-approved products for a particular indication. 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. We may need to conduct expensive pharmaco-economic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain the FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. In addition, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Further, obtaining reimbursement for our product may be particularly difficult because of the higher prices often associated with branded drugs and drugs administered under the supervision of physicians. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. In addition, companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or biological products. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or biological products, will apply to companion diagnostics.

We may develop products that, 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 biopharmaceutical 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, 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 HHS 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, or EU, 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 EU member states allow companies to fix their own prices for medicines, but monitor and control company profits. 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 adequate coverage and reimbursement. The downward pressure on the rise in healthcare costs in general and pharmaceutical products in particular has become intense. As a result, in the EU, increasingly high barriers are being erected to the entry of new products. In the United States, the emphasis on managed care, the increasing influence of health maintenance organizations, and additional legislative changes has increased and we expect will continue to increase the pressure on product pricing. In addition, 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, Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively 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, or AMP;

- a Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts, which through subsequent legislative amendments, will be increased to 70%, starting in 2019, 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 beginning in 2014 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 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 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;

- a requirement to annually report certain information regarding drug samples that manufacturers and distributors provide to physicians;

- establishment of a Center for Medicare and Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending that began on January 1, 2011; and

- a licensure framework for follow on biologic products.

Since its enactment, there have been executive, legal and Congressional challenges to certain aspects of the ACA. On June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Further, prior to the U.S. Supreme Court ruling, President Biden issued an executive order that initiated a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental authorities to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024.

On August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and through a newly established manufacturer discount program. It is unclear how other healthcare reform measures, if any, will impact our business. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

Further legislation or regulation could be passed that could harm our business, results of operations and financial condition. Other legislative changes have been proposed and adopted since the ACA was enacted. For example, in August 2011, the Budget Control Act of 2011 was signed into law, which, among other things, included aggregate reductions to Medicare payments to providers, which went into effect beginning on April 1, 2013 and, due to subsequent legislative amendments, will stay in effect through 2032. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

More recently, 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 pharmaceutical manufacturer to make its product candidates available to eligible patients as a result of the Right to Try Act.

Additionally, 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. For example, the IRA, among other things, (1) directs HHS to negotiate the price of certain single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented. It is currently unclear how the IRA will be implemented but it is likely to have a significant effect on the pharmaceutical industry. Further, in response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect additional state, federal and foreign healthcare reform measures to be adopted in the future, any of which could limit the amounts that federal, state and foreign governments will pay for health products, which could result in reduced demand for our products, if approved or additional pricing pressure.

For instance, in December 2021, the EU Regulation No 2021/2282 on Health Technology Assessment, or HTA, amending Directive 2011/24/EU, was adopted. While the Regulation entered into force in January 2022, it will only begin to apply from January 2025 onwards, with preparatory and implementation-related steps to take place in the interim. Once the Regulation becomes applicable, it will have a phased implementation depending on the concerned products. This regulation is intended to boost cooperation among EU member states in assessing health technologies, including new medicinal products, as well as certain high-risk medical devices, and providing the basis for cooperation at the EU level for joint clinical assessments in these areas. The regulation will permit EU member states to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU member states will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement.

The Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act, or 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 the company 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.

Data Privacy and Security Laws

Numerous state, federal and foreign laws, regulations and standards govern the collection, use, access to, confidentiality and security of health-related and other personal information, and could apply now or in the future to our operations or the operations of our partners. In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws and consumer protection laws and regulations govern the collection, use, disclosure, and protection of health-related and other personal information. In addition, certain foreign laws govern the privacy and security of personal data, including health-related data. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

Additional Regulation

In addition to the foregoing, state, federal and foreign 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.

Foreign Government Regulation

To market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of our products.

Whether or not we obtain FDA approval of a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Approval by one regulatory authority does not ensure approval by regulatory authorities in other jurisdictions. The approval process varies from country to country, can involve additional testing beyond that required by FDA, and may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing, promotion, and reimbursement vary greatly from country to country. Failure to comply with applicable foreign regulatory requirements, may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Non-Clinical Studies and Clinical Trials

Similarly to the United States, the various phases of non-clinical and clinical research in the European Union, or EU are subject to significant regulatory controls.

Non-clinical studies are performed to demonstrate the health or environmental safety of new chemical or biological substances. Non-clinical studies must be conducted in compliance with the principles of good laboratory practice, as set forth in EU Directive 2004/10/EC. In particular, non-clinical studies, both in vitro and in vivo, must be planned, performed, monitored, recorded, reported and archived in accordance with the GLP principles, which define a set of rules and criteria for a quality system for the organizational process and the conditions for non-clinical studies. These GLP standards reflect the Organization for Economic Co-operation and Development requirements.

Clinical trials of medicinal products in the EU must be conducted in accordance with EU and national regulations and the International Conference on Harmonization, or ICH, guidelines on GCPs, as well as the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. If the sponsor of the clinical trial is not established within the EU, it must appoint an EU entity to act as its legal representative. The sponsor must take out a clinical trial insurance policy, and in most EU countries, the sponsor is liable to provide ‘no fault’ compensation to any study subject injured in the clinical trial.

The regulatory landscape related to clinical trials in the EU has been subject to recent changes. The EU Clinical Trials Regulation, or CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. Unlike directives, the CTR is directly applicable in all EU member states without the need for EU member states to further implement it into national law. The CTR notably harmonizes the assessment and supervision processes for clinical trials throughout the EU via a Clinical Trials Information System, which contains a centralized EU portal and database.

While the Clinical Trials Directive required a separate clinical trial application to be submitted in each EU member state in which the clinical trial takes place, to both the competent national health authority and an independent ethics committee, much like the FDA and IRB respectively, the CTR introduces a centralized process and only requires the submission of a single application for multi-jurisdictional trials. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each EU member state, leading to a single decision per EU member state. The application must include, among other things, a copy of the trial protocol and an investigational medicinal product dossier containing information about the manufacture and quality of the medicinal product under investigation. The assessment procedure of the application has been harmonized as well, including a joint assessment by all EU member states concerned, and a

separate assessment by each EU member state with respect to specific requirements related to its own territory, including ethics rules. Each EU member state's decision is communicated to the sponsor via the centralized EU portal. Once the application is approved, clinical study development may proceed.

The CTR foresees a three-year transition period. The extent to which ongoing and new clinical trials will be governed by the CTR varies. Clinical trials for which an application was submitted (i) prior to January 31, 2022 under the Clinical Trials Directive, or (ii) between January 31, 2022 and January 31, 2023 and for which the sponsor has opted for the application of the Clinical Trials Directive remain governed by said Directive until January 31, 2025 at the latest. After this date, all clinical trials (including those which are ongoing) will become subject to the provisions of the CTR.

Medicinal products used in clinical trials must be manufactured in accordance with Good Manufacturing Practice, or cGMP. Other national and EU-wide regulatory requirements may also apply.

Marketing Authorization

In order to market our future product candidates in the EU and many other foreign jurisdictions, we must obtain separate regulatory approvals. More concretely, in the EU, medicinal product candidates can only be commercialized after obtaining a marketing authorization, or MA. To obtain regulatory approval of a product candidate under EU regulatory systems, we must submit a Marketing Authorization Application, or MAA. The process for doing this depends, among other things, on the nature of the medicinal product. There are two types of MAs:

- "Centralized MAs" are issued by the European Commission through the centralized procedure following an opinion of the Committee for Medicinal Products for Human Use, or CHMP, of the European Medicines Agency, or EMA, and are valid throughout the EU. The centralized procedure is compulsory for certain types of medicinal products such as (i) medicinal products derived from biotechnological processes, (ii) designated orphan medicinal products, (iii) advanced therapy medicinal products, or ATMPs (such as gene therapy, somatic cell therapy and tissue engineered products) and (iv) medicinal products containing a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative diseases or autoimmune diseases and other immune dysfunctions, and viral diseases. The centralized procedure is optional for products containing a new active substance not authorized in the EU before May 20, 2004, or that represent a significant therapeutic, scientific or technical innovation, or whose authorization would be in the interest of public health in the EU.

- Where a product has already been authorized for marketing in an EU member state, this national MA can be recognized in another member state through the mutual recognition procedure. If the product has not received a national MA in any member state at the time of application, it can be approved simultaneously in various member states through the decentralized procedure. Under the decentralized procedure an identical dossier is submitted to the competent authorities of each of the member states in which the MA is sought, one of which is selected by the applicant as the reference member state.

- "National MAs" are issued by the competent authorities of individual EU member states, only cover their respective territory, and are available for product candidates not falling within the mandatory scope of the centralized procedure or which are not subject to the decentralized or mutual recognition procedures.

Under the centralized procedure the maximum timeframe for the evaluation of an MAA by the EMA is 210 days, excluding clock stops. In exceptional cases, the CHMP might perform an accelerated review of a MAA in no more than 150 days (not including clock stops). In March 2016, the EMA launched an initiative, the

PRIME scheme, a voluntary scheme aimed at enhancing the EMA's support for the development of medicines that target unmet medical needs. It is based on increased interaction and early dialogue with companies developing promising medicines, to optimize their product development plans and speed up their evaluation to help them reach patients earlier. Product developers that benefit from PRIME designation can expect to be eligible for accelerated assessment but this is not guaranteed. Many benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and accelerated MAA assessment once a dossier has been submitted. Importantly, a dedicated contact and rapporteur from the CHMP is appointed early in the PRIME scheme facilitating increased understanding of the product at EMA's committee level. An initial meeting initiates these relationships and includes a team of multidisciplinary experts at the EMA to provide guidance on the overall development and regulatory strategies.

Moreover, in the EU, a "conditional" MA may be granted in cases where all the required safety and efficacy data are not yet available. The conditional MA is subject to conditions to be fulfilled for generating the missing data or ensuring increased safety measures. It is valid for one year and has to be renewed annually until fulfillment of all the conditions. Once the pending studies are provided, it can become a "standard" MA. However, if the conditions are not fulfilled within the timeframe set by the EMA, the MA ceases to be renewed.

Furthermore, MA may also be granted "under exceptional circumstances" when the applicant can show that it is unable to provide comprehensive data on the efficacy and safety under normal conditions of use even after the product has been authorized and subject to specific procedures being introduced. This may arise in particular when the intended indications are very rare and, in the present state of scientific knowledge, it is not possible to provide comprehensive information, or when generating data may be contrary to generally accepted ethical principles. This MA is close to the conditional MA as it is reserved to medicinal products to be approved for severe diseases or unmet medical needs and the applicant does not hold the complete data set legally required for the grant of a MA. However, unlike the conditional MA, the applicant does not have to provide the missing data and will never have to. Although the MA "under exceptional circumstances" is granted definitively, the risk-benefit balance of the medicinal product is reviewed annually and the MA is withdrawn in case the risk-benefit ratio is no longer favorable.

Additional Requirements Applicable to Human Cells and Tissues-Based Products

Under EU law, cell-based products must also comply with Directive (EC) No. 2004/23 of the European Parliament and of the Council of March 31, 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells, or the Tissues and Cells Directive.

This Directive describes the conditions and quality requirements which must be applied when sourcing the cells intended for manufacturing of the cell-based medicinal product. EU directives not being of direct application, these requirements are implemented under national law, in each EU member state, and as such applicable requirements may vary from one EU member state to another, as each is free to implement measures which are more stringent than those set out under the Tissues and Cells Directive.

Amongst other things, the Tissues and Cells Directive requires the following:

- tissue and cell procurement and testing must be conducted by persons appropriately trained and experienced;
- tissue and cells establishments must in particular (i) be accredited, designated, authorized or licensed by the national competent authority, (ii) perform appropriate controls to ensure compliance with applicable requirements, (iii) maintain records of their activities, and (iv) implement a quality system based on good practices principles set out by the European Commission;

- a traceability system must be implemented such that the tissues and cells can be traced from the donor to the recipient, which includes appropriate labelling of said tissues and cells;

- import and export of human tissues and cells must be undertaken by establishments which are duly be accredited, designated, authorized or licensed by the national competent authority, and these tissues and cells must comply with the requirements set out under the Tissues and Cells Directive; and

- a system for the notification of serious adverse events and reactions must be implemented.

On July 14, 2022, the European Commission issued a proposal for a regulation on substances of human origin, or the SoHOs Proposal. Unlike directives, regulations are directly applicable, i.e., without the need for adoption of EU member state laws implementing them, in all EU member states. The SoHOs Proposal aims to repeal, replace, and aggregate the existing regulatory framework applicable to human blood, tissue and cells, consisting of Directive 2002/98/EC on blood and blood components and the Tissue and Cells Directive. Once a final text is adopted, it will come into force although there will be a 2-year transition period before most provisions apply and a 3-year period for some particular provisions.

Data and Marketing Exclusivity

In the EU, new products granted an MA (*i.e.*, reference products) generally receive eight years of data exclusivity and an additional two years of market exclusivity. If granted, the data exclusivity period prevents generic and biosimilar applicants from relying on the preclinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar MA in the EU during a period of eight years from the date on which the reference product was first authorized in the EU. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until ten years have elapsed from the initial MA of the reference product in the EU. The overall 10-year market exclusivity period can be extended to a maximum of eleven years if, during the first eight years of those ten years, the MA holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. However, there is no guarantee that a product will be considered by the EU's regulatory authorities to be a new chemical or biological entity, and products may not qualify for data exclusivity.

In the EU, there is a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product, for example, because of differences in raw materials or manufacturing processes. For such products, the results of appropriate preclinical or clinical trials must be provided, and guidelines from the EMA detail the type of quantity of supplementary data to be provided for different types of biological product. There are no such guidelines for complex biological products, such as gene or cell therapy medicinal products, and so it is unlikely that biosimilars of those products will currently be approved in the EU. However, guidance from the EMA states that they will be considered in the future in light of the scientific knowledge and regulatory experience gained at the time.

Orphan Medicinal Products

The criteria for designating an "orphan medicinal product" in the EU are similar in principle to those in the United States. A medicinal product can be designated as an orphan if its sponsor can establish that: (1) the product is intended for the diagnosis, prevention or treatment of a life threatening or chronically debilitating condition (2) either (a) such condition affects not more than five in 10,000 persons in the EU when the application is made, or (b) the product, without the benefits derived from the orphan status, would not generate sufficient return in the EU to justify the necessary investment; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized for marketing in the EU or, if such method exists, the product will be of significant benefit to those affected by that condition.

Orphan designation must be requested before submitting an MAA. An EU orphan designation entitles a party to incentives such as reduction of fees or fee waivers, protocol assistance, and access to the centralized procedure. Upon grant of a MA, orphan medicinal products are entitled to a ten years of market exclusivity for the approved indication, which means that the competent authorities cannot accept another MAA, or grant a MA, or accept an application to extend a MA for a similar medicinal product for the same indication for a period of ten years. The period of market exclusivity is extended by two years for orphan medicinal products that have also complied with an agreed pediatric investigation plan, or PIP. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The orphan exclusivity period may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for which it received orphan destination, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity or where the prevalence of the condition has increased above the threshold. Additionally, MA may be granted to a similar product for the same indication at any time if (i) the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior; (ii) the applicant consents to a second orphan medicinal product application; or (iii) the applicant cannot supply enough orphan medicinal product.

Pediatric Development

In the EU, MAAs for new medicinal products have to include the results of studies conducted in the pediatric population, in compliance with a PIP agreed with the EMA's Pediatric Committee, or PDCO. The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the drug for which MA is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures of the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when these data is not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant clinical benefit over existing treatments for pediatric patients. Once the MA is obtained in all the EU member states and study results are included in the product information, even when negative, the product is eligible for six months' supplementary protection certificate extension (if any is in effect at the time of approval) or, in the case of orphan pharmaceutical products, a two year extension of the orphan market exclusivity is granted.

Post-Approval Requirements

Similar to the United States, both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the European Commission and/or the competent regulatory authorities of the EU member states. The holder of a MA must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance, or QPPV, who is responsible for the establishment and maintenance of that system, and oversees the safety profiles of medicinal products and any emerging safety concerns. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports, or PSURs.

All new MAA must include a risk management plan, or RMP, describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the MA. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies.

The advertising and promotion of medicinal products is also subject to laws concerning promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices. All advertising and promotional activities for the product must be consistent with the approved summary

of product characteristics, and therefore all off-label promotion is prohibited. Direct-to-consumer advertising of prescription medicines is also prohibited in the EU. Although general requirements for advertising and promotion of medicinal products are established under EU directives, the details are governed by regulations in each EU member state and can differ from one country to another.

The aforementioned EU rules are generally applicable in the European Economic Area, or EEA, which consists of the 27 EU member states plus Norway, Liechtenstein and Iceland.

Failure to comply with EU and EU member state laws that apply to the conduct of clinical trials, manufacturing approval, MA of medicinal products and marketing of such products, both before and after grant of the MA, manufacturing of pharmaceutical products, statutory health insurance, bribery and anti-corruption or with other applicable regulatory requirements may result in administrative, civil or criminal penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials, or to grant MA, product withdrawals and recalls, product seizures, suspension, withdrawal or variation of the MA, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties.

Brexit and the Regulatory Framework in the United Kingdom

Since the end of the Brexit transition period on January 1, 2021, Great Britain, or GB (England, Scotland and Wales) has not been directly subject to EU laws.

The EU laws that have been transposed into UK law through secondary legislation remain applicable in GB. Under the Medicines and Medical Devices Act 2021, the Secretary of State or an ‘appropriate authority’ has delegated powers to amend or supplement existing regulations in the area of medicinal products and medical devices. This allows new rules to be introduced in the future by way of secondary legislation, which aims to allow flexibility in addressing regulatory gaps and future changes in the fields of human medicines, clinical trials and medical devices. It is currently unclear to what extent the UK Government will seek to align its regulations with the EU.

Under the terms of the Ireland/Northern Ireland Protocol, EU laws still generally apply to Northern Ireland. However, on February 27, 2023 the UK Government and the European Commission reached a political agreement in the “Windsor Framework” to address discrepancies in the Protocol’s operation. The Windsor Framework proposes that Northern Ireland will be fully integrated under the regulatory authority of the MHRA; these proposed changes will be introduced by secondary legislation.

The UK regulatory framework in relation to clinical trials is derived from existing EU legislation (as implemented into UK law, through secondary legislation). New EU legislation, such as the (EU) CTR, is not applicable in GB and there may be divergent local requirements in GB from the EU in the future. The MHRA has introduced changes to national licensing procedures, including procedures to prioritize access to new medicines that will benefit patients, including a 150-day assessment and a rolling review procedure. All existing EU MAs for centrally authorized products were automatically converted or grandfathered into UK MAs free of charge on January 1, 2021, unless the MA holder chooses to opt-out. In order to use the centralized procedure to obtain a MA that will be valid throughout the EEA, companies must be established in the EEA. Therefore after Brexit, companies established in the UK can no longer use the EU centralized procedure and instead an EEA entity must hold any centralized MAs. In order to obtain a UK MA to commercialize products in the UK, an applicant must be established in the UK and must follow one of the UK national authorization procedures or one of the remaining post-Brexit international cooperation procedures to obtain an MA to commercialize products in the UK. The MHRA may rely on a decision taken by the European Commission on the approval of a new (centralized procedure) MA when determining an application for a UK authorization; or use the MHRA’s decentralized or mutual recognition procedures which enable MAs approved in EU member states (or Iceland, Liechtenstein, Norway) to be granted in the UK.

There will be no pre-MA orphan designation. Instead, the MHRA will review applications for orphan designation in parallel to the corresponding MA application. The criteria are essentially the same, but have been

tailored for the market, i.e., the prevalence of the condition in GB, rather than the EU, must not be more than five in 10,000. Should an orphan designation be granted, the period or market exclusivity will be set from the date of first approval of the product in GB.

Rest of World Government Regulation

For other countries outside of Europe, such as some countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials must be conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we or our potential collaborators fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Employees and Human Capital Resources

As of March 31, 2023, we employed 108 employees, all of whom are full-time, consisting of clinical, research, operations, regulatory, and finance personnel. Thirty-six of our employees hold Ph.D., M.D. or M.D. equivalent degrees. None of our employees is subject to a collective bargaining agreement. We consider our relationship with our employees to be good.

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

- ***Talent development, compensation and retention***—We strive to provide our employees with a rewarding work environment, including the opportunity for growth, success and professional development. We provide a competitive compensation and benefits package, including broad-based bonus and equity plans, a 401(k) plan and a multi-layered recognition program—all designed to attract and retain a skilled and diverse workforce.

- ***Health and safety***—We support the health and safety of our employees by providing comprehensive insurance benefits, an employee assistance program, wellness days and other additional benefits which are intended to assist employees to manage their well-being.

- ***Inclusion and diversity***—We are committed to efforts to increase diversity and foster an inclusive work environment that supports our workforce.

Facilities

We have entered into a lease agreement for 19,474 square feet of space for our headquarters in San Diego, California, which expires in March 2025 with an option to extend up to another three years. We believe that our existing facility is adequate to meet our current needs, and that suitable additional alternative spaces will be available in the future on commercially reasonable terms.

Legal Proceedings

From time to time, we have been or may become involved in material legal proceedings or be subject to claims arising in the ordinary course of our business. We are currently not party to any legal proceedings material to our operations or of which any of our property is the subject, nor are we aware of any such proceedings that are contemplated by a government authority. Regardless of outcome, such proceedings or claims can have an adverse impact on us because of defense and settlement costs, diversion of resources, and other factors, and there can be no assurances that favorable outcomes will be obtained.

MANAGEMENT

Executive Officers and Directors

The following table provides information regarding our executive officers and directors, including their ages, as of July 1, 2023:

Name	Age	Position(s)
Executive Officers		
Sammy Farah, M.B.A., Ph.D.	51	President, Chief Executive Officer and Director
Venkat Ramanan, Ph.D.	54	Chief Financial Officer
Michael Burgess, MBChB, Ph.D.	60	Interim Chief Medical Officer and Director
Stewart Abbot, Ph.D.	56	Chief Scientific Officer
Saryah Azmat	34	Chief Business Officer
Vijay Chiruvolu, Ph.D.	61	Interim Chief Technology Officer
P. Joseph Campisi, Jr.	62	Chief Legal Officer
Non-Employee Directors		
Jerel Davis, Ph.D.(2) (3)	46	Director and Chair
Robert Gould, Ph.D.(1) (3)	68	Director
Rishi Gupta(1) (2)	46	Director
Stefan Larson, Ph.D.(a)	47	Director
Patrick Machado(1) (2)	59	Director
Santhosh Palani, Ph.D.(b)	40	Director
Kanya Rajangam, Ph.D.(3)	50	Director

(a) Dr. Larson will resign from our board of directors effective as of immediately prior to the effectiveness of the registration statement of which this prospectus forms a part.
(b) Dr. Palani will resign from our board of directors effective as of immediately prior to the effectiveness of the registration statement of which this prospectus forms a part.
(1) Member of the audit committee.
(2) Member of the compensation committee.
(3) Member of the nominating and corporate governance committee.

Executive Officers

Sammy Farah, M.B.A., Ph.D. has served as our President and Chief Executive Officer and a member of our board of directors since October 2015. Prior to joining us, Dr. Farah served as President of Synthetic Genomics Vaccines, Inc. from September 2011 to October 2015 and prior to that, as Chief Business Officer at Immune Design Corp. Dr. Farah also served at Versant Ventures, a global healthcare investment firm, where he specialized in biotechnology investing and new company formation. Dr. Farah has an M.B.A. in finance from the Wharton School at the University of Pennsylvania, a Ph.D. in chemical engineering from Stanford University, a M.S. in biotechnology from Northwestern University and a B.S. in biochemical engineering from the Massachusetts Institute of Technology. We believe that Dr. Farah is qualified to serve on our board of directors based on his experience leading, managing, and investing in a number of biotechnology and pharmaceutical companies.

Venkat Ramanan, Ph.D. has served as our Chief Financial Officer since February 2022. Prior to joining us, Dr. Ramanan served in multiple roles at Seagen Inc. (Nasdaq: SGEN), a biotechnology company focused on developing and commercializing monoclonal antibody-based therapies for the treatment of cancer, including as Senior Vice President of Finance from 2019 to February 2022 and as Vice President of Finance from 2016 to 2019. Prior to Seagen, Dr. Ramanan served in various roles at Gilead Sciences (Nasdaq: GILD), including Director of Manufacturing Finance, Director of Finance-Emerging Markets and Director of Corporate Finance.

Dr. Ramanan has a Ph.D. and M.S. in engineering mechanics from the Ohio State University and a B.Tech in mechanical engineering from the Indian Institute of Technology.

Michael Burgess, MBChB, Ph.D. has served as a member of our board of directors since June 2021 and as our interim Chief Medical Officer since March 2022. Prior to this, Dr. Burgess served as our President of Research and Development from October 2017 to May 2021. Dr. Burgess has also served on the board of directors of Synlogic, Inc. (Nasdaq: SYBX) since 2021. Dr. Burgess has served as the Head of Research and Development at Springworks Therapeutics (Nasdaq: SWTX), a biotechnology company engaged in the development of therapies for rare diseases and cancer, since May 2021. Prior to Springworks Therapeutics, Dr. Burgess served in various roles at Bristol-Myers Squibb (NYSE: BMY), a biopharmaceutical company, including as Senior Vice President Cardiovascular, Fibrosis and Immunoscience Development and Senior Vice President Head of Exploratory Clinical and Translation Research from January 2013 to October 2017. Dr. Burgess has an MBChB and a Ph.D. in molecular biology from the University of Bristol. We believe that Dr. Burgess is qualified to serve as our interim Chief Medical Officer and on our board of directors based on his leadership roles at a number of biotechnology and pharmaceutical companies.

Stewart Abbot, Ph.D. has served as our Chief Scientific Officer since June 2021. Prior to joining us, Dr. Abbot served as Chief Scientific Officer and Chief Scientific and Operating Officer at Adicet Bio (Nasdaq: ACET), a biotechnology company engaged in the development of allogeneic immunotherapies, from July 2018 to July 2021. Prior to Adicet Bio, Dr. Abbot served in various roles at Fate Therapeutics (Nasdaq: FATE), a company engaged in the development of cellular immunotherapies, including as Chief Development Officer and Vice President Translational Research from July 2015 to July 2018. Dr. Abbot has a Ph.D. in cell biology and pathology from the University of London, an M.Sc. in biomedical engineering from the University of Strathclyde, and a B.Sc. in biological sciences from the University of Edinburgh.

Saryah Azmat has served as our Chief Business Officer since February 2021. Prior to this, Ms. Azmat served as our Senior Vice President, Business Development and Corporate Strategy from November 2019 to January 2021. Prior to joining us, Ms. Azmat served in various roles at Bristol-Myers Squibb (NYSE: BMY), a biopharmaceutical company, including as Business Development Director, Business Development Manager, Business Development Associate Director, and Business Development Associate from February 2014 to October 2019. Ms. Azmat has a B.A. in engineering sciences and a B.E. in biomedical engineering from Dartmouth College.

Vijay Chiruvolu, Ph.D. has served as our interim Chief Technology Officer since March 2023. Prior to joining us, Dr. Chiruvolo served as the Chief Technical Officer at Instil Bio (Nasdaq: TIL), a clinical-stage cell therapy company, from July 2020 to September 2022. Prior to Instil Bio, Dr. Chiruvolu served as Senior Vice President, Global Process Development-Cell Therapy at Kite Pharma, Inc./Gilead Sciences, a biotechnology company engaged in developing cancer immunotherapy products, from March 2018 to July 2020. Dr. Chiruvolu has a Ph.D. in Engineering (Biochemical) from the University of Nebraska Lincoln and an M.B.A. from Pennsylvania State University.

P. Joseph Campisi, Jr. has served as our Chief Legal Officer since January 2023. Prior to this, Mr. Campisi served as our Senior Vice President and General Counsel from August 2021 to December 2022. Prior to joining us, Mr. Campisi served as Executive Vice President and General Counsel of Scorpion Therapeutics, a biotechnology company engaged in the development of therapeutic solutions for cancer, from March 2020 to July 2021. Mr. Campisi also served as Senior Vice President and Deputy General Counsel of the Transactional Practice Group of Bristol-Myers Squibb (NYSE: BMY) from August 2016 to January 2020, and as Associate General Counsel from July 2003 to August 2016, prior to which he was a partner at the law firm of Pillsbury Winthrop Shaw Pittman LLP. Mr. Campisi holds a J.D. from Hofstra University School of Law, an M.B.A. in finance from St. John’s University, and a B.S. in accounting from St. John’s University.

Non-Employee Directors

Jerel Davis, Ph.D. has served as a member of our board of directors since October 2015, and as the chair of our board of directors since December 2018. Upon completion of this offering, Dr. Davis will step down as chair of our board of directors and serve as the lead independent director of our board of directors. Dr. Davis also serves on the boards of directors of several other biotechnology and pharmaceutical companies, including serving as a member of the board of directors of Graphite Bio, Inc. (Nasdaq: GRPH) since October 2019, as a member of the board of directors of Chinook Therapeutics (Nasdaq: KDNY) since December 2018, and as a member of the board of directors of Repare Therapeutics (Nasdaq: RPTX) from September 2016 to June 2023. Dr. Davis has served as Managing Director at Versant Ventures, a global healthcare investment firm, since 2015. Dr. Davis has a Ph.D. in population genetics from Stanford University and a B.S. in mathematics and biology from Pepperdine University. We believe that Dr. Davis's broad and extensive experience in the life sciences industry as an investor and launching numerous life sciences companies qualifies him to serve on our board of directors.

Robert Gould, Ph.D. has served as a member of our board of directors since January 2019. Dr. Gould has served as a member of the board of directors of Fulcrum Therapeutics (Nasdaq: FULC), a biopharmaceutical company specializing in genetically defined diseases, since June 2016 and also served as President and Chief Executive Officer of Fulcrum Therapeutics from July 2016 to March 2021. Dr. Gould has completed post-doctoral research in neuropharmacology at The Johns Hopkins University, has a Ph.D. in biochemistry from the University of Iowa, and has a B.S. in chemistry from Spring Arbor University. We believe that Dr. Gould is qualified to serve on our board of directors based on his experience leading and managing a number of biotechnology and pharmaceutical companies.

Rishi Gupta has served as a member of our board of directors since October 2016. Mr. Gupta also serves on the boards of directors of several other biotechnology and pharmaceutical companies, including serving as a member of the board of Verona Pharma PLC (Nasdaq: VRNA) since July 2016 and Enliven Therapeutics (Nasdaq: ELVN) since July 2019. Mr. Gupta has been a Partner at OrbiMed Advisors, a healthcare and biotechnology investment firm since June 2013. Mr. Gupta has a J.D. from the Yale Law School and an A.B. in biochemical sciences from Harvard College. We believe that Mr. Gupta is qualified to serve on our board of directors because of his experience in biotechnology investing and his experience serving on the boards of public and private companies.

Stefan Larson, Ph.D. has served as a member of our board of directors since January 2019. Dr. Larson resigned from our board of directors effective as of immediately prior to the effectiveness of the registration statement of which this prospectus forms a part. Dr. Larson has served as a Partner at Sectoral Asset Management, a healthcare investment advisor since September 2018. Prior to this, Dr. Larson served as Venture Partner at Versant Ventures, a global healthcare investment firm, from July 2013 to August 2018. Dr. Larson served as Chief Executive Officer at Northern Biologics, a biotechnology company specializing in the development of antibody-based therapeutics, from October 2014 to November 2017. Dr. Larson has served on the board of directors of Prilenia Therapeutics since 2020. Dr. Larson has a Ph.D. in biophysics from Stanford University, an M.Sc. in molecular genetics from the University of Toronto, and a B.Sc. in biology from McGill University. We believe that Dr. Larson is qualified to serve on our board of directors based on his experience leading and managing a number of biotechnology and healthcare investment companies.

Patrick Machado has served as a member of our board of directors since August 2018. Mr. Machado also serves on the boards of directors of several other biotechnology and pharmaceutical companies, including serving as a member of the board of directors of ACELYRIN, INC. (Nasdaq: SLRN) since May 2021, as a member of the board of directors of Chimerix Inc. (Nasdaq: CMRX) since June 2014, as a member of the board of directors of Adverum Biotechnologies (Nasdaq: ADVM) since March 2017, as a member of the board of directors of Xenon Pharmaceuticals (Nasdaq: XENE) since November 2020, as a member of the board of directors of Arcus Biosciences (NYSE: RCUS) since December 2019, and as a member of the board of directors of Therachon from January to July 2019. Mr. Machado also previously served on the board of directors of Inotek

Pharmaceuticals Corporation from 2016 to 2018, on the board of directors of Endocyte from 2018 to 2019, on the board of directors of Principia Biopharma (Nasdaq: PRNB) from 2019 to 2020, on the board of directors of Scynexis (Nasdaq: SCYX) from 2015 to 2019, on the board of directors of Roivant Sciences (Nasdaq: ROIV) from 2016 to 2022, and on the board of directors of Turning Point Therapeutics (Nasdaq: TPTX) from 2019 to 2022. Mr. Machado was the co-founder and a board member of Medivation Inc., which has since been acquired by Pfizer, Inc. Mr. Machado has a J.D. from Harvard Law School and a B.A. in German and B.S. in Economics from Santa Clara University. We believe that Mr. Machado is qualified to serve on our board of directors based on his experience leading and managing a number of biotechnology and pharmaceutical companies and his extensive experience dealing with the operational and financial issues of biopharmaceutical companies.

Santhosh Palani, Ph.D. has served as a member of our board of directors since June 2021. Dr. Palani resigned from our board of directors effective as of immediately prior to the effectiveness of the registration statement of which this prospectus forms a part. Dr. Palani has served as an Investment Partner at PFM Health Sciences, a healthcare investment advisor since June 2020. Prior to this role, Dr. Palani served as Principal, Biotech Venture Capital Investor at New Enterprise Associates, a venture capital firm, from May 2018 to May 2020. Dr. Palani served as Vice President, Equity Research of Cowen and Company, an investment bank and financial services company, from March 2016 to May 2018. Dr. Palani has a Ph.D. in bioengineering from the University of Pennsylvania and completed his postdoctoral work in biochemistry and molecular biophysics at Columbia University. Dr. Palani also holds an M.S. in chemical engineering from Texas A&M University and a B.S. in chemical engineering from the University of Madras. We believe that Dr. Palani is qualified to serve on our board of directors based on his experience investing in biotechnology companies.

Kanya Rajangam, Ph.D. has served as a member of our board of directors since November 2021. Dr. Rajangam has served as Chief Medical Officer of Nkarta Therapeutics (Nasdaq: NKTX), a clinical-stage biotechnology company advancing the development of allogeneic natural killer cell therapies for cancer, since September of 2019, prior to which she was Senior Vice President and Chief Medical Officer of Nkarta Therapeutics from December 2018 to September 2019. Dr. Rajangam also served as Senior Vice President and Chief Medical Officer at Atara Biotherapeutics, Inc. (Nasdaq: ATRA), an allogeneic T cell immunotherapy company, from August 2017 to September 2018, and as Chief Medical Officer at Cleave Biosciences from December 2016 to July 2017. Dr. Rajangam holds a Ph.D. in biomedical engineering from Northwestern University and an M.B.B.S. from St. John’s Medical College, Bangalore, India. Dr. Rajangam also completed a general surgical residency at the Postgraduate Institute of Medical Education and Research, Chandigarh, India. We believe that Dr. Rajangam is qualified to serve on our board of directors based on her extensive medical expertise and experience leading and managing a number of biotechnology companies.

Board Composition

Our board of directors currently consists of nine members. All the members of our board of directors were elected under the provisions of our Voting Agreement, which is defined below.

Under the terms of our Voting Agreement, the stockholders who are party to the Voting Agreement have agreed to vote their respective shares to elect: (i) one independent director designated by the holders of a majority of the aggregate voting power of our common stock, currently Robert Gould, (ii) two directors designated by certain affiliates of Versant Venture Management, LLC, currently Dr. Michael Burgess and Dr. Jerel Davis, (iii) one director designated by OrbiMed Private Investments VI, currently Rishi Gupta, (iv) one director designated by New Emerging Medical Opportunities Fund IV SCSp, currently Dr. Stefan Larson, (v) one director who shall be our current Chief Executive Officer, currently Sammy Farah, M.B.A., Ph.D., (vi) one director designated by a majority of the directors elected pursuant to clauses (ii), (iii), (iv), and (vii), currently Patrick Machado, (vii) one director designated by certain affiliates of PFM Health Sciences, LP, or PFM, currently Dr. Santhosh Palani, and (viii) one independent director initially designated by the holders of a majority of the shares of our common stock issued pursuant to the Myst Merger Agreement, who is independent, has experience relevant to our industry and is reasonably acceptable to at least a majority of our board of directors, currently Dr. Kanya Rajangam.

The Voting Agreement will terminate upon the closing of this offering, and thereafter no stockholder will have any special rights regarding the election or designation of the members of our board of directors. Our current directors elected to our board of directors pursuant to the Voting Agreement will continue to serve as directors until their successors are duly elected and qualified by holders of our common stock.

In accordance with the terms of our amended and restated certificate of incorporation, which will be effective immediately following the closing of this offering, and the adoption of our amended and restated bylaws, which will be effective immediately prior to the closing of this offering, our board of directors will be divided into three classes, Class I, Class II and Class III, with members of each class serving staggered three-year terms. Effective upon the closing of this offering, our board of directors will be divided into the following classes:

- Class I, which will consist of Rishi Gupta, Robert Gould, Ph.D. and Michael Burgess, MBChB, Ph.D., whose terms will expire at the annual meeting of stockholders to be held in 2024;
- Class II, which will consist of Jerel Davis, Ph.D. and Kanya Rajangam, Ph.D., whose terms will expire at the annual meeting of stockholders to be held in 2025; and
- Class III, which will consist of Sammy Farah, M.B.A., Ph.D. and Patrick Machado, whose terms will expire at the annual meeting of stockholders to be held in 2026.

At each annual meeting of stockholders to be held after the initial classification, 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 their election and until their successors are duly elected and qualified. The authorized size of our board of directors is currently nine members, and may be changed only by resolution by a majority of the board of directors. We expect that additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. This classification of the board of directors may have the effect of delaying or preventing changes in our control or management. Our directors may be removed for cause by the affirmative vote of the holders of at least 66 2/3% of our voting stock.

Director Independence

Applicable Nasdaq rules require a majority of a listed company's board of directors to be comprised of independent directors within one year of listing. In addition, Nasdaq rules require that, subject to specified exceptions, each member of a listed company's audit, compensation and nominating and corporate governance committees be independent and that audit committee members also satisfy independence criteria set forth in Rule 10A-3 under the Exchange Act. The Nasdaq independence definition includes a series of objective tests, such as that the director is not, and has not been for at least three years, one of our employees, that neither the director nor any of his family members has engaged in various types of business dealings with us and that the director is not associated with the holders of more than 5% of our common stock. In addition, under applicable Nasdaq rules, a director will only qualify as an "independent director" if, in the opinion of the listed 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.

Our board of directors has determined that all of our directors, except Drs. Farah and Burgess are independent directors, as defined under applicable Nasdaq rules. In making such determination, our board of directors considered the relationships that each such non-employee director has with our company and all other facts and circumstances that 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.

There are no family relationships among any of our directors or executive officers.

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. Our board of directors does not have a standing risk management committee, but rather administers this oversight function directly through the board of directors as a whole, as well as through various standing committees of our board of directors that address risks inherent in their respective areas of oversight. In particular, our board of directors is responsible for monitoring and assessing strategic risk exposure and our audit committee has the responsibility to consider and discuss our major financial risk exposures and the steps our management has taken to monitor and control these exposures, including guidelines and policies to govern the process by which risk assessment and management is undertaken. The audit committee also monitors compliance with legal and regulatory requirements.

Board Committees

Our board of directors has established an audit committee, compensation committee and a nominating and corporate governance committee, each of which operate pursuant to a committee charter. Our board of directors may establish other committees to facilitate the management of our business. The composition and functions of each committee are described below.

Audit Committee

Upon completion of this offering, our audit committee will consist of Patrick Machado, Robert Gould, Ph.D., and Rishi Gupta, with Mr. Machado serving as chair of the audit committee. Our board of directors has determined that each of these individuals meets the independence requirements of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act, Rule 10A-3 under the Exchange Act, and the applicable listing standards of Nasdaq. Each member of our audit committee can read and understand fundamental financial statements in accordance with Nasdaq audit committee requirements. In arriving at this determination, the board has examined each audit committee member's scope of experience and the nature of their prior and/or current employment.

Our board of directors has determined that Mr. Machado qualifies as an audit committee financial expert within the meaning of the SEC regulations and meets the financial sophistication requirements of the applicable listing standards of Nasdaq. In making this determination, our board has considered Mr. Machado formal education and previous and current experience in financial and accounting roles. Both our independent registered public accounting firm and management periodically meet privately with our audit committee.

The functions of this committee include, among other things:

- helping our board of directors oversee our corporate accounting and financial reporting processes;
- managing the selection, engagement, qualifications, independence, and performance of a qualified firm to serve as the independent registered public accounting firm to audit our financial statements;
- discussing the scope and results of the audit with the independent registered public accounting firm, and reviewing, with management and the independent accountants, our interim and year-end operating results;
- developing procedures for employees to submit concerns anonymously about questionable accounting or audit matters;
- reviewing related person transactions;
- obtaining and reviewing a report by the independent registered public accounting firm, that describes our internal quality control procedures, any material issues with such procedures, and any steps taken to deal with such issues when required by applicable law; and

- approving, or, as permitted, pre-approving, audit and permissible non-audit services to be performed by the independent registered public accounting firm.

We believe that the composition and functioning of our audit committee complies with all applicable requirements of the Sarbanes-Oxley Act, and all applicable SEC and Nasdaq rules and regulations. We intend to comply with future requirements to the extent they become applicable to us.

Compensation Committee

Upon completion of this offering, our compensation committee will consist of Rishi Gupta, Patrick Machado and Jerel Davis, Ph.D. with Mr. Gupta serving as chair of the compensation committee. Each of these individuals is a "non-employee director", as defined in Rule 16b-3 promulgated under the Exchange Act. Our board of directors has determined that each of these individuals is "independent" as defined under the applicable listing standards of Nasdaq, including the standards specific to members of a compensation committee. The functions of this committee include, among other things:

- reviewing and approving the compensation of our Chief Executive Officer, other executive officers and senior management;
- reviewing and approving the compensation paid to our directors;
- reviewing and approving the compensation arrangements with our executive officers and other senior management;
- administering our equity incentive plans and other benefit programs;
- reviewing, adopting, amending, and terminating the terms of any employment agreements, stock option plans, stock appreciation rights plans, severance arrangements, pension and profit-sharing plans, incentive plans, stock bonus plans, stock purchase plans, bonus plans, deferred compensation plans, change-of-control protections, and any other compensatory arrangements for our executive officers and other senior management;
- reviewing, evaluating and recommending to our board of directors succession plans for our executive officers; and
- reviewing and establishing general policies relating to compensation and benefits of our employees, including our overall compensation philosophy.

We believe that the composition and functioning of our compensation committee complies with all applicable requirements of the Sarbanes-Oxley Act, and all applicable SEC and Nasdaq rules and regulations. We intend to comply with future requirements to the extent they become applicable to us.

Nominating and Corporate Governance Committee

Upon completion of this offering, our nominating and corporate governance committee will consist of Jerel Davis, Ph.D., Robert Gould, Ph.D. and Kanya Rajangam, Ph.D., with Dr. Davis serving as chair of the nominating and corporate governance committee. Our board of directors has determined that each of these individuals is "independent" as defined under the applicable listing standards of Nasdaq and SEC rules and regulations. The functions of this committee include, among other things:

- identifying, reviewing and evaluating candidates to serve on our board of directors;

- considering and making recommendations to our board of directors regarding the composition and chairmanship of the committees of our board of directors;
- instituting plans or programs for the continuing education of our board of directors and orientation of new directors;
- developing and making recommendations to our board of directors regarding corporate governance guidelines and matters; and
- overseeing periodic evaluations of the board of directors' performance, including committees of the board of directors and management.

We believe that the composition and functioning of our nominating and corporate governance committee complies with all applicable requirements of the Sarbanes-Oxley Act, and all applicable SEC and Nasdaq rules and regulations. We intend to comply with future requirements to the extent they become applicable to us.

Our board of directors may from time to time establish other committees.

Compensation Committee Interlocks and Insider Participation

None of our directors who serve as a member of our compensation committee is, or has at any time during the past year been, one of our officers or employees. None of our executive officers currently serves, or in the past year has served, as a member of the board of directors or compensation committee of any other entity that has one or more executive officers serving on our board of directors or compensation committee.

Code of Business Conduct and Ethics

Effective upon the closing of this offering, we have adopted a Code of Business Conduct and Ethics, or the Code of Conduct, applicable to all of our employees, executive officers and directors. This includes our principal executive officer, principal financial officer and principal accounting officer or controller, or persons performing similar functions. Following the closing of this offering, the Code of Conduct will be available on our website at www.turnstonebio.com. We intend to disclose on our website any future amendments of our Code of Conduct or waivers that exempt any principal executive officer, principal financial officer, principal accounting officer or controller, persons performing similar functions or our directors from provisions in the Code of Conduct.

Non-Employee Director Compensation

We have previously provided cash and equity-based compensation to certain of our non-employee directors. In addition, all of our non-employee directors are entitled to reimbursement of direct expenses incurred in connection with attending meetings of our board of directors or committees thereof.

The following table sets forth information regarding the compensation our non-employee directors earned for service on our board of directors during the year ended December 31, 2022. Dr. Burgess, our interim Chief Medical Officer, is also a member of our board of directors and was a non-employee director until March 2022 when he was appointed as our interim Chief Medical Officer. Dr. Farah, our President and Chief Executive Officer is also a member of our board of directors but did not receive any additional compensation for his service as a director. The compensation of Dr. Farah is set forth in the section titled "Executive Compensation—Summary Compensation Table."

Name	Fees Earned or Paid in Cash ($)	Option Awards[4][5] ($)	All Other Compensation ($)	Total ($)
Jerel Davis, Ph.D., Rishi Gupta, Stefan Larson, Ph.D. and Santhosh Palani, Ph.D.	—	—	—	—
Patrick Machado[1]	30,000	245,836	—	275,836
Kanya Rajangam, Ph.D.[2]	27,500	383,600	—	411,100
Michael Burgess, MBChB, Ph.D.[3]	136,742	280,000	267	417,009
Robert Gould, Ph.D.[1]	—	355,844	—	355,844

(1) The amounts reported in these rows reflect compensation approved by our board of directors.
(2) The amount reported in this column for Dr. Rajangam was paid pursuant to an offer letter we entered into with Dr. Rajangam, as further described below.
(3) The amounts reported in this row for Dr. Burgess were paid pursuant to the offer letters we entered into with him, as further described below. Dr. Burgess served as a non-employee director from June 2021 until his appointment as our interim Chief Medical Officer effective March 2022. During the year ended December 31, 2022, we paid Dr. Burgess an aggregate of $48,333 in cash for his services to us as a non-employee director. After Dr. Burgess was appointed as our interim Chief Medical Officer, he did not receive any additional compensation from us for his services as a director. In addition, during the year ended December 31, 2022, in connection with Dr. Burgess' employment as our interim Chief Medical Officer, he earned a base salary of $136,742, was granted an option to purchase up to 25,040 shares of our common stock at an exercise price of $11.18 per share, subject to our standard terms and vesting schedule, and we paid $267 in life insurance premiums for his benefit.
(4) The amounts reported in this column reflect the aggregate grant date fair value of the stock options granted to the non-employee director during 2022 under the 2018 Plan, computed in accordance with Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, Topic 718 and do not reflect dollar amounts actually received by the non-employee director or the economic value that may be received by the non-employee director upon stock option exercise or any sale of the underlying shares of common stock. The assumptions used in calculating the grant date fair value of the stock options reported in this column are set forth in the notes to our audited consolidated financial statements included elsewhere in this prospectus.
(5) The table below sets forth the aggregate number of shares subject to outstanding stock options, as of December 31, 2022, beneficially owned by each of our non-employee directors for the year ended December 31, 2022.

Name	Number of Shares Underlying Outstanding Options as of December 31, 2022
Jerel Davis, Ph.D., Rishi Gupta, Stefan Larson, Ph.D., Santhosh Palani, Ph.D.	—
Patrick Machado	61,720
Kanya Rajangam, Ph.D.	35,056
Michael Burgess, MBChB, Ph.D.	210,423
Robert Gould, Ph.D.	52,903

Narrative to the Employee Director Compensation Table

Kanya Rajangam, Ph.D.

Dr. Rajangam joined our board of directors in November 2021. In October 2021, we entered into an offer letter with Dr. Rajangam pursuant to which we agreed to pay her a cash retainer of $30,000 per year for

service on our board of directors payable on a quarterly basis. In addition, pursuant to the offer letter, Dr. Rajangam received an option to purchase up to 35,056 shares of our common stock at an exercise price of $10.94 per share, as compensation for joining our board of directors. The shares subject to the option vest over four years, with 25% of the shares having vested on the first anniversary of the effective date of the offer letter, and the remainder continuing to vest monthly in substantially equal installments over the remaining period, subject to Dr. Rajangam's continuous service on each vesting date.

Michael Burgess, MBChB, Ph.D.

We entered into an offer letter with Dr. Burgess effective March 2022, or the March 2022 Offer Letter, which governs the current terms of his employment. The March 2022 Offer Letter provides that Dr. Burgess will be employed in 12-month terms that automatically renew on March 14 of each year unless either party gives written notice of termination at least 90 days in advance of March 14. Pursuant to the March 2022 Offer Letter, Dr. Burgess is entitled to an annual base salary of $475,000 and an incentive bonus of 40% of his annual base salary, based upon the achievement of a combination of personal and company performance goals. Dr. Burgess' incentive bonus for 2022 was prorated. In addition, pursuant to the March 2022 Offer Letter, Dr. Burgess received an option to purchase up to 25,040 shares of our common stock, which vest and become exercisable as follows: (i) 25% of the stock options vest and become exercisable one year following the grant date and (ii) the remaining 75% vest in 36 successive equal monthly installments thereafter, in each case, subject to the holder's continuous service through the applicable vesting date. Dr. Burgess also joined our board of directors in June 2021. In connection with joining our board of directors, we previously entered into an offer letter with Dr. Burgess, or the May 2021 Offer Letter, pursuant to which we agreed to pay him a cash retainer of $50,000 per year for service on our board of directors and as Executive Chairman of Research and Development. However, following the execution of the March 2022 Offer Letter, Dr. Burgess was no longer entitled to compensation for his service on our board of directors. In addition, pursuant to the May 2021 Offer Letter, Dr. Burgess received an option to purchase (i) up to 87,359 shares of our common stock pursuant to the 2016 Plan, of which 9,099 shares were unvested as of the effective date of the May 2021 Offer Letter, and (ii) up to 98,023 shares of our common stock pursuant to the 2018 Plan, of which 53,096 shares were unvested as of the effective date of the May 2021 Offer Letter. The unvested shares each vest in a series of 48 successive equal monthly installments measure from the effective date of the May 2021 Offer Letter, subject to Dr. Burgess' continuous service on each vesting date.

Pursuant to Dr. Burgess' offer letter, we must provide Dr. Burgess with not less than three months' written advance notice if we wish to terminate him for without "cause" (as defined in the offer letter). However, we have the right to accelerate the termination of his employment, in our sole discretion, so long as we continue to pay Dr. Burgess' during such three-month notice period. Dr. Burgess must also provide us with not less than three months' written advance notice if he wishes to terminate his employment. Dr. Burgess' severance benefits are contingent upon his execution of a separation agreement (including a release of claims against us) and his continued compliance with his nondisclosure, assignment of inventions, and non-competition agreement with us.

2023 Non-Employee Director Compensation Policy

Our board of directors adopted a non-employee director compensation policy in June 2023 that became effective upon the execution and delivery of the underwriting agreement related to this offering and will be applicable to all of our non-employee directors. This compensation policy provides that each such non-employee director will receive the following compensation for service on our board of directors:

- an annual cash retainer of $40,000 (plus an additional $30,000 for the non-executive chair of our board of directors);
- an additional annual cash retainer of $7,500, $5,000 and $4,000 for service as a member of the audit committee, compensation committee and the nominating and corporate governance committee, respectively;

- an additional annual cash retainer of $15,000, $10,000 and $8,000 for service as chair of the audit committee, compensation committee and the nominating and corporate governance committee, respectively;

- an initial option grant to purchase 25,540 shares of our common stock on the date of each such non-employee director's appointment to our board of directors; and

- an annual option grant to purchase 12,770 shares of our common stock on the date of each of our annual stockholder meetings.

Each of the option grants described above under the non-employee director compensation policy will be granted under our 2023 Plan, the terms of which are described in more detail below under the section titled "Executive Compensation—Employee Benefit Plans—2023 Equity Incentive Plan." Each such option grant will vest and become exercisable subject to the director's continuous service to us through the earlier of the first anniversary of the date of grant or the next annual stockholder meeting. The term of each option will be ten years, subject to earlier termination as provided in the 2023 Plan.

EXECUTIVE COMPENSATION

Our named executive officers for the year ended December 31, 2022, consisting of our principal executive officer and the next two most highly compensated executive officers who were serving in such capacity as of December 31, 2022, were:

- Sammy Farah, M.B.A., Ph.D., our President and Chief Executive Officer;
- Venkat Ramanan, Ph.D., our Chief Financial Officer; and
- Saryah Azmat, our Chief Business Officer.

Emerging Growth Company Status

We are an "emerging growth company," as defined in the JOBS Act. As an emerging growth company we will be exempt from certain requirements related to executive compensation, including the requirements to hold a nonbinding advisory vote on executive compensation and to provide information relating to the ratio of total compensation of our chief executive officer to the median of the annual total compensation of all of our employees, each as required by the Investor Protection and Securities Reform Act of 2010, which is part of the Dodd-Frank Wall Street Reform and Consumer Protection Act.

Summary Compensation Table

The following table presents all of the compensation awarded to or earned by or paid to our named executive officers during the fiscal year ended December 31, 2022.

Name and Principal Position	Fiscal Year	Salary ($)[1]	Stock Awards ($)	Option Awards ($)[2]	Non-Equity Incentive Plan Compensation ($)[3]	All Other Compensation ($)	Total ($)
Sammy Farah, M.B.A., Ph.D. *President, Chief Executive Officer and Director*	2022	501,333	—	2,607,633	163,897	13,282[4]	3,286,145
Venkat Ramanan, Ph.D. *Chief Financial Officer*	2022	345,241	—	1,960,000	—	891[5]	2,306,132
Saryah Azmat *Chief Business Officer*	2022	364,000	—	577,285	114,660	1,069[5]	1,057,014

(1) Each named executive officer's base salary is a fixed component of annual compensation for performing specific duties and functions, and has been established taking into account each individual's roles, responsibilities, skills and expertise. For Dr. Ramanan, the amounts shown represent the pro rata portion of his annual salary earned during 2022 from commencement of his employment as our Chief Financial Officer in February 2022 through December 31, 2022.

(2) In accordance with SEC rules, amounts reported in the column represent the aggregate grant date fair value of the stock options granted to our named executive officers during fiscal year 2022 under our 2018 Plan, computed in accordance with FASB ASC Topic 718. The assumptions used in calculating the grant date fair value of the stock options reported in this column are set forth in the notes to our audited consolidated financial statements included elsewhere in this prospectus. This amount does not reflect the actual economic value that may be realized by the named executive officer. All of the stock awards were granted under the 2018 Plan, the terms of which plan are described in the subsection titled "—Employee Benefit Plans—2018 Equity Incentive Plan."

(3) Amounts shown represent annual performance-based bonuses which are determined based upon the achievement of a combination of personal and company performance. For more information, see the subsection below titled "—Narrative to the Summary Compensation Table—Annual Incentive Compensation."

(4) Represents life insurance premiums for Dr. Farah's benefit, employer contributions to the 401(k) retirement plan, and tax preparation services for Dr. Farah in the amounts of $1,069, $9,150 and $3,063, respectively.

(5) Represents life insurance premiums for the employees' benefit.

Narrative to the Summary Compensation Table

Annual Base Salary

Our named executive officers receive a base salary to compensate them for services rendered to us. The base salary payable to each named executive officer is intended to provide a fixed component of compensation reflecting the executive's skill set, experience, role and responsibilities. Dr. Farah's, Dr. Ramanan's and Ms. Azmat's respective annual base salaries were $501,333, $412,000 and $364,000 for the year ended December 31, 2022, respectively. However, the amount paid to Dr. Ramanan for his service during the year ended December 31, 2022 was $345,241, which reflects the pro rata portion of his base salary earned during 2022 from his commencement of employment as our Chief Financial Officer in February 2022 through December 31, 2022.

Annual Incentive Compensation

Our named executive officers are eligible to receive annual incentive compensation based on the satisfaction of individual and corporate performance objectives established by our board of directors. Each named executive officer has a target annual incentive opportunity, calculated as a percentage of their respective annual base salary. For 2022, the target annual incentive opportunities as a percentage of base salary for our named executive officers were 40% for Dr. Farah and 35% for Dr. Ramanan and Ms. Azmat. The amounts of any annual incentives earned are determined after the end of the year, based on the achievement of the designated corporate and individual performance objectives, and may be paid in cash or equity. Based on these metrics, for the year ended December 31, 2022, our board of directors determined that Dr. Farah's and Ms. Azmat's respective annual bonuses were $163,897 and $114,660, respectively, as reflected in the column of the Summary Compensation Table above titled "Non-Equity Incentive Plan Compensation." Dr. Ramanan did not receive a bonus during the year ended December 31, 2022 because he was not employed with us until February 2022, and our annual incentive compensation are determined after the end of the fiscal year.

Equity-Based Incentive Awards

We believe that equity awards provide our executives with a strong link to our long-term performance, create an ownership culture and help to align the interests of our executives and our stockholders. To date, we have only used stock option grants for this purpose because we believe they are an effective means by which to align the long-term interests of our executive officers with those of our stockholders. The use of stock options also can provide tax and other advantages to our executive officers relative to other forms of equity compensation. We believe that our equity awards are an important retention tool for our executive officers, as well as for our other employees.

We award stock options broadly to our employees, including to our non-executive employees. Grants to our executives and other employees are made at the discretion of our board of directors and are not made at any specific time period during a year.

Prior to this offering, all of the stock options we have granted were made pursuant to either our 2016 Plan or our 2018 Plan. Following this offering, we will grant equity incentive awards under the terms of our 2023 Plan. The terms of our equity plans are described under the section titled "—Employee Benefit Plans" below.

Outstanding Equity Awards as of December 31, 2022

The following table sets forth certain information about outstanding equity awards granted to our named executive officers that remain outstanding as of December 31, 2022.

			Option Awards			
Name	Grant Date	Vesting Commencement Date	Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options Unexercisable	Option Exercise Price ($)(7)	Option Expiration Date
Sammy Farah, M.B.A., Ph.D.	12/08/2015(1)	12/08/2015	114,958	—	1.51	12/08/2025
President, Chief Executive Officer and Director	12/14/2016(1)	12/14/2016	23,457(3)	—	1.59	12/14/2026
	12/14/2016(1)	12/14/2016	1,862(4)	—	1.59	12/14/2026
	01/30/2017(1)	01/30/2017	77,237(5)	—	1.59	01/30/2027
	01/30/2017(1)	01/30/2017	15,441(6)	—	1.59	01/30/2027
	06/10/2019(2)	06/10/2019	33,279	4,754(8)	9.34	06/10/2029
	06/10/2019(2)	06/10/2019	233,292	33,327(9)	9.34	06/10/2029
	01/20/2022(2)	01/20/2022	—	238,304(10)	10.94	01/20/2032
Venkat Ramanan, Ph.D.	06/30/2022(2)	2/28/2022	—	19,511(11)	11.18	06/30/2032
Chief Financial Officer	06/30/2022(2)	2/28/2022	—	155,768(12)	11.18	06/30/2032
Saryah Azmat	11/01/2019(2)	11/01/2019	32,994	9,809(13)	9.34	11/01/2029
Chief Business Officer	11/01/2019(2)	11/01/2019	62,271	18,513(14)	9.34	11/01/2029
	01/20/2022(2)	01/20/2022	—	52,756(15)	10.94	01/20/2032

(1) Option award was granted under the 2016 Plan.
(2) Option award was granted under the 2018 Plan.
(3) Represents an incentive stock option, or ISO, award which vests over a period of four years with 25% of the shares underlying the option vesting on the one year anniversary of the December 14, 2016, vesting commencement date and 1/48th of the shares underlying the option vesting on a monthly basis thereafter, subject to continued service through each vesting date.
(4) Represents a nonqualified stock option, or NSO, award which vests over a period of four years with 25% of the shares underlying the option vesting on the one year anniversary of the December 14, 2016, vesting commencement date and 1/48th of the shares underlying the option vesting on a monthly basis thereafter, subject to continued service through each vesting date.
(5) Represents an ISO award which vests over a period of four years with 25% of the shares underlying the option vesting on the one year anniversary of the January 30, 2017, vesting commencement date and 1/48th of the shares underlying the option vesting on a monthly basis thereafter, subject to continued service through each vesting date.
(6) Represents a NSO award which vests over a period of four years with 25% of the shares underlying the option vesting on the one year anniversary of the January 30, 2017, vesting commencement date and 1/48th of the shares underlying the option vesting on a monthly basis thereafter, subject to continued service through each vesting date
(7) All of the option awards were granted with a per share exercise price equal to the fair market value of one share of our common stock on the date of grant, as determined by our board of directors.
(8) Represents an ISO award which vests over a period of four years with 25% of the shares underlying the option vesting on the one year anniversary of the June 10, 2019, vesting commencement date and 1/48th of the shares underlying the option vesting on a monthly basis thereafter, subject to continued service through each vesting date.
(9) Represents a NSO award which vests over a period of four years with 25% of the shares underlying the option vesting on the one year anniversary of the June 10, 2019, vesting commencement date and 1/48th of the shares underlying the option vesting on a monthly basis thereafter, subject to continued service through each vesting date.
(10) Represents a NSO award which vests over a period of four years with 25% of the shares underlying the option vesting on the one year anniversary of the January 20, 2022, vesting commencement date and 1/48th of the shares underlying the option vesting on a monthly basis thereafter, subject to continued service through each vesting date.
(11) Represents an ISO award which vests over a period of four years with 25% of the shares underlying the option vesting on the one year anniversary of the February 28, 2022, vesting commencement date and 1/48th of the shares underlying the option vesting on a monthly basis thereafter, subject to continued service through each vesting date.
(12) Represents a NSO award which vests over a period of four years with 25% of the shares underlying the option vesting on the one year anniversary of the February 28, 2022, vesting commencement date and 1/48th of the shares underlying the option vesting on a monthly basis thereafter, subject to continued service through each vesting date.

(13) Represents an ISO award which vests over a period of four years with 25% of the shares underlying the option vesting on the one year anniversary of the November 1, 2019 vesting commencement date and 1/48th of the shares underlying the option vesting on a monthly basis thereafter, subject to continued service through each vesting date.
(14) Represents a NSO award which vests over a period of four years with 25% of the shares underlying the option vesting on the one year anniversary of the November 1, 2019 vesting commencement date and 1/48th of the shares underlying the option vesting on a monthly basis thereafter, subject to continued service through each vesting date.
(15) Represents a NSO award which vests over a period of four years with 25% of the shares underlying the option vesting on the one year anniversary of the January 20, 2022 vesting commencement date and 1/48th of the shares underlying the option vesting on a monthly basis thereafter, subject to continued service through each vesting date.

Pension Benefits

Our named executive officers did not participate in, or otherwise receive any benefits under, any pension or retirement plan sponsored by us during the year ended December 31, 2022.

Nonqualified Deferred Compensation

Our named executive officers did not participate in, or earn any benefits under, a non-qualified deferred compensation plan sponsored by us during the year ended December 31, 2022.

Other Compensation and Benefits

All of our executive officers, including our named executive officers, are eligible to participate in our employee benefit plans, including our paid time off, medical, dental, vision, life, disability and accidental death and dismemberment insurance plans, in each case on the same basis as all of our other employees.

401(k) Plan

We are a participating employer in the TriNet 401(k) plan that provides eligible U.S. employees, including our named executive officers, with an opportunity to save for retirement on a tax advantaged basis. TriNet is a professional employer organization, which provides human resources services for us. Eligible employees are able to defer compensation up to certain limits imposed by the Code. We have the ability to make matching and discretionary contributions to the 401(k) plan. The 401(k) plan is intended to be qualified under Section 401(a) of the Code, with the related trust intended to be tax exempt under Section 401(a) of the Code. As a tax-qualified retirement plan, contributions and earnings on deferred amounts are generally not taxable to a participating employee until withdrawn or distributed from the 401(k) plan.

Employment Arrangements

Below are descriptions of employment agreements or offer letters with our named executive officers. For a discussion of the severance pay and other benefits to be provided in connection with a termination of employment and/or a change in control under the arrangements with our executive officers, see the subsection titled "—Potential Payments upon Termination or Change in Control" below.

Sammy Farah, M.B.A., Ph.D.—President, Chief Executive Officer and Director

Turnstone Canada entered into an offer letter with Dr. Farah in August 2015, which governs the current terms of his employment. Dr. Farah's offer letter set forth his initial annual base salary, eligibility to receive an annual incentive bonus based upon the achievement of certain objectives as determined by our board of directors and certain terms of his initial equity award. Dr. Farah's offer letter also provided for a one-time reimbursement for moving expenses.

Venkat Ramanan, Ph.D.—Chief Financial Officer

We entered into an offer letter with Dr. Ramanan in December 2021, which generally governs the terms of his employment, including his initial annual base salary of $412,000 and eligibility to receive an annual

incentive bonus of 35% of his annual base salary, based upon the achievement of a combination of personal and company performance goals. In addition, pursuant to the offer letter, Dr. Ramanan received an option to purchase up to 175,280 shares of our common stock, which vest and become exercisable as follows: (i) 25% of the stock options vest and become exercisable one year following the grant date and (ii) the remaining 75% vest in 36 successive equal monthly installments thereafter, in each case, subject to Dr. Ramanan's continuous service through the applicable vesting date. Dr. Ramanan commenced employment with us in February 2022. Dr. Ramanan's offer letter provides for a one-time reimbursement for up to $75,000 of moving expenses.

Saryah Azmat—Chief Business Officer

Turnstone Canada entered into an offer letter with Ms. Azmat in September 2019, which generally governs the terms of her employment. Ms. Azmat's offer letter set forth her initial annual base salary, eligibility to earn an annual incentive bonus based upon the achievement of a combination of personal and company performance goals, and a one-time signing bonus and reimbursement for moving expenses upon hire. Ms. Azmat also received an option to purchase up to 123,587 shares of our common stock, which vest and become exercisable as follows: (i) 25% of the stock options vest and become exercisable one year following the grant date and (ii) the remaining 75% vest in 36 successive equal monthly installments thereafter, in each case, subject to Ms. Azmat's continuous service through the applicable vesting date.

Potential Payments upon Termination or Change in Control

Regardless of the manner in which a named executive officer's service terminates, each named executive officer is entitled to receive amounts earned during his or her term of service, including unpaid salary and unused vacation. In addition, each of our named executive officers' stock awards are subject to the terms of our 2018 Plan and award agreements thereunder. A description of the termination and change in control provisions in the 2018 Plan, and awards granted thereunder is provided below under the section titled "—2018 Equity Incentive Plan."

Severance Benefits

Drs. Farah and Ramanan are eligible to receive certain severance benefits pursuant to the terms of their offer letters as described below.

Sammy Farah, M.B.A., Ph.D.—President, Chief Executive Officer and Director

Dr. Farah's offer letter provides that if his employment is terminated by Turnstone Canada without "cause" (as defined in the offer letter), he will be entitled to (i) the termination and severance payment required by the Employment Standards Act, 2000, as amended or replaced, or the ESA, (ii) three months of his base salary less the amount paid under (i), and (iii) one month base salary for every completed year of service, provided that the foregoing severance package shall not be more than the greater of (y) six months of his base salary or (z) the termination and severance pay required by the ESA. If Dr. Farah's employment is terminated by Turnstone Canada without "cause" within twelve months of a "sale of the company," he will be entitled to the greater of six months of his base salary or the termination and severance pay required by the ESA. In the event Dr. Farah's employment is terminated by Turnstone Canada without "cause", he will also be entitled to a continuation of health benefits for the shorter of (i) six months for a termination not within twelve months of a "sale of the company" or twelve months for a termination within twelve months of a "sale of the company", and (ii) until he finds alternate employment. Dr. Farah's severance benefits are contingent upon his execution of a release of claims in a form satisfactory to Turnstone Canada and his continued compliance with the terms of his offer letter (which includes non-solicitation, non-competition, and non-disparagement covenants). In the event Dr. Farah would like to resign, he must provide us with a minimum of sixty days' advance written notice.

Venkat Ramanan, Ph.D.—Chief Financial Officer

Dr. Ramanan's offer letter provides that if his employment is terminated by us without "cause" (as defined in the offer letter), he will be entitled to (i) nine months of his then base salary and (ii) up to nine months of health care continuation coverage. Dr. Ramanan's severance benefits are contingent upon his execution of a separation agreement (including a release of claims against us) and his continued compliance with his nondisclosure, assignment of inventions, and non-competition agreements with us.

Equity Incentive Plans

2023 Equity Incentive Plan

Our board of directors adopted the 2023 Plan, that became effective upon the execution of the underwriting agreement related to this offering. Our 2023 Plan came into existence upon its adoption by our board of directors, but no grants were made under our 2023 Plan prior to its effectiveness. Once our 2023 Plan became effective, no further grants will be made under the 2018 Plan.

Types of Awards. Our 2023 Plan provides for the grant of incentive stock options, or ISOs, non-qualified stock options, or NSOs, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance-based awards and other awards, or collectively, awards. ISOs may be granted only to our employees, including our officers, and the employees of our affiliates. All other awards may be granted to our employees, including our officers, our non-employee directors and consultants and the employees and consultants of our affiliates.

Authorized Shares. The maximum number of shares of common stock that may be issued under our 2023 Plan is 2,733,887 shares, which is the sum of: (i) 1,889,435 new shares, plus (ii) up to 712,503 shares available for issuance under the 2018 Plan as of the effective date of the 2023 Plan, plus (iii) up to 120,949 shares of our common stock subject to awards granted under our 2016 Plan and our 2018 Plan that, after the effective date of our 2023 Plan, expire or otherwise terminate without having been exercised in full or are forfeited to or repurchased by us. The number of shares of common stock reserved for issuance under our 2023 Plan will automatically increase on January 1 of each year, beginning on January 1, 2024 (assuming the 2023 Plan becomes in effective in 2023), and continuing through and including January 1, 2033, by 5% of the aggregate number of shares of common stock of all classes issued and outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by our board of directors prior to the applicable January 1. The maximum number of shares that may be issued upon the exercise of ISOs under our 2023 Plan is 8,168,660 shares.

Shares issued under our 2023 Plan will be authorized but unissued or reacquired shares of common stock. Shares subject to awards granted under our 2023 Plan that expire or terminate without being exercised in full, or that are paid out in cash rather than in shares, will not reduce the number of shares available for issuance under our 2023 Plan. Additionally, shares issued pursuant to awards under our 2023 Plan that we repurchase or that are forfeited, as well as shares used to pay the exercise price of an award or to satisfy the tax withholding obligations to an award, will become available for future grant under our 2023 Plan.

The maximum number of shares of common stock subject to stock awards granted under the 2023 Plan or otherwise during any calendar year beginning in 2023 to any non-employee director, taken together with any cash fees paid by us to such non-employee director during such calendar year for service on the board of directors, will not exceed $750,000 in total value (calculating the value of any such stock awards based on the grant date fair value of such stock awards for financial reporting purposes), or, with respect to the calendar year in which a non-employee director is first appointed or elected to our board of directors, $120,000.

Plan Administration. Our board of directors, or a duly authorized committee of our board of directors, may administer our 2023 Plan. Our board of directors has delegated concurrent authority to administer our 2023

Plan to the compensation committee under the terms of the compensation committee's charter. We sometimes refer to our board of directors, or the applicable committee with the power to administer our equity incentive plans, as the administrator. The administrator may also delegate to one or more persons or bodies the authority to (i) designate employees (other than officers) to receive specified awards, and (ii) determine the number of shares subject to such awards. Such persons or bodies may not grant a stock award to themself and neither our board nor any committee may delegate authority to any person or body (who is not a member of our board or such body that is not comprised solely of members of our board) the authority to determine the fair market value of our common stock for purposes of the 2023 Plan.

The administrator has the authority to determine the terms of awards, including recipients, the exercise, purchase or strike price of awards, if any, the number of shares subject to each award, the fair market value of a share of common stock, the vesting schedule applicable to the awards, together with any vesting acceleration, and the form of consideration, if any, payable upon exercise or settlement of the award and the terms of the award agreements for use under our 2023 Plan.

In addition, subject to the terms of the 2023 Plan, the administrator also has the power to modify outstanding awards under our 2023 Plan, including the authority to reprice any outstanding option or stock appreciation right, cancel and re-grant any outstanding option or stock appreciation right in exchange for new stock awards, cash or other consideration, or take any other action that is treated as a repricing under generally accepted accounting principles, with the consent of any materially adversely affected participant.

Stock Options. ISOs and NSOs are granted pursuant to stock option agreements adopted by the administrator. The administrator determines the exercise price for a stock option, within the terms and conditions of the 2023 Plan, provided that the exercise price of a stock option generally cannot be less than 100% of the fair market value of our common stock on the date of grant. Options granted under the 2023 Plan vest at the rate specified in the stock option agreement as specified in the stock option agreement by the administrator.

The administrator determines the term of stock options granted under the 2023 Plan, up to a maximum of ten years. Unless the terms of an optionholder's stock option agreement provide otherwise, if an optionholder's service relationship with us, or any of our affiliates, ceases for any reason other than disability, death or cause, the optionholder may generally exercise any vested options for a period of three months following the cessation of service. The option term may be extended if either an exercise of the option or an immediate sale of shares acquired upon exercise of the option following such a termination of service is prohibited by applicable securities laws or our insider trading policy. If an optionholder's service relationship with us or any of our affiliates ceases due to disability or death, or an optionholder dies within a certain period following cessation of service, the optionholder or a beneficiary may generally exercise any vested options for a period of 12 months in the event of disability and 18 months in the event of death. In the event of a termination for cause, options generally terminate immediately upon the termination of the individual for cause. In no event may an option be exercised beyond the expiration of its term.

Acceptable consideration for the purchase of common stock issued upon the exercise of a stock option will be determined by the administrator and may include (i) cash, check, bank draft or money order, (ii) a broker-assisted cashless exercise, (iii) the tender of shares of common stock previously owned by the optionholder, (iv) a net exercise of the option if it is an NSO and (v) other legal consideration approved by the administrator.

Options may not be transferred to third-party financial institutions for value. Unless the administrator provides otherwise, options generally are not transferable except by will, the laws of descent and distribution or pursuant to a domestic relations order. An optionholder may designate a beneficiary, however, who may exercise the option following the optionholder's death.

Tax Limitations on ISOs. The aggregate fair market value, determined at the time of grant, of common stock with respect to ISOs that are exercisable for the first time by an option holder during any calendar year

under all of our stock plans may not exceed $100,000. Options or portions thereof that exceed such limit will be treated as NSOs. No ISOs may be granted to any person who, at the time of the grant, owns or is deemed to own stock possessing more than 10% of our total combined voting power or that of any of our parent or subsidiary corporations, unless (i) the option exercise price is at least 110% of the fair market value of the stock subject to the option on the date of grant and (ii) the term of the ISO does not exceed five years from the date of grant.

Restricted Stock Awards. Restricted stock awards are granted pursuant to restricted stock award agreements adopted by the administrator. Restricted stock awards may be granted in consideration for cash, check, bank draft or money order, services rendered to us or our affiliates or any other form of legal consideration. Common stock acquired under a restricted stock award may, but need not, be subject to a share repurchase option in our favor in accordance with a vesting schedule to be determined by the administrator. A restricted stock award may be transferred only upon such terms and conditions as set by the administrator. Except as otherwise provided in the applicable award agreement, restricted stock awards that have not vested may be forfeited or repurchased by us upon the participant's cessation of continuous service for any reason.

Restricted Stock Unit Awards. Restricted stock unit awards are granted pursuant to restricted stock unit award agreements adopted by the administrator. Restricted stock unit awards may be granted in consideration for any form of legal consideration. A restricted stock unit award may be settled by cash, delivery of stock, a combination of cash and stock as deemed appropriate by the administrator or in any other form of consideration set forth in the restricted stock unit award agreement. Additionally, dividend equivalents may be credited in respect of shares covered by a restricted stock unit award. Except as otherwise provided in the applicable restricted stock unit award agreement, restricted stock units that have not vested will be forfeited upon the participant's cessation of continuous service for any reason.

Stock Appreciation Rights. Stock appreciation rights are granted pursuant to stock appreciation right grant agreements adopted by the administrator. The administrator determines the strike price for a stock appreciation right, which generally cannot be less than 100% of the fair market value of common stock on the date of grant. Upon the exercise of a stock appreciation right, we will pay the participant an amount equal to the product of (i) the excess of the per share fair market value of common stock on the date of exercise over the strike price, multiplied by (ii) the number of shares of common stock with respect to which the stock appreciation right is exercised. A stock appreciation right granted under the 2023 Plan vests at the rate specified in the stock appreciation right agreement as determined by the administrator.

The administrator determines the term of stock appreciation rights granted under the 2023 Plan, up to a maximum of ten years. Unless the terms of a participant's stock appreciation right agreement provide otherwise, if a participant's service relationship with us or any of our affiliates ceases for any reason other than cause, disability or death, the participant may generally exercise any vested stock appreciation right for a period of three months following the cessation of service. The stock appreciation right term may be further extended if exercise of the stock appreciation right following such a termination of service is prohibited by applicable securities laws. If a participant's service relationship with us, or any of our affiliates, ceases due to disability or death, or a participant dies within a certain period following cessation of service, the participant or a beneficiary may generally exercise any vested stock appreciation right for a period of 12 months in the event of disability and 18 months in the event of death. In the event of a termination for cause, stock appreciation rights generally terminate immediately upon the occurrence of the event giving rise to the termination of the individual for cause. In no event may a stock appreciation right be exercised beyond the expiration of its term.

Performance Awards. Our 2023 Plan permits the grant of performance-based stock and cash awards. The compensation committee can structure such awards so that the stock or cash will be issued or paid pursuant to such award only following the achievement of certain pre-established performance goals during a designated performance period. Performance awards that are settled in cash or other property are not required to be valued in whole or in part by reference to, or otherwise based on, the common stock.

The performance goals may be based on any measure of performance selected by our board of directors. The compensation committee may establish performance goals on a company-wide basis, with respect to one or more business units, divisions, affiliates or business segments, and in either absolute terms or relative to the performance of one or more comparable companies or the performance of one or more relevant indices. Unless specified otherwise (i) in the award agreement at the time the award is granted or (ii) in such other document setting forth the performance goals at the time the goals are established, the compensation committee will appropriately make adjustments in the method of calculating the attainment of the performance goals as follows: (1) to exclude restructuring and/or other nonrecurring charges; (2) to exclude exchange rate effects; (3) to exclude the effects of changes to generally accepted accounting principles; (4) to exclude the effects of any statutory adjustments to corporate tax rates; (5) to exclude the effects of items that are "unusual" in nature or occur "infrequently" as determined under generally accepted accounting principles; (6) to exclude the dilutive effects of acquisitions or joint ventures; (7) to assume that any business divested by us achieved performance objectives at targeted levels during the balance of a performance period following such divestiture; (8) to exclude the effect of any change in the outstanding shares of common stock by reason of any stock dividend or split, stock repurchase, reorganization, recapitalization, merger, consolidation, spin-off, combination or exchange of shares or other similar corporate change, or any distributions to common stockholders other than regular cash dividends; (9) to exclude the effects of stock-based compensation and the award of bonuses under our bonus plans; (10) to exclude costs incurred in connection with potential acquisitions or divestitures that are required to be expensed under generally accepted accounting principles and (11) to exclude the goodwill and intangible asset impairment charges that are required to be recorded under generally accepted accounting principles.

Other Awards. The administrator may grant other awards based in whole or in part by reference to common stock. The administrator will set the number of shares under the award and all other terms and conditions of such awards.

Changes to Capital Structure. In the event there is a specified type of change in our capital structure, such as a stock split, reverse stock split or recapitalization, appropriate adjustments will be made to (i) the class and maximum number of shares reserved for issuance under the 2023 Plan; (ii) the class and maximum number of shares by which the share reserve may increase automatically each year; (iii) the class and maximum number of shares that may be issued upon the exercise of ISOs and (iv) the class and number of shares and exercise price, strike price, or purchase price, if applicable, of all outstanding awards.

Corporate Transactions. The following applies to stock awards under the 2023 Plan in the event of a corporate transaction, unless otherwise provided in a participant's stock award agreement or other written agreement with us or one of our affiliates or unless otherwise expressly provided by the administrator at the time of grant. Under the 2023 Plan, a corporate transaction is generally the consummation of (i) a sale or other disposition of all or substantially all of our assets, (ii) a sale or other disposition of at least 50 percent of our outstanding securities, (iii) a merger, consolidation or similar transaction following which we are not the surviving corporation or (iv) a merger, consolidation or similar transaction following which we are the surviving corporation but the shares of common stock outstanding immediately prior to such transaction are converted or exchanged into other property by virtue of the transaction.

In the event of a corporate transaction, any stock awards outstanding under the 2023 Plan may be assumed, continued or substituted by any surviving or acquiring corporation (or its parent company), and any reacquisition or repurchase rights held by us with respect to the stock award may be assigned to the successor (or its parent company). If the surviving or acquiring corporation (or its parent company) does not assume, continue or substitute such stock awards, then (i) with respect to any such stock awards that are held by participants whose continuous service has not terminated prior to the effective time of the corporate transaction, or current participants, the vesting (and exercisability, if applicable) of such stock awards will be accelerated in full to a date prior to the effective time of the corporate transaction (contingent upon the effectiveness of the corporate transaction), and such stock awards will terminate if not exercised (if applicable) at or prior to the effective time of the corporate transaction, and any reacquisition or repurchase rights held by us with respect to such stock

awards will lapse (contingent upon the effectiveness of the corporate transaction), and (ii) any such stock awards that are held by persons other than current participants will terminate if not exercised (if applicable) prior to the effective time of the corporate transaction, except that any reacquisition or repurchase rights held by us with respect to such stock awards will not terminate and may continue to be exercised notwithstanding the corporate transaction. In addition, the plan administrator may also provide, in its sole discretion, that the holder of a stock award that will terminate upon the occurrence of a corporate transaction if not previously exercised will receive a payment, if any, equal to the excess of the value of the property the participant would have received upon exercise of the stock award over the exercise price otherwise payable in connection with the stock award.

A stock award may be subject to additional acceleration of vesting and exercisability upon or after a change in control as may be provided in an applicable award agreement or other written agreement, but in the absence of such provision, no such acceleration will occur.

Transferability. A participant may not transfer awards under our 2023 Plan other than by will, the laws of descent and distribution or as otherwise provided under our 2023 Plan.

Plan Amendment or Termination. Our board of directors has the authority to amend, suspend or terminate our 2023 Plan, provided that such action does not materially impair the existing rights of any participant without such participant's written consent. Certain material amendments also require the approval of our stockholders. No ISOs may be granted after the tenth anniversary of the date our board of directors adopted our 2023 Plan. No awards may be granted under our 2023 Plan while it is suspended or after it is terminated.

2023 Employee Stock Purchase Plan

Our board of directors adopted the 2023 Employee Stock Purchase Plan, or the ESPP, that became effective immediately prior to the execution date of the underwriting agreement related to this offering. The purpose of our ESPP will be to secure the services of new employees, to retain the services of existing employees, and to provide incentives for such individuals to exert maximum efforts toward our success and that of our affiliates. Our ESPP will include two components. One component will be designed to allow eligible U.S. employees to purchase our common stock in a manner that may qualify for favorable tax treatment under Section 423 of the Code. The other component will permit the grant of purchase rights that do not qualify for such favorable tax treatment in order to allow deviations necessary to permit participation by eligible employees who are foreign nationals or employed outside of the United States while complying with applicable foreign laws.

Authorized Shares. The maximum aggregate number of shares of common stock that may be issued under our ESPP is 222,287 shares. The number of shares of common stock reserved for issuance under our ESPP will automatically increase on January 1 of each calendar year, beginning on January 1, 2024 (assuming the ESPP becomes effective in 2023) and continuing through and including January 1, 2033, by the lesser of (i) 1% of the aggregate number of shares of common stock of all classes issued and outstanding on December 31 of the preceding calendar year, (ii) 666,860 shares and (iii) a number of shares determined by our board of directors. Shares subject to purchase rights granted under our ESPP that terminate without having been exercised in full will not reduce the number of shares available for issuance under our ESPP.

Plan Administration. Our board of directors, or a duly authorized committee thereof, will administer our ESPP. The ESPP is implemented through a series of offerings with specific terms approved by the administrator and under which eligible employees are granted purchase rights to purchase shares of common stock on specified dates during such offerings. Under the ESPP, we may specify offerings with durations of not more than 27 months, and we may specify shorter purchase periods within each offering. Each offering will have one or more purchase dates on which shares of common stock will be purchased for our eligible employees participating in the offering. An offering under the ESPP may be terminated under certain circumstances.

Payroll Deductions. Generally, all regular employees, including executive officers, employed by us or by any of our designated affiliates, may participate in the ESPP and may contribute, normally through payroll

deductions, with a maximum dollar amount as designated by the board. Unless otherwise determined by the administrator, common stock will be purchased for the accounts of employees participating in the ESPP at a price per share equal to the lower of (i) 85% of the fair market value of a share of common stock on the first date of an offering or (ii) 85% of the fair market value of a share of common stock on the date of purchase.

Limitations. Our employees, including executive officers, or any of our designated affiliates may have to satisfy one or more of the following service requirements before participating in our ESPP, as determined by the administrator: (i) customary employment with us or one of our affiliates for more than 20 hours per week and more than five months per calendar year, or (ii) continuous employment with us or one of our affiliates for a minimum period of time, not to exceed two years, prior to the first date of an offering. An employee may not be granted rights to purchase stock under our ESPP if such employee (1) immediately after the grant would own stock possessing 5% or more of the total combined voting power or value of common stock, or (2) holds rights to purchase stock under our ESPP that would accrue at a rate that exceeds $25,000 worth of our stock for each calendar year that the rights remain outstanding.

Changes to Capital Structure. In the event that there occurs a change in our capital structure through such actions as a stock split, merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large nonrecurring cash dividend, liquidating dividend, combination of shares, exchange of shares, change in corporate structure or similar transaction, our board of directors will make appropriate adjustments to (i) the number of shares reserved under the ESPP, (ii) the maximum number of shares by which the share reserve may increase automatically each year, (iii) the number of shares and purchase price of all outstanding purchase rights and (iv) the number of shares that are subject to purchase limits under ongoing offerings.

Corporate Transactions. In the event of certain corporate transactions, including: (i) a sale of all or substantially all of our assets, (ii) the sale or disposition of 50% of our outstanding securities, (iii) the consummation of a merger or consolidation where we do not survive the transaction, and (iv) the consummation of a merger or consolidation where we do survive the transaction but the shares of our common stock outstanding immediately before such transaction are converted or exchanged into other property by virtue of the transaction, any then-outstanding rights to purchase our stock under the ESPP may be assumed, continued or substituted for by any surviving or acquiring entity (or its parent company). If the surviving or acquiring entity (or its parent company) elects not to assume, continue or substitute for such purchase rights, then the participants' accumulated payroll contributions will be used to purchase shares of common stock within 10 business days (or such other period specified by our board of directors) prior to such corporate transaction, and such purchase rights will terminate immediately.

Plan Amendment or Termination. The administrator has the authority to amend or terminate our ESPP, provided that except in certain circumstances such amendment or termination may not materially impair any outstanding purchase rights without the holder's consent. We will obtain stockholder approval of any amendment to our ESPP as required by applicable law or listing requirements.

2018 Equity Incentive Plan

Our board of directors adopted and our stockholder approved our 2018 Plan in December 2018. As of March 31, 2023, there were 269,708 shares of common stock remaining available for the future grant of stock awards under our 2018 Plan. As of March 31, 2023, options to purchase 2,495,301 shares of common stock were outstanding under the 2018 Plan and no shares of restricted stock were outstanding under the 2018 Plan. On January 21, 2022, the 2018 Plan was amended to increase the shares of common stock reserved for issuance under the 2018 Plan to 2,993,912 shares. No further stock awards will be granted under our 2018 Plan on or after the effectiveness of our 2023 Plan; however, awards outstanding under our 2018 Plan will continue to be governed by their existing terms.

Types of Awards. Our 2018 Plan provides for the grant of ISOs to employees (including officers and directors who are also employees) of our company or any parent or subsidiaries of our company, and for the grant of NSOs, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance awards and other stock awards to employees, officers, directors, and consultants of our company or any parents or subsidiaries of our company.

Plan Administration. Our board of directors administers and interprets the provisions of the 2018 Plan. The board of directors may delegate its authority to a committee of the board of directors. Under our 2018 Plan, the plan administrator has the authority to, among other things, approve award recipients, determine the numbers and types of stock awards to be granted, determine the applicable fair market value and the provisions of each stock award, including the period of their exercisability and the vesting schedule applicable to a stock award, construe and interpret the 2018 Plan and awards granted thereunder, prescribe, amend, modify, and rescind or terminate rules and regulations for the administration of the 2018 Plan. Under the 2018 Plan, the plan administrator may, with the consent of any adversely affected participant, reduce the exercise, purchase or strike price of any outstanding stock awards, issue new awards in exchange for the surrender and cancellation of any or all outstanding awards and reprice options or stock appreciation rights.

Our board of directors may also delegate to one or more our officers the authority to do one or both of the following (i) designate employees who are not officers to be recipients of options and stock appreciation rights (and, to the extent permitted by applicable law, other stock awards) and, to the extent permitted by applicable law, the terms of such awards, and (ii) determine the number of shares of common stock to be subject to such stock awards granted to such employees; *provided*, *however*, that our board of directors shall set forth resolutions regarding such delegation that will specify the total number of shares of common stock that may be subject to the stock awards granted by such officer and that such officer may not grant a stock award to himself or herself.

Stock Options. Options are granted under stock option agreements in such form and containing such provisions as approved by the plan administrator. The plan administrator determines the exercise price for stock options, within the terms and conditions of the 2018 Plan, provided that the exercise price of a stock option generally may not be less than 100% of the fair market value of our common stock on the date of grant. Options granted under the 2018 Plan vest at the rate specified in the stock option agreement and pursuant to the rules as determined by the plan administrator. The plan administrator determines the term of stock options granted under the 2018 Plan, up to a maximum of 10 years. However, any person who owns (or is deemed to own pursuant to Section 424(b) of the Code) stock possessing more than 10% of the total combined voting power of all classes of our stock, will not be granted an ISO unless the exercise price of such Option is at least 110% of the fair market value on the grant date and the option is not exercisable after the expiration of five years from the date of grant. If a holder's service relationship with us or any of our affiliates ceases for any reason other than disability, death, or cause the holder may generally exercise any vested option for a period of up to 90 days following the cessation of service, or such other period of time set forth in the stock option agreement. If a holder's service relationship with us or any of our affiliates ceases due to disability, then options vested as of the termination date may generally be exercised within 12 months following the date of termination, or such other period of time set forth in the stock option agreement. If a holder's service relationship with us or any of our affiliates ceases due to death (or the holder dies within three months after a termination other than for cause), then options vested as of the termination date may generally be exercised within 18 months following the date of termination, or such other period of time set forth in the stock option agreement. In no event may an option be exercised beyond the expiration of its term. If a holder's service relationship with us or any of our affiliates ceases due to termination for cause, the holder's vested options will expire on the holder's termination date. The exercise price for shares issued under the 2018 Plan are payable in cash, shares or other forms of consideration as determined by the plan administrator, including but not limited to a broker-assisted cashless exercise or a net exercise. Unless the plan administrator provides otherwise, options generally are not transferable except by will or the laws of descent and distribution.

Restricted Stock Awards. The plan administrator determines to whom an offer of restricted stock will be made, the number of shares the person may purchase, the purchase price, the restrictions to which the shares will be subject and other terms and conditions. If a participant's service relationship with us ends for any reason, we may reacquire any or all of the shares of common stock held by the participant that have not vested as of the date the participant terminates service with us through, but not limited to, a repurchase right.

Changes to Capital Structure. In the event of any merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large nonrecurring cash dividend, stock split, reverse stock split, liquidating dividend, combination of shares, exchange of shares, change in corporate structure or any similar equity restructuring transaction affecting shares without consideration, then in order to prevent diminution or enlargement of the benefits or potential benefits intended to be made available under the 2018 Plan the plan administrator will appropriately and proportionately adjust (i) the class(es) and maximum number of securities subject to the 2018 Plan, (ii) the class(es) and maximum number of securities that may be issued pursuant to the exercise of ISOs and (iii) the class(es) and number of securities and price per share of stock subject to outstanding stock awards.

Transactions. In the event of a corporate transaction or change in control (as defined in the 2018 Plan), unless otherwise provided in the agreement evidencing the transaction, the outstanding awards under the 2018 Plan shall be, contingent upon the closing or completion of the transaction:

- assumed, continued or substituted by the acquiring or succeeding corporation;
- reacquisition or repurchase by the acquiring or succeeding corporation
- terminated to the extent unvested or unexercised upon or immediately prior to the consummation of such transaction contemplated;
- accelerated and become fully or partially exercisable and terminating if not exercised on or prior to the transaction;
- terminated in exchange for consideration, if any, equal to the excess of (A) the value of the property the holder would have received upon the exercise of the stock award immediately prior to the effective time of the transaction, over (B) any exercise price payable by such holder in connection with such exercise; or
- any one or more of the foregoing.

A stock award may be subject to additional acceleration of vesting and exercisability upon or after a change in control as may be provided in the award agreement for such stock award or as may be provided in any other written agreement between us and the holder.

Under the 2018 Plan, a transaction is generally defined as the occurrence of any of the following events: (i) a sale or other disposition of all or substantially all of the consolidated assets of our company and our subsidiaries, (ii) a sale or other disposition of more than 50% of the outstanding securities of the company, (iii) a merger, consolidation or similar transaction following which the company is not the surviving corporation, or (iv) a merger, consolidation or similar transaction following which the company is the surviving corporation but the shares of common stock outstanding immediately preceding the merger, consolidation or similar transaction are converted or exchanged by virtue of the merger, consolidation or similar transaction into other property, whether in the form of securities, cash or otherwise.

Plan Amendment or Termination. Our board of directors may terminate, suspend or amend the 2018 Plan at any time and, upon a dissolution or liquidation of our company, all outstanding stock awards (other than

stock awards consisting of vested and outstanding shares of common stock not subject to a forfeiture condition or our right of repurchase) will terminate unless our board of directors provides otherwise. Unless sooner terminated, the 2018 Plan terminates in ten years from the effective date.

Amended and Restated Equity Incentive Plan

Our Amended and Restated Equity Incentive Plan, or the 2016 Plan, was adopted by Turnstone Canada in October 2016 and assumed by us in December 2018. The 2016 Plan was suspended upon adoption of our 2018 Equity Incentive Plan, or the 2018 Plan and no further awards were made under the 2016 Plan following such time; however, awards outstanding under the 2016 Plan continue in full effect in accordance with their existing terms.

Plan Administration. Our board of directors has the sole and complete authority and discretion to take any actions it deems necessary or advisable for the administration of our 2016 Plan. Our board of directors has the authority to delegate the 2016 Plan's administration to a committee of our board of directors. Our board of directors may cancel, amend adjust or otherwise change any award as the board of directors may consider appropriate under the 2016 Plan.

Types of Awards. Our 2016 Plan provided for the grant of or ISOs, NSOs, as well as restricted stock and restricted stock units. As of March 31, 2023, only options were outstanding under the 2016 Plan.

Stock Options. The exercise price of options granted under our 2016 Plan was determined by the board of directors on the date of grant. Options expire at the time determined by our board of directors, but was in no event more than ten years after they were granted, and generally expire earlier if the optionholder's service terminates.

Changes in Capitalization. If we at any time change the number of shares of common stock issued without new consideration (such as by stock dividend or stock split), the total number of shares of common stock reserved for issuance under the 2016 Plan and the exercise price and number of shares of common stock covered by each then-outstanding award will (to the extent appropriate) be proportionally adjusted in order to preserve the rights and obligations of the optionholders.

Other Events Affecting the Company. In the event of an amalgamation, arrangement, combination, merger or other reorganization involving our company by exchange of the common stock or by sale or lease of assets that, in the opinion of our board of directors, warrants the replacement or amendment of any existing awards, the board of directors will authorize such steps to be taken as may be equitable an appropriate to that end.

Transferability. Subject to applicable law, a participant may not transfer options under our 2016 Plan except as permitted by our board of directors.

Plan Amendment or Termination. Our board of directors has the authority to amend or terminate our 2016 Plan at any time without stockholder approval.

Limitations on Liability and Indemnification Matters

Immediately following the closing of this offering, our amended and restated certificate of incorporation will contain provisions that limit the liability of our current and former directors for monetary damages to the fullest extent permitted by Delaware law. Delaware law provides that directors of a corporation will not be personally liable for monetary damages for any breach of fiduciary duties as directors, except liability for:

- any breach of the director's duty of loyalty to the corporation or its stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;

- unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the Delaware General Corporation Law; or

- any transaction from which the director derived an improper personal benefit.

This limitation of liability does not apply to liabilities arising under federal securities laws and does not affect the availability of equitable remedies such as injunctive relief or rescission.

Our amended and restated certificate of incorporation to be in effect immediately following the closing of this offering will provide that we are authorized to indemnify our directors and officers to the fullest extent permitted by Delaware law. Our amended and restated bylaws to be in effect immediately prior to the closing of this offering will provide that we are required to indemnify our directors and executive officers to the fullest extent permitted by Delaware law. Our amended and restated bylaws will also provide that, upon satisfaction of certain conditions, we are required to advance expenses incurred by a director or executive officer in advance of the final disposition of any action or proceeding, and permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in that capacity regardless of whether we would otherwise be permitted to indemnify him or her under the provisions of Delaware law. Our amended and restated bylaws will also provide our board of directors with discretion to indemnify our other officers and employees when determined appropriate by our board of directors. We have entered and expect to continue to enter into agreements to indemnify our directors, executive officers and other employees as determined by our board of directors. With certain exceptions, these agreements provide for indemnification for related expenses, including, among other things, attorneys' fees, judgments, fines and settlement amounts incurred by any of these individuals in any action or proceeding. We believe that these provisions and agreements are necessary to attract and retain qualified persons as directors and officers. We also maintain customary directors' and officers' liability insurance.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation, to be in effect immediately following the closing of this offering, and amended and restated bylaws, to be in effect immediately prior to the closing of this offering, may discourage stockholders from bringing a lawsuit against our directors for breach of their fiduciary duty. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and other stockholders. Further, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damage awards against directors and officers as required by these indemnification provisions. At present, there is no pending litigation or proceeding involving any of our directors, officers or employees for which indemnification is sought, and we are not aware of any threatened litigation that may result in claims for indemnification.

Rule 10b5-1 Sales Plans

Our directors and executive officers may adopt written plans, known as Rule 10b5-1 plans, in which they will contract with a broker to buy or sell shares of our common stock on a periodic basis. Under a Rule 10b5-1 plan, a broker executes trades pursuant to parameters established by the director or executive officer when entering into the plan, without further direction from them. The director or executive officer may amend a Rule 10b5-1 plan in some circumstances and may terminate a Rule 10b5-1 plan at any time. Our directors and executive officers also may buy or sell additional shares outside of a Rule 10b5-1 plan when they are not in possession of material nonpublic information subject to compliance with the terms of our insider trading policy and any applicable 10b5-1 guidelines. Prior to 180 days after the date of this offering, subject to early termination, the sale of any shares under such Rule 10b5-1 plan would be subject to the lock-up agreement that the director or executive officer has entered into with the underwriters in connection with this offering.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following is a summary of transactions since January 1, 2020 and any currently proposed transactions to which we have been a participant in which the amount involved exceeded or will exceed the lesser of $120,000 or 1% of the average of our total assets as of December 31, 2021 and 2022, and in which any of our then directors, executive officers or holders of more than 5% of any class of our capital stock at the time of such transaction, or any members of their immediate family, had or will have a direct or indirect material interest, other than compensation arrangements which are described in the sections titled “Executive Compensation” and “Management—Non-Employee Director Compensation.”

Series D Preferred Stock Financing

In June 2021, we entered into a preferred stock purchase agreement with certain investors, including beneficial owners of greater than 5% of our capital stock and affiliates of members of our board of directors, pursuant to which we issued and sold to such investors an aggregate of 29,285,356 shares of our Series D preferred stock at a purchase price of $2.73174 per share for aggregate gross proceeds of approximately $80.0 million. However, prospective investors should not rely on the investment decisions of our existing investors, as these investors may have different risk tolerances and have received their shares in prior offerings at prices lower than the price offered to the public in this offering.

The table below sets forth the aggregate number of shares of Series D preferred stock issued and sold to holders of more than 5% of our capital stock and entities affiliated with certain of our directors in connection with the issuance of our Series D preferred stock:

Name	Series D Preferred Stock Purchased (#)	Aggregate Purchase Price ($)
Entities affiliated with Versant Venture Management, LLC(1)	2,196,402	$ 5,999,999.20
OrbiMed Private Investments VI, LP(2)	1,830,335	$ 4,999,999.34
New Emerging Medical Opportunities Fund IV SCSp(3)	732,134	$ 1,999,999.74
Entities affiliated with PFM Health Sciences, LP(4)	4,392,804	$ 11,999,998.41
F-Prime Capital Partners Healthcare Fund V LP(5)	732,134	$ 1,999,999.74

(1) Jerel Davis, a member of our board of directors, is a managing director at Versant Venture Management, LLC.
(2) Rishi Gupta, a member of our board of directors, is a director at OrbiMed Advisors LLC, an entity affiliated with Orbimed.
(3) Stefan Larson, a member of our board of directors, is a partner at New Emerging Medical Opportunities Fund IV SCSp.
(4) Santhosh Palani, a member of our board of directors, is a partner at PFM Health Sciences, LP.
(5) Entities affiliated with F-Prime Capital hold more than 5% of our capital stock.

Investors’ Rights Agreement

In June 2021, in connection with the issuance and sale of our Series D preferred stock, we entered the Rights Agreement, with, among others, certain holders of more than 5% of our outstanding capital stock, including entities affiliated with Versant Venture Management, LLC, OrbiMed Private Investments VI, LP, F-Prime Capital Partners Healthcare Fund V LP, and FACIT Inc., or FACIT, and including certain affiliates of our directors. New Emerging Medical Opportunities Fund IV SCSp and Entities affiliated with PFM, which each has a director on our board of directors, were also parties to the Rights Agreement.

The Rights Agreement grants certain rights to the holders of our outstanding convertible preferred stock, including certain registration rights with respect to the registrable securities held by them. See the section titled “Description of Capital Stock—Registration Rights” for additional information.

In addition, the Rights Agreement imposes certain affirmative obligations on us, including our obligation to, among other things, grant each investor who holds shares of our convertible preferred stock a right of first offer with respect to future sales of our equity, excluding the shares to be offered and sold in this offering, and grant certain information and inspection rights to such Investors. Each of these obligations will terminate in connection with the closing of this offering.

Voting Agreement

In June 2021, in connection with the issuance and sale of our Series D preferred stock, we entered into a Second Amended and Restated Voting Agreement, or the Voting Agreement, with, among others, certain holders of more than 5% of our outstanding capital stock, including entities affiliated with Versant Venture Management, LLC, OrbiMed Private Investments VI, LP, F-Prime Capital Partners Healthcare Fund V LP, and FACIT Inc. New Emerging Medical Opportunities Fund IV SCSp and Entities affiliated with PFM, which each has a director on our board of directors, were also parties to the Voting Agreement.

Pursuant to the Voting Agreement, certain affiliates of Versant Venture Management, LLC have the right to designate two members to be elected to our board of directors, while each of OrbiMed Private Investments VI, LP and New Emerging Medical Opportunities Fund IV SCSp has the right to designate one member. See "Management—Board Composition." The Voting Agreement will terminate by its terms in connection with the closing of this offering and none of our stockholders will have any continuing rights regarding the election or designation of members of our board of directors following this offering.

Right of First Refusal and Co-Sale Agreement

In June 2021, in connection with the issuance and sale of our Series D preferred stock, we entered into a Second Amended and Restated Right of First Refusal and Co-Sale Agreement, or the Co-Sale Agreement, with, among others, certain holders of more than 5% of our outstanding capital stock, including entities affiliated with Versant Venture Management, LLC, OrbiMed Private Investments VI, LP, F-Prime Capital Partners Healthcare Fund V LP, and FACIT Inc. New Emerging Medical Opportunities Fund IV SCSp and Entities affiliated with PFM Health Sciences, LP, which each has a director on our board of directors, were also parties to the Co-Sale Agreement.

Pursuant to the Co-Sale Agreement, we have a right of first refusal in respect of certain sales of securities by certain holders of our common stock and convertible preferred stock, including holders of more than 5% of our outstanding capital stock. To the extent we do not exercise such right in full, certain holders of our capital stock are entitled to certain rights of first refusal and co-sale in respect of such sale. The Co-Sale Agreement will terminate in connection with the closing of this offering.

Management Rights Letters

In connection with the issuance and sale of our Series D preferred stock, we entered into management rights letters with certain purchasers of our convertible preferred stock, including holders of more than 5% of our capital stock and entities with which certain of our directors are affiliated, pursuant to which such entities were granted certain management rights, including the right to consult with and advise our management on significant business issues, review our operating plans, examine our books and records and inspect our facilities. These management rights letters will terminate upon completion of this offering.

Public Offering Participation Rights

In connection with the issuance and sale of our Series D preferred stock, in June 2021, we entered into a letter agreement with certain entities, including PFM, an affiliate of Santhosh Palani, a member of our board of directors. The letter agreement grants PFM the option, but not the obligation, to purchase at least up to a number of shares of our common stock equal to PFM's percentage equity ownership (assuming the conversion of all outstanding preferred stock into common stock and the exercise of all outstanding convertible securities) in this offering. As of March 31, 2023, PFM held 549,980 shares of our common stock (assuming the conversion of all outstanding preferred stock into common stock and the exercise of all outstanding convertible securities), or an approximate 3.02% equity ownership in our company (assuming the conversion of all outstanding preferred stock into common stock and the exercise of all outstanding convertible securities). As a result, under the letter

agreement, PFM has the option (but not the obligation) to purchase up to 175,160 shares of our common stock in this offering. If PFM decides to exercise this option, then they must purchase our common stock in this offering at the public offering price, subject to compliance with applicable securities laws, as well as the right to purchase a specified percentage of any of our securities offered or sold in a private placement contemporaneous or conditioned on this offering (except as described below) at the price offered to other investors in such placement. The letter agreement further provides that, under certain circumstances in which PFM is unable to participate in this offering, we are required to offer PFM shares of our common stock through a separate private placement to be concurrent with this offering. We intend to offer PFM the right to purchase shares in this offering.

Pursuant to the Takeda Letter Agreement, Takeda has agreed to submit a non-binding indication of interest to participate in this offering by purchasing at the public offering price per share the number of shares of our common stock with an aggregate value of $8.0 million or such lesser amount as determined by us in our sole discretion, or the Takeda IPO Shares. Under the Takeda Agreement, Takeda's original equity commitment of up to $20.0 million was partially fulfilled by Takeda's purchase in June 2021 of 1,830,335 shares of our Series D preferred stock at a purchase price of $2.73174 per share for aggregate gross proceeds of approximately $5.0 million, and all of Takeda's remaining obligations under the Takeda Agreement expired upon the termination of the Takeda Agreement on July 6, 2023. If Takeda decides to participate in this offering pursuant to the Takeda Letter Agreement, then they must purchase our common stock in this offering at the public offering price, subject to compliance with applicable securities laws. If Takeda does not participate in this offering, the underwriters determine it is not advisable for Takeda to participate in this offering, or Takeda's participation in this offering is prohibited under U.S. federal securities laws or any other applicable laws, then, Takeda is obligated to purchase at the public offering price per share an aggregate number of shares of our common stock equal to the number of Takeda IPO Shares in a private placement contemporaneous with and conditioned on this offering. Takeda's agreement to participate in this offering or a concurrent private placement will expire on July 31, 2023.

In addition, if Takeda does not submit an indication of interest to participate in this offering, unless we determine otherwise, in our sole discretion, then we shall sell and Takeda shall purchase in a private placement effected substantially concurrent with this public offering such number of our common shares equal to the number of Takeda IPO Shares at the public offering price. The closing of this public offering is a condition precedent to the closing of the private placement.

Employment Arrangements

We have entered into employment agreements and offer letters with certain of our executive officers. For more information regarding these agreements with our executive officers, see "Executive Compensation—Employment Arrangements."

Equity Grants

We have granted options to purchase shares of our common stock to certain of our executive officers and directors. For more information regarding the options granted to our executive officers and directors, see the sections titled "Executive Compensation" and "Management—Non-Employee Director Compensation."

Indemnification Agreements

We have entered into indemnification agreements with certain of our current directors and executive officers and we plan to enter into indemnification agreements with each of our directors and executive officers in connection with this offering. The indemnification agreements, to be in effect upon the closing of this offering, and our amended and restated bylaws, to be in effect immediately prior to the closing of this offering, require us to indemnify our directors and executive officers to the fullest extent permitted by Delaware law. For more information regarding these agreements, see "Executive Compensation—Limitations on Liability and Indemnification Matters."

Reserved Share Program

At our request, an affiliate of BofA Securities, Inc., a participating underwriter, has reserved for sale, at the initial public offering price, up to 5.0% of the shares offered by this prospectus for sale to some of our directors, officers, employees, and certain other related parties to us. If these persons purchase reserved shares it will reduce the number of shares available for sale to the general public. Any reserved shares that are not so purchased will be offered by the underwriters to the general public on the same terms as the other shares offered by this prospectus.

Related Person Transaction Policy

Prior to this offering, we did not had a formal policy regarding approval of transactions with related parties. In connection with this offering, we have adopted a written related person transaction policy that sets forth our procedures for the identification, review, consideration and approval or ratification of related person transactions. The policy became effective immediately upon the execution of the underwriting agreement for this offering. For purposes of our policy only, a related person transaction is a transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we and any related person are, were or will be participants and in which the amount involved exceeds the lesser of $120,000 or 1% of the average of our total assets at year end for the last two completed fiscal years. Transactions involving compensation for services provided to us as an employee or director are not covered by this policy. A related person is any executive officer, director or beneficial owner of more than 5% of any class of our voting securities, including any of their immediate family members and any entity owned or controlled by such persons.

All of the transactions described above were entered into prior to the adoption of the written related person transaction policy, but all were approved by our board of directors considering similar factors to those described above.

PRINCIPAL STOCKHOLDERS

The following table sets forth information regarding beneficial ownership of our common stock as of March 31, 2023 by:

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

We have determined beneficial ownership in accordance with the rules of the SEC. Under these rules, beneficial ownership includes any shares of common stock as to which the individual or entity has sole or shared voting power or investment power. Applicable percentage ownership before the offering is based on 15,522,015 shares of common stock outstanding as of March 31, 2023, after giving effect to the conversion of all outstanding shares of our convertible preferred stock into an aggregate of 12,493,879 shares of common stock.

Applicable percentage ownership after the offering is based on 15,522,015 shares of common stock outstanding as of March 31, 2023, after giving effect to the conversion of all outstanding shares of our convertible preferred stock into an aggregate of 12,493,879 shares of common stock and the issuance of 6,666,667 shares of common stock upon the closing of this offering. The table assumes no exercise by the underwriters of their option to purchase up to 1,000,000 additional shares of our common stock.

The table below does not reflect any shares of our common stock that our directors and executive officers may purchase in this offering, including through the reserved share program described under “Underwriting—Reserved Share Program.”

In computing the number of shares beneficially owned by an individual or entity and the percentage ownership of that person, shares of common stock subject to options held by such person that are currently exercisable or will become exercisable within 60 days of March 31, 2023 are considered outstanding, although these shares are not considered outstanding for purposes of computing the percentage ownership of any other person.

Unless noted otherwise, the address of all listed stockholders is c/o 9310 Athena Circle Suite 300, La Jolla, California 92037.

Each of the stockholders listed has sole voting and investment power with respect to the shares beneficially owned by the stockholder unless noted otherwise, subject to community property laws where applicable.

Name and Address of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned	
		Before Offering	After Offering
Greater than 5% stockholders			
Entities affiliated with Versant Ventures(1)	3,156,692	20.3%	14.2%
OrbiMed Private Investments VI, LP(2)	2,682,599	17.3%	12.1%
Entities affiliated with F-Prime Capital(3)	1,133,987	7.3%	5.1%
FACIT Inc.(4)	1,020,636	6.6%	4.6%
Directors and Named Executive Officers			
Sammy Farah, M.B.A., Ph.D.(5)	610,697	3.8%	2.7%
Michael Burgess, MBChB, Ph.D.(6)	185,381	1.2%	*
Jerel Davis, Ph.D.(1)	3,156,692	20.3%	14.2%
Robert Gould, Ph.D.(7)	31,222	*	*
Rishi Gupta(2)	2,682,599	17.3%	12.1%
Stefan Larson, Ph.D.(8)	517,648	3.3%	2.3%
Patrick Machado(9)	38,485	*	*
Santhosh Palani(10)	549,980	3.5%	2.5%
Kanya Rajangam, Ph.D. (11).	13,146	*	*
Venkat Ramanan, Ph.D.(12)	54,774	*	*
Saryah Azmat(13)	117,539	*	*
All current executive officers and directors as a group (14 persons)(14)	8,089,178	48.4%	34.6%

* Represents beneficial ownership of less than 1%.

(1) Consists of (i) 988,832 shares of common stock issuable upon conversion of our Series A convertible preferred stock, 442,055 shares of common stock issuable upon conversion of our Series B-1 convertible preferred stock 957,787 shares of common stock issuable upon conversion of our Series B-2 convertible preferred stock and 140,190 shares of common stock issuable upon conversion of our Series C convertible preferred stock, in each case held by Versant Venture Capital V, L.P., or Versant V, (ii) 75,255 shares of common stock issuable upon conversion of our Series A convertible preferred stock, 33,642 shares of common stock issuable upon conversion of our Series B-1 convertible preferred stock, 72,892 shares of common stock issuable upon conversion of our Series B-2 convertible preferred stock and 10,669 shares of common stock issuable upon conversion of our Series C convertible preferred stock, in each case held by Versant Venture Capital V (Canada) LP, or Versant V Canada, (iii) 32,971 shares of common stock issuable upon conversion of our Series A convertible preferred stock, 14,739 shares of common stock issuable upon conversion of our Series B-1 convertible preferred stock, 31,936 shares of common stock issuable upon conversion of our Series B-2 convertible preferred stock and 4,667 shares of common stock issuable upon conversion of our Series C convertible preferred stock, in each case held by Versant Ophthalmic Affiliates Fund I, L.P., or Versant Ophthalmic, (iv) 29,744 shares of common stock issuable upon conversion of our Series A convertible preferred stock, 13,297 shares of common stock issuable upon conversion of our Series B-1 convertible preferred stock, 28,810 shares of common stock issuable upon conversion of our Series B-2 convertible preferred stock and 4,216 shares of common stock issuable upon conversion of our Series C convertible preferred stock, in each case held by Versant Affiliates Fund V, L.P., or Versant Affiliates V and (v) 274,990 shares of common stock issuable upon conversion of our Series D convertible preferred stock held by Versant Vantage II, L.P. or Versant Vantage II. Versant V, Versant V Canada, Versant Ophthalmic, Versant Affiliates V and Versant Vantage II are collectively referred to as the Versant Entities. Versant Ventures V, LLC is the general partner of each of Versant V, Versant Ophthalmic and Versant Affiliates V and has voting and dispositive control over the shares held by such entities. Versant Ventures V (Canada), L.P. is the general partner of Versant V Canada and Versant Ventures V GP-GP (Canada), Inc. is the sole general partner of Versant Ventures V (Canada), L.P. and has voting and dispositive control over the shares held by Versant V Canada. Dr. Jerel Davis, Brad Bolzon, Dr. Woiwode, William Link, Samuel Colella, Kirk Nielsen and Robin Praeger, the managing directors of Versant Ventures V, LLC and the directors of Versant Ventures V GP-GP (Canada), Inc., may be deemed to possess voting and dispositive control over the shares held by Versant V, Versant V Canada, Versant Ophthalmic and Versant Affiliates V and may be deemed to have indirect beneficial ownership of the shares held by Versant V, Versant V Canada, Versant Ophthalmic and Versant Affiliates V but disclaim beneficial ownership of such securities, except to the extent of their respective pecuniary interest therein, if any. Versant Vantage II GP, L.P. is the sole general partner of Versant Vantage II and Versant Vantage II GP-GP, LLC is the sole general partner of Versant Vantage II GP,

L.P. and has voting and dispositive control over the shares held by Versant Vantage II. Each of Bradley J. Bolzon, Jerel C. Davis, Ph.D., Alexander Mayweg, Clare Ozawa, Robin L. Praeger, and Thomas Woiwode Ph.D., are the managing directors of Versant Vantage II GP-GP, LLC, may be deemed to possess voting and dispositive control over the shares held by Versant Vantage II and may be deemed to have indirect beneficial ownership of the shares held by Versant Vantage II but disclaims beneficial ownership of such securities, except to the extent of their respective pecuniary interest therein, if any. Dr. Jerel Davis is a member of our board of directors. The address for each of the Versant Entities and individuals is One Sansome Street, Suite 1650, San Francisco, California 94104.

(2) Consists of (a) 937,372 shares of common stock issuable upon conversion of our Series B-1 convertible preferred stock, (b) 1,249,829 shares of common stock issuable upon conversion of our Series B-2 convertible preferred stock, (c) 266,240 shares of common stock issuable upon conversion of our Series C convertible preferred stock, and (229,158 shares of common stock issuable upon conversion of our Series D convertible preferred stock, in each case held by OrbiMed Private Investments VI, LP, or OPI VI. OrbiMed Capital GP VI LLC, or GP VI, is the general partner of OPI VI. OrbiMed Advisors LLC, or OrbiMed Advisors, is the managing member of GP VI. By virtue of such relationships, GP VI and OrbiMed Advisors may be deemed to have voting and investment power with respect to the shares held by OPI VI and as a result may be deemed to have beneficial ownership of such shares. OrbiMed Advisors exercises investment and voting power through a management committee composed of Carl L. Gordon, Sven H. Borho, and W. Carter Neild. Mr. Gupta, a member of our board of directors, is a director of OrbiMed Advisors. Each of GP VI and OrbiMed Advisors disclaims beneficial ownership of the shares held by OPI VI. The address of each of GP VI, OPI VI, OrbiMed Advisors, and Mr. Gupta is c/o OrbiMed Advisors LLC, 601 Lexington Avenue, 54th Floor, New York, New York 10022.

(3) Consists of (i) 483,684 shares of common stock issuable upon conversion of our Series B-1 convertible preferred stock held by F-Prime Capital Partners Healthcare Fund V LP, or F-Prime, (ii) 150,809 shares of common stock issuable upon conversion of our Series B-2 convertible preferred stock held by F-Prime, (iii) 106,496 shares of common stock issuable upon conversion of our Series C convertible preferred stock held by F-Prime, (iv) 91,663 shares of common stock issuable upon conversion of our Series D convertible preferred stock held by F-Prime, (v) 296,396 shares of common stock issuable upon conversion of our Series B-2 convertible preferred stock held by Impresa Fund III Limited Partnership and (vi) 4,939 shares of common stock issuable upon conversion of our Series B-2 convertible preferred stock held by F-Prime Capital Partners Healthcare Advisors Fund V LP. F-Prime Capital Partners Healthcare Advisors Fund V LP is the general partner of F-Prime. F-Prime Capital Partners Healthcare Advisors Fund V LP is solely managed by Impresa Management LLC, the managing member of its general partner and its investment manager. Impresa Fund III Limited Partnership is solely managed by Impresa Management LLC, its general partner and its investment manager. Impresa Management LLC is owned, directly or indirectly, by various shareholders and employees of FMR LLC. Impresa Management LLC is managed on a day-to-day basis by its Chief Financial Officer, Matthew Borden, and as such, Mr. Borden may be deemed to have voting and dispositive power with respect to all shares held by the above entities. The individual and each of the entities listed above expressly disclaims beneficial ownership of the securities listed above, except to the extent of their respective pecuniary interest therein, if any. The business address of these entities is 245 Summer Street, Boston, Massachusetts 02210.

(4) Consists of 419,421 shares of common stock, 281,700 shares of common stock issuable upon conversion of our Series A convertible preferred stock, 114,114 shares of common stock issuable upon conversion of our Series B-1 convertible preferred stock, 152,153 shares of common stock issuable upon conversion of our Series B-2 and 53,248 shares of common stock issuable upon conversion of our Series C convertible preferred stock, in each case held by FACIT Inc., or FACIT. FACIT is the investment fund of the Ontario Institute for Cancer Research and the Ontario Institute for Cancer Research may be deemed to have indirect beneficial ownership of the shares held by FACIT but disclaims beneficial ownership of such securities, except to the extent of their respective pecuniary interest therein, if any. The board of directors of FACIT possesses the power to vote or to direct the vote of the shares reported herein, and no one, in his or her individual capacity, possesses voting and/or investment control over the securities owned by FACIT. The business address of FACIT is MaRS Centre 661 University Ave., Suite 510, Toronto, Ontario, Canada M5G 0A3.

(5) Consists of 610,697 shares of common stock underlying options to purchase common stock held by Dr. Farah that are currently exercisable or would be exercisable within 60 days of March 31, 2023.

(6) Consists of 185,381 shares of common stock underlying options to purchase common stock held by Dr. Burgess that are currently exercisable or would be exercisable within 60 days of March 31, 2023.

(7) Consists of 31,222 shares of common stock underlying options to purchase common stock held by Dr. Gould that are currently exercisable or would be exercisable within 60 days of March 31, 2023.

(8) Consists of 425,985 shares of common stock issuable upon conversion of our Series C convertible preferred stock and 91,663 shares of common stock issuable upon conversion of our Series D convertible preferred stock, in each case held by New Emerging Medical Opportunities Fund IV SCSp, NEMO IV. Sectoral Asset Management Inc., or Sectoral, is the manager of NEMO IV and may be deemed to have indirect beneficial ownership of the shares held by NEMO IV but disclaims beneficial ownership of such securities, except to the extent of their respective pecuniary interest therein, if any. Dr. Stefan Larson, a member of our board of directors, is a partner of Sectoral. The business address of each of NEMO IV, Sectoral and Dr. Larson is Sectoral Asset Management, 1010 Sherbrooke St. West, Suite 1610, Montreal, Quebec, Canada H3A 2R7.

(9) Consists of 38,485 shares of common stock underlying options to purchase common stock held by Mr. Machado that are currently exercisable or would be exercisable within 60 days of March 31, 2023.

(10) Consists of (i) 375,820 shares of common stock issuable upon conversion of our Series D convertible preferred stock held by PFM Healthcare Master Fund, L.P., (ii) 36,665 shares of common stock issuable upon conversion of our Series D convertible preferred stock held by Partner Investments, L.P., and (iii) 137,495 shares of common stock issuable upon conversion of shares of our Series D

convertible preferred stock beneficially owned by PFM Healthcare Growth Equity Holdings I, LLC. PFM Health Sciences, LP is the investment advisor of PFM Healthcare Master Fund, L.P., Partner Investments, L.P., and PFM Healthcare Growth Equity Holdings I, LLC (collectively, the PFM Funds) and by virtue of those relationships may be deemed to have voting power and investment power over the securities held by the PFM Funds and as a result may be deemed to have beneficial ownership of such securities. Dr. Santhosh Palani, a member of our board of directors, is an investment partner at PFM Health Sciences, LP, and may be deemed to have indirect beneficial ownership of the shares held by PFM Funds, but disclaims beneficial ownership of such securities, except to the extent of their respective pecuniary interest therein, if any. The business address for Dr. Palani and the PFM Funds is 4 Embarcadero Center, Suite 3500, San Francisco, California 94111.

(11) Consists of 13,146 shares of common stock underlying options to purchase common stock held by Ms. Rajangam that are currently exercisable or would be exercisable within 60 days of March 31, 2023.

(12) Consists of 54,774 shares of common stock underlying options to purchase common stock held by Dr. Ramanan that are currently exercisable or would be exercisable within 60 days of March 31, 2023.

(13) Consists of 117,539 shares of common stock underlying options to purchase common stock held by Ms. Azmat that are currently exercisable or would be exercisable within 60 days of March 31, 2023.

(14) Consists of 1,182,259 shares of common stock underlying options to purchase common stock held by all current executive officers and directors as a group that are currently exercisable or would be exercisable within 60 days of March 31, 2023.

DESCRIPTION OF CAPITAL STOCK

General

The following description 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, each of which will become effective upon the closing of this offering. Copies of these documents have been filed with the SEC as exhibits to our registration statement, of which this prospectus forms a part. The descriptions of the common stock and preferred stock reflect changes to our capital structure that will be in effect on the closing of this offering.

Upon filing of our amended and restated certificate of incorporation and the closing of this offering, our authorized capital stock will consist of 490,000,000 shares of common stock, par value $0.001 per share, and 10,000,000 shares of preferred stock, par value $0.001 per share. All of our authorized shares of preferred stock will be undesignated.

As of March 31, 2023, we had 15,522,015 shares of common stock outstanding, held of record by 72 stockholders, assuming the conversion of all outstanding shares of our convertible preferred stock into 12,493,879 shares of common stock upon the closing of this offering.

Common Stock

Voting Rights

Each holder of common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders. The affirmative vote of holders of at least 66 2/3% of the voting power of all of the then-outstanding shares of capital stock, voting as a single class, will be required to amend certain provisions of our amended and restated certificate of incorporation, including provisions relating to amending our amended and restated bylaws, the classified board, the size of our board, removal of directors, director liability, vacancies on our board, special meetings, stockholder notices, actions by written consent and exclusive jurisdiction.

Dividends

Subject to preferences that may apply to any outstanding convertible preferred stock, holders of our common stock are entitled to receive ratably any dividends that our board of directors may declare out of funds legally available for that purpose on a non-cumulative basis.

Liquidation

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities, subject to the satisfaction of any liquidation preference granted to the holders of any outstanding shares of convertible preferred stock.

Rights and Preferences

Holders of our common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of our convertible preferred stock that we may designate and issue in the future.

Preferred Stock

Upon the closing of this offering, all outstanding shares of convertible preferred stock will convert into shares of our common stock on a one-to-one basis. As of March 31, 2023, we had 12,493,879 shares of convertible preferred stock outstanding, held of record by 33 stockholders. Immediately after the completion of this offering, our certificate of incorporation will be amended and restated to delete all references to such shares of convertible preferred stock. Under the amended and restated certificate of incorporation, our board of directors will have the authority, without further action by the stockholders, to issue up to 10,000,000 shares of convertible preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding.

Our board of directors may authorize the issuance of convertible 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 convertible 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 our control that may otherwise benefit holders of our common stock and may adversely affect the market price of the common stock and the voting and other rights of the holders of common stock. We have no current plans to issue any shares of convertible preferred stock.

Stock Options

As of March 31, 2023, 2,495,301 shares of common stock were issuable upon the exercise of outstanding stock options, at a weighted-average exercise price of $8.86 per share. For additional information regarding terms of our equity incentive plans, see the section titled “Executive Compensation—Equity Incentive Plans.”

Registration Rights

Upon the completion of this offering, certain holders of shares of our common stock, including certain of those shares of our common stock that will be issued in connection with this offering upon the conversion of our convertible preferred stock, will initially be entitled to certain rights with respect to registration of such shares under the Securities Act. These shares are referred to as registrable securities. The registration of shares of our common stock pursuant to the exercise of the registration rights described below would enable the holders to trade these shares without restriction under the Securities Act when the applicable registration statement is declared effective.

Myst Merger Agreement

Pursuant to the Myst Merger Agreement, we have agreed to use commercially reasonable efforts to (i) cause a registration statement covering the sale on a continuous basis of the shares of our common stock to be declared effective as soon as reasonably practicable after filing such registration statement or (ii) register the resale of such shares of our common stock under an existing registration statement without amendment. As of March 31, 2023, 756,643 shares of our common stock have been issued pursuant to the Myst Merger Agreement. Langer has waived his registration rights in connection with this offering.

Investors’ Rights Agreement

In June 2021, in connection with the issuance and sale of our Series D preferred stock, we entered into the Rights Agreement. The Rights Agreement grants certain rights to the holders of our outstanding convertible preferred stock, including certain registration rights with respect to the registrable securities held by them. The

holders of these registrable securities possess registration rights pursuant to the terms of the Rights Agreement and are described in additional detail below. However, the necessary percentage of holders waived, their rights to notice of this offering and to include their shares of registrable securities in this offering.

As of the completion of this offering, after giving effect to the conversion of all outstanding shares of our convertible preferred stock into 12,493,879 shares of our common stock in connection with the completion of the offering, there would have been an aggregate of 12,493,879 shares of common stock that are entitled to these demand, piggyback and Form S-3 registration rights pursuant to the Rights Agreement. We will pay the registration expenses, other than the underwriting discounts and selling commissions, of the shares registered pursuant to the demand, piggyback and Form S-3 registrations described below.

Generally, in an underwritten offering, the managing underwriter, if any, has the right, subject to specified conditions, to limit the number of shares the holders may include. The demand, piggyback and Form S-3 registration rights described below will expire no later than five years after the completion of this offering, or with respect to any particular holder, at such time that such holder can sell its shares under Rule 144 of the Securities Act during any three-month period.

Demand Registration Rights

After this offering, the holders of an aggregate of 12,493,879 shares of our common stock will be entitled to certain demand registration rights pursuant to the Rights Agreement. At any time beginning 180 days after the completion of this offering, the holders of a majority of the registrable securities then outstanding may request that we register all or a portion of their shares. Such request for registration must cover at least 25% of the registrable securities then outstanding.

Piggyback Registration Rights

In connection with this offering, the holders of an aggregate of 12,493,879 shares of our common stock were entitled to certain piggyback registration rights pursuant to the Rights Agreement, After this offering, in the event that we propose to register any of our securities under the Securities Act, either for our own account or for the account of other security holders, the holders of registrable securities will be entitled to certain piggyback registration rights allowing the holder to include their shares in such registration, subject to certain marketing and other limitations. As a result, whenever we propose to file a registration statement under the Securities Act, other than with respect to: (i) a demand registration; (ii) the registration of securities relating to the sale or grant of securities to employees to a stock option, stock purchase, equity incentive or similar plan; (iii) the registration of securities relating to a SEC Rule 145 transaction; (iii) the registration of securities on any form that does not include substantially the same information as would be required on a Form S-1 or Form S-3; or (iv) the registration of common stock that is being registered that is issuable upon conversion of debt securities that are also being registered, then holders of these shares are entitled to notice of the registration and have the right to include their shares in the registration, subject to limitations that the underwriters may impose on the number of shares included in the offering.

S-3 Registration Rights

After this offering, the holders of an aggregate of 12,493,879 shares of our common stock will be entitled to certain Form S-3 registration rights pursuant to the Rights Agreement. Such holders of registrable securities can make a request that we register their shares on Form S-3 if we are qualified to file a registration statement on Form S-3 and such holders hold registrable securities in an anticipated aggregate offering amount of at least $1.0 million, net of applicable selling expenses. We will not be required to effect a registration on Form S-3 within 90 days of a registration initiated by us, to effect more than two registrations on Form S-3 within any 12-month period or to effect any registration that our board of directors deems in good faith to be materially detrimental to our company and our stockholders.

Anti-Takeover Provisions of Delaware Law and Our Charter Documents

Section 203 of the Delaware General Corporation Law

We are subject to Section 203 of the DGCL, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions:

- before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon completion 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 (but not the outstanding voting stock owned by the interested stockholder) those shares owned (1) by persons who are directors and also officers and (2) 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
- on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines a "business combination" to include the following:

- any merger or consolidation involving the corporation or any direct or indirect majority-owned subsidiary of the corporation and the interested stockholder;
- any sale, lease, exchange, mortgage, pledge, transfer or other disposition of 10% or more of the assets of the corporation or of any direct or indirect majority-owned subsidiary involving the interested stockholder (in one transaction or a series of transactions);
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation or by any direct or indirect majority-owned subsidiary of the corporation of any stock of the corporation or of such subsidiary to the interested stockholder;
- any transaction involving the corporation or any direct or indirect majority-owned subsidiary of the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation or any such subsidiary beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits by or through the corporation or any direct or indirect majority-owned subsidiary.

In general, Section 203 defines an "interested stockholder" as an entity or person who, together with the person's affiliates and associates, beneficially owns, or within three years prior to the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation.

Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws

Among other things, our amended and restated certificate of incorporation and amended and restated bylaws will:

- permit our board of directors to issue, without further action by the stockholders, shares of undesignated preferred stock with terms, rights and preferences determined by our board of directors that may be senior to our common stock;
- provide that the authorized number of directors may be changed only by resolution of our board of directors;
- provide that our board of directors will be classified into three classes of directors with each class serving three-year staggered terms;
- provide that, subject to the rights of any series of convertible preferred stock to elect directors, directors may only be removed for cause, which removal may be effected, subject to any limitation imposed by law, by the holders of at least sixty-six and two-thirds percent (66 2/3%) of the voting power of all of our then-outstanding shares of the capital stock entitled to vote generally at an election of directors;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent or electronic transmission;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide advance notice in writing, and also specify requirements as to the form and content of a stockholder's notice;
- provide that special meetings of our stockholders may be called only by the chairman of our board of directors, our chief executive officer or president or by our board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors; and
- not provide for cumulative voting rights, therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose.

The amendment of any of these provisions would require approval by the holders of at least 66 2/3% of the voting power of all of our then-outstanding common stock entitled to vote generally in the election of directors, voting together as a single class.

The combination of these provisions will make it more difficult for our existing stockholders to replace our board of directors as well as for another party to obtain control of us by replacing our board of directors. Because our board of directors has the power to retain and discharge our officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated convertible preferred stock makes it possible for our board of directors to issue convertible preferred stock with voting or other rights or preferences that could impede the success of any attempt to change our control.

These provisions are intended to enhance the likelihood of continued stability in the composition of our board of directors and its policies and to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to reduce our vulnerability to hostile takeovers and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and may have the effect of delaying changes in our control or management. As a consequence, these provisions may also inhibit fluctuations in the market price of our stock that could result from actual or rumored takeover attempts. We believe that the benefits of these provisions, including increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure our company, outweigh the disadvantages of discouraging takeover proposals, because negotiation of takeover proposals could result in an improvement of their terms.

Choice of Forum

Our amended and restated certificate of incorporation will provide that the Court of Chancery of the state of Delaware and the federal district court for the District of Delaware of the United States will be the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

- 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 DGCL, our amended and restated certificate of incorporation, or our amended and restated bylaws; or
- any action seeking to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation, or our amended and restated bylaws;
- any action to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware; and
- any action asserting a claim against us that is governed by the internal affairs doctrine.

The provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation will also provide that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act, including all causes of action asserted against any defendant named in such complaint. For the avoidance of doubt, this provision is intended to benefit and may be enforced by us, our officers and directors, the underwriters to any offering giving rise to such complaint, and any other professional entity whose profession gives authority to a statement made by that person or entity and who has prepared or certified any part of the documents underlying the offering.

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. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

This exclusive forum provision may result in increased costs to stockholders to bring a claim. Further, this exclusive forum provision 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, which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find either exclusive-forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could seriously harm our business.

Our amended and restated certificate of incorporation will further provide 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, subject to and contingent upon a final adjudication in the State of Delaware of the enforceability of such exclusive forum provision.

Limitation on Liability and Indemnification Matters

See the section titled "Executive Compensation—Limitations on Liability and Indemnification Matters."

Listing

Our common stock has been approved for listing on Nasdaq Global Market under the trading symbol "TSBX."

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Equiniti Trust Company, LLC. The transfer agent's address is 6201 15th Avenue Brooklyn, New York 11219.

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, no public market existed for our common stock. Future sales of our common stock in the public market, or the availability of such shares for sale in the public market, could adversely affect market prices prevailing from time to time. As described below, only a limited number of shares will be available for sale shortly after this offering due to contractual and legal restrictions on resale. Nevertheless, sales of our common stock in the public market after such restrictions lapse, or the perception that those sales may occur, could adversely affect the prevailing market price at such time and our ability to raise equity capital in the future.

Based on the number of shares outstanding as of March 31, 2023 and assuming the conversion of all outstanding shares of our convertible preferred stock into 12,493,879 shares of our common stock upon the closing of this offering and assuming no exercise of the underwriters' option to purchase additional shares, 22,188,682 shares of common stock will be outstanding. All of the shares of common stock sold in this offering will be freely tradable without restrictions or further registration under the Securities Act, except for any shares sold to our "affiliates," as that term is defined under Rule 144 under the Securities Act. The remaining 15,522,015 shares of common stock held by existing stockholders are "restricted securities," as that term is defined in Rule 144 under the Securities Act. Restricted securities may be sold in the public market only if registered or if their resale qualifies for exemption from registration described below under Rule 144 promulgated under the Securities Act or another available exemption.

As a result of the lock-up agreements described below and the provisions of Rules 144 and 701 under the Securities Act, the shares of common stock that will be deemed restricted securities after this offering will be available for sale in the public market as follows:

- none of the existing restricted shares will be eligible for immediate sale upon the completion of this offering; and
- 15,522,015 restricted shares will be eligible for sale in the public market upon expiration of lock-up agreements 180 days after the date of this prospectus, subject in certain circumstances to the volume, manner of sale and other limitations under Rule 144 and Rule 701 under the Securities Act, which are summarized below.

Rule 144

In general, non-affiliate persons who have beneficially owned restricted shares of our common stock for at least six months, and any affiliate of the company who owns either restricted or unrestricted shares of our common stock, are entitled to sell their securities without registration with the SEC under an exemption from registration provided by Rule 144 under the Securities Act.

Non-Affiliates

Any person who is not deemed to have been one of our affiliates at the time of, or at any time during the three months preceding, a sale may sell an unlimited number of restricted securities under Rule 144 if:

- the restricted securities have been held for at least six months, including the holding period of any prior owner other than one of our affiliates (subject to certain exceptions);
- we have been subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale; and
- we are current in our Exchange Act reporting at the time of sale.

Any person who is not deemed to have been an affiliate of ours at the time of, or at any time during the three months preceding, a sale and has held the restricted securities for at least one year, including the holding period of any prior owner other than one of our affiliates, will be entitled to sell an unlimited number of restricted securities without regard to the length of time we have been subject to Exchange Act periodic reporting or whether we are current in our Exchange Act reporting. Non-affiliate resales are not subject to the manner of sale, volume limitation or notice filing provisions of Rule 144.

Affiliates

Persons seeking to sell restricted securities who are our affiliates at the time of, or any time during the three months preceding, a sale, would be subject to the restrictions described above. They are also subject to additional restrictions, by which such person would be required to comply with the manner of sale and notice provisions of Rule 144 and would be entitled to sell within any three-month period only that number of securities that does not exceed the greater of either of the following:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately 221,886 shares immediately after the completion of this offering; or
- the average weekly trading volume of our common stock on the stock exchange on which our shares are listed during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

Additionally, persons who are our affiliates at the time of, or any time during the three months preceding, a sale may sell unrestricted securities under the requirements of Rule 144 described above, without regard to the six-month holding period of Rule 144, which does not apply to sales of unrestricted securities.

Rule 701

Rule 701 under the Securities Act, as in effect on the date of this prospectus, permits resales of shares in reliance upon Rule 144 but without compliance with certain restrictions of Rule 144, including the holding period requirement. Most of our employees, executive officers or directors who purchased shares under a written compensatory plan or contract may be entitled to rely on the resale provisions of Rule 701, but all holders of Rule 701 shares are required to wait until 90 days after the date of this prospectus before selling their shares. However, substantially all Rule 701 shares are subject to lock-up agreements as described below and in the section titled “Underwriting” and will become eligible for sale upon the expiration of the restrictions set forth in those agreements.

Form S-8 Registration Statements

We intend to file one or more registration statements on Form S-8 under the Securities Act to register all shares of common stock subject to outstanding stock options and common stock issued or issuable under our 2023 Plan, ESPP, 2018 Plan and 2016 Plan. We expect to file the registration statement covering shares offered pursuant to our stock plans as soon as practicable after the closing of this offering, permitting the resale of such shares by non-affiliates in the public market without restriction under the Securities Act and the sale by affiliates in the public market, subject to compliance with the resale provisions of Rule 144 and expiration or release from the terms of the lock-up agreements described below and in the section titled “Underwriting”.

Lock-up Arrangements

We, our executive officers and directors and the holders of substantially all of our outstanding shares of common stock and securities exercisable for or convertible into our common stock have entered into lock-up agreements with the underwriters or otherwise agreed, subject to certain exceptions, that we and they will not,

directly or indirectly, offer, sell, contract to sell, pledge, grant any option to purchase, make any short sale, or otherwise dispose of or hedge any of our shares of common stock, any options or warrants to purchase shares of our common stock, or any securities convertible into, shares of our common stock, without the prior written consent of the representatives for a period of 180 days from the date of this prospectus.

Registration Rights

Upon the closing of this offering, the holders of 13,250,522 shares of our common stock, including Langer and certain holders of common stock issuable upon the conversion of our convertible preferred stock, or their transferees, will be entitled to specified rights with respect to the registration of their registrable shares under the Securities Act, subject to certain limitations and the expiration, waiver or termination of the lock-up agreements. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act immediately upon effectiveness of the registration. See the section titled “Description of Capital Stock—Registration Rights” for additional information.

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS

The following is a general discussion of the material U.S. federal income tax considerations of the acquisition, ownership and disposition of our common stock by "Non-U.S. Holders" (as defined below). This discussion is for general information purposes only and does not consider all aspects of U.S. federal income taxation that may be relevant to particular Non-U.S. Holders in light of their individual circumstances or to certain types of Non-U.S. Holders subject to special tax rules, including partnerships or other pass-through entities for U.S. federal income tax purposes (or investors therein), banks, financial institutions or other financial services entities, broker-dealers, insurance companies, tax-exempt organizations, pension plans, real estate investment trusts, controlled foreign corporations, passive foreign investment companies, corporations that accumulate earnings to avoid U.S. federal income tax, persons who use or are required to use mark-to-market accounting, persons that hold our shares as part of a "straddle," a "hedge", a "conversion transaction," "synthetic security", integrated investment or other risk reduction strategy, persons that have a "functional currency" other than the U.S. dollar, certain former citizens or permanent residents of the United States, persons who hold or receive shares of our common stock pursuant to the exercise of an employee stock option or otherwise as compensation, and persons that own or are deemed to own (directly, indirectly or constructively) more than 5% of our common stock (except to the extent specifically set forth below). In addition, this discussion does not address the effects of any applicable gift or estate tax, the potential application of the alternative minimum tax, the Medicare contribution tax on net investment income, the base erosion and anti-abuse tax, special tax accounting rules under Section 451(b) of the Code, or any tax considerations that may apply to Non-U.S. Holders of our common stock under state, local or non-U.S. tax laws.

This discussion is based on the Internal Revenue Code of 1986, as amended, or the Code, and applicable Treasury Regulations promulgated thereunder and rulings, administrative pronouncements and judicial decisions that are issued and available as of the date of this registration statement, all of which are subject to change or differing interpretations at any time with possible retroactive effect. We have not sought, and will not seek, any ruling from the Internal Revenue Service, or the IRS, with respect to the tax consequences discussed herein, and there can be no assurance that the IRS or a court will not take a position contrary to the tax consequences discussed below or that any position taken by the IRS would not be sustained. This discussion is limited to a Non-U.S. Holder who will hold our common stock as a "capital asset" within the meaning of Section 1221 of the Code (generally, property held for investment). For purposes of this discussion, the term "Non-U.S. Holder" means a beneficial owner of our common stock that is not a partnership (or entity or arrangement treated as a partnership for U.S. federal income tax purposes) and is not, for U.S. federal income tax purposes, treated as any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation (or other entity treated as a corporation) created or organized in the United States or under the laws of the United States or of any state thereof or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust if (i) a court within the United States can exercise primary supervision over the trust's administration and one or more U.S. persons (within the meaning of Section 7701(a)(30) of the Code) have the authority to control all of the trust's substantial decisions or (ii) the trust has a valid election in effect under applicable U.S. Treasury Regulations to be treated as a U.S. person for U.S. federal income tax purposes.

If a partnership (or entity or arrangement treated as a partnership for U.S. federal income tax purposes) is a beneficial owner of our common stock, the tax treatment of such partnership and a partner in such partnership generally will depend upon the status of the partner and the activities of the partnership. If you are a partner of a partnership holding our shares, you should consult your tax advisor regarding the tax consequences of the purchase, ownership, and disposition of our A common stock.

THIS SUMMARY IS NOT INTENDED TO BE TAX ADVICE. PROSPECTIVE INVESTORS SHOULD CONSULT THEIR OWN TAX ADVISORS REGARDING THE PARTICULAR U.S. FEDERAL INCOME TAX CONSEQUENCES TO THEM OF ACQUIRING, OWNING AND DISPOSING OF OUR COMMON STOCK, AS WELL AS ANY TAX CONSEQUENCES ARISING UNDER ANY STATE, LOCAL OR NON-U.S. TAX LAWS, ANY OTHER U.S. FEDERAL TAX LAWS OR ANY APPLICABLE INCOME TAX TREATY.

Distributions on Our Common Stock

As described in the section titled "Dividend Policy," we have never declared or paid, and do not anticipate declaring or paying, in the foreseeable future, any cash dividends on our capital stock. In general, however, subject to the discussions below regarding effectively connected income and under the headings "Information Reporting and Backup Withholding" and "Foreign Accounts," distributions, if any, paid on our common stock to a Non-U.S. Holder (to the extent paid out of our current or accumulated earnings and profits, as determined under U.S. federal income tax principles) will constitute dividends and be subject to U.S. withholding tax at a rate equal to 30% of the gross amount of the dividend, or a lower rate prescribed by an applicable income tax treaty. Any distribution not constituting a dividend (because such distribution exceeds our current and accumulated earnings and profits) will be treated first as reducing the Non-U.S. Holder's adjusted tax basis in its shares of our common stock, but not below zero, and to the extent it exceeds the Non-U.S. Holder's adjusted tax basis, as capital gain from the sale or exchange of such shares of Common Stock (see "Gain on Sale, Exchange or Other Taxable Disposition of Our Common Stock" below).

A Non-U.S. Holder who claims the benefit of an applicable income tax treaty generally will be required to satisfy certain certification and other requirements prior to the distribution date. Such Non-U.S. Holders generally must provide us and/or our paying agent, as applicable, with a properly executed IRS Form W-8BEN or IRS Form W-8BEN-E (or other appropriate form) claiming an exemption from or reduction in withholding under an applicable income tax treaty. Such certificate must be provided before the payment of dividends and must be updated periodically. If a Non-U.S. Holder holds common stock through a financial institution or other agent acting on the Non-U.S. Holder's behalf, the Non-U.S. Holder will be required to provide appropriate documentation to the agent, which then will be required to provide certification to us or our paying agent, either directly or through intermediaries. If tax is withheld in an amount in excess of the amount applicable under an income tax treaty, a refund of the excess amount generally may be obtained by a Non-U.S. Holder by timely filing an appropriate claim for refund with the IRS. Non-U.S. Holders should consult their tax advisors regarding their entitlement to benefits under an applicable income tax treaty.

Dividends that are effectively connected with a Non-U.S. Holder's conduct of a U.S. trade or business (and, if required by an applicable income tax treaty, attributable to a U.S. permanent establishment or U.S. fixed base of the Non-U.S. Holder) generally will not be subject to U.S. federal withholding tax if a properly executed IRS Form W-8ECI, stating that the dividends are so connected, is furnished to us (or, if stock is held through a financial institution or other agent, to such agent). In general, such effectively connected dividends will be subject to U.S. federal income tax on a net income basis at the regular rates applicable to U.S. residents. A corporate Non-U.S. Holder receiving effectively connected dividends may also be subject to an additional "branch profits tax," which is imposed, under certain circumstances, at a rate of 30% (or such lower rate as may be specified by an applicable income tax treaty) on the corporate Non-U.S. Holder's effectively connected dividends, subject to certain adjustments. Non-U.S. Holders should consult their tax advisors regarding any applicable income tax treaties that may provide for different rules.

Gain on Sale, Exchange or Other Taxable Disposition of Our Common Stock

Subject to the discussion below under the headings "Information Reporting and Backup Withholding" and "Foreign Accounts," a Non-U.S. Holder generally will not be subject to U.S. federal income tax or

withholding tax on any gain realized upon such holder's sale, exchange or other disposition of shares of our common stock unless:

(1) the gain is effectively connected with a trade or business carried on by the Non-U.S. Holder within the United States (and, if required by an applicable income tax treaty, attributable to a U.S. permanent establishment or U.S. fixed base of the Non-U.S. Holder);

(2) the Non-U.S. Holder is a nonresident alien individual who is present in the United States for 183 days or more in the taxable year of disposition and certain other conditions are met; or

(3) we are or have been a "United States real property holding corporation" for U.S. federal income tax purposes at any time during the shorter of the five-year period ending on the date of disposition or the period that the Non-U.S. Holder held the common stock, and, in the case where shares of our common stock are regularly traded on an established securities market, the Non-U.S. Holder owns or is treated as owning (directly, indirectly or constructively) more than 5% of our common stock at any time during the foregoing period.

Net gain realized by a Non-U.S. Holder described in clause (1) above generally will be subject to U.S. federal income tax in the same manner as if the Non-U.S. Holder were a resident of the United States. Any gains of a corporate Non-U.S. Holder described in clause (1) above may also be subject to an additional "branch profits tax" at a 30% rate, or such lower rate as may be specified by an applicable income tax treaty, on such effectively connected gain, as adjusted for certain items.

Gain realized by an individual Non-U.S. Holder described in clause (2) above will be subject to a flat 30% tax, or such lower rate specified in an applicable income tax treaty, which gain may be offset by U.S. source capital losses, even though the individual is not considered a resident of the United States, provided that the Non-U.S. Holder has timely filed U.S. federal income tax returns with respect to such losses.

For purposes of clause (3) above, a corporation is a United States real property holding corporation, or USRPHC, if the fair market value of its United States real property interests equals or exceeds 50% of the sum of the fair market value of its United States real property interests, the fair market value of its worldwide real property interests, and its other assets used or held for use in a trade or business. We believe that we are not, and we do not anticipate that we will become, a USRPHC. However, because the determination of whether we are a USRPHC depends on the fair market value of our U.S. real property interests relative to the fair market value of our other business assets, there can be no assurance that we will not become a USRPHC in the future. Even if we were or became a USRPHC, a Non-U.S. Holder would not be subject to U.S. federal income tax on a sale, exchange or other taxable disposition of our common stock by reason of our status as a USRPHC so long as our common stock is regularly traded on an established securities market (within the meaning of the applicable regulations) and such Non-U.S. Holder does not own and is not deemed to own (directly, indirectly or constructively) more than 5% of our outstanding common stock at any time during the shorter of the five-year period ending on the date of disposition and such holder's holding period. However, no assurance can be provided that our common stock will be regularly traded on an established securities market for purposes of the rules described above. If we are a USRPHC and either our common stock is not regularly traded on an established securities market or a Non-U.S. Holder holds or is deemed to hold (directly, indirectly or constructively) more than 5% of our outstanding common stock during the applicable testing period, such Non-U.S. Holder will generally be taxed on any gain in the same manner as gain that is effectively connected with the conduct of a U.S. trade or business, except that the branch profits tax generally will not apply.

If we are a USRPHC and our common stock is not regularly traded on an established securities market, a Non-U.S. Holder's proceeds received on the disposition of shares will also generally be subject to withholding at a rate of 15%. Prospective investors are encouraged to consult their own tax advisors regarding the possible consequences to them if we are, or were to become, a USRPHC.

Information Reporting and Backup Withholding

Generally, we must report annually to the IRS and to each Non-U.S. Holder the amount of dividends paid, the name and address of the recipient, and the amount, if any, of tax withheld. These information reporting requirements apply even if withholding was not required because the dividends were effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States or withholding was reduced by an applicable income tax treaty. Under applicable income tax treaties or other agreements, the IRS may make its reports available to the tax authorities in the Non-U.S. Holder's country of residence or country in which the Non-U.S. Holder was established.

Dividends paid to a Non-U.S. Holder that is not an exempt recipient generally will be subject to backup withholding, currently at a rate of 24%, unless the applicable withholding agent does not have actual knowledge or reason to know the holder is a United States person and the Non-U.S. Holder certifies to the payor as to its foreign status, which certification may generally be made on an applicable IRS Form W-8, or the Non-U.S. Holder otherwise establishes an exemption. However, information returns are required to be filed with the IRS in connection with any distributions on our common stock paid to the Non-U.S. Holder, regardless of whether such distributions constitute dividends or whether any tax was actually withheld.

Proceeds from the sale or other disposition of common stock by a Non-U.S. Holder effected by or through a U.S. office of a broker will generally be subject to information reporting and backup withholding, currently at a rate of 24%, unless the Non-U.S. Holder provides a properly executed IRS Form W-8BEN, IRS Form W-8BEN-E or other documentary evidence required for establishing non-U.S. person status and the applicable withholding agent does not have actual knowledge or reason to know that such holder is a United States person or the Non-U.S. Holder otherwise establishes an exemption. Payment of disposition proceeds effected outside the United States by or through a non-U.S. office of a non-U.S. broker generally will not be subject to information reporting or backup withholding if the payment is not received in the United States. Information reporting, but generally not backup withholding, will apply to such a payment if the broker has certain connections with the United States unless the broker has documentary evidence in its records that the beneficial owner thereof is a Non-U.S. Holder and specified conditions are met or an exemption is otherwise established.

Backup withholding is not an additional tax. Any amount withheld under the backup withholding rules from a payment to a Non-U.S. Holder that results in an overpayment of taxes generally will be refunded, or credited against the holder's U.S. federal income tax liability, if any, provided that the required information is timely furnished to the IRS.

Foreign Accounts

Sections 1471 through 1474 of the Code (commonly referred to as the Foreign Account Tax Compliance Act, or FATCA) impose a U.S. federal withholding tax of 30% on certain payments to a foreign financial institution (as specifically defined by applicable rules) unless such institution enters into an agreement with the U.S. government to withhold on certain payments and to collect and annually provide to the U.S. tax authorities substantial information regarding U.S. account holders of such institution (which includes certain equity holders of such institution, as well as certain account holders that are foreign entities with U.S. owners). FATCA also generally imposes a federal withholding tax of 30% on certain payments, including dividends paid on, and (subject to the proposed Treasury Regulations discussed below) the gross proceeds of a disposition of, our common stock to a non-financial foreign entity unless such entity provides the withholding agent with either a certification that it does not have any substantial direct or indirect U.S. owners or provides identifying information regarding each substantial direct and indirect U.S. owner of the entity. An intergovernmental agreement between the United States and an applicable foreign country may modify those requirements. The withholding tax described above will not apply if the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from the rules.

The withholding provisions described above currently apply to payments of dividends. The U.S. Treasury Department has released proposed regulations which, if finalized in their present form, would eliminate the federal withholding tax of 30% that otherwise would apply to the gross proceeds of a disposition of our common stock. In its preamble to such proposed regulations, the U.S. Treasury Department stated that taxpayers may generally rely on the proposed regulations until final regulations are issued.

UNDERWRITING

BofA Securities, Inc., Leerink Partners LLC and Piper Sandler & Co., or the Representatives, are acting as representatives of each of the underwriters named below. Subject to the terms and conditions set forth in an underwriting agreement among us and the Representatives, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the number of shares of common stock set forth opposite its name below.

Underwriter	Number of Shares
BofA Securities, Inc.	2,733,334
Leerink Partners LLC	2,250,000
Piper Sandler & Co.	1,683,333
Total	6,666,667

Subject to the terms and conditions set forth in the underwriting agreement, the underwriters have agreed, severally and not jointly, to purchase all of the shares sold under the underwriting agreement if any of these shares are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the nondefaulting underwriters may be increased or the underwriting agreement may be terminated.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, or to contribute to payments the underwriters may be required to make in respect of those liabilities.

The underwriters are offering the shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel, including the validity of the shares, and other conditions contained in the underwriting agreement, such as the receipt by the underwriters of officer's certificates and legal opinions. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

Commissions and Discounts

The Representatives have advised us that the underwriters propose initially to offer the shares to the public at the public offering price set forth on the cover page of this prospectus and to dealers at that price less a concession not in excess of $0.504 per share. After the initial offering, the public offering price, concession or any other term of the offering may be changed.

The following table shows the public offering price, underwriting discount and proceeds before expenses to us. The information assumes either no exercise or full exercise by the underwriters of their option to purchase additional shares.

	Per Share	Without Option	With Option
Public offering price	$ 12.00	$ 80,000,004	$ 92,000,004
Underwriting discount	$ 0.84	$ 5,600,000	$ 6,440,000
Proceeds, before expenses, to us	$ 11.16	$ 74,400,004	$ 85,560,004

The expenses of the offering, not including the underwriting discount, are estimated at $4.3 million and are payable by us. We have also agreed to reimburse the underwriters for certain of their expenses in an amount up to $40,000.

Option to Purchase Additional Shares

We have granted an option to the underwriters, exercisable for 30 days after the date of this prospectus, to purchase up to 1,000,000 additional shares at the public offering price, less the underwriting discount. If the underwriters exercise this option, each will be obligated, subject to conditions contained in the underwriting agreement, to purchase a number of additional shares proportionate to that underwriter's initial amount reflected in the above table.

No Sales of Similar Securities

We, our executive officers and directors and our other existing security holders have agreed not to sell or transfer any common stock or securities convertible into, exchangeable for, exercisable for, or repayable with common stock, for 180 days after the date of this prospectus without first obtaining the written consent of the Representatives. Specifically, we and these other persons have agreed, with certain limited exceptions, not to directly or indirectly

- offer, pledge, sell or contract to sell any common stock,
- sell any option or contract to purchase any common stock,
- purchase any option or contract to sell any common stock,
- grant any option, right or warrant for the sale of any common stock,
- lend or otherwise dispose of or transfer any common stock,
- request or demand that we file or make a confidential submission of a registration statement related to the common stock, or
- enter into any swap or other agreement that transfers, in whole or in part, the economic consequence of ownership of any common stock whether any such swap or transaction is to be settled by delivery of shares or other securities, in cash or otherwise.

The restrictions described in the immediately preceding paragraph contained in the lock-up agreements between the representatives on behalf of underwriters and our executive officers, directors and existing security holders are subject to certain exceptions, including with respect to:

- transfer of shares (i) as a bona fide gift or gifts, (ii) to any trust for the direct or indirect benefit of the person or the immediate family of the person, (iii) as a distribution to limited partners, members, stockholders or other equity holders, (iv) to the person's affiliates or to any investment fund or other entity that, directly or indirectly, controls or manages, is controlled or managed by, or is under common control or management with, the person, (v) by will or intestate succession upon the person's death, in such case provided any filing under Section 16 of the Exchange Act during the restricted period clearly indicates in footnotes thereto that the filing relates to the circumstances described or (vi) pursuant to a court or regulatory agency order, a qualified domestic order or in connection with a divorce settlement, in such case provided that, any filing under Section 16 of the Exchange Act during the restricted period shall clearly indicate in the footnotes thereto that the filing relates to the circumstances described above; provided in each case that (1) a lock-up agreement is signed by the donee, trustee, distributee, or transferee, as the case may be, for the balance of the restricted period, (2) any such transfer shall not involve a disposition for value, (3) in the case of clauses (i) through (iv), no filing under Section 16 of the Exchange Act or other public announcement shall be required during the restricted period and (4) the person does not otherwise voluntarily effect any public filing or report regarding such transfers during the restricted period;

- transfer of shares to the company upon (i) a vesting event of any equity award granted under any equity incentive plan or stock purchase plan of the company described in this prospectus, or (ii) upon the exercise by the undersigned of options or warrants in accordance with the lock-up agreement, in each case, on a "net" or "cashless" exercise basis, and/or to cover tax withholding obligations of the undersigned in connection therewith, provided, in each case, that (1) any filing under Section 16 of the Exchange Act made during the restricted period shall clearly indicate in the footnotes thereto that (A) the filing relates to the circumstances described above, as applicable, and (B) no shares were sold by the reporting person other than such transfers to the company as described above and (2) the person does not otherwise voluntarily effect any other public filings or reports regarding such transfers during the restricted period;

- transactions of shares of common stock or any other securities acquired in this offer or in open market transactions after the completion of the offering, provided that no filing under Section 16(a) of the Exchange Act is required or voluntarily made during the restricted period in connection with subsequent sales of our common stock or other securities acquired in this offering or in such open market transactions; or

- the conversion of the outstanding preferred stock of the company described herein into shares of common stock of the company, provided that such shares of common stock remain subject to the terms of a lock-up agreement.

This lock-up provision applies to common stock and to securities convertible into or exchangeable or exercisable for or repayable with common stock. It also applies to common stock owned now or acquired later by the person executing the agreement or for which the person executing the agreement later acquires the power of disposition.

BofA Securities, Inc., Leerink Partners LLC and Piper Sandler & Co., 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 with or without notice. In addition, in the event that any security holder holding in excess of 5% of our outstanding shares, or a major holder, is granted an early release from the lock-up restrictions with respect to our securities in an aggregate amount in excess of 1% of our issued and outstanding shares (whether in one or multiple releases), then each other major holder automatically will be granted an equivalent early release from its obligations under the lock-up agreement on a pro-rata basis. Such release shall not be applicable in the event of an underwritten primary or secondary public offering or sale of our common stock during the period ending 180 days after the date of this prospectus.

Nasdaq Global Market Listing

Our common stock has been approved for listing on Nasdaq under the symbol "TSBX."

Before this offering, there has been no public market for our common stock. The initial public offering price was determined through negotiations between us and the Representatives. In addition to prevailing market conditions, the factors considered in determining the initial public offering price were:

- the valuation multiples of publicly traded companies that the Representatives believe to be comparable to us,

- our financial information,

- the history of, and the prospects for, our company and the industry in which we compete,

- an assessment of our management, its past and present operations, and the prospects for, and timing of, our future revenues,
- the present state of our development, and
- the above factors in relation to market values and various valuation measures of other companies engaged in activities similar to ours.

An active trading market for the shares may not develop. It is also possible that after the offering the shares will not trade in the public market at or above the initial public offering price.

The underwriters do not expect to sell more than 5% of the shares in the aggregate to accounts over which they exercise discretionary authority.

Price Stabilization, Short Positions and Penalty Bids

Until the distribution of the shares is completed, SEC rules may limit underwriters and selling group members from bidding for and purchasing our common stock. However, the Representatives may engage in transactions that stabilize the price of the common stock, such as bids or purchases to peg, fix or maintain that price.

In connection with the offering, the underwriters may purchase and sell our common stock in the open market. These transactions may include short sales, purchases on the open market to cover positions created by short sales and stabilizing transactions. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering. “Covered” short sales are sales made in an amount not greater than the underwriters’ option to purchase additional shares described above. The underwriters may close out any covered short position by either exercising their option to purchase additional shares or purchasing shares in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the option granted to them. “Naked” short sales are sales in excess of such option. 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 our common stock in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of shares of common stock made by the underwriters in the open market prior to the completion of the offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the Representatives have repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Similar to other purchase transactions, the underwriters’ purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. The underwriters may conduct these transactions on Nasdaq, in the over-the-counter market or otherwise.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. In addition, neither we nor any of the underwriters make any representation that the Representatives will engage in these transactions or that these transactions, once commenced, will not be discontinued without notice.

Electronic Distribution

In connection with the offering, certain of the underwriters or securities dealers may distribute prospectuses by electronic means, such as e-mail.

Other Relationships

Some of the underwriters and their affiliates have engaged in, and may in the future engage in, investment banking and other commercial dealings in the ordinary course of business with us or our affiliates. They have received, or may in the future receive, customary fees and commissions for these transactions.

In addition, in the ordinary course of their business activities, the underwriters and their 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. Such investments and securities activities may involve securities and/or instruments of ours or our affiliates. The underwriters and their affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or financial instruments and may hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Reserved Share Program

At our request, an affiliate of BofA Securities, Inc., a participating underwriter, has reserved for sale, at the initial public offering price, up to 5.0% of the shares offered by this prospectus for sale to some of our directors, officers, employees and certain related parties to us. If these persons purchase reserved shares it will reduce the number of shares available for sale to the general public. Any reserved shares that are not so purchased will be offered by the underwriters to the general public on the same terms as the other shares offered by this prospectus.

European Economic Area

In relation to each Member State of the European Economic Area, each a Relevant State, no shares have been offered or will be offered pursuant to the global offering to the public in that Relevant State prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Relevant State or, where appropriate, approved in another Relevant State and notified to the competent authority in that Relevant State, all in accordance with the Prospectus Regulation, except that offers of shares may be made to the public in that Relevant 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 global coordinator for any such offer; or

c. in any other circumstances falling within Article 1(4) of the Prospectus Regulation, provided that no such offer of shares shall require the Issuer or any Manager to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

Each person in a Relevant State who initially acquires any shares or to whom any offer is made will be deemed to have represented, acknowledged and agreed to and with our company and the Managers that it is a qualified investor within the meaning of the Prospectus Regulation.

In the case of any shares being offered to a financial intermediary as that term is used in Article 5(1) of 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 to the public other than their offer or resale in a Relevant State to qualified investors, in circumstances in which the prior consent of the underwriters has been obtained to each such proposed offer or resale.

The company, the underwriters and their affiliates will rely upon the truth and accuracy of the foregoing representations, acknowledgements and agreements.

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 "Prospectus Regulation" means Regulation (EU) 2017/1129.

The above selling restriction is in addition to any other selling restrictions set out below.

In connection with the offering, BofA Securities, Inc., Leerink Partners LLC and Piper Sandler & Co. are not acting for anyone other than the issuer and will not be responsible to anyone other than the issuer for providing the protections afforded to their clients nor for providing advice in relation to the offering.

Notice to Prospective Investors in the United Kingdom

In relation to the United Kingdom, or the UK, no shares have been offered or will be offered pursuant to the global offering to the public in the UK prior to the publication of a prospectus in relation to the shares which has been approved by the Financial Conduct Authority in the UK in accordance with the UK Prospectus Regulation and the FSMA, except that offers of shares may be made to the public in the UK 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 under the UK Prospectus Regulation;

b. to fewer than 150 natural or legal persons (other than qualified investors as defined under the UK Prospectus Regulation), subject to obtaining the prior consent of the global coordinator for any such offer; or

c. at any time in other circumstances falling within section 86 of the FSMA,

provided that no such offer of shares shall require the issuer or any manager to publish a prospectus pursuant to Section 85 of the FSMA or Article 3 of the UK Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the UK Prospectus Regulation.

Each person in the UK who initially acquires any shares or to whom any offer is made will be deemed to have represented, acknowledged and agreed to and with the company and the Managers that it is a qualified investor within the meaning of the UK Prospectus Regulation.

In the case of any shares being offered to a financial intermediary as that term is used in Article 5(1) of the UK 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 to the public other than their offer or resale in the UK to qualified investors, in circumstances in which the prior consent of the underwriters has been obtained to each such proposed offer or resale.

The company, the underwriters and their affiliates will rely upon the truth and accuracy of the foregoing representations, acknowledgements and agreements.

For the purposes of this provision, the expression an "offer to the public" in relation to any shares in the UK 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, 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, and the expression "FSMA" means the Financial Services and Markets Act 2000.

In connection with the offering, the Representatives are not acting for anyone other than the issuer and will not be responsible to anyone other than the issuer for providing the protections afforded to their clients nor for providing advice in relation to the offering.

This document is for distribution only to persons who (i) have professional experience in matters relating to investments and who qualify as investment professionals within the meaning of Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, or as amended, the Financial Promotion Order, (ii) are persons falling within Article 49(2)(a) to (d) ("high net worth companies, unincorporated associations etc.") of the Financial Promotion Order, (iii) are outside the United Kingdom, or (iv) are persons to whom an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial Services and Markets Act 2000, as amended, or FSMA), in connection with the issue or sale of any securities may otherwise lawfully be communicated or caused to be communicated (all such persons together being referred to as "relevant persons"). This document is directed only at relevant persons and must not be acted on or relied on by persons who are not relevant persons. Any investment or investment activity to which this document relates is available only to relevant persons and will be engaged in only with relevant persons.

Notice to Prospective Investors in Switzerland

The shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or SIX, or on any other stock exchange or regulated trading facility in Switzerland. This document 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 document nor any other offering or marketing material relating to the shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

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

Notice to Prospective Investors in the Dubai International Financial Centre

This prospectus relates to an exempt offer in accordance with the Offered Securities Rules of the Dubai Financial Services Authority, or 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.

Notice to Prospective Investors in Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, the shares were not offered or sold or caused to be made the subject of an invitation for subscription or purchase and will not be offered or sold or caused to be made the subject of an invitation for subscription or purchase, and this prospectus or any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares, has not been circulated or distributed, nor will it be circulated or distributed, whether directly or indirectly, to any person in Singapore other than (i) to an institutional investor (as defined in Section 4A of the Securities and Futures Act (Chapter 289) of Singapore, as modified or amended from time to time, or the SFA, pursuant to Section 274 of the SFA, (ii) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, 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 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 a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

securities or securities-based derivatives contracts (each term as defined in Section 2(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 pursuant to an offer made under Section 275 of the SFA except:

(b) to an institutional investor or to a relevant person, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA; where no consideration is or will be given for the transfer; where the transfer is by operation of law; or as specified in Section 276(7) of the SFA.

Notice to Prospective Investors in Canada

The shares 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 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 provisions 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.

LEGAL MATTERS

The validity of the shares of common stock offered hereby will be passed upon for us by Cooley LLP, New York, New York. Certain legal matters will be passed upon for the underwriters by Latham & Watkins LLP. As of the date of this prospectus, GC&H Investments, LLC, an entity comprised of partners and associates of Cooley LLP, beneficially owns 28,238 shares of common stock issuable upon the conversion of our convertible preferred stock.

EXPERTS

Ernst & Young LLP, independent registered public accounting firm, has audited our consolidated financial statements at December 31, 2022 and 2021, and for each of the two years in the period ended December 31, 2022, as set forth in their report (which contains an explanatory paragraph describing conditions that raise substantial doubt about the company's ability to continue as a going concern as described in Note 1 to the audited consolidated financial statements). We've included our financial statements in the prospectus and elsewhere in the registration statement in reliance on Ernst & Young LLP's report, given on their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE 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 being offered by this prospectus. This prospectus, which constitutes part of the registration statement, does not contain all of the information in the registration statement and its exhibits. For further information with respect to our company and the common stock offered by this prospectus, we refer you to the registration statement and its exhibits. Statements contained in this prospectus as to the contents of any contract or any other document referred to are not necessarily complete, and in each instance, we refer you to the copy of the contract or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference.

You can read our SEC filings, including the registration statement, over the internet at the SEC's website at www.sec.gov. Upon completion of this offering, we will be subject to the information reporting requirements of the Exchange Act, and we will file reports, proxy statements and other information with the SEC. These reports, proxy statements and other information will be available at the website of the SEC referred to above. We also maintain a website at www.turnstonebio.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 in, or that can be accessed through, our website is not part of, and is not incorporated into, this prospectus or the registration statement of which this prospectus forms a part, and investors should not rely on such information in marking a decision to purchase our common stock in this offering.

INDEX TO THE CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors of Turnstone Biologics Corp.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Turnstone Biologics Corp. (the Company) as of December 31, 2022 and 2021, the related consolidated statements of operations and comprehensive income (loss), redeemable convertible preferred stock and stockholders' deficit and cash flows for the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2022 and 2021, and the results of its operations and its cash flows for the years then ended in conformity with U.S. generally accepted accounting principles.

The Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has incurred a loss in the current year, negative cash flows from operations, and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

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

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

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2018.

San Diego, California
May 12, 2023,
except for the second paragraph of Note 14, as to which the date is
July 17, 2023

TURNSTONE BIOLOGICS CORP.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share amounts)

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 34,731	$ 123,381
Restricted cash	382	382
Short-term investments	47,330	37,638
Accounts receivable—collaboration agreement	8,728	6,715
Prepaid and other current assets	6,830	9,227
Total current assets	98,001	177,343
Other assets, noncurrent	2,582	536
Operating lease right of use assets	4,631	2,570
Property and equipment, net	9,724	6,795
Total assets	$ 114,938	$ 187,244
Liabilities, redeemable convertible preferred stock and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 3,435	$ 28
Accrued expenses and other current liabilities	14,287	21,260
Operating lease liability, current	1,961	659
Deferred revenue, current	15,144	33,029
Total current liabilities	34,827	54,976
Deferred revenue, noncurrent	4,162	39,374
Operating lease liability, noncurrent	3,205	2,024
Other liabilities, noncurrent	2,267	967
Total liabilities	44,461	97,341
Redeemable convertible preferred stock		
Series A redeemable convertible preferred stock $0.001 par value; 11,250,000 shares authorized, issued and outstanding at December 31, 2022 and 2021 (liquidation preference of $8,643 as of December 31, 2022)	8,643	8,582
Series B-1 redeemable convertible preferred stock $0.001 par value; 16,285,156 shares authorized, issued and outstanding at December 31, 2022 and 2021 (liquidation preference of $12,611 at December 31, 2022)	12,611	12,611
Series B-2 redeemable convertible preferred stock $0.001 par value; 25,065,538 shares authorized, issued and outstanding at December 31, 2022 and 2021 (liquidation preference of $28,860 at December 31, 2022)	28,860	28,860
Series C redeemable convertible preferred stock $0.001 par value; 17,905,288 shares authorized, issued and outstanding at December 31, 2022 and 2021 (liquidation preference of $42,100 at December 31, 2022)	42,100	42,048
Series D redeemable convertible preferred stock $0.001 par value; 29,285,356 and 29,285,356 shares authorized, issued and outstanding at December 31, 2022 and 2021 (liquidation preference of $80,000 at December 31, 2022)	79,730	79,653
Total redeemable convertible preferred stock	171,944	171,754
Stockholders' deficit		
Common stock, $0.001 par value; 147,892,358 shares authorized, 2,915,757 and 2,550,478 shares issued and outstanding as of December 31, 2022 and December 31, 2021, respectively	3	3
Additional paid-in capital	20,501	9,115
Accumulated other comprehensive loss	(413)	(245)
Accumulated deficit	(121,558)	(90,724)
Total stockholders' deficit	(101,467)	(81,851)
Total liabilities, redeemable convertible preferred stock and stockholders' deficit	$ 114,938	$ 187,244

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

TURNSTONE BIOLOGICS CORP.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)
(in thousands, except share and per share data)

	Year Ended December 31,	
	2022	2021
Collaboration revenue	$ 73,300	$ 101,293
Operating expenses:		
Research and development	86,703	54,754
General and administrative	18,223	13,546
Total operating expenses	104,926	68,300
Income (loss) from operations	(31,626)	32,993
Other income (expense), net	933	708
Net income (loss) before income taxes	(30,693)	33,701
Provision for income taxes	(141)	(432)
Net income (loss)	$ (30,834)	$ 33,269
Other comprehensive income (loss):		
Unrealized loss on available-for-sale debt securities	(168)	(22)
Total comprehensive income (loss)	$ (31,002)	$ 33,247
Net income (loss)	$ (30,834)	$ 33,269
Less: accretion of preferred stock to redemption value	(190)	(190)
Less: undistributed earnings allocable to participating securities	—	(29,600)
Net income (loss) attributable to common stockholders, basic and diluted	$ (31,024)	$ 3,479
Weighted-average number of shares used in computing net earnings (loss) per share		
Basic	2,484,569	2,149,550
Diluted	2,484,569	2,702,347
Net income (loss) per share attributable to common stockholders		
Basic	$ (12.49)	$ 1.62
Diluted	$ (12.49)	$ 1.29

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

Turnstone Biologics Corp.
Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Deficit
(in thousands, except share amounts)

	Series A Redeemable Convertible Preferred Stock		Series B-1 Redeemable Convertible Preferred Stock		Series B-2 Redeemable Convertible Preferred Stock		Series C Redeemable Convertible Preferred Stock		Series D Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at December 31, 2020	11,250,000	$ 8,500	16,285,156	$ 12,611	25,065,538	$ 28,860	17,905,288	$ 41,978	—	$ —	2,453,892	$ 3	$ 6,354	$ (223)	$ (123,993)	$ (117,859)
Issuance of Series D redeemable convertible preferred stock, net of issuance costs of $308									29,285,356	$ 79,615						—
Accretion of redeemable convertible preferred stock issuance costs		$ 82						$ 70		$ 38			$ (190)			(190)
Exercise of stock options											96,586		$ 339			339
Stock-based compensation expense													$ 2,612			2,612
Unrealized loss on available-for-sale debt securities														$ (22)		(22)
Net income															$ 33,269	33,269
Balance at December 31, 2021	11,250,000	$ 8,582	16,285,156	$ 12,611	25,065,538	$ 28,860	17,905,288	$ 42,048	29,285,356	$ 79,653	2,550,478	$ 3	$ 9,115	$ (245)	$ (90,724)	$ (81,851)
Issuance of common stock upon Myst milestone achievement											212,203		$ 5,000			5,000
Moffitt performance-based common stock award											91,721		$ 2,050			2,050
Accretion of redeemable convertible preferred stock issuance costs		$ 61						$ 52		$ 77			$ (190)			(190)
Exercise of stock options											61,355		$ 156			$ 157
Stock-based compensation expense													$ 4,368			4,368
Unrealized loss on available-for-sale debt securities														$ (168)		(168)
Net income (loss)															$ (30,834)	(30,834)
Balance at December 31, 2022	11,250,000	$ 8,643	16,285,156	$ 12,611	25,065,538	$ 28,860	17,905,288	$ 42,100	29,285,356	$ 79,730	2,915,767	$ 3	$ 20,501	$ (413)	$ (121,558)	$ (101,467)

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

TURNSTONE BIOLOGICS CORP.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31, 2022	2021
Operating Activities		
Net income (loss)	$ (30,834)	$ 33,269
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Stock-based compensation expense	4,368	2,612
Unrealized foreign exchange loss	—	21
Depreciation and amortization	3,901	1,390
Impairment of ROU asset	497	—
Expense related to Moffitt performance-based common stock award	2,051	—
Non-cash operating lease cost	—	622
Amortization/(Accretion) of premium on short term investments	(98)	542
Change in fair value of contingent consideration liability	7,019	1,670
Changes in operating assets and liabilities:		
Accounts receivable—collaboration agreement	(2,013)	(2,366)
Prepaid and other current assets	351	(2,671)
Tax liability	—	(101)
Operating lease liabilities	(1,735)	(629)
Accounts payable	3,407	(2,157)
Accrued compensation and other accrued liabilities	(4,879)	4,106
Deferred revenue	(53,097)	(81,937)
Net cash flows used in operating activities	(71,062)	(45,629)
Investing Activities		
Proceeds from maturities of short-term investments	49,750	41,445
Purchase of short-term investments	(59,512)	(41,387)
Purchases of property and equipment	(5,170)	(3,406)
Net cash flows used in investing activities	(14,932)	(3,348)
Financing Activities		
Proceeds from issuance of redeemable convertible preferred stock, net of issuance costs	—	79,615
Payment of contingent consideration related to Myst milestone	(2,813)	
Proceeds from exercise of stock options	157	339
Net cash flows provided by and (used in) financing activities	(2,656)	79,954
Net increase (decrease) in cash, cash equivalents and restricted cash	(88,650)	30,977
Cash, cash equivalents and restricted cash at beginning of the period	123,763	92,786
Cash, cash equivalents and restricted cash at end of the period	$ 35,113	$ 123,763
Supplemental Disclosure of Cash Flow Information:		
Cash paid for income taxes	83	2,014
Supplemental Disclosure of Non-Cash Investing and Financing Activities:		
Accretion of redeemable convertible preferred stock	190	190
Equipment purchases included in accrued expenses	—	1,281
Additions to ROU assets obtained by assuming operating lease liabilities	4,218	—
Issuance of common stock to settle Myst contingent consideration liability	5,000	—

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

1. Nature of the Business and Basis of Presentation

Organization

Turnstone Biologics Corp. (the "Company" or "Turnstone") is a clinical stage biotechnology company focused on developing new medicines to treat and cure patients with solid tumors. Turnstone is pioneering a differentiated approach to tumor infiltrating lymphocytes ("TILs"). The Company is developing next generation TIL therapies by selecting the most potent and tumor-reactive T cells ("Selected TILs"). The Company has initiated two Phase 1 clinical trials for its lead Selected TIL product candidate, TIDAL-01, for the treatment of breast cancer, colorectal cancer, uveal melanoma and other non-cutaneous and cutaneous melanomas.

Turnstone Biologics Inc. ("Turnstone Canada") was incorporated as a Canadian corporation on March 27, 2014. On December 13, 2018, Turnstone Biologics Corp. was incorporated under the laws of the State of Delaware. On December 14, 2018, the Company completed a reorganization from Canada to the United States (the "Reorganization"). In connection with the Reorganization, all of the shareholders of Turnstone Canada exchanged their shares in Turnstone Canada for shares of the newly incorporated Delaware entity, as a result of which Turnstone Canada became the newly incorporated Delaware entity's wholly owned subsidiary. The corporate reorganization was a common control reorganization applied on a retrospective basis. The Company's headquarters are located in San Diego, California.

Liquidity and Capital Resources

Going Concern

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business, and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or amounts and classification of liabilities that may result from the outcome of this uncertainty. Management is required to perform a two-step analysis over the Company's ability to continue as a going concern. Management must first evaluate whether there are conditions and events that raise substantial doubt about the Company's ability to continue as a going concern (Step 1). If management concludes that substantial doubt is raised, management is also required to consider whether its plans alleviate that doubt (Step 2).

The Company incurred a loss in the current year and negative cash flows from operations and management's cash flow forecasts indicate that based on the Company's expected future operating losses and negative cash flows, there is substantial doubt about the Company's ability to continue as a going concern for 12 months after the date the consolidated financial statements for the year ended December 31, 2022 were issued. The Company's ability to continue as a going concern is dependent upon its ability to raise additional funding. Management intends to raise additional capital through equity offerings, debt financings or other capital sources, including potential collaborations, licenses and other similar arrangements. However, the Company may not be able to secure additional financing in a timely manner or on favorable terms, if at all. Furthermore, if the Company issues equity securities to raise additional funds, its existing stockholders may experience dilution, and the new equity securities may have rights, preferences and privileges senior to those of the Company's existing stockholders. If the Company raises additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish valuable rights to its current and potential future product candidates and programs on terms that are not favorable to the Company. If the Company is unable to raise capital when needed or on attractive terms, it would be forced to delay, reduce or eliminate its research and development programs or other operations. If any of these events occur, the Company's ability to achieve the development and commercialization goals would be adversely affected.

Sources of Liquidity

Since the Company's inception, the Company has devoted substantially all of its efforts and financial resources to organizing and staffing the Company, business planning, raising capital, discovering product candidates and securing related intellectual property rights, and conducting research and development activities for its Selected TIL programs and product candidates. The Company does not have any products approved for sale, has not generated any revenue from product sales, and incurred net losses from commencement of its operations through December 31, 2022. The Company's expenses primarily have been for research and development and related administrative costs. The Company has financed its operations through the issuance and sale of shares of the Company's redeemable convertible preferred stock and from collaboration revenue received pursuant to certain collaboration agreements.

The Company had net loss of $30.8 million for the year ended December 31, 2022, an accumulated deficit of $121.6 million as of December 31, 2022, and will require substantial additional capital to fund operations for the next several years. As of December 31, 2022, the Company had $82.4 million of cash, cash equivalents, restricted cash, and short-term investments. Cash used in operating activities for the year end December 31, 2022 was $71.1 million. Management believes that the currently available resources, including cash, will not provide sufficient funds to enable the Company to meet its operating plan for at least the next 12 months from the date of issuance of these financial statements.

The Company intends to fund future operations and future capital funding needs through equity and/or debt financings, as well as possible asset sales, licensing transactions, and collaborations or strategic partnerships with other companies. The sale of equity or convertible debt could result in additional dilution to stockholders. The incurrence of indebtedness would result in debt service obligations and could result in operating and financial covenants that would restrict the Company's operations. The Company can provide no assurance that sufficient financing will be available on acceptable terms, if at all. If the Company is not able to secure adequate additional funding it may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible, and/or suspend or curtail planned programs. Any of these actions could materially harm the Company's business.

Risks and Uncertainties

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations and the ability to secure additional capital to fund operations. Product candidates currently under development will require significant additional research and development efforts, including non-clinical and clinical testing and regulatory approval, prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure and extensive compliance and reporting capabilities. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements include the accounts of the Company and its subsidiaries. Intercompany transactions have been eliminated in consolidation. The Company's consolidated financial statements have been prepared in accordance with United States generally accepted accounting principles ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative accounting principles generally accepted in the United States as found in the Accounting Standard Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB").

Principles of Consolidation

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

Use of Estimates

The preparation of consolidated financial statements in accordance with GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. On an ongoing basis, management evaluates its estimates, including those related to accrued expenses, contingent liabilities, revenue recognition, the valuation of equity-based compensation, common stock, restricted common stock, and income taxes. The Company bases its estimates on various assumptions that the Company believes to be reasonable under the circumstances. Actual results could differ from those estimates.

Segment Reporting

The Company has determined that it operates and manages one operating segment, which is the business of developing and commercializing therapeutics. The Company's chief operating decision maker, its chief executive officer, reviews financial information on an aggregate basis for the purpose of allocating resources.

Cash and Cash Equivalents

Cash and cash equivalents consist of checking, money market and highly liquid investments that are readily convertible to cash and that have an original maturity of three months or less from date of purchase. The carrying amounts approximate fair value due to the short maturities of these instruments.

Restricted Cash and Investments

Restricted cash consists of certificate of deposit accounts that are pledged as collateral for the Company's New York and San Diego facility leases. Restricted cash was approximately $0.4 million as of December 31, 2022 and 2021, respectively.

The Company invests its excess cash in investment grade, short-term, fixed income securities and recognizes purchased securities on the settlement date. All investments have been classified as "available-for-sale" in the consolidated balance sheets, and are carried at estimated fair value based upon quoted market prices or pricing models for similar securities. Management determines the appropriate classification of its investments at the time of purchase and re-evaluates such designation as of each balance sheet date. Unrealized gains and losses on available-for-sale securities are included in accumulated other comprehensive income (loss), net of tax effects. The Company periodically reviews available-for-sale securities for other-than temporary declines in fair value below the cost basis, and whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Realized gains and losses are reported in other income (expense), net. Interest on short-term investments is included in interest and other income, net. The Company's investments are classified as current assets, even though the stated maturity date may be one year or more beyond the current balance sheet date, which reflects management's intention to use the proceeds from sales of these securities to fund its operations, as necessary.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash and cash equivalents, investments and restricted cash. The Company's investment policy restricts cash investments to high credit quality, investment grade investments. The Company's investment

policy provides guidelines and limits regarding investment type, concentration, credit quality, and maturity aimed at maintaining sufficient liquidity to satisfy operating and working capital requirements along with strategic initiatives, preserving capital, and minimizing risk of capital loss while generating returns on its investments. The Company is exposed to credit risk in the event of default by the issuer or the institutions holding the cash and cash equivalents to the extent of the amounts recorded on the balance sheets.

The Company has a concentration of credit risk associated with the receivables due from its collaborator Takeda Pharmaceutical Company ("Takeda"). As of December 31, 2022 and 2021, Takeda accounted for 100% of the Company's accounts receivable balance. As of December 31, 2022 and 2021, there were no reserves against accounts receivable. During the years ended December 31, 2022 and 2021, the Company did not recognize any charges for write-offs of accounts receivable.

The Company has no off-balance sheet risk, such as foreign exchange contracts, option contracts or other foreign-hedging arrangements.

Fair Value Measurements

The Company applies fair value accounting for all financial assets and liabilities and non-financial assets and liabilities that are recognized or disclosed at fair value in the consolidated financial statements on a recurring basis. Fair value is defined as the exchange price that would be received for an asset or an exit price that would be paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The fair value hierarchy requires that an entity maximize the use of observable inputs when estimating fair value. The fair value hierarchy includes the following three-level classification which is based on the market observability of the inputs used for estimating the fair value of the assets or liabilities being measured:

Level 1—Quoted market prices in active markets for identical assets or liabilities.

Level 2—Observable inputs other than quoted prices in active markets for identical assets and liabilities, quoted prices for identical or similar assets or liabilities in inactive markets, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3—Inputs that are generally unobservable and typically reflect management's estimate of assumptions that a market participant would use in pricing the asset or liability.

Fair value accounting is applied for all financial assets and liabilities and non-financial assets and liabilities that are recognized at fair value in the consolidated financial statements on a recurring basis (at least annually). To the extent the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair values requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized as Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

Investment Tax Credits

The Company claims Scientific Research and Experimental Development ("SR&ED") deductions and related investment tax credits for income tax purposes based upon management's interpretation of the applicable legislation in the *Income Tax Act* (Canada). Investment tax credits are subject to Canada Revenue Agency review and assessment of the eligibility of the Company's research expenditures. These tax credits are applied to reduce the related research and development expenses incurred in the year recognized. Actual investment tax credits received may differ from those estimated and recorded in these consolidated financial statements.

Property and Equipment

Property and equipment are recorded at cost, less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the respective assets, which are two to three years for computer equipment and software, and five years for laboratory, office equipment and furniture. Leasehold improvements are amortized over the shorter of the useful life or the remaining term of the lease.

Impairment of Long-Lived Assets

The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. Recoverability of these assets is determined by comparing the forecasted undiscounted net cash flows of the operation to which the assets relate to the carrying amount. If the operation is determined to be unable to recover the carrying amount of its assets, then these assets are written down first, followed by other long-lived assets of the operation to fair value. Fair value is determined based on discounted cash flows or appraised values, depending on the nature of the assets. For the years ended December 31, 2022 and 2021, there was $0.5 million and $0, respectively, recorded in impairment losses recognized for long-lived assets related to the sub-lease of the Company's New York office (*See Note 11—Leases* for additional information).

Revenue Recognition

The Company enters into collaboration arrangements that may include the receipt of payments for up-front license fees, success-based milestone payments, full time equivalent based payments for research services, and royalties on any future sales of commercialized products that result from the collaborations.

Effective January 1, 2017, the Company adopted the provisions of ASC Topic 606, *Revenue from Contacts with Customers* ("ASC 606"). Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects 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, the Company performs the following five steps: (i) identification of the contract(s) with the customer, (ii) identification of the promised goods or services in the contract and determination of whether the promised goods or services are performance obligations, (iii) measurement of the transaction price, (iv) allocation of the transaction price to the performance obligations, and (v) recognition of revenue when (or as) the Company satisfies each performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect consideration it is entitled to in exchange for the goods or services it transfers to the customer.

The Company accounts for a contract with a customer that is within the scope of ASC 606 when all of the following criteria are met: (i) the arrangement has been approved by the parties and the parties are committed to perform their respective obligations, (ii) each party's rights regarding the goods or services to be transferred can be identified, (iii) the payment terms for the goods and services to be transferred can be identified, (iv) the arrangement has commercial substance and (v) collection of substantially all of the consideration to which the Company will be entitled in exchange for the goods or services that will be transferred to the customer is probable.

The Company estimates the transaction price based on the amount of consideration the Company expects for transferring the promised goods or services in the contract. The consideration may include both fixed consideration and variable consideration. At the inception of each arrangement that includes variable consideration, the Company evaluates the amount of the potential payments and the likelihood that the payments will be received. The Company utilizes either the most likely amount method or expected value method to estimate the transaction price based on which method better predicts the amount of consideration expected to be received. If it is probable that a significant revenue reversal would not occur, the variable consideration is included in the transaction price.

For arrangements that include development and regulatory milestone payments, 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 revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company's control or the licensee's control, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. At the end of each reporting period, the Company re-evaluates the probability of achievement of such milestones and any related constraint, and if necessary, adjusts the estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect collaboration revenue and net income (loss) in the period of adjustment.

For sales-based royalties, including milestone payments based on the level of sales, the Company determines whether the sole or predominant item to which the royalties relate is a license. When the license is the sole or predominant item to which the sales-based royalty relates, the Company recognizes revenue at the later of: (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

The Company allocates the transaction price based on the estimated standalone selling price. The Company must develop assumptions that require judgment to determine the standalone selling price for each performance obligation identified in the contract. The Company utilizes key assumptions to determine the standalone selling price, which may include other comparable transactions, pricing considered in negotiating the transaction and the estimated costs. Certain variable consideration is allocated specifically to one or more performance obligations in a contract when the terms of the variable consideration related to the satisfaction of the performance obligation and the resulting amounts allocated to each performance obligation are consistent with the amounts the Company would expect to receive for each performance obligation.

For performance obligations, which consist of licenses and other promises, the Company utilizes judgment to assess the nature of the combined performance obligation in order to determine whether the combined performance obligation is satisfied over time or at a point in time. The Company determines the appropriate method of measuring progress of combined performance obligations satisfied over time for purposes of recognizing revenue determined on a contract by contract basis (*See Note 6—Agreements* for additional information). The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition. If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company will recognize revenue from non-refundable, up-front fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license.

The Company receives payments from customers based on billing schedules established in each contract. Up-front payments and fees are recorded as deferred revenue upon receipt or when due until the Company performs its obligations under these arrangements. Amounts are recorded as accounts receivable when the Company's right to consideration is unconditional.

Research and Development Expenses

Research and development costs are expensed as incurred. Research and development costs consist of payroll and other personnel-related expenses, materials and supplies, preclinical expenses, manufacturing expenses, contract research and development services, and consulting costs, as well as allocations of facilities and other overhead costs. Costs of certain development activities, such as manufacturing, are recognized based on an evaluation of the progress to completion of specific tasks. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the consolidated financial statements as prepaid or accrued research and development costs. Non-refundable advance payments for goods or services to be received in the future for use in research and development activities are deferred and capitalized. The capitalized amounts are expensed as the related goods are delivered or the services

are performed. Costs associated with collaboration agreements are included in research and development expense. Assets acquired that are used for research and development and which have no alternative use are expensed to research and development costs.

Preclinical and Clinical Trial Accruals

The Company makes estimates of its accrued expenses as of each balance sheet date in the consolidated financial statements based on the facts and circumstances known at that time. Accrued expenses for preclinical studies and clinical trials are based on estimates of costs incurred and fees that may be associated with services provided by contract research organizations ("CROs"), clinical trial investigational sites and other clinical trial-related activities. Payments under certain contracts with such parties depend on factors such as successful enrollment of patients, site initiation and the completion of clinical trial milestones. In accruing for these services, the Company estimates the time period over which services will be performed and the level of effort to be expended in each period. If possible, the Company obtains information regarding unbilled services directly from these service providers. However, the Company may be required to estimate these services based on other available information. If the Company underestimates or overestimates the activities or fees associated with a study or service at a given point in time, adjustments to research and development expenses may be necessary in future periods. Historically, estimated accrued liabilities have approximated actual expense incurred. Subsequent changes in estimates may result in a material change in accruals.

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.

Stock-Based Compensation

The Company measures the cost of employee, nonemployee and director services received in exchange for an award of equity instruments based on the fair value of the award on the date of grant and recognizes the related expense over the period during which the employee, nonemployee or director is required to provide service in exchange for the award on a straight-line basis.

The Company estimates the fair value of options granted using the Black-Scholes option pricing model ("Black-Scholes") and the fair value of common stock to determine the fair value of restricted stock. The determination of fair value for stock-based awards on the date of grant using an option-pricing model requires management to make certain assumptions regarding a number of variables. Upon adoption of ASU 2016-09, the Company can make an accounting policy election to either estimate the number of share-based awards that are expected to vest, or account for forfeitures when they occur. The Company elected to account for forfeitures when they occur. As such, the Company recognizes stock-based compensation expense, over the requisite service period, based on the vesting provisions of the individual grants.

The Black-Scholes option pricing model requires inputs based on certain subjective assumptions, including (a) the expected stock price volatility, (b) the expected term of the award, (c) the risk-free interest rate and (d) expected dividend yield. Due to the lack of a public market for the Company's common stock and lack of company- specific historical and implied volatility data, the Company has based its computation of expected volatility on the average historical volatility of a representative group of public companies with similar characteristics to the Company, including stage of product development and life science industry focus. The historical volatility is calculated based on a period of time commensurate with the expected term. The Company uses the simplified method as prescribed by the U.S. Securities and Exchange Commission Staff Accounting Bulletin No. 107, *Share-Based Payment*, to calculate the expected term for options granted to employees as it does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the

expected term. The expected term is applied to the stock option grant group as a whole, as the Company does not expect substantially different exercise or post-vesting termination behavior among its employee population. The risk-free interest rate is based on a treasury instrument whose term is consistent with the expected term of the stock options. The expected dividend yield is assumed to be zero as the Company has never paid dividends and has no current plans to pay any dividends on its common stock.

Determination of Fair Value of Common Stock

There are significant judgments and estimates inherent in the determination of the fair value of the Company's common stock. These estimates and assumptions include a number of objective and subjective factors, including, among other things, external market conditions, the prices at which the Company sold shares of its convertible preferred stock, the superior rights and preferences of securities senior to its common stock at the time of, and the likelihood of, achieving a liquidity event, such as an initial public offering or sale of the Company. The approach to estimating the fair market value of common stock is consistent with the methods outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, *Valuation of Privately-Held Company Equity Securities Issued as Compensation* (the "Practice Aid").

In valuing the Company's common stock, the equity value of the business was determined using the backsolve method, a form of the subject company transaction method, wherein the equity value for a privately held company is derived from a recent transaction in the company's own securities. The value is then allocated using the hybrid method allocation methodology. For grants made prior to September 30, 2018, in accordance with the Practice Aid, the Company determined the option pricing method ("OPM"), was the most appropriate method for determining the fair value of the Company's common stock based on its stage of development and other relevant factors. For grants made subsequent to September 30, 2018, the Company used a hybrid method, which is a hybrid between the OPM and the probability-weighted expected return method ("PWERM"). The hybrid method is a combination of the PWERM and OPM. The OPM allocates the overall Company value to the various share classes based on differences in liquidation preferences, participation rights, dividend policy and conversion rights, using a series of call options. The call right is valued using a Black-Scholes option pricing model. The PWERM employs additional information not used in the OPM, including various market approach calculations depending upon the likelihood of various discrete future liquidity scenarios, such as an initial public offering or sale of the Company, as well as the probability of remaining a private company. In a hybrid method, various exit scenarios are analyzed. A discount for lack of marketability of the Company's common stock is then applied to arrive at an indication of value for the common stock.

Redeemable Convertible Preferred Stock

The Company records all proceeds from redeemable convertible preferred stock ("Preferred Stock") net of issuance costs. The Company classifies Preferred Stock outside of stockholders' deficit due to certain events that are outside of the Company's control, including sale or transfer of control of the Company, or redemption upon the election of the required majority of the Preferred Stockholders any time after June 29, 2026, as holders of the Preferred Stock could cause redemption of the shares in these situations. The Company adjusts the carrying values of the Preferred Stock to the ultimate redemption values over the period from issuance to the earliest redemption date.

Income Taxes

The Company accounts for the effect of income taxes in its consolidated financial statements using the asset and liability method in accordance with ASC Topic 740, Income Taxes ("ASC 740"). This process involves estimating actual current tax liabilities together with assessing the impact of carryforward and temporary differences resulting from the differing treatment of items such as depreciation for tax and accounting purposes. These differences result in deferred tax assets and liabilities which are measured using enacted tax rates expected to apply to taxable income in the year in which those temporary differences are expected to reverse.

The Company regularly assesses the likelihood that the deferred income tax assets will be realized. A valuation allowance to reduce the deferred tax assets to the amount that the Company believes is more likely than not to be realized is established based on their judgement of all available positive and negative evidence. The assessment is completed on a taxing jurisdiction basis for each tax-paying component and takes into account a number of types of evidence, including:

- the nature and history of current or cumulative financial reporting income or losses;
- sources of future taxable income;
- the anticipated reversal or expiration dates of deferred tax assets; and
- tax planning strategies.

The Company has established a valuation allowance to offset its gross deferred tax assets as of December 31, 2022 and 2021 due to the uncertainty of realizing future tax benefits primarily related to net operating loss carryforwards and income tax credits in Canada.

The Company applies ASC 740-10 Income Taxes which requires a two-step approach to recording a tax benefit in the consolidated financial statements. The first step requires an evaluation of the tax position to determine whether it is “more likely than not”, based on the technical merits, that it will be sustained on audit. Provided that the tax position satisfies the recognition step, the Company then measures and records the position at the largest amount of tax benefit that is greater than 50 percent likely of being realized upon settlement of the audit. The Company considers many factors when evaluating and estimating its tax positions and tax benefits, which may require periodic adjustments and may not accurately anticipate actual outcomes. The Company recognizes accrued interest and penalties related to unrecognized tax benefits. There were no accrued interest and penalties as of December 31, 2022.

Net Earnings (Loss) Per Share

The Company applies the two-class method to compute basic and diluted net earnings (loss) per share because it has issued redeemable convertible preferred stock that meet the definition of participating securities. The two-class method determines net earnings (loss) per share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires earnings available to common stockholders for the period to be allocated between common and participating securities based upon their respective rights to share in the earnings as if all earnings for the period had been distributed. During periods of loss, there is no allocation required under the two-class method since the participating securities do not have a contractual obligation to fund the losses of the Company.

Basic net earnings (loss) per share attributable to common stockholders is calculated by dividing the net earnings (loss) attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period.

Diluted net earnings (loss) per share is computed by giving effect to all potentially dilutive securities outstanding for the period using the treasury stock method or the if-converted method based on the nature of such securities. For periods in which the Company reports net losses, diluted net loss per common share attributable to common stockholders is the same as basic net loss per common share attributable to common stockholders, because potentially dilutive common shares are not assumed to have been issued if their effect is anti-dilutive.

Foreign Currency

The accumulated other comprehensive loss on the balance sheet includes foreign currency translation adjustments through December 31, 2015 recorded in connection with the change in functional currency from the

Canadian dollar to the U.S. dollar. Gains or losses resulting from transactions denominated in foreign currencies are recorded as a component of other income or expense, within the consolidated statements of operations and comprehensive income (loss).

Leases

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present. Operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected lease term. The interest rate implicit in lease contracts is typically not readily determinable. As such, the Company utilizes its incremental borrowing rate, which is the rate incurred to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment. Certain adjustments to the right-of-use asset may be required for items such as initial direct costs paid or incentives received.

The Company has elected to combine lease and non-lease components as a single component. The lease expense is recognized over the expected term on a straight-line basis. The lease term for all of the Company's leases includes the non-cancellable period of the lease plus any additional periods covered by either a Company option to extend (or not to terminate) the lease that the Company is reasonably certain to exercise. Variable lease payments associated with the Company's leases are recognized when the event, activity, or circumstance in the lease agreement on which those payments are assessed occurs. Variable lease payments are presented in the Company's consolidated statements of operations and comprehensive income (loss) in the same line item as expense arising from fixed lease payments for operating leases. Balances related to operating leases are recognized on the consolidated balance sheets as right-of-use assets, operating lease liabilities, current and operating lease liabilities, non-current.

Contingent Consideration

Consideration paid related to the Myst Merger Agreement (as defined below) may include potential future payments that are contingent upon the Company achieving certain milestones in the future. Contingent consideration liabilities are measured at their estimated fair value as of the date of the consolidated balance sheets using a probability-based income approach based on the monetary value of the milestone payment discounted for the likelihood of achieving the milestone and a present value factor based on the timing of when the milestone is expected to be achieved.

Contingent consideration liabilities expected to be settled within 12 months after the balance sheet date are presented in current liabilities, with the non-current portion recorded under long term liabilities in the consolidated balance sheets. Changes in the fair value of the contingent consideration are recorded as research and development expenses in the consolidated statement of operations.

Recently Adopted Accounting Pronouncements

In December 2019, the FASB issued ASU 2019-12, Income Taxes ("Topic 740"): Simplifying the Accounting for Income Taxes. The amendments in ASU 2019-12 are intended to simplify various aspects related to accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistent application. ASU 2019-12 was effective for the Company beginning January 1, 2022 and had no material impact on its consolidated financial statements.

Accounting Pronouncements Not Yet Adopted

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments—Credit Losses (Topic 326)—Measurement of Credit Losses on Financial Instruments, which has been subsequently amended by ASU

No. 2018-19, ASU No. 2019-04, ASU No. 2019-05, ASU No. 2019-10, ASU No. 2019-11 and ASU No. 2021-03 ("ASU 2016-13"). The provisions of ASU 2016-13 modify the impairment model to utilize an expected loss methodology in place of the currently used incurred loss methodology and require a consideration of a broader range of reasonable and supportable information to inform credit loss estimates. ASU 2016-13 is effective for the Company on January 1, 2023, with early adoption permitted. The Company is currently in the process of evaluating the impact of ASU 2016-13 on the consolidated financial statements.

3. Fair Value of Financial Assets and Liabilities

For a description of the fair value hierarchy and our fair value methodology, (*See Note 2—Summary of Significant Accounting Policies* for additional information). As of December 31, 2022 and 2021, the Company's restricted cash which is maintained as collateral in connection with its New York and San Diego facility leases (*See Note 2—Summary of Significant Accounting Policies* for additional information) are valued using Level 1 inputs. The Company's highly liquid money market funds included within cash equivalents, restricted cash and U.S. treasury securities are valued using Level 1 inputs. The Company classifies its federal agency securities as Level 2. There were no transfers in or out of Level 1 and Level 2 during the periods presented. U.S. treasury securities are bonds issued by the U.S. government and are fully backed by the U.S. government. Given the frequency at which U.S. treasury securities trade and the accessibility of observable, quoted prices for such assets in active markets, they are recognized as Level 1 assets. Federal agency securities are bonds and notes issued by government-sponsored enterprises, including Fannie Mae, Freddie Mac and the Federal Home Loan Bank. Since federal agency securities typically do not trade as frequently as U.S. government agency securities and no exchange exists to price such investments, they are recognized as Level 2 assets.

The Company had $6.0 million and $6.8 million in contingent consideration liabilities as of December 31, 2022, and 2021 related to the Myst Merger Agreement. The contingent considerations balances are comprised of two potential milestone payments as well as the remaining unpaid liability of $2.2 million from the milestone achievement as of December 31, 2022 and three potential milestone payments as of December 31, 2021 measured at fair value (S*ee Note 7—Asset Acquisition* for additional information). The fair value of the contingent consideration is estimated based on the monetary value of the milestone discounted for the likelihood of achieving the milestone and a present value factor based on the timing of when the milestone is expected to be achieved. The value for the contingent consideration balance is based on significant inputs not observable in the market which represents a Level 3 measurement within the fair value hierarchy.

The following tables represents a summary of the financial assets and liabilities that are measured on a recurring basis at fair value as of December 31, 2022 and 2021 *(in thousands)*:

	December 31, 2022			
	Level 1	Level 2	Level 3	Fair Value
Financial assets:				
Money market funds	$ 9,238	$ —	$ —	$ 9,238
Restricted cash[1]	382	—	—	382
U.S. government and agency securities[2]	30,649	16,681	—	47,330
Total financial assets	$40,269	$16,681	$ —	$ 56,950
Financial liabilities:				
Contingent consideration[3]	$ —	$ —	$5,994	$ 5,994
Total financial liabilities	$ —	$ —	$5,994	$ 5,994

	December 31, 2021			
	Level 1	Level 2	Level 3	Fair Value
Financial assets:				
Money market funds	$ 2,235	$ —	$ —	$ 2,235
Restricted cash[1]	382	—	—	382
U.S. government and agency securities[2]	32,641	4,997	—	37,638
Total financial assets	$35,258	$4,997	$ —	$40,255
Financial liabilities:				
Contingent considerations[3]	$ —	$ —	$6,788	$ 6,788
Total financial liabilities	$ —	$ —	$6,788	$ 6,788

(1) Restricted cash serves as deposits for the Company's New York and San Diego office leases.

(2) Included in short-term investments on the consolidated balance sheets and are classified as available-for sale debt securities.

(3) Contingent consideration related to the Myst Merger Agreement.

The following significant unobservable inputs were used in the valuation of the contingent consideration payable to the sole common stockholder of Myst pursuant to the Myst Merger Agreement at December 31, 2022 and December 31, 2021.

Contingent Consideration Liability	Fair Value as of December 31, 2022 (in thousands)	Valuation Technique	Unobservable Input	Range
Milestone payments	$ 5,994	Discounted cash flow	Likelihood of occurrence	20% - 100%
			Discount rate	22%
			Expected term (in years)	0.25 - 3.0

Contingent Consideration Liability	Fair Value as of December 31, 2021 (in thousands)	Valuation Technique	Unobservable Input	Range
Milestone payments	$ 6,788	Discounted cash flow	Likelihood of occurrence	10% - 50%
			Discount rate	22%
			Expected term (in years)	0.5 - 4.0

The following table reflects the activity for the Company's contingent consideration, measured at fair value using Level 3 inputs (in thousands):

Contingent consideration at December 31, 2021	$ 6,788
Changes in the fair value of contingent consideration	$ 7,019
Cash Payment of Myst milestone	$(2,813)
Equity issuance related to milestone achievement	(5,000)
Contingent consideration at December 31, 2022	$ 5,994

As of December 31, 2022 and 2021, no material fair value adjustments were required for non-financial assets and liabilities.

The following tables show the Company's cash, cash equivalents and available-for-sale securities by significant investment category as of December 31, 2022 and 2021 (in thousands), respectively:

	December 31, 2022			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Level 1: Money market funds	$ 9,238	$ —	$ —	$ 9,238
Restricted cash	382	—	—	382
U.S. government and agency securities	30,761	—	(112)	30,649
Level 2: U.S. government and agency securities	16,759	—	(78)	16,681
Total financial assets	$ 57,140	$ —	$ (190)	$ 56,950
Classified as:				
Cash and cash equivalents				$ 9,238
Restricted cash				382
Short-term investments				47,330
				$ 56,950

	December 31, 2021			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Level 1: Money market funds	$ 2,235	$ —	$ —	$ 2,235
Restricted cash	382	—	—	382
U.S. government and agency securities	32,659	—	(18)	32,641
Level 2: U.S. government and agency securities	5,001	—	(4)	4,997
Total financial assets	$ 40,277	$ —	$ (22)	$ 40,255
Classified as:				
Cash and cash equivalents				$ 2,235
Restricted cash				382
Short-term investments				37,638
				$ 40,255

While short-term investments are available-for-sale, it is not more likely than not that the Company will be required to sell the investments before recovery of their amortized cost bases, which may be maturity.

The Company reviews short-term investments for impairment during each reporting period to determine if any of the securities have experienced an other-than-temporary decline in fair value. Credit losses are recognized up to the amount equal to the difference between the fair value and the amortized cost basis and recorded as an allowance for credit losses in the consolidated balance sheets with a corresponding adjustment to earnings. Unrealized losses that are not related to credit losses are recognized in accumulated other comprehensive loss. Unrealized losses were not significant for the investments held in the Company's portfolio as of December 31, 2022 and 2021. There were no impairment losses or expected credit losses related to its short-term investments during the years ended December 31, 2022 and 2021.

4. Property and Equipment, Net

Property and equipment as of December 31, 2022 and 2021 include the following (*in thousands*):

	Year Ended December 31,	
	2022	2021
Computer equipment and software	$ 376	$ 375
Laboratory equipment	12,901	5,045
Furniture	758	510
Leasehold improvements	1,308	1,308
Construction in progress	—	2,935
	15,343	10,173
Less accumulated depreciation and amortization	(5,619)	(3,378)
Total property and equipment, net	$ 9,724	$ 6,795

During 2022, the Company opened a new laboratory in San Diego resulting in $2.9 million being transferred form construction in process to laboratory equipment and the additional acquisition of $4.9 million in laboratory equipment.

Property and equipment depreciation and amortization expense for the years ended December 31, 2022 and 2021 was $2.2 million and $1.4 million, respectively.

The gain (loss) on disposal of property and equipment was $0.1 million and $0 for 2022 and 2021, respectively.

5. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities as of December 31, 2022 and 2021 consisted of the following *(in thousands):*

	Year Ended December 31,	
	2022	2021
Research and development expense	$ 6,688	$ 10,508
Professional and consulting expense	1,170	1,429
Compensation	2,366	2,097
Tax liability, current	252	252
Contingent consideration, current	3,791	5,885
Other current liabilities	20	1,089
Total accrued expenses and other current liabilities	$ 14,287	$ 21,260

6. Agreements

AbbVie BioTechnology Ltd.

Collaboration Agreement

In September 2017, the Company entered into an exclusive research, option and license collaboration agreement (the “AbbVie Agreement”) with AbbVie Biotechnology Ltd. (“AbbVie”). The AbbVie Agreement was focused on the research and development of up to three oncolytic viral immunotherapy targets, including the Ad-MG1-MAGEA3 therapy program (“MAGEA Program”) and up to two research-stage candidates (each a

"Research Program"), for which AbbVie had the option to obtain exclusive global development and commercialization rights upon the completion of contractual research and development services by the Company related to each of the three programs. If AbbVie exercised its option rights, for any of the up to three programs, AbbVie would have been responsible for all costs thereafter, including continued development, manufacturing and commercialization.

The AbbVie Agreement included a nonrefundable up-front payment of $90.0 million. AbbVie also agreed to pay the Company up to an aggregate of $220.0 million in option exercise and development milestone payments and up to an aggregate of $110.0 million upon the achievement of certain regulatory milestone events.

Under the AbbVie Agreement, the Company was obligated to use commercially reasonable efforts to perform research and development activities, under mutually agreed upon work plans. The work plans include: (i) MAGEA Program research and development services, which focus on completing Phase 1 and 2a clinical trials; and (ii) Research Programs services aimed to screen and develop two MG1 Maraba virus candidates that are ready for an investigational new drug application ("IND") submission. The Company was solely responsible for the costs and expenses incurred during the research and development stages of these programs through the delivery of data packages to AbbVie which trigger an option decision by AbbVie. After the delivery of the data packages for each program, the Company would not be obligated to perform any further research and development services.

The Company's research and development activities were conducted pursuant to the plans agreed to by the parties and overseen by a joint governance committee ("JGC"). The JGC consisted of an equal number of representatives from the Company and AbbVie and was responsible to oversee, review, and recommend direction of each program and variations of or modifications to the research plans.

Under the AbbVie Agreement, upon exercise of the MAGEA Option or Research Program Options, AbbVie was required to use commercially reasonable efforts to develop and commercialize at least one licensed product with respect to the related option candidate in each of the United States, the United Kingdom, France, Germany, Italy, Spain, and Japan. After exercise of an Option, AbbVie was solely responsible for all development and commercialization activities relating to the licensed product at its sole cost and expense.

Under its collaboration with AbbVie, the Company was eligible to receive development, regulatory and commercialization milestone payments for each licensed product for which AbbVie exercises the MAGEA and Research Options. Collectively, should AbbVie exercise all three license options, the Company was eligible for up to $90.0 million of development milestones associated with the initiation of certain registration studies of the MAGEA Program and the Research Programs, up to $85.0 million of regulatory milestones associated with the regulatory approval by the U.S. Food and Drug Administration ("FDA"), European Medicines Agency ("EMA") and Japanese Pharmaceuticals and Medical Devices Agency ("PMDA"), of the first licensed product related to the MAGEA Program and the first licensed product from the Research Programs. Additionally, the Company could earn $600 million in commercialization milestones associated with the first commercial sales in the United States, Japan and other major markets as well as milestones payable upon the achievement of certain net sales thresholds of licensed product that result from the MAGEA Program and Research Programs. The Company was also eligible to receive tiered, escalating royalties, in a range from a high-single digit to a low-teen percentage of aggregate net sales of each licensed product, subject to potential reductions in certain circumstances.

On June 12, 2021, the AbbVie Agreement was terminated following notice previously provided by AbbVie and in accordance with the AbbVie Agreement's original terms.

Accounting Analysis

The Company assessed the promised goods and services under the AbbVie Agreement in accordance with ASC 606, and determined that the AbbVie Agreement includes the following performance obligations: (i) research and development services for the completion of Phase 1 and 2a clinical trials for MAGEA and

delivery of related data package to AbbVie ("MAGEA Research Services"); and (ii) research and development services for the identification of up to two Research Programs and delivery of related data packages ready for IND submission to AbbVie ("Research Program Services"). The MAGEA Research Services are governed by their own work plan within the AbbVie Agreement and AbbVie can benefit from these services without the performance of any services related to Research Program Services, these represent a distinct performance obligation. Similarly, the Research Program Services are considered to be a distinct performance obligation to perform a body of research on the identified targets with the goal of identifying up to two product candidates as governed by its own research plans for which AbbVie can benefit from absent the MAGEA Research Services.

The Company received a non-refundable up-front payment of $90.0 million, of which $20.0 million was paid at inception, in September 2017 and $70.0 million was received in March 2018, in accordance with the AbbVie Agreement, which represents the transaction price at inception. The Company could have earned $15.0 million in milestones for each Research Program related to the achievement of certain success criteria during the provision of the Research Program Services. The Company used the most likely method to value this variable consideration as there are only two possible outcomes of achieving the individual milestones and concluded that no amounts would be included in the transaction price as it is not probable that the milestones will be achieved. This is due to the uncertainty surrounding the ability to achieve the success criteria contained in the Research Program Services development plan. Additional consideration to be paid to the Company upon the exercise of the MAGEA Option or Research Program Options by AbbVie and upon the achievement of certain development, regulatory and commercialization milestones, that are achievable only after the exercise of the license options, are excluded from the transaction price, as they relate to option fees and milestones that can only be achieved after the option exercise.

The Company has allocated the transaction price to the separate performance obligations based on their relative standalone selling price. The Company determined the standalone selling price for each performance obligation based on internal estimates of the costs to perform the research and development services, including internal expenses and expenses with third parties for services and supplies, inclusive of a reasonable profit margin. Significant inputs used to determine the total expense of the research services include the length of time required, the internal hours expected to be incurred on the services, and the number and costs of various studies that will be performed to complete the MAGEA Research Services and Research Program Services.

Based on the relative standalone selling price, the allocation of the transaction price to the separate performance obligations was as follows:

Performance Obligations	Allocation of Transaction Price
MAGEA Research Services	$ 63.9 million
Research Program Services	$ 26.1 million
Total	$ 90.0 million

Costs incurred relating to the AbbVie Agreement consist of internal and external research and development costs, which primarily include salaries and benefits, lab supplies, and preclinical research studies. All of these costs are included in research and development expenses in the Company's statement of operations during the year ended December 31, 2021.

The Company recognizes the amounts associated with these services on a proportional performance basis over the contract term using input-based measurements of total cost of research and development incurred to estimate the proportion performed as compared to the estimated total cost and remeasures its progress towards completion at the end of each reporting period. There were no significant changes in estimate recorded prior to contract termination in 2021.

For the year ended December 31, 2021, the Company recognized $69.8 million of collaboration revenue related to the AbbVie Agreement. At the date of the termination of the AbbVie Agreement, the remaining

deferred revenue associated with the non-refundable payments was recognized as collaboration revenue as there were no remaining performance obligations following the termination of the AbbVie Agreement. As of December 31, 2021, the deferred revenue balance in connection with the AbbVie Agreement was $0.

Takeda Pharmaceutical Company Limited

Collaboration Agreement

In November 2019, the Company entered into a discovery, collaboration and license agreement ("Takeda Agreement") with Millennium Pharmaceuticals, Inc. (also known as "Takeda Oncology"), a wholly owned subsidiary of Takeda Pharmaceutical Company Limited ("Takeda"). Under the Takeda Agreement, the Company agreed to collaborate with Takeda to co-develop and co-commercialize TBio-6517 (also known as "RIVAL-01") ("Development Program") and to conduct discovery programs to identify additional novel product candidates based on its vaccinia virus platform for independent development ("Discovery Program").

Under the Takeda Agreement, the Company granted Takeda and its affiliates a worldwide, irrevocable, non-transferable, co-exclusive, sublicensable license under certain of the Company's know-how and patent rights ("Turnstone Technology") to make, use, sell, offer for sale, develop, manufacture, and commercialize, or otherwise exploit TBio-6517 ("Licensed Compound") and products containing TBio-6517 ("Takeda Licensed Products") in all fields. Takeda granted the Company and the Company's affiliates an irrevocable, non- transferable, non-exclusive, sublicensable license under certain know-how and patent rights of Takeda ("Takeda Technology") to make, use, sell, offer for sale, develop, manufacture, and commercialize, or otherwise exploit the Licensed Compound and Takeda Licensed Products in all fields in accordance with joint development, commercialization, and medical affairs plans under the Takeda Agreement.

Under the Takeda Agreement, the Company also granted to Takeda and its affiliates a worldwide, non-transferable, non-exclusive, sublicensable license under Turnstone Technology to conduct joint discovery and research activities in all fields in accordance with joint research and discovery plans. Under the Takeda Agreement, Takeda granted the Company a license to Takeda Technology to conduct discovery and research activities in all fields in accordance with joint research and discovery plans. The Company also granted to Takeda and its affiliates an exclusive option to obtain a worldwide, irrevocable, non-transferable, exclusive, sublicensable license under Turnstone Technology to make, use, sell, offer for sale, develop, manufacture, and commercialize, or otherwise exploit (i) selected discovery virus candidates generated and evaluated by the parties under a joint discovery program ("Selected Discovery Candidates"), and (ii) any corresponding licensed products containing a Selected Discovery Candidate ("Licensed Discovery Products"). Takeda may exercise this option with respect to two virus candidates and within a specified option exercise period. The Company granted Takeda and its affiliates a non-exclusive, perpetual, irrevocable, worldwide, sublicensable and fully paid-up license under certain of the Company's know-how and patents relating to manufacturing improvements developed under the Takeda Agreement solely for use in connection with the manufacture of products that do not comprise or incorporate, and that are not based on, an oncolytic virus. Takeda granted the Company and the Company's affiliates a non-exclusive, perpetual, irrevocable, worldwide, sublicensable and fully paid-up license under certain of Takeda's know-how and patents relating to manufacturing improvements developed under the Takeda Agreement solely for use in connection with the manufacture of any and all products. With respect to discovery virus candidates for which Takeda does not exercise its option, Takeda granted the Company a non-exclusive, perpetual, worldwide, sublicensable and royalty-bearing license under certain of its know-how and patents that is necessary or reasonably useful for the exploitation of such declined discovery virus candidates ("Declined Candidate License").

Responsibilities for the development of Licensed Compounds and Takeda Licensed Products are delineated pursuant to a joint development plan under the terms of the Takeda Agreement. The Company will be responsible for all activities under the joint development plan prior to completion of a Phase 2a clinical trial and Takeda will be responsible for all activities in the joint development plan upon and after completion of the

Phase 2a clinical trial. Responsibilities relating to manufacturing, medical affairs, and commercialization of Licensed Compounds and Takeda Licensed Products are delineated pursuant to a manufacturing working plan, joint medical affairs plan and joint commercialization plan, respectively. The Company has the right to reduce or opt-out of its share of responsibilities for costs and expenses of certain development or commercialization activities for the Takeda Licensed Compounds and Takeda Licensed Products. Responsibilities for the discovery and research of Selected Discovery Candidates are delineated pursuant to joint discovery and research plans under the terms of the Takeda Agreement.

Under the Takeda Agreement, Takeda paid the Company a non-refundable payment of $50.0 million in November 2019, and an additional non-refundable payment of $30.0 million in April, 2020, for the option to license up to two Selected Discovery Candidates, with additional consideration of $15.0 million to be paid by Takeda to the Company for each exercise of such option.

Under the Takeda Agreement, the Company has the right to reduce its share of funding obligations with respect to development activities for the Licensed Compound and Takeda Licensed Products (the "Development Opt-Down Right"), or to opt-out of all further funding obligations with respect to development activities for the Licensed Compound and Takeda Licensed Products (the "Development Opt-Out Right"). Unless and until the Company exercises the Development Opt-Down Right, the parties will share evenly in any operating profits or losses with respect to joint development activities, joint medical affairs activities, and joint commercialization activities. If the Company exercises its Development Opt-Down Right, then starting from the effective date of the exercise of the right, Takeda will bear (and be entitled to) 70% and the Company will bear (and be entitled to) 30% of the operating profits or losses with respect to joint development activities, joint medical affairs activities, and joint commercialization activities. Takeda is obligated to pay the Company (i) up to $200.0 million in aggregate upon achievement of certain clinical and regulatory milestones for the first Takeda Licensed Product to achieve the applicable development milestone event, (ii) up to $150.0 million in aggregate for one-time payments upon achievement of certain sales milestones for each Takeda Licensed Product, (iii) up to $240.0 million in aggregate (if Takeda exercises both options to Selected Discovery Candidates) upon achievement of certain clinical and regulatory milestones for the first Takeda Licensed Discovery Product to achieve applicable development milestone events, and (iv) up to $300.0 million in aggregate (if Takeda exercises both options to Selected Discovery Candidates) for one-time payments upon achievement of certain sales milestones for a Licensed Discovery Product. If the Company exercises its Development Opt-Out Right for the Takeda Licensed Products, then in lieu of the profit and loss share arrangement described above, the Company is entitled to receive tiered low- to high- teen percentage royalties on net sales of all Takeda Licensed Products by the Company or the Company's sublicensees during the royalty term, which commences on the first commercial sale of a Takeda Licensed Product in a country and ends on the later of the expiration of all licensed patents covering such Licensed Product in such country or ten years after the date of the first commercial sale in such country ("Royalty Term"). For Licensed Discovery Products, the Company is entitled to receive tiered high-single digit to low-teen percentage royalties on net sales of all Licensed Discovery Products by the Company or the Company's sublicensees during the Royalty Term. Royalty payments are subject to customary reductions.

Takeda has the right to terminate for convenience as follows: (i) prior to the expiration of the option exercise period related to a Discovery Virus Candidate, Takeda may terminate the Takeda Agreement related to such Discovery Virus Candidate and the Discovery Program with 90 days' notice, (ii) prior to any commercial sale, Takeda may terminate the Takeda Agreement either in its entirety or on a compound-by-compound or region-by-region basis, with six months' notice and (iii) after a commercial sale, Takeda may terminate the Takeda Agreement either in its entirety or on a compound-by-compound or region-by-region basis, with 12 months' notice.

Termination of Development Program

On June 13, 2022, Takeda provided six months' written notice to terminate the Development Program in accordance with its termination for convenience rights, with such termination being effective as of December 13,

2022. During the six months' notice period, the Company was obligated to continue providing the necessary Development Program services to wind down the program. Upon the effective termination date of December 13, 2022, Takeda's co-exclusive license to TBio-6517 terminated and the Company is no longer obligated to pursue development of TBio-6517.

Termination of Discovery Program

On January 6, 2023, Takeda provided written notice to the Company that it was exercising its right to terminate the remainder of the Takeda Agreement, with such termination being effective as of July 6, 2023 ("Termination Effective Date"). On the Termination Effective Date, all options and licenses granted under the Takeda Agreement will terminate (except for the Declined Candidate License) and Takeda will grant the Company a non-exclusive license under the patent rights and know-how controlled by Takeda as of the Termination Effective Date necessary for the Company to exploit the Licensed Compound and Takeda Licensed Products in the form existing as of the Termination Effective Date for any use worldwide, subject to a royalty to be agreed upon by Takeda and the Company.

Accounting Analysis

The Company assessed the promised goods and services under the Takeda Agreement in accordance with ASC 606, and determined that, at inception, the Takeda Agreement includes the following performance obligations: (i) research, development and manufacturing services under the Development Program for the completion of clinical trials through Phase 2a for RIVAL-01 and a co-exclusive license to exploit RIVAL-01 ("Development Program Performance Obligation"); and (ii) research and development services under the Discovery Program to identify and optimize four Selected Discovery Candidates for further development ("Discovery Program Performance Obligation"). The individual promises under the Development Program including research, development, manufacturing for clinical trials, and the co-exclusive license to RIVAL-01 are not individually distinct as they represent inputs into a combined output of advancing RIVAL-01 through the Phase 2a clinical trial. Therefore, all promises under the Development Program represent a single performance obligation. Similarly, the research and development services under the Discovery Program represent a single research program aimed at generating four Selected Discovery Candidates and therefore represents a single performance obligation. The Development Program promises are distinct from the promises under the Discovery Program, as the benefits under each program are separately identifiable. Each program has a separate work plan and the promises to be provided under the Development Program do not relate to the promises to be provided under the Discovery Program.

The Company concluded that Takeda's license options under the Discovery Program do not represent material rights, and therefore are not performance obligations, as the Company is entitled to an additional $15.0 million payment for each license option exercised, which approximates the estimated standalone selling price of the underlying license.

The total transaction price at contract inception is $158.6 million, comprised of the following components:

- Fixed consideration of $80.0 million including a non-refundable up-front payment of $50.0 million in November 2019 and another non-refundable payment of $30.0 million that was due on April 1, 2020 and received in April 2020.

- Variable consideration related to the expense sharing under the Development Program. These amounts are determinable based on the Development Program plan and budget, and the Company has a contractual right to the payment of costs incurred under the agreed upon plan. Consistent with the expected value method, the Company estimated that it will receive $58.6 million under the expense sharing through the completion of the Phase 2a clinical trial. The Company has concluded

that these amounts do not require a constraint and are included in the transaction price at inception. The Company has evaluated this estimate at each reporting date and updated the estimate based on information available.

- Variable consideration for the development milestones under the Development Program. The Company uses the most likely amount method to value this variable consideration as there are only two possible outcomes of achieving the individual milestones. Under the Development Program, the first milestone of $20.0 million is due upon acceptance of the IND by the FDA. At inception, the Company concluded that achievement of this milestone was highly probable and therefore the $20.0 million was included in the transaction price, and was received in March 2020. The second milestone of $15.0 million under the Development Program is due upon the initiation of the first Phase 2 clinical trial for a licensed product. The Company has determined that the most likely amount is $15.0 million, however, the Company will not include this $15.0 million milestone in the transaction price until it becomes probable that a significant reversal of cumulative revenue will not occur.

Additional consideration to be paid to the Company includes development and sales milestones, profit and loss share, royalties and option exercise payments. These additional payments are achievable only after the completion of the Phase 2a clinical trial under the Development Program or exercise of the license options under the Discovery Program and therefore are excluded from the transaction price. Additionally, Takeda's equity purchase commitments of up to $20.0 million are at fair value and therefore no non-cash consideration has been included as a component of the transaction price.

The Company allocated the transaction price to the separate performance obligations based on their relative standalone selling prices. The Company determined the standalone selling price of the Development Program Performance Obligation based on the costs incurred to develop RIVAL-01 plus the estimated costs to perform the research, development and manufacturing services through the completion of the Phase 2a clinical trial, inclusive of a reasonable profit margin. The Company determined the standalone selling price of the Discovery Program Performance Obligation based on the estimated costs to discover and research four Selected Discovery Candidates, inclusive of a reasonable profit margin. Significant inputs used to determine the standalone selling prices of the performance obligations include the length of time required, the internal hours expected to be incurred on the services, and the amount of third-party expenses that will be incurred to complete the performance obligations.

The Company recognizes the amounts associated with these performance obligations on a proportional performance basis over the contract term using input-based measurements of total cost of research and development incurred to estimate the proportion performed as compared to the estimated total cost and remeasures its progress towards completion at the end of each reporting period.

As of December 31, 2021 the transaction price was updated to $192.6 million to reflect an increase in the variable consideration related to the expense sharing under the Development Program from $58.6 million at inception to $92.6 million.

The Company determined that the notice of termination on June 13, 2022 represented a modification of the arrangement under ASC 606 and that the transaction price should be updated and re-allocated to the Development Program Performance Obligation and the Discovery Program Performance Obligation based on their original standalone selling prices, as follows:

Performance Obligations	Price Pre-Modification	Price at Modification
Development Program	$ 166.3 million	$ 134.3 million
Discovery Program	$ 26.3 million	$ 21.2 million
Total	$ 192.6 million	$ 155.5 million

Additionally, the Company updated its measure of progress for each performance obligation as of the modification date and recorded a cumulative adjustment that increased revenue by $31.6 million on the partially satisfied remaining performance obligations, as the remaining services to be performed under each of the performance obligations are not distinct from the services prior to the modification.

Costs incurred relating to the Takeda Agreement consist of internal and external research and development costs, which primarily include salaries and benefits, lab supplies, and preclinical research studies. All of these costs are included in research and development expenses in the Company's consolidated statements of operations and comprehensive income (loss) during the years ended December 31, 2022 and 2021.

The deferred revenue balance in connection with the Takeda Agreement as of December 31, 2022 and 2021 was $19.3 million and $72.4 million, respectively, which is classified as either current or noncurrent in the accompanying balance sheet based on the periods the performance obligations are expected to be performed. The Company expected to recognize the deferred revenue balance within two years. The Company recognized collaboration revenue related to the Takeda Agreement for the years ended December 31, 2022 and 2021 of $73.3 million and $31.4 million, respectively. Revenue recognized in 2022 and 2021 of $51.6 million and $12.1 million, respectively, related to amounts included in deferred revenue liability balances at the period ending December 31, 2021 and 2020. Receivables related to reimbursable costs expected to be received from Takeda for research and development services performed under the Development Program for the years ended December 31, 2022 and 2021 were $8.7 million and $6.7 million, respectively.

H. Lee Moffitt Cancer Center

Master Collaboration Agreement

In January 2021, the Company entered into an amended and restated master collaboration agreement (the "Moffitt Agreement"), with Moffitt, to amend a then-existing master collaboration agreement from November 2019, as amended March 2020, between Moffitt and the Company's now wholly-owned subsidiary, Myst Therapeutics LLC, with the intent to continue to work collaboratively in the research of cancer immunotherapies.

Each party granted the other party a right to use its research materials for performance of the research plans agreed to by the parties (the "Research Plans"). Each party granted the other party a non-exclusive, worldwide, sublicensable, perpetual, irrevocable, royalty-free license under all inventions invented in performance of a Research Plan and invented jointly by the Company and Moffitt (the "Joint Inventions") (with certain exclusions) to make, use, sell, offer for sale, import products and services and/or otherwise practice such inventions.

The Company granted Moffitt a royalty free, non-sublicensable, non-transferable, perpetual, non-exclusive license to use and practice certain inventions invented solely by the Company in the performance of a Research Plan for its internal non-commercial research purposes.

Moffitt granted the Company (i) a royalty-free, sublicensable, non-transferable, perpetual, non-exclusive license to use and practice certain inventions invented solely by Moffitt in the performance of a Research Plan ("Moffitt Inventions"), (a) for internal, non-commercial research purposes outside the field of ACT and/or (b) to research, develop, make, use, sell, offer to sell, or import products and/or services in the field of ACT and (ii) a royalty free, sublicensable, non-transferable, perpetual, non-exclusive license to use and practice certain inventions invented in performance of a Research Plan or through the use of specified Moffitt research materials.

Moffitt granted the Company an option to obtain, with terms to be negotiated in good faith under commercially reasonable terms, a royalty-bearing, sublicensable exclusive license in the Moffitt Inventions, the TCR Inventions, and/or Moffitt's interest in Joint Inventions. The Company can exercise this option at any time within six months after Moffitt informs the Company of any new invention, and upon the Company's exercise, the parties will have a period of six months to negotiate the terms of such exclusive license.

The Moffitt Agreement will expire upon the later of (i) four years from the effective date of the Moffitt Agreement or (ii) the termination or expiration of all Research Plans in effect under the Moffitt Agreement, unless extended upon mutual written agreement of the parties. Either party may terminate the Moffitt Agreement for cause upon any uncured breach by the other party or upon the insolvency of the other party.

Moffitt Alliance Agreement

In June 2022, the Company entered into a life science alliance agreement with Moffitt (the "Alliance Agreement"), in order to further expand the Company's relationship and support the Company's existing agreements with Moffitt (the "Underlying Agreements"). Pursuant to the Alliance Agreement, the Company will have priority access to Moffitt's scientific research, manufacturing, and clinical capabilities for the development of novel TIL therapies, including expedited clinical trial activation, enhanced patient screening and data sharing, access to Moffitt's cellular therapies research and development infrastructure, expanded molecular data sets and biospecimens for research, and allocated cGMP manufacturing capacity for the Company's product candidates.

Under the Alliance Agreement, the Company is obligated to use commercially reasonable efforts to further develop TIL Products, to manufacture TIL Products, to obtain regulatory approval for at least one TIL Product in the United States and to commercialize TIL Products in all countries in which regulatory approval for a TIL Product has been obtained. For purposes of the Alliance Agreement, TIL Product means any pharmaceutical, biopharmaceutical, or biotechnology TIL product that has been developed by us or Moffitt and is advanced into clinical development under an IND sponsored by Moffitt.

Pursuant to the Alliance Agreement, the Company agreed to pay to Moffitt a total amount of at least $17.5 million (the "Alliance Funding Amount"), for research, development and manufacturing related services that will be paid in five equal annual installments on June 1st of each year starting on June 1, 2023. However, the aggregate amount the Company pays to Moffitt for all fees, costs, expenses and other payments pursuant to any Underlying Agreement with Moffitt entered into subsequent to February 7, 2022 may be credited against the Alliance Funding Amount. This reimbursement amount will be calculated annually at the conclusion of each payment period, and, to the extent the Company's annual aggregate payments to Moffitt exceed the applicable annual installment amount, the Company will receive a reduction in the amount due for future installment payments based on a predetermined formula agreed to by the parties. During 2022, the Company incurred expenses with Moffitt of $2.6 million toward the first years' annual installment.

In connection with the execution of the Alliance Agreement, the Company issued Moffitt 91,721 shares of its common stock. As partial consideration under the Alliance Agreement, the Company also agreed to issue Moffitt an additional 366,884 shares of its common stock in the aggregate upon the satisfaction of certain clinical and regulatory milestones with respect to TIL Products. The issuances of common stock are treated as performance-based stock awards. For the year ended December 31, 2022, $2.0 million was recorded in research and development expense in the consolidated statements of operations and comprehensive income (loss) for the 91,721 shares issued in connection with the execution of the contract and the achievement of the first milestone with the start of the Phase 1 trial. In addition, upon achievement of certain thresholds for aggregate net sales of all TIL Products, the Company is required to make tiered sales-based milestones payments to Moffitt of up to an aggregate of $50.0 million. With respect to each of the equity and sales milestones described above, TIL products include any pharmaceutical, biopharmaceutical or biotechnology TIL product that is developed by the Company or Moffitt and is advanced into clinical development under an IND sponsored by Moffitt.

Unless earlier terminated, the Alliance Agreement will remain in effect for a term of five years and may be extended for additional periods upon the mutual written consent of both parties. Either party may terminate the Alliance Agreement in the event of (i) the other party's material breach of the Alliance Agreement that remains uncured after ninety days of receiving written notice of such breach (or in the case of breach of payment obligations, within ten days), (ii) the other party's insolvency and (iii) a pandemic event resulting in government lockdowns or orders that legally compel such party to cease operations or that result in material disruptions in the

available workforce and prevents such party from performing its contractual obligations for a period of more than six months. At any time after June 1, 2025, either party may terminate the Alliance Agreement without cause upon sixty days prior written notice to the other party (a "Termination for Convenience"). Upon a Termination for Convenience, the terminating party shall pay to the other party a termination fee in an amount equal to a low double digit percentage of the then remaining Alliance Funding Amount. Termination or expiry of one or more Underlying Agreements does not affect the term of the Alliance Agreement, which will continue to apply to the remaining ongoing Underlying Agreements.

7. Asset Acquisition

In December 2020, the Company entered into the Agreement and Plan of Merger and Reorganization (the "Myst Merger Agreement"), by and among the Company, Flatiron Merger Sub I, Inc. ("Merger Sub"), Flatiron Merger Sub II, LLC ("Merger LLC"), a direct, wholly-owned subsidiary of the Company, Myst Therapeutics, Inc. ("Myst"), and Timothy Langer, the sole common stockholder of Myst ("Langer"). Pursuant to the Myst Merger Agreement, the business combination (the "Merger") was effected in two steps. The first step was the merger of Merger Sub with and into Myst. The second step was the merger of Myst with and into Merger LLC. The Merger closed on December 14, 2020, and the effective date of the Merger was January 20, 2021. As a result of the Merger, the separate existences of Merger Sub and Myst ceased, and Merger LLC became the Company's wholly-owned subsidiary.

Pursuant to the Myst Merger Agreement, on December 15, 2020, the Company paid the former equity holders of Myst, (the "Myst Holders"), a one-time up-front payment of $9.0 million in cash. The Company paid an additional cash consideration of $1.0 million to the Myst Holders on June 14, 2022. The Company also issued Langer up to 725,920 shares of the Company's common stock. Of these shares, 362,960 shares of the Company's common stock were issued upon the closing of the Merger and the remaining 362,960 shares of the Company's common stock were held in escrow with 25% vesting in December of each year that Langer remains an employee of the Company. As of December 31, 2022, Langer is still employed by the Company and 181,480 shares of the Company's common stock have vested and been released from escrow, with the remaining 181,480 shares of the Company's common stock to be released in equal annual installments over the next two years based on his continued employment. This restricted equity grant is accounted for as a compensatory arrangement under ASC Topic 718, Compensation-Stock Compensation ("ASC 718"), as continued service is required under the agreement.

In addition, under the Myst Merger Agreement, each Myst Holder is entitled to receive certain payments as consideration based on the achievement by the Company of three predefined milestones. The initial milestone is the closing of an initial public offering, which will be triggered by the closing of this offering, the second milestone is the first acceptance by the FDA of an IND filed by, on behalf of or for the benefit of the Company, or the Company's sublicensees for a product being developed by or on behalf of the Company or its sublicensees that is claimed as a product or method of making or using the product by a pending or issued Myst patent claim existing at the time of such acceptance, and the third milestone is the occurrence of the earlier of (i) the commencement of the first registration study for a product being developed by, on behalf of or for the benefit of the Company that is claimed as a product or a method of making or using the product by an issued Myst patent claim existing as of the time of such commencement or (ii) the issuance of a Myst patent claim that claims a product or method of making or using the product then being developed by, on behalf of or for the benefit of the Company, or its sublicensees, that is or was the subject of a registration study that has or had commenced. The milestones are not contingent on one another, and the milestones do not need to be achieved in any specific order.

Within 45 days of the achievement of the initial milestone, which the closing of this offering triggers, the Company is obligated to pay the Myst Holders an aggregate amount equal to $3.0 million. At the Company's election, the Company may pay this consideration in cash or in shares of the Company's common stock. The fair market value of the Company's common stock measured after this offering, is the volume weighted-average closing price of the Company's common stock on Nasdaq for the consecutive 20 trading day period ending on

the last trading day on or prior to the date on which the milestone was earned pursuant to the Myst Merger Agreement.

Within 45 days of the achievement of the second milestone, the Company is obligated to pay the Myst Holders an aggregate amount equal to $10.0 million. At the Company's election, the Company may pay this consideration in cash or in shares of the Company's common stock. In May 2022, this $10.0 million milestone was achieved. The Company elected to pay $5.0 million in the Company's common stock and $5.0 million in cash. Pursuant to a letter agreement dated July 25, 2022 between the Company and the former equityholders of Myst regarding the $10.0 million milestone payment that became due and owing to the Myst Holders, the Company agreed to pay to the former optionholders of Myst on or before July 28, 2022 $0.6 million in cash, with the remaining $9.4 million payable to Langer as follows: (i) on or before July 28, 2022, $2.2 million in cash, (ii) on or before July 31, 2022, $5.0 million in shares of the Company's common stock and (iii) on or before January 10, 2023, $2.2 million in cash. On June 8, 2022, the Company issued Langer 212,203 shares of the Company's common stock to settle the $5.0 million obligation payable in common stock. The Company then paid the Myst Holders $2.8 million in July 2022, with $2.2 million paid to Langer and $0.6 million paid to the remaining Myst Holders, and the remaining $2.2 million was paid to Langer in January 2023.

Within 45 days of the achievement of the third milestone, the Company is obligated to pay the Myst Holders an aggregate amount equal to $20.0 million. At the Company's election, the Company may pay this consideration in cash or in shares of its common stock.

Additionally, the Company assumed an ongoing research and development contract obligation of approximately $1.5 million and committed to spend at least $30.0 million for building out cell therapy infrastructure and continued research and development.

The Company accounted for the merger with Myst pursuant to the Myst Merger Agreement as an asset acquisition as substantially all of the fair value of the gross assets acquired was concentrated in the acquired in-process research and development of Myst and did not have an alternate future use. The Company recognized a $19.4 million charge to research and development expense at the time of the completion of the asset acquisition during the year ended December 31, 2020. The Company determined that the milestone payments are separate units of account and accounted for the initial milestone as a derivative in accordance with ASC 815 and the second and third milestones as liabilities in accordance with ASC 480. In connection with the initial public offering, the Company reassessed its initial accounting of the milestone payments and concluded that they should be viewed as one unit of account because the milestone payments are not legally detachable from each other. The milestone payments, as one unit of account, would be classified as a liability in accordance with ASC 480 and measured at fair value, with changes in the fair value recorded in earnings. Regardless of whether the milestone payments are viewed as one unit of account or three units of account, because they are all subject to fair value measurement, the financial reporting effect of the contingent consideration arrangement as one unit of account or three units of account is substantially the same. As a liability under ASC 480, the contingent consideration will continue to be recorded at fair value until settled. The adjustment to the fair value of the contingent consideration of $7.0 million and $1.6 million were included in research and development expense in the Company's consolidated statements of operations for the years ended December 31, 2022, and 2021, respectively.

8. Stockholders' Equity

Series A Preferred Stock

From October 2015 to October 2016, the Company issued a total of 11,250,000 shares of series A preferred stock (the "Series A Preferred Stock") at CDN$1.00 per share (equivalent to $0.74 per share, based on a conversion ratio of 1.344 Canadian dollars to one U.S. dollar) for total net proceeds of CDN$ 10.9 million (equivalent to $8.1 million based on a conversion ratio of 1.344 Canadian dollars to one U.S. dollar).

Series B Preferred Stock

In October 2016, the Company issued a total of 16,285,156 shares of series B-1 preferred stock (the "Series B-1 Preferred Stock") at $0.77 per share for total net proceeds of $12.3 million. In November 2018, the Company issued 25,065,538 shares of series B-2 preferred stock (the "Series B-2 Preferred Stock", and together with the Series B-1 Preferred Stock, the "Series B Preferred Stock") at $1.15 per share for total net proceeds of $28.9 million.

Series C Preferred Stock

The Company issued a total of 17,905,288 shares of series C preferred stock (the "Series C Preferred Stock") at $2.35 per share in January 2019 for net proceeds of $41.8 million.

Series D Preferred Stock

The Company issued a total of 29,285,356 shares of series D preferred stock (the "Series D Preferred Stock") at $2.73 per share in June 2021 for net proceeds of $79.8 million.

The rights and preferences of the Preferred Stock as of December 31, 2022, are summarized below, which relate to each of the Series A, Series B, Series C and Series D Preferred Stock unless specified otherwise.

Conversion

The holders of Preferred Stock have the right, at any time and at the holder's discretion, to convert, without payment of any additional consideration, in whole or in part, such holder's Preferred Stock into common stock at the then applicable conversion price, which shall initially be one share of common stock for one share of Preferred Stock. The Preferred Stock will be automatically converted into common stock at the then applicable conversion price, upon the earlier of a qualified initial public offering or the election of a required majority of the holders of Preferred Stock.

Voting

The holders of the Preferred Stock are entitled to vote on any matters on which holders of common stock are entitled to vote, on an as-converted basis. Holders of Preferred Stock and holders of common stock are required to vote together as a single class, except for meetings at which only holders of another specified class of shares are entitled to vote. Each Preferred Stockholder is entitled to such number of votes equal to the number of shares of common stock issuable upon the exercise of any conversion rights attaching to such Preferred Stock at the date of such vote, using the applicable conversion price.

Dividends

The holders of the Series A and Series B Preferred Stock are entitled to receive non-cumulative dividends at the rate of 8% per annum and the holders of the Series C and Series D Preferred Stock are entitled to receive non-cumulative dividends at the rate of 10% per annum when and if declared by the board of directors and in preference to the common stock. After the Preferred dividend is paid, the Preferred Stock participates in any dividend paid to common stock on an as-converted basis (participating). Through December 31, 2022, the Company has not declared or paid dividends and has no present intention of paying any dividends in the foreseeable future.

Liquidation Preference

In the event of a liquidation event, the holders of Preferred Stock are entitled to receive, in preference to the holders of common stock, an amount equal to their initial issue price plus the aggregate of all declared but unpaid dividends and may then participate in the distribution of any residual assets with the common stock on an as-converted basis.

If the amount to distribute is insufficient to pay the liquidation preference in full, then the Preferred Stock receive the distribution ratably in proportion to the respective amounts which would otherwise be payable in respect of the shares held by them upon such distribution if all amounts payable on or with respect to such shares were paid in full.

Redemption

At the option of the holders of at least a majority of the then outstanding shares of Preferred Stock, consenting or voting together as a single class on an as-converted to Common Stock basis (the "Required Majority"), at any time after June 29, 2026, each holder of Preferred Stock shall be entitled to require the Company to redeem all or any of the outstanding Preferred Stock held by those holders electing at a price equal to the Redemption Price which is defined as initial issue price plus declared but unpaid dividends.

The Company is accreting the carrying value of the Preferred Stock up to the full redemption value over the period from issuance to the earliest redemption date. The Company recorded accretion totaling $0.2 million in 2022 and 2021, respectively. As of December 31, 2022 and 2021, the full redemption value of the Preferred Stock is $171.9 million and $171.8 million, respectively. As of December 31, 2022, no shares have been redeemed.

The Company has assessed whether there are any embedded derivatives or beneficial conversion option relating to the Preferred Stock and determined that none exist.

Anti-Dilution Protection

If the Company issues additional securities without consideration or for consideration per share less than the initial issue price of a series of Preferred Stock (other than certain customary exceptions), then the conversion price for the applicable series of Preferred Stock will be adjusted using a broad-based weighted average anti-dilution formula.

Common Stock

As of December 31, 2022, the Company's certificate of incorporation, as amended and restated, authorized the Company to issue 147,892,358 shares of common stock, $0.001 par value per share. The common stockholders are entitled to receive dividends, in subordination to the Series A, Series B, Series C and Series D Preferred Stock, if and when declared by the board of directors. In the event of dissolution, the common stock ranks in seniority behind the Series A, Series B, Series C and Series D Preferred Stock. The holders of common stock are entitled to one vote for each share held.

Shares of common stock reserved for future issuance, on an as-if-converted basis, as of December 31, 2022 and 2021, consists of the following:

	Year Ended December 31,	
	2022	2021
Series A redeemable convertible preferred stock	1,408,502	1,408,502
Series B-1 redeemable convertible preferred stock	2,038,903	2,038,903
Series B-2 redeemable convertible preferred stock	3,138,208	3,138,208
Series C redeemable convertible preferred stock	2,241,740	2,241,740
Series D redeemable convertible preferred stock	3,666,526	3,666,526
Stock options, issued and outstanding	2,529,982	1,759,275
Common stock, available for future issuance	255,685	830,774
	15,279,546	15,083,928

9. Equity Based Compensation

2018 Equity Incentive Plan

In December 2018, the Company adopted the 2018 Equity Incentive Plan (the "2018 Plan") which provides for the Company to grant incentive stock options or nonqualified stock options for the purchase of common stock, or restricted shares or other stock-based awards, to employees, members of the board of directors and consultants of the Company. The Company assumed all of the outstanding options under the amended and restated Equity Incentive Plan of Turnstone Biologics Inc. dated October 1, 2016 (the "Prior Plan") in connection with the corporate reorganization in December 2018. However, there were no changes to the terms of the options requiring modification accounting.

All options granted under the 2018 Plan will have an exercise price, a vesting period determine by the Company's board of directors and ten-year term as determined and approved by the Company's board of directors (the board of directors may delegate authority to one of the boards' committees) at the time of grant. The terms and conditions of the restricted shares are determined by the board of directors at the grant date.

The majority of grants outstanding have been approved with a four-year vesting schedule with 25% vesting after one year and the remainder vesting evenly over the remaining 36 months. The total number of shares of common stock that may be issued under the 2018 Plan was 4,382,011 shares when the 2018 Plan was adopted. As of December 31, 2022, 255,686 shares were available to be issued under the 2018 Plan.

A summary of the stock option activity under the 2018 Plan is as follows:

	Number of Shares Underlying Outstanding Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding—December 31, 2020	1,569,725	$ 6.30	6.9	$ 6,300
Options granted	358,116	$ 10.62		
Options exercised	(96,586)	$ 0.31		
Options canceled/forfeited	(71,980)	$ 7.90		
Outstanding—December 31, 2021	1,759,275	$ 7.26	7.2	$ 6,912
Options granted	951,565	$ 11.02		
Options exercised	(61,355)	$ 2.55		
Options canceled/forfeited	(119,503)	$ 5.75		
Outstanding—December 31, 2022	2,529,982	$ 8.86	6.8	$ 5,886
Exercisable—December 31, 2022	1,231,412	$ 6.86	5.4	$ 5,290
Vested and expected to vest—December 31, 2022	2,529,982	$ 8.86	6.8	$ 5,886

The fair value of each stock option granted to employees and directors was estimated on the date of grant using the Black-Scholes option-pricing model, with the following range of assumptions for the years ended December 31, 2022 and 2021:

	Year Ended December 31,	
	2022	2021
Employee Stock Options:		
Risk-free interest rate	1.7-3.6%	0.8-1.1%
Expected term (in years)	5.7-6.0	5.6-6.1
Dividend yield	0%	0%
Volatility	86.3-87.2%	89.8-91.2%
Weighted-average exercise price of stock options granted	$ 11.02	$ 10.62

The expense related to awards granted to employees and directors was $4.4 million and $2.6 million for the years ended December 31, 2022 and 2021, respectively. The weighted-average grant date Black Scholes fair market value of options granted to employees, directors and consultants during the years ended December 31, 2022 and 2021 was $7.91 per share and $9.02 per share, respectively.

Stock-based compensation expense for all stock awards included in the Company's statements of operations as of December 31, 2022 and 2021 are as follows (*in thousands*):

	Year Ended December 31,	
	2022	2021
Research and development	$ 2,167	$ 1,852
General and administrative	2,201	760
Total stock-based compensation	$ 4,368	$ 2,612

As of December 31, 2022, the Company was authorized to issue a total of 147,892,358 shares of common stock and 255,686 shares of common stock were available for future grant. As of December 31, 2022, the Company had unrecognized stock-based compensation expense of $8.9 million, related to stock options, which is expected to be recognized over a weighted-average period of 2.7 years.

Restricted Stock

In December 2020, Langer received 725,290 shares as payment related to the Myst Merger Agreement. Of the total issued, the Company restricted 362,960 shares to vest over a four-year period in equal annual installments. As of December 31, 2022, 181,480 shares remain unvested and the Company had $1.8 million in unrecognized stock-based compensation expense related to unvested restricted stock which is expected to be recognized evenly over 2.0 years.

10. Income Taxes

The following table represents the components of net income (loss) before income taxes (*in thousands*):

	Year Ended December 31,	
	2022	2021
Domestic	$ (22,065)	$ (32,658)
Foreign	(8,628)	66,359
Income (loss) before provision for income taxes	$ (30,693)	$ 33,701

The income tax provision consisted of the following for the years ended December 31, 2022 and 2021 (*in thousands*):

	Year Ended December 31,	
	2022	2021
Current:		
Federal	$ 80	$ 96
State taxes	61	336
Deferred:		
Federal	—	—
State	—	—
Total tax provision	$ 141	$ 432

The reconciliation of the expected provision for income tax recovery to the actual provision for income tax expense reported for the years ended December 31, 2022 and 2021 is as follows *(in thousands)*:

	Year Ended December 31,	
	2022	2021
Income (loss) before income taxes	$(30,693)	$33,701
Statutory rate	21%	21%
Expected income tax expenses (recovery)	(6,446)	7,037
Permanent differences	260	138
Foreign rate differential	(462)	3,871
Canada ITC credits	(1,617)	(1,661)
Federal R&D credit	(1,637)	—
Unrecognized tax benefit	22	—
State tax	(2,422)	(569)
Myst transaction	1,877	525
Other	(4)	(1,081)
Change in valuation allowance	10,570	(7,828)
Provision for income taxes (recovery) expenses	$ 141	$ 432

The significant components of the Company's deferred income tax assets as of December 31, 2022 and 2021 are as follows (*in thousands*):

	Year Ended December 31,	
	2022	2021
Deferred tax assets:		
Credits	$ 7,960	$ 4,825
Accruals	108	353
Stock compensation	1,111	506
State taxes	33	15
Right-of-use lease liability	1,319	666
Property and equipment	144	173
Intangibles	16,858	3,308
Tax losses	7,253	4,299
Deferred revenue	5,290	12,918
Total deferred tax assets	$ 40,076	$ 27,063
Deferred tax liability:		
Right-of-use lease asset	$ (1,174)	$ (635)
Property and equipment	(1,665)	(80)
Total deferred tax liability	$ (2,839)	$ (715)
Valuation allowance	(37,237)	(26,348)
Net deferred tax assets	$ —	$ —

As of December 31, 2022, the Company had approximately $2.3 million of U.S. federal and $1.0 million of state net operating loss, or NOL, carryforwards. The Company's U.S. federal NOL carryforwards can be carried forward indefinitely, but use of such carryforwards is limited to 80% of taxable income. If not utilized, the Company's state NOL carryforwards will begin to expire at various dates beginning in 2038.

Furthermore, under Section 382 of the Internal Revenue Code of 1986, the amount of benefits from the Company's NOL carryforwards may be impaired or limited if we incur a cumulative ownership change of more

than 50% over a three-year period. The Company has not conducted an analysis as to whether such a change of ownership has occurred, but if such a change has occurred or occurs in the future, the Company will be limited regarding the amount of NOL carryforwards that can be utilized annually in the future to offset taxable income. Any such annual limitation may significantly reduce the value of the Company's NOL carryforwards before they expire, which could result in greater tax liabilities than the Company would incur in the absence of such a limitation.

The Company has determined that it is not more likely than not that it will realize all of its deferred tax assets, and therefore a valuation allowance has been established against the deferred tax assets for Canadian and U.S. State jurisdictions. The Company files federal and provincial income tax returns in Canada and federal, state and local U.S. Income tax returns.

For the Canadian Entity the Company estimates SR&ED expenditures and claims investment tax credits for income tax purposes based on management's interpretation of the applicable legislation in the Income Tax Act (the "Act") and related provincial legislation. These claims are subject to audit by the tax authorities. In the opinion of management, the treatment of research and development expenditures for income tax purposes is appropriate. Any difference between recorded refundable tax credits and amounts ultimately received is recorded when the amount becomes known.

In the ordinary course of its business for the U.S. entity, the Company incurs costs that, for tax purposes, are determined to be qualified research expenditures within the meaning of IRC §41 and are, therefore, eligible for the Increasing Research Activities credit under IRC §41. The federal Research and Development credit ("R&D Credit") carryforward as of December 31, 2022 is $2.3 million that will expire in 2039, and the California R&D credit carryforward of $1.0 million as of December 31, 2022 has no expiration date.

As of December 31, 2022, the Company has total uncertain tax benefits of $0.8 million related to the R&D credit, of which $0.8 million is recorded as a reduction of the deferred tax asset related credit carryforward. If the uncertain tax benefits were to be recognized, there would be an impact to the effective tax rate. No interest or penalties have been recorded related to the uncertain tax positions. The Company's policy is to include interest and penalties related to uncertain tax benefits as other expense.

The aggregate changes in the balances of the Company's gross unrecognized tax benefits during 2022 were as follows (*in thousands*):

December 31, 2021	$ (72)
Increases in balances related to tax positions taken during a prior period	—
Increases in balances related to tax positions taken during the current period	(785)
Decreases in balances related to tax positions tax during the prior period	—
December 31, 2022	$(857)

It is not expected that there will be a significant change in uncertain tax position in the next 12 months.

The Company is subject to U.S. federal and state income tax as well as to income tax in multiple state jurisdictions. In the normal course of business, the Company is subject to examination by tax authorities. As of the date of the consolidated financial statements, there are no tax examinations in progress. The statute of limitations for tax years ended after December 31, 2019 are open for state and federal tax purposes.

At December 31, 2022, the Canadian Entity had carryforward balances which are available to offset future years' taxable income. At December 31, 2022 the Company had non-refundable investment tax credits amounting to $7.3 million that begin to expire in 2038 and an SR&ED expenditure pool of $22.2 million that does not expire. During 2022 the Company expects to utilize $0.0 million of non-capital losses and $1.1 million of investment tax credits to offset its 2022 Canada tax liability.

On June 29, 2020, the California governor signed Assembly Bill 85 (“A.B. 85”), which includes several tax measures close a gap in the budget created by the COVID-19 pandemic. The most significant provisions of the bill are (i) the suspension of taxpayers’ ability to deduct net operating losses during tax years 2020, 2021, and 2022; and (ii) the limitation on the amount of tax that can be offset by business credits to $5 million for tax years 2020, 2021, and 2022. For corporate taxpayers, if their income subject to California taxation is less than $1.0 million the suspension does not apply. The Company is not expecting its California net operating loss carryover to be subject to suspension during the 2021 tax year. On February 9, 2022, the California Governor signed Senate Bill 113 “SB 113”. SB 113 removes the suspension of NOL and the limitation on the amount of tax that can be offset by business credits to $5.0 million provisions included in A.B. 85 for the 2022 tax year. Thus, the Company is not expecting its net operating loss carryover to be limited for the tax year ending December 31, 2022.

11. Leases

Operating Leases

The Company leases office space for its corporate headquarters, located in San Diego, California, New York, New York and Ontario, Canada and laboratories throughout Canada. Operating lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term. In calculating the present value of the lease payments, the Company has elected to utilize its incremental borrowing rate based on the original lease term and not the remaining lease term. The Company determines if an arrangement is a lease by considering whether there is an identified asset and the contract conveys the right to control its use. Leases with an initial term of 12 months or less are not recorded on the balance sheet. The Company’s lease terms may include options to extend or terminate a lease. If the lease includes non-lease components (i.e., common area maintenance) that are paid separately from rent based on actual costs incurred and therefore are not included in the right-of-use asset and lease liability but are reflected as an expense in the period incurred.

In July 2018, the Company entered into a lease agreement for approximately 6,500 square feet of office space in New York, New York. The term of the lease is seven years and three months, starting November 1, 2018. The lease requires the Company to share in prorated expenses and property taxes based upon actual amounts incurred. The lease contains escalating rent clauses which require higher rent payments in future years. In September 2022, the Company made the decision to sublease this space and executed a sublease in November 2022 for the remaining term of the lease. Since the Company is still responsible for making the lease payments, there was no impact to the operating lease liability from the sublease. However, since the sublease payment does not cover the entire lease payment, the carrying value of the operating right of use asset, including leasehold improvements, was analyzed and determined to be impaired resulting in a $0.5 million reduction in the operating right of use asset as of September 2022.

In January 2019, the Company executed an agreement to lease approximately 6,000 square feet of laboratory space at Carleton University in Ontario, Canada. The initial term of the lease is three years and started in November 2019 at a rate of approximately $0.1 million per year. In November 2022 the lease was extended for a one year period with the option to renew for an additional one year term.

In May 2019, the Company entered into a noncancelable operating lease for approximately 9,423 square feet located at 12 York Street, Ontario, Canada. The term of the lease is five years, starting December 1, 2019 and includes one renewal option for a period of five years. The lease requires the Company to share in prorated expenses and property taxes based upon actual amounts incurred. The lease contains escalating rent clauses which require higher rent payments in future years.

In June 2021, the Company entered into a lease agreement for approximately 19,474 square feet of office and laboratory space in San Diego, California. The initial term of the lease is 38 months with one renewal option for a period of three years and commenced in March 2022. The lease requires the Company to share in

prorated expenses and property taxes based upon actual amounts incurred. The lease contains escalating rent clauses which require higher rent payments in future years.

The Company recorded rent expense of $2.3 million and $1.2 million for the years ended December 31, 2022 and 2021, respectively. Cash paid for operating lease liabilities was $2.0 million and $0.8 million for the years ended December 31, 2022 and 2021, respectively. The table below summarizes the Company's total lease costs included in its consolidated financial statements, as well as other required quantitative disclosures (*in thousands*).

	Year Ended December 31, 2022
Operating lease cost	$ 1,956
Short-term lease costs	263
Variable leases costs	52
Sublease income	(21)
Total lease cost	$ 2,250

	Year Ended December 31, 2021
Operating lease costs	$ 829
Short-term lease costs	284
Variable leases costs	110
Total lease costs	$ 1,223

The present value assumptions used in calculating the present value of the lease payments were as follows:

	Year Ended December 31, 2022
Weighted-average remaining lease term in years	2.6
Weighted-average discount rate	4.96%

The minimum aggregate future operating lease commitments at December 31, 2022 are as follows (*in thousands*):

	Minimum Lease Payments
2023	$ 2,168
2024	2,131
2025	1,106
2026	101
2027	—
Total undiscounted lease payments	$ 5,506
Less: imputed interest	(339)
Total operating lease liability	5,166
Less: current portion of operating lease liability	(1,961)
Operating lease liability, noncurrent	$ 3,205

12. Net Earnings (Loss) per Share

The following table sets forth the computation of the basic and diluted net loss per share during the years ended December 31, 2022 and 2021 (*in thousands, except share and per share data*):

	Year Ended December 31,	
	2022	2021
Net income (loss)	$ (30,834)	$ 33,269
Less: accretion of Preferred Stock to redemption value	(190)	(190)
Less: undistributed earnings allocable to participating securities	—	(29,600)
Net income (loss) attributable to common stockholders, basic and diluted	$ (31,024)	$ 3,479
Weighted-average number of basic shares used in computing net earnings (loss) per share	2,484,569	2,149,550
Effect of dilutive securities		
Stock options	—	484,148
Restricted stock	—	68,644
Weighted-average number of diluted shares used in computing net earnings (loss) per share	2,484,569	2,702,347
Net earnings (loss) per share		
Basic	$ (12.49)	$ 1.62
Diluted	$ (12.49)	$ 1.29

The following outstanding potentially dilutive shares were excluded from the computation of diluted net loss per share attributable to common stockholders for the year ended December 31, 2022, because including them would have been anti-dilutive (on an as-converted basis).

Redeemable convertible preferred stock	12,493,879
Options to purchase common stock	2,529,982
Total	15,023,861

13. Legal Proceedings

The Company is not a party to any material legal matters or claims and does not have contingency reserves established for any litigation liabilities as of December 31, 2022 and 2021.

14. Subsequent Events

The Company evaluated subsequent events through May 12, 2023, which represents the date the consolidated financial statements were issued, for events requiring adjustment to or disclosure in the consolidated financial statements. The Company has further evaluated subsequent events for disclosure purposes through July 17, 2023. Except as discussed in the footnotes or below, there are no events that require adjustment to or disclosure in the consolidated financial statements.

On July 14, 2023, the Company effected a 1-for-7.9872 reverse stock split of its common stock. The par value and the authorized number of shares of the common stock were not adjusted as a result of the reverse stock split. The reverse stock split resulted in an adjustment to the Preferred Stock conversion price to reflect a proportional decrease in the number of shares of common stock to be issued upon conversion. The accompanying consolidated financial statements and notes to the consolidated financial statements give retroactive effect to the reverse stock split for all periods presented.

Turnstone Biologics Corp.
Condensed Consolidated Balance Sheets
(unaudited)
(in thousands, except share and per share amounts)

	March 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 33,512	$ 34,731
Restricted cash	116	382
Short-term investments	30,457	47,330
Accounts receivable - collaboration agreement	4,483	8,728
Prepaid and other current assets	6,870	6,830
Total current assets	75,438	98,001
Other assets, noncurrent	2,804	2,582
Operating lease right of use assets	4,169	4,631
Property and equipment, net	9,852	9,724
Total assets	$ 92,263	$ 114,938
Liabilities, redeemable convertible preferred stock and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 844	$ 3,435
Accrued expenses and other current liabilities	12,583	14,287
Operating lease liability, current	1,980	1,961
Deferred revenue, current	0	15,144
Total current liabilities	15,407	34,827
Deferred revenue, noncurrent	0	4,162
Operating lease liability, noncurrent	2,713	3,205
Other liabilities, noncurrent	2,402	2,267
Total liabilities	20,522	44,461
Redeemable convertible preferred stock		
Series A redeemable convertible preferred stock $0.001 par value; 11,250,000 shares authorized, issued and outstanding at March 31, 2023 and December 31, 2022 (liquidation preference of $8,643 as of March 31, 2023)	8,643	8,643
Series B-1 redeemable convertible preferred stock $0.001 par value; 16,285,156 shares authorized, issued and outstanding at March 31, 2023 and December 31, 2022 (liquidation preference of $12,611 at March 31, 2023)	12,611	12,611
Series B-2 redeemable convertible preferred stock $0.001 par value; 25,065,538 shares authorized, issued and outstanding at March 31, 2023 and December 31, 2022 (liquidation preference of $28,860 at March 31, 2023)	28,860	28,860
Series C redeemable convertible preferred stock $0.001 par value; 17,905,288 shares authorized, issued and outstanding at March 31, 2023 and December 31, 2022 (liquidation preference of $42,100 at March 31, 2023)	42,100	42,100
Series D redeemable convertible preferred stock $0.001 par value; 29,285,356 and 29,285,356 shares authorized, issued and outstanding at March 31, 2023 and December 31, 2022 (liquidation preference of $80,000 at March 31, 2023)	79,750	79,730
Total redeemable convertible preferred stock	171,964	171,944
Stockholders' deficit		
Common stock, $0.001 par value; 147,892,358 shares authorized, 3,028,136 and 2,915,757 shares issued and outstanding as of March 31, 2023 and December 31, 2022, respectively	3	3
Additional paid-in capital	21,556	20,501
Accumulated other comprehensive loss	(292)	(413)
Accumulated deficit	(121,490)	(121,558)
Total stockholders' deficit	(100,223)	(101,467)
Total liabilities, redeemable convertible preferred stock and stockholders' deficit	$ 92,263	$ 114,938

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

Turnstone Biologics Corp.
Condensed Consolidated Statements of Operations and Comprehensive Income (Loss)
(unaudited)
(in thousands, except share and per share data)

	Three Months Ended March 31,	
	2023	2022
Collaboration revenue	$ 19,306	$ 10,718
Operating expenses:		
Research and development	15,668	18,701
General and administrative	4,032	4,698
Total operating expenses	19,700	23,399
Loss from operations	(394)	(12,681)
Other income (expense), net	380	85
Net income (loss) before income taxes	(14)	(12,596)
Benefit (provision) for income taxes	82	(20)
Net income (loss)	$ 68	$ (12,616)
Other comprehensive income (loss):		
Unrealized gain (loss) on available-for-sale debt securities	121	(94)
Total comprehensive income (loss)	$ 189	$ (12,710)
Net income (loss)	$ 68	$ (12,616)
Less: accretion of preferred stock to redemption value	$ (20)	$ (57)
Less: undistributed earnings allocable to participating securities	$ (48)	$ —
Net income (loss) attributable to common stockholders, basic and diluted	$ —	$ (12,673)
Weighted-average number of shares used in computing net earnings (loss) per share		
Basic	2,786,017	2,279,287
Diluted	2,786,017	2,279,287
Net income (loss) per share attributable to common stockholders		
Basic	$ 0.00	$ (5.56)
Diluted	$ 0.00	$ (5.56)

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

Turnstone Biologics Corp.
Condensed Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Deficit
(unaudited)
(in thousands, except share amounts)

	Series A Redeemable Convertible Preferred Stock		Series B-1 Redeemable Convertible Preferred Stock		Series B-2 Redeemable Convertible Preferred Stock		Series C Redeemable Convertible Preferred Stock		Series D Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at December 31, 2021	11,250,000	$ 8,582	16,285,156	$ 12,611	25,065,538	$ 28,860	17,905,288	$ 42,048	29,285,356	$ 79,653	2,550,478	$ 3	$ 9,115	$ (245)	$ (90,724)	$ (81,851)
Accretion of redeemable convertible preferred stock issuance costs		$ 21						$ 17		$ 19			$ (57)			(57)
Exercise of stock options											1,064		$ 10			10
Stock-based compensation expense													$ 962			962
Unrealized loss on available-for-sale debt securities														$ (94)		(94)
Net loss															$ (12,616)	(12,616)
Balance at March 31, 2022	11,250,000	$ 8,603	16,285,156	$ 12,611	25,065,538	$ 28,860	17,905,288	$ 42,065	29,285,356	$ 79,672	2,551,542	$ 3	$ 10,030	$ (339)	$ (103,340)	$ (93,646)
Balance at December 31, 2022	11,250,000	$ 8,643	16,285,156	$ 12,611	25,065,538	$ 28,860	17,905,288	$ 42,100	29,285,356	$ 79,730	2,915,757	$ 3	$ 20,501	$ (413)	(121,558)	(101,467)
Moffitt performance based common stock award											91,721					—
Accretion of redeemable convertible preferred stock issuance costs										$ 20			$ (20)			(20)
Exercise of stock options											20,658		$ 83			83
Stock-based compensation expense													$ 992			992
Unrealized gain on available-for-sale debt securities														$ 121		121
Net income															$ 68	68
Balance at March 31, 2023	11,250,000	$ 8,643	16,285,156	$ 12,611	25,065,538	$ 28,860	17,905,288	$ 42,100	29,285,356	$ 79,750	3,028,136	$ 3	$ 21,556	$ (292)	$ (121,490)	$ (100,223)

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

Turnstone Biologics Corp.
Condensed Consolidated Statements of Cash Flows
(unaudited)
(in thousands)

	Three Months Ended March 31,	
	2023	2022
Operating Activities		
Net income (loss)	$ 68	$ (12,616)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Stock-based compensation expense	992	962
Gain on disposal of property and equipment	(38)	—
Depreciation and amortization	709	711
Amortization/(Accretion) of premium on short term investments	(256)	109
Change in fair value of contingent consideration liability	615	346
Changes in operating assets and liabilities:		
Accounts receivable - collaboration agreement	4,245	855
Prepaid and other current assets	(262)	(1,345)
Tax liability	23	—
Operating lease liabilities	(11)	(138)
Accounts payable	(2,640)	(780)
Change in contingent consideration liability	(1,289)	—
Accrued compensation and other accrued liabilities	(20)	303
Deferred revenue	(19,306)	(4,862)
Net cash flows used in operating activities	(17,170)	(16,455)
Investing Activities		
Proceeds from maturities of short-term investments	17,250	13,000
Purchase of short-term investments	—	(13,105)
Proceeds from sale of property and equipment	130	—
Purchases of property and equipment	(880)	(613)
Net cash flows provided by (used in) investing activities	16,500	(718)
Financing Activities		
Payment of contingent consideration related to Myst milestone	(898)	—
Proceeds from exercise of stock options	83	10
Net cash flows provided by (used in) financing activities	(815)	10
Net decrease in cash, cash equivalents and restricted cash	(1,485)	(17,163)
Cash, cash equivalents and restricted cash at beginning of the period	35,113	123,763
Cash, cash equivalents and restricted cash at end of the period	$ 33,628	$ 106,600
Supplemental Disclosure of Non-Cash Investing and Financing Activities:		
Accretion of redeemable convertible preferred stock	20	57
Additions to ROU assets obtained from new operating leases	—	4,117
Equipment purchases included in accrued expenses	49	1,206

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

1. Nature of the Business and Basis of Presentation

Organization

Turnstone Biologics Corp. (the "Company" or "Turnstone") is a clinical stage biotechnology company focused on developing new medicines to treat and cure patients with solid tumors. Turnstone is pioneering a differentiated approach to tumor infiltrating lymphocytes ("TILs"). The Company is developing next generation TIL therapies by selecting the most potent and tumor-reactive T cells ("Selected TILs"). The Company has initiated two Phase 1 clinical trials for its lead Selected TIL product candidate, TIDAL-01, for the treatment of breast cancer, colorectal cancer, uveal melanoma and other non-cutaneous and cutaneous melanomas.

Turnstone Biologics Inc. ("Turnstone Canada") was incorporated as a Canadian corporation on March 27, 2014. On December 13, 2018, Turnstone Biologics Corp. was incorporated under the laws of the State of Delaware. On December 14, 2018, the Company completed a reorganization from Canada to the United States (the "Reorganization"). In connection with the Reorganization, all of the shareholders of Turnstone Canada exchanged their shares in Turnstone Canada for shares of the newly incorporated Delaware entity, as a result of which Turnstone Canada became the newly incorporated Delaware entity's wholly owned subsidiary. The corporate reorganization was a common control reorganization applied on a retrospective basis. The Company's headquarters are located in San Diego, California.

Liquidity and Capital Resources

Going Concern

The accompanying condensed consolidated financial statements have been prepared assuming the Company will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business, and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or amounts and classification of liabilities that may result from the outcome of this uncertainty. Management is required to perform a two-step analysis over the Company's ability to continue as a going concern. Management must first evaluate whether there are conditions and events that raise substantial doubt about the Company's ability to continue as a going concern (Step 1). If management concludes that substantial doubt is raised, management is also required to consider whether its plans alleviate that doubt (Step 2).

The Company reported net income in and negative cash flows from operations during the three months ended March 31, 2023 and management's cash flow forecasts indicate that based on the Company's expected future operating losses and negative cash flows, there is substantial doubt about the Company's ability to continue as a going concern for 12 months after the date the condensed consolidated financial statements for the three months ended March 31, 2023 were issued. The Company's ability to continue as a going concern is dependent upon its ability to raise additional funding. Management intends to raise additional capital through equity offerings, debt financings or other capital sources, including potential collaborations, licenses and other similar arrangements. However, the Company may not be able to secure additional financing in a timely manner or on favorable terms, if at all. Furthermore, if the Company issues equity securities to raise additional funds, its existing stockholders may experience dilution, and the new equity securities may have rights, preferences and privileges senior to those of the Company's existing stockholders. If the Company raises additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish valuable rights to its current and potential future product candidates and programs on terms that are not favorable to the Company. If the Company is unable to raise capital when needed or on attractive terms, it would be forced to delay, reduce or eliminate its research and development programs or other operations. If any of these events occur, the Company's ability to achieve the development and commercialization goals would be adversely affected.

Sources of Liquidity

Since the Company's inception, the Company has devoted substantially all of its efforts and financial resources to organizing and staffing the Company, business planning, raising capital, discovering product candidates and securing related intellectual property rights, and conducting research and development activities for its Selected TIL programs and product candidates. The Company does not have any products approved for sale, and has not generated any revenue from product sales and have incurred net losses since commencement of the Company's operations through March 31, 2023, except for the year ended December 31, 2021 and three months ended March 31, 2023. The Company's expenses primarily have been for research and development and related administrative costs. The Company has financed its operations through the issuance and sale of shares of the Company's redeemable convertible preferred stock and from collaboration received pursuant to certain collaboration agreements.

The Company had net income of $0.1 million for the three months ended March 31, 2023, an accumulated deficit of $121.5 million as of March 31, 2023, and will require substantial additional capital to fund operations for the next several years. As of March 31, 2023, the Company had $64.0 million of cash, cash equivalents, and short-term investments. Cash used in operating activities for the three months ended March 31, 2023 was $17.2 million. Management believes that the currently available resources, including cash, will not provide sufficient funds to enable the Company to meet its operating plan for at least the next 12 months from the date of issuance of these condensed consolidated financial statements.

The Company intends to fund future operations and future capital funding needs through equity and/or debt financings, as well as possible asset sales, licensing transactions, and collaborations or strategic partnerships with other companies. The sale of equity or convertible debt could result in additional dilution to stockholders. The incurrence of indebtedness would result in debt service obligations and could result in operating and financial covenants that would restrict the Company's operations. The Company can provide no assurance that sufficient financing will be available on acceptable terms, if at all. If the Company is not able to secure adequate additional funding it may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible, and/or suspend or curtail planned programs. Any of these actions could materially harm the Company's business.

Risks and Uncertainties

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations and the ability to secure additional capital to fund operations. Product candidates currently under development will require significant additional research and development efforts, including non-clinical and clinical testing and regulatory approval, prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure and extensive compliance and reporting capabilities. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

2. Summary of Significant Accounting Policies

Basis of Presentation of Unaudited Condensed Consolidated Financial Information

The accompanying condensed consolidated financial statements of the Company for the three months ended March 31, 2023 and 2022 have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") for interim financial information and pursuant to the requirements for reporting on Regulation S-X. Accordingly, they do not include all the information and footnotes required by GAAP for audited financial statements. However, such information reflects all adjustments (consisting solely of

normal recurring adjustments), which are, in the opinion of management, necessary for the fair presentation of the Company's financial position and results of operations. Results shown for interim periods are not necessarily indicative of the results that may be expected for the year ended December 31, 2023 or for any other period. The condensed consolidated balance sheet as of December 31, 2022 was derived from the audited consolidated financial statements included elsewhere in this prospectus. These condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements included elsewhere in this prospectus. Certain prior period amounts reported in the Company's condensed consolidated financial statements and accompanying notes have been reclassified to conform to the current period presentation. Any reference in these notes to applicable guidance is meant to refer to the authoritative accounting principles generally accepted in the United States as found in the Accounting Standard Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB").

Principles of Consolidation

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

Use of Estimates

The preparation of consolidated financial statements in accordance with GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. On an ongoing basis, management evaluates its estimates, including those related to accrued expenses, contingent liabilities, revenue recognition, the valuation of equity-based compensation, common stock, restricted common stock, and income taxes. The Company bases its estimates on various assumptions that the Company believes to be reasonable under the circumstances. Actual results could differ from those estimates.

Segment Reporting

The Company has determined that it operates and manages one operating segment, which is the business of developing and commercializing therapeutics. The Company's chief operating decision maker, its chief executive officer, reviews financial information on an aggregate basis for the purpose of allocating resources.

Cash and Cash Equivalents

Cash and cash equivalents consist of checking, money market and highly liquid investments that are readily convertible to cash and that have an original maturity of three months or less from the date of purchase. The carrying amounts approximate fair value due to the short maturities of these instruments.

Restricted Cash and Investments

Restricted cash consists of certificate of deposit accounts that are pledged as collateral for the Company's San Diego facility lease as of March 31, 2023 and the San Diego and New York facility leases as of December 31, 2022. Restricted cash was approximately $0.1 million and $0.4 million as of March 31, 2023 and December 31, 2022, respectively.

The Company invests its excess cash in investment grade, short-term, fixed income securities and recognizes purchased securities on the settlement date. All investments have been classified as "available-for-sale" in the consolidated balance sheets, and are carried at estimated fair value based upon quoted market prices or pricing models for similar securities. Management determines the appropriate classification of its investments at the time of purchase and re-evaluates such designation as of each balance sheet date.

The Company assesses its available-for-sale securities under the available-for-sale security impairment model in ASC 326 as of each reporting date in order to determine if a portion of any decline in fair value below carrying value is the result of a credit loss. The Company records credit losses in the condensed consolidated statements of operations and comprehensive loss as credit loss expense, which is limited to the difference between the fair value and the amortized cost of the security. To date, the Company has not recorded any credit losses on its available-for-sale securities. Declines in fair value below carrying value attributable to non-credit related factors are recorded as accumulated other comprehensive income, which is a separate component of stockholders' equity.

Realized gains and losses are reported in other income (expense), net. Interest on short-term investments is included in interest and other income, net. The Company's investments are classified as current assets, even though the stated maturity date may be one year or more beyond the current balance sheet date, which reflects management's intention to use the proceeds from sales of these securities to fund its operations, as necessary.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash and cash equivalents, investments and restricted cash. The Company's investment policy restricts cash investments to high credit quality, investment grade investments. The Company's investment policy provides guidelines and limits regarding investment type, concentration, credit quality, and maturity aimed at maintaining sufficient liquidity to satisfy operating and working capital requirements along with strategic initiatives, preserving capital, and minimizing risk of capital loss while generating returns on its investments. The Company is exposed to credit risk in the event of default by the issuer or the institutions holding the cash and cash equivalents to the extent of the amounts recorded on the balance sheets.

The Company records accounts receivable for amounts invoiced to a collaborator, for which the Company has an unconditional right to consideration. For amounts to which the Company has an unconditional right to consideration but has not yet invoiced the collaborator, the Company records unbilled accounts receivable. The Company estimates an allowance for credit losses based on the creditworthiness of its collaborator, current economic conditions and future economic conditions, as may be applicable. If a receivable is deemed to be uncollectible, the balance is charged against the allowance. As of March 31, 2023 and December 31, 2022, Takeda accounted for 98% and 100%, respectively, of the Company's accounts receivable balance and no allowance was recorded. Accounts receivable and unbilled accounts receivable are presented in accounts receivable, net on the condensed consolidated balance sheets. During the three months ended March 31, 2023 and 2022, the Company did not recognize any charges for write-offs of accounts receivable.

The Company has no off-balance sheet risk, such as foreign exchange contracts, option contracts or other foreign-hedging arrangements.

Fair Value Measurements

The Company applies fair value accounting for all financial assets and liabilities and non-financial assets and liabilities that are recognized or disclosed at fair value in the consolidated financial statements on a recurring basis. Fair value is defined as the exchange price that would be received for an asset or an exit price that would be paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The fair value hierarchy requires that an entity maximize the use of observable inputs when estimating fair value. The fair value hierarchy includes the following three-level classification which is based on the market observability of the inputs used for estimating the fair value of the assets or liabilities being measured:

Level 1 – Quoted market prices in active markets for identical assets or liabilities.

Level 2 – Observable inputs other than quoted prices in active markets for identical assets and liabilities, quoted prices for identical or similar assets or liabilities in inactive markets, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 – Inputs that are generally unobservable and typically reflect management's estimate of assumptions that a market participant would use in pricing the asset or liability.

Fair value accounting is applied for all financial assets and liabilities and non-financial assets and liabilities that are recognized at fair value in the consolidated financial statements on a recurring basis (at least annually). To the extent the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair values requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized as Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

Investment Tax Credits

The Company claims Scientific Research and Experimental Development ("SR&ED") deductions and related investment tax credits for income tax purposes based upon management's interpretation of the applicable legislation in the *Income Tax Act* (Canada). Investment tax credits are subject to Canada Revenue Agency review and assessment of the eligibility of the Company's research expenditures. These tax credits are applied to reduce the related research and development expenses incurred in the year recognized. Actual investment tax credits received may differ from those estimated and recorded in these consolidated financial statements.

Property and Equipment

Property and equipment are recorded at cost, less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the respective assets, which are two to three years for computer equipment and software, and five years for laboratory, office equipment and furniture. Leasehold improvements are amortized over the shorter of the useful life or the remaining term of the lease.

Impairment of Long-Lived Assets

The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. Recoverability of these assets is determined by comparing the forecasted undiscounted net cash flows of the operation to which the assets relate to the carrying amount. If the operation is determined to be unable to recover the carrying amount of its assets, then these assets are written down first, followed by other long-lived assets of the operation to fair value. Fair value is determined based on discounted cash flows or appraised values, depending on the nature of the assets. For the three months ended March 31, 2023 and 2022, there was no impairment recorded in losses recognized for long-lived assets.

Revenue Recognition

The Company enters into collaboration arrangements that may include the receipt of payments for up-front license fees, success-based milestone payments, full time equivalent based payments for research services, and royalties on any future sales of commercialized products that result from the collaborations.

Effective January 1, 2017, the Company adopted the provisions of ASC Topic 606, *Revenue from Contacts with Customers* ("ASC 606"). Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects 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, the Company performs the following five steps: (i) identification of the contract(s) with the customer, (ii) identification of the promised goods or services in the contract and determination of whether the promised goods or services are performance obligations, (iii) measurement of the transaction price, (iv) allocation of the transaction price to the performance obligations, and (v) recognition of revenue when (or as) the Company satisfies each performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect consideration it is entitled to in exchange for the goods or services it transfers to the customer.

The Company accounts for a contract with a customer that is within the scope of ASC 606 when all of the following criteria are met: (i) the arrangement has been approved by the parties and the parties are committed to perform their respective obligations, (ii) each party's rights regarding the goods or services to be transferred can be identified, (iii) the payment terms for the goods and services to be transferred can be identified, (iv) the arrangement has commercial substance and (v) collection of substantially all of the consideration to which the Company will be entitled in exchange for the goods or services that will be transferred to the customer is probable.

The Company estimates the transaction price based on the amount of consideration the Company expects for transferring the promised goods or services in the contract. The consideration may include both fixed consideration and variable consideration. At the inception of each arrangement that includes variable consideration, the Company evaluates the amount of the potential payments and the likelihood that the payments will be received. The Company utilizes either the most likely amount method or expected value method to estimate the transaction price based on which method better predicts the amount of consideration expected to be received. If it is probable that a significant revenue reversal would not occur, the variable consideration is included in the transaction price.

For arrangements that include development and regulatory milestone payments, 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 revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company's control or the licensee's control, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. At the end of each reporting period, the Company re-evaluates the probability of achievement of such milestones and any related constraint, and if necessary, adjusts the estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect collaboration revenue and net income (loss) in the period of adjustment.

For sales-based royalties, including milestone payments based on the level of sales, the Company determines whether the sole or predominant item to which the royalties relate is a license. When the license is the sole or predominant item to which the sales-based royalty relates, the Company recognizes revenue at the later of: (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

The Company allocates the transaction price based on the estimated standalone selling price. The Company must develop assumptions that require judgment to determine the standalone selling price for each performance obligation identified in the contract. The Company utilizes key assumptions to determine the standalone selling price, which may include other comparable transactions, pricing considered in negotiating the transaction and the estimated costs. Certain variable consideration is allocated specifically to one or more performance obligations in a contract when the terms of the variable consideration related to the satisfaction of the performance obligation and the resulting amounts allocated to each performance obligation are consistent with the amounts the Company would expect to receive for each performance obligation.

For performance obligations, which consist of licenses and other promises, the Company utilizes judgment to assess the nature of the combined performance obligation in order to determine whether the

combined performance obligation is satisfied over time or at a point in time. The Company determines the appropriate method of measuring progress of combined performance obligations satisfied over time for purposes of recognizing revenue determined on a contract by contract basis (See *Note 6 - Agreements* for additional information). The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition. If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company will recognize revenue from non-refundable, up-front fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license.

The Company receives payments from customers based on billing schedules established in each contract. Up-front payments and fees are recorded as deferred revenue upon receipt or when due until the Company performs its obligations under these arrangements. Amounts are recorded as accounts receivable when the Company's right to consideration is unconditional.

Research and Development Expenses

Research and development costs are expensed as incurred. Research and development costs consist of payroll and other personnel-related expenses, materials and supplies, preclinical expenses, manufacturing expenses, contract research and development services, and consulting costs, as well as allocations of facilities and other overhead costs. Costs of certain development activities, such as manufacturing, are recognized based on an evaluation of the progress to completion of specific tasks. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the consolidated financial statements as prepaid or accrued research and development costs. Non-refundable advance payments for goods or services to be received in the future for use in research and development activities are deferred and capitalized. The capitalized amounts are expensed as the related goods are delivered or the services are performed. Costs associated with collaboration agreements are included in research and development expense. Assets acquired that are used for research and development and which have no alternative use are expensed to research and development costs.

Preclinical and Clinical Trial Accruals

The Company makes estimates of its accrued expenses as of each balance sheet date in the consolidated financial statements based on the facts and circumstances known at that time. Accrued expenses for preclinical studies and clinical trials are based on estimates of costs incurred and fees that may be associated with services provided by contract research organizations ("CROs"), clinical trial investigational sites and other clinical trial-related activities. Payments under certain contracts with such parties depend on factors such as successful enrollment of patients, site initiation and the completion of clinical trial milestones. In accruing for these services, the Company estimates the time period over which services will be performed and the level of effort to be expended in each period. If possible, the Company obtains information regarding unbilled services directly from these service providers. However, the Company may be required to estimate these services based on other available information. If the Company underestimates or overestimates the activities or fees associated with a study or service at a given point in time, adjustments to research and development expenses may be necessary in future periods. Historically, estimated accrued liabilities have approximated actual expense incurred. Subsequent changes in estimates may result in a material change in accruals.

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.

Stock-Based Compensation

The Company measures the cost of employee, nonemployee and director services received in exchange for an award of equity instruments based on the fair value of the award on the date of grant and recognizes the related expense over the period during which the employee, nonemployee or director is required to provide service in exchange for the award on a straight-line basis.

The Company estimates the fair value of options granted using the Black-Scholes option pricing model ("Black-Scholes") and the fair value of common stock to determine the fair value of restricted stock. The determination of fair value for stock-based awards on the date of grant using an option-pricing model requires management to make certain assumptions regarding a number of variables. Upon adoption of ASU 2016-09, the Company can make an accounting policy election to either estimate the number of share-based awards that are expected to vest, or account for forfeitures when they occur. The Company elected to account for forfeitures when they occur. As such, the Company recognizes stock-based compensation expense, over the requisite service period, based on the vesting provisions of the individual grants.

The Black-Scholes option pricing model requires inputs based on certain subjective assumptions, including (a) the expected stock price volatility, (b) the expected term of the award, (c) the risk-free interest rate and (d) expected dividend yields. Due to the lack of a public market for the Company's common stock and lack of company- specific historical and implied volatility data, the Company has based its computation of expected volatility on the average historical volatility of a representative group of public companies with similar characteristics to the Company, including stage of product development and life science industry focus. The historical volatility is calculated based on a period of time commensurate with the expected term. The Company uses the simplified method as prescribed by the U.S. Securities and Exchange Commission Staff Accounting Bulletin No. 107, *Share-Based Payment*, to calculate the expected term for options granted to employees as it does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. The expected term is applied to the stock option grant group as a whole, as the Company does not expect substantially different exercise or post-vesting termination behavior among its employee population. The risk-free interest rate is based on a treasury instrument whose term is consistent with the expected term of the stock options. The expected dividend yield is assumed to be zero as the Company has never paid dividends and has no current plans to pay any dividends on its common stock.

Determination of Fair Value of Common Stock

There are significant judgments and estimates inherent in the determination of the fair value of the Company's common stock. These estimates and assumptions include a number of objective and subjective factors, including, among other things, external market conditions, the prices at which the Company sold shares of its convertible preferred stock, the superior rights and preferences of securities senior to its common stock at the time of, and the likelihood of, achieving a liquidity event, such as an initial public offering or sale of the Company. The approach to estimating the fair market value of common stock is consistent with the methods outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, *Valuation of Privately-Held Company Equity Securities Issued as Compensation* (the "Practice Aid").

In valuing the Company's common stock, the equity value of the business was determined using the backsolve method, a form of the subject company transaction method, wherein the equity value for a privately held company is derived from a recent transaction in the company's own securities. The value is then allocated using the hybrid method allocation methodology. For grants made prior to September 30, 2018, in accordance with the Practice Aid, the Company determined the option pricing method ("OPM"), was the most appropriate method for determining the fair value of the Company's common stock based on its stage of development and other relevant factors. For grants made subsequent to September 30, 2018, the Company used a hybrid method, which is a hybrid between the OPM and the probability-weighted expected return method ("PWERM"). The hybrid method is a combination of the PWERM and OPM. The OPM allocates the overall Company value to the

various share classes based on differences in liquidation preferences, participation rights, dividend policy and conversion rights, using a series of call options. The call right is valued using a Black-Scholes option pricing model. The PWERM employs additional information not used in the OPM, including various market approach calculations depending upon the likelihood of various discrete future liquidity scenarios, such as an initial public offering or sale of the Company, as well as the probability of remaining a private company. In a hybrid method, various exit scenarios are analyzed. A discount for lack of marketability of the Company's common stock is then applied to arrive at an indication of value for the common stock.

Redeemable Convertible Preferred Stock

The Company records all proceeds from redeemable convertible preferred stock ("Preferred Stock") net of issuance costs. The Company classifies Preferred Stock outside of stockholders' deficit due to certain events that are outside of the Company's control, including sale or transfer of control of the Company, or redemption upon the election of the required majority of the Preferred Stockholders any time after June 29, 2026, as holders of the Preferred Stock could cause redemption of the shares in these situations. The Company adjusts the carrying values of the Preferred Stock to the ultimate redemption values over the period from issuance to the earliest redemption date.

Income Taxes

The Company accounts for the effect of income taxes in its consolidated financial statements using the asset and liability method in accordance with ASC Topic 740, Income Taxes ("ASC 740"). This process involves estimating actual current tax liabilities together with assessing the impact of carryforward and temporary differences resulting from the differing treatment of items such as depreciation for tax and accounting purposes. These differences result in deferred tax assets and liabilities which are measured using enacted tax rates expected to apply to taxable income in the year in which those temporary differences are expected to reverse.

The Company regularly assesses the likelihood that the deferred income tax assets will be realized. A valuation allowance to reduce the deferred tax assets to the amount that the Company believes is more likely than not to be realized is established based on their judgement of all available positive and negative evidence. The assessment is completed on a taxing jurisdiction basis for each tax-paying component and takes into account a number of types of evidence, including:

- the nature and history of current or cumulative financial reporting income or losses;
- sources of future taxable income;
- the anticipated reversal or expiration dates of deferred tax assets; and
- tax planning strategies.

The Company has established a valuation allowance to offset its gross deferred tax assets as of March 31, 2023 and December 31, 2022 due to the uncertainty of realizing future tax benefits primarily related to net operating loss carryforwards and income tax credits in Canada.

The Company applies ASC 740-10 Income Taxes which requires a two-step approach to recording a tax benefit in the consolidated financial statements. The first step requires an evaluation of the tax position to determine whether it is "more likely than not", based on the technical merits, that it will be sustained on audit. Provided that the tax position satisfies the recognition step, the Company then measures and records the position at the largest amount of tax benefit that is greater than 50 percent likely of being realized upon settlement of the audit. The Company considers many factors when evaluating and estimating its tax positions and tax benefits, which may require periodic adjustments and may not accurately anticipate actual outcomes. The Company recognizes accrued interest and penalties related to unrecognized tax benefits. There were no accrued interest and penalties as of March 31, 2023 and December 31, 2022.

Net Earnings (Loss) Per Share

The Company applies the two-class method to compute basic and diluted net earnings (loss) per share because it has issued redeemable convertible preferred stock that meets the definition of participating securities. The two-class method determines net earnings (loss) per share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires earnings available to common stockholders for the period to be allocated between common and participating securities based upon their respective rights to share in the earnings as if all earnings for the period had been distributed. During periods of loss, there is no allocation required under the two-class method since the participating securities do not have a contractual obligation to fund the losses of the Company.

Basic net earnings (loss) per share attributable to common stockholders is calculated by dividing the net earnings (loss) attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period.

Diluted net earnings (loss) per share is computed by giving effect to all potentially dilutive securities outstanding for the period using the treasury stock method or the if-converted method based on the nature of such securities. For periods in which the Company reports net losses, diluted net loss per common share attributable to common stockholders is the same as basic net loss per common share attributable to common stockholders, because potentially dilutive common shares are not assumed to have been issued if their effect is anti-dilutive.

Foreign Currency

The accumulated other comprehensive loss on the balance sheet includes foreign currency translation adjustments through December 31, 2015 recorded in connection with the change in functional currency from the Canadian dollar to the U.S. dollar. Gains or losses resulting from transactions denominated in foreign currencies are recorded as a component of other income or expense, within the condensed statements of operations and comprehensive income (loss).

Leases

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present. Operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected lease term. The interest rate implicit in lease contracts is typically not readily determinable. As such, the Company utilizes its incremental borrowing rate, which is the rate incurred to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment. Certain adjustments to the right-of-use asset may be required for items such as initial direct costs paid or incentives received.

The Company has elected to combine lease and non-lease components as a single component. The lease expense is recognized over the expected term on a straight-line basis. The lease term for all of the Company’s leases includes the non-cancellable period of the lease plus any additional periods covered by either a Company option to extend (or not to terminate) the lease that the Company is reasonably certain to exercise. Variable lease payments associated with the Company’s leases are recognized when the event, activity, or circumstance in the lease agreement on which those payments are assessed occurs. Variable lease payments are presented in the Company’s condensed consolidated statements of operations and comprehensive income (loss) in the same line item as expense arising from fixed lease payments for operating leases. Balances related to operating leases are recognized on the condensed consolidated balance sheets as right-of-use assets, operating lease liabilities, current and operating lease liabilities, non-current.

Contingent Consideration

Consideration paid related to the Myst Merger Agreement (as defined below) may include potential future payments that are contingent upon the Company achieving certain milestones in the future. Contingent

consideration liabilities are measured at their estimated fair value as of the date of the condensed consolidated balance sheets using a probability-based income approach based on the monetary value of the milestone payment discounted for the likelihood of achieving the milestone and a present value factor based on the timing of when the milestone is expected to be achieved.

Contingent consideration liabilities expected to be settled within 12 months after the balance sheet date are presented in current liabilities, with the non-current portion recorded under other liabilities, non-current in the condensed consolidated balance sheets. Changes in the fair value of the contingent consideration are recorded as research and development expenses in the condensed consolidated statement of operations and comprehensive income (loss).

Recently Adopted Accounting Pronouncements

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments—Credit Losses (Topic 326)—Measurement of Credit Losses on Financial Instruments, which has been subsequently amended by ASU No. 2018-19, ASU No. 2019-04, ASU No. 2019-05, ASU No. 2019-10, ASU No. 2019-11 and ASU No. 2021-03 ("ASU 2016-13"). The provisions of ASU 2016-13 modify the impairment model to utilize an expected loss methodology in place of the currently used incurred loss methodology and require a consideration of a broader range of reasonable and supportable information to inform credit loss estimates. ASU 2016-13 is effective for the Company on January 1, 2023. The adoption did not have a material impact on the condensed consolidated financial statements.

3. Fair Value of Financial Assets and Liabilities

For a description of the fair value hierarchy and our fair value methodology, (See *Note 2 – Summary of Significant Accounting Policies* for additional information). As of March 31, 2023 and December 31, 2022, the Company's restricted cash which is maintained as collateral in connection with its New York and San Diego facility leases (S*ee Note 2 – Summary of Significant Accounting Policies* for additional information) are valued using Level 1 inputs. The Company's highly liquid money market funds included within cash equivalents, restricted cash and U.S. treasury securities are valued using Level 1 inputs. The Company classifies its federal agency securities as Level 2. There were no transfers in or out of Level 1 and Level 2 during the periods presented. U.S. treasury securities are bonds issued by the U.S. government and are fully backed by the U.S. government. Given the frequency at which U.S. treasury securities trade and the accessibility of observable, quoted prices for such assets in active markets, they are recognized as level 1 assets. Federal agency securities are bonds and notes issued by government-sponsored enterprises, including Fannie Mae, Freddie Mac and the Federal Home Loan Bank. Since Federal agency securities typically do not trade as frequently as U.S. government agency securities and no exchange exists to price such investments, they are recognized as Level 2 assets.

The Company had $4.4 million and $6.0 million in contingent consideration liabilities as of March 31, 2023 and December 31, 2022, respectively, related to the Myst Merger Agreement. The contingent consideration balances are comprised of two potential milestone payments as of March 31, 2023 and two potential milestone payments as well as the remaining unpaid liability of $2.2 million from the milestone achievement as of December 31, 2022 measured at fair value (S*ee Note 7 - Asset Acquisition* for additional information). The fair value of the contingent consideration is estimated based on the monetary value of the milestone discounted for the likelihood of achieving the milestone and a present value factor based on the timing of when the milestone is expected to be achieved. The value for the contingent consideration balance is based on significant inputs not observable in the market which represents a Level 3 measurement within the fair value hierarchy.

The following tables represents a summary of the financial assets and liabilities that are measured on a recurring basis at fair value *(in thousands)*:

	March 31, 2023			
	Level 1	Level 2	Level 3	Fair Value
Financial assets:				
Money market funds	$31,155	$ —	$ —	$ 31,155
Restricted cash[1]	116	—	—	116
U.S. government and agency securities[2]	15,623	14,834	—	30,457
Total financial assets	$46,894	$14,834	$ —	$ 61,728
Financial liabilities:				
Contingent consideration[3]	$ —	$ —	$4,422	$ 4,422
Total financial liabilities	$ —	$ —	$4,422	$ 4,422

	December 31, 2022			
	Level 1	Level 2	Level 3	Fair Value
Financial assets:				
Money market funds	$ 9,238	$ —	$ —	$ 9,238
Restricted cash[1]	382	—	—	382
U.S. government and agency securities[2]	30,649	16,681	—	47,330
Total financial assets	$40,269	$16,681	$ —	$ 56,950
Financial liabilities:				
Contingent consideration[3]	$ —	$ —	$5,994	$ 5,994
Total financial liabilities	$ —	$ —	$5,994	$ 5,994

(1) Restricted cash serves as deposits for the Company's San Diego office lease as of March 31, 2023 and New York and San Diego office leases as of December 31, 2022.

(2) Included in short-term investments on the consolidated balance sheets and are classified as available-for sale debt securities.

(3) Contingent consideration related to the Myst Merger Agreement.

The following significant unobservable inputs were used in the valuation of the contingent consideration payable to the sole common stockholder of Myst pursuant to the Myst Merger Agreement:

Contingent Consideration Liability	Fair Value as of March 31, 2023 (in thousands)	Valuation Technique	Unobservable Input	Range
Milestone payments	$ 4,422	Discounted cash flow	Likelihood of occurrence	20% - 75%
			Discount rate	22%
			Expected term (in years)	0.25 - 2.75

Contingent Consideration Liability	Fair Value as of December 31, 2022 (in thousands)	Valuation Technique	Unobservable Input	Range
Milestone payments	$ 5,994	Discounted cash flow	Likelihood of occurrence	20% - 100%
			Discount rate	22%
			Expected term (in years)	0.25 - 2.75

The following table reflects the activity for the Company's contingent consideration, measured at fair value using Level 3 inputs (*in thousands*):

Contingent consideration at December 31, 2022	$ 5,994
Cash payment of Myst milestone	(2,187)
Changes in the fair value of contingent consideration	615
Contingent consideration at March 31, 2023	$ 4,422

As of March 31, 2023 and December 31, 2022, no material fair value adjustments were required for non-financial assets and liabilities.

The following tables show the Company's cash, cash equivalents and available-for-sale securities by significant investment category *(in thousands)*:

	March 31, 2023			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Level 1: Money market funds	$ 31,155	$ —	$ —	$ 31,155
Restricted cash	116	—	—	116
U.S. government securities	15,647	—	(24)	15,623
Level 2: U.S. agency securities	14,879	—	(45)	14,834
Total financial assets	$ 61,797	$ —	$ (69)	$ 61,728
Classified as:				
Cash and cash equivalents				$ 31,155
Restricted cash				116
Short-term investments				30,457
				$ 61,728

	December 31, 2022			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Level 1: Money market funds	$ 9,238	$ —	$ —	$ 9,238
Restricted cash	382	—	—	382
U.S. government securities	30,761	—	(112)	30,649
Level 2: U.S. agency securities	16,759	—	(78)	16,681
Total financial assets	$ 57,140	$ —	$ (190)	$ 56,950
Classified as:				
Cash and cash equivalents				$ 9,238
Restricted cash				382
Short-term investments				47,330
				$ 56,950

While short-term investments are available-for-sale, it is not more likely than not that the Company will be required to sell the investments before recovery of their amortized cost bases, which may be maturity.

The Company reviews short-term investments for impairment during each reporting period. Impairment losses related to credit losses (if any) are recorded as an allowance for credit losses with an offsetting entry to interest income, net. No impairment losses related to credit losses were recognized for the three months ended March 31, 2023 and 2022. Credit losses are recognized up to the amount equal to the difference between the fair

value and the amortized cost basis and recorded as an allowance for credit losses in the condensed consolidated balance sheets with a corresponding adjustment to earnings. Unrealized losses that are not related to credit losses are recognized in accumulated other comprehensive loss. Unrealized losses were not significant for the investments held in the Company's portfolio as of March 31, 2023 and December 31, 2022. There were no impairment losses or expected credit losses related to its short-term investments during the three months ended March 31, 2023 and 2022.

4. Property and Equipment, Net

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

	March 31, 2023	December 31, 2022
Computer equipment and software	$ 376	$ 376
Laboratory equipment	13,466	12,901
Furniture	743	758
Leasehold improvements	1,308	1,308
	15,893	15,343
Less accumulated depreciation and amortization	(6,041)	(5,619)
Total property and equipment, net	$ 9,852	$ 9,724

Property and equipment depreciation and amortization expense for the three months ended March 31, 2023 and 2022, was $0.7 million and $0.7 million, respectively.

5. Accrued Expenses and Other Current Liabilities

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

	March 31, 2023	December 31, 2022
Research and development expense	$ 8,065	$ 6,688
Professional and consulting expense	987	1,170
Compensation	1,319	2,366
Tax liability, current	69	252
Contingent consideration, current	2,107	3,791
Other current liabilities	36	20
Total accrued expenses and other current liabilities	$ 12,583	$ 14,287

6. Agreements

Takeda Pharmaceutical Company Limited

Collaboration Agreement

In November 2019, the Company entered into a discovery, collaboration and license agreement ("Takeda Agreement") with Millennium Pharmaceuticals, Inc. (also known as Takeda Oncology), a wholly owned subsidiary of Takeda Pharmaceutical Company Limited (Takeda). Under the Takeda Agreement, the Company agreed to collaborate with Takeda to co-develop and co-commercialize TBio-6517 (also known as RIVAL-01) ("Development Program") and to conduct discovery programs to identify additional novel product candidates based on its vaccinia virus platform for independent development ("Discovery Program").

Under the Takeda Agreement, the Company granted Takeda and its affiliates a worldwide, irrevocable, non-transferable, co-exclusive, sublicensable license under certain of the Company's know-how and patent rights ("Turnstone Technology") to make, use, sell, offer for sale, develop, manufacture, and commercialize, or otherwise exploit TBio-6517 ("Licensed Compound") and products containing TBio-6517 ("Takeda Licensed Products") in all fields. Takeda granted the Company and the Company's affiliates an irrevocable, non-transferable, non-exclusive, sublicensable license under certain know-how and patent rights of Takeda ("Takeda Technology") to make, use, sell, offer for sale, develop, manufacture, and commercialize, or otherwise exploit the Licensed Compound and Takeda Licensed Products in all fields in accordance with joint development, commercialization, and medical affairs plans under the Takeda Agreement.

Under the Takeda Agreement, the Company also granted to Takeda and its affiliates a worldwide, non-transferable, non-exclusive, sublicensable license under Turnstone Technology to conduct joint discovery and research activities in all fields in accordance with joint research and discovery plans. Under the Takeda Agreement, Takeda granted the Company a license to Takeda Technology to conduct discovery and research activities in all fields in accordance with joint research and discovery plans. The Company also granted to Takeda and its affiliates an exclusive option to obtain a worldwide, irrevocable, non-transferable, exclusive, sublicensable license under Turnstone Technology to make, use, sell, offer for sale, develop, manufacture, and commercialize, or otherwise exploit (i) selected discovery virus candidates generated and evaluated by the parties under a joint discovery program ("Selected Discovery Candidates"), and (ii) any corresponding licensed products containing a Selected Discovery Candidate ("Licensed Discovery Products"). Takeda may exercise this option with respect to two virus candidates and within a specified option exercise period. The Company granted Takeda and its affiliates a non-exclusive, perpetual, irrevocable, worldwide, sublicensable and fully paid-up license under certain of the Company's know-how and patents relating to manufacturing improvements developed under the Takeda Agreement solely for use in connection with the manufacture of products that do not comprise or incorporate, and that are not based on, an oncolytic virus. Takeda granted the Company and the Company's affiliates a non-exclusive, perpetual, irrevocable, worldwide, sublicensable and fully paid-up license under certain of Takeda's know-how and patents relating to manufacturing improvements developed under the Takeda Agreement solely for use in connection with the manufacture of any and all products. With respect to discovery virus candidates for which Takeda does not exercise its option, Takeda granted the Company a non-exclusive, perpetual, worldwide, sublicensable and royalty-bearing license under certain of its know-how and patents that is necessary or reasonably useful for the exploitation of such declined discovery virus candidates ("Declined Candidate License").

Responsibilities for the development of Licensed Compounds and Takeda Licensed Products are delineated pursuant to a joint development plan under the terms of the Takeda Agreement. The Company will be responsible for all activities under the joint development plan prior to completion of a Phase 2a clinical trial and Takeda will be responsible for all activities in the joint development plan upon and after completion of the Phase 2a clinical trial. Responsibilities relating to manufacturing, medical affairs, and commercialization of Licensed Compounds and Takeda Licensed Products are delineated pursuant to a manufacturing working plan, joint medical affairs plan and joint commercialization plan, respectively. The Company has the right to reduce or opt-out of its share of responsibilities for costs and expenses of certain development or commercialization activities for the Takeda Licensed Compounds and Takeda Licensed Products. Responsibilities for the discovery and research of Selected Discovery Candidates are delineated pursuant to joint discovery and research plans under the terms of the Takeda Agreement.

Under the Takeda Agreement, Takeda paid the Company a non-refundable payment of $50.0 million in November, 2019 and an additional non-refundable payment of $30.0 million in April, 2020, for the option to license up to two Selected Discovery Candidates, with additional consideration of $15.0 million to be paid by Takeda to the Company for each exercise of such option.

Under the Takeda Agreement, the Company has the right to reduce its share of funding obligations with respect to development activities for the Licensed Compound and Takeda Licensed Products (the "Development

Opt-Down Right"), or to opt-out of all further funding obligations with respect to development activities for the Licensed Compound and Takeda Licensed Products (the "Development Opt-Out Right"). Unless and until the Company exercises the Development Opt-Down Right, the parties will share evenly in any operating profits or losses with respect to joint development activities, joint medical affairs activities, and joint commercialization activities. If the Company exercises its Development Opt-Down Right, then starting from the effective date of the exercise of the right, Takeda will bear (and be entitled to) 70% and the Company will bear (and be entitled to) 30% of the operating profits or losses with respect to joint development activities, joint medical affairs activities, and joint commercialization activities. Takeda is obligated to pay the Company (i) up to $200.0 million in aggregate upon achievement of certain clinical and regulatory milestones for the first Takeda Licensed Product to achieve the applicable development milestone event, (ii) up to $150.0 million in aggregate for one-time payments upon achievement of certain sales milestones for each Takeda Licensed Product, (iii) up to $240.0 million in aggregate (if Takeda exercises both options to Selected Discovery Candidates) upon achievement of certain clinical and regulatory milestones for the first Takeda Licensed Discovery Product to achieve applicable development milestone events, and (iv) up to $300.0 million in aggregate (if Takeda exercises both options to Selected Discovery Candidates) for one-time payments upon achievement of certain sales milestones for a Licensed Discovery Product. If the Company exercises its Development Opt-Out Right for the Takeda Licensed Products, then in lieu of the profit and loss share arrangement described above, the Company is entitled to receive tiered low- to high- teen percentage royalties on net sales of all Takeda Licensed Products by the Company or the Company's sublicensees during the royalty term, which commences on the first commercial sale of a Takeda Licensed Product in a country and ends on the later of the expiration of all licensed patents covering such Licensed Product in such country or ten years after the date of the first commercial sale in such country ("Royalty Term"). For Licensed Discovery Products, the Company is entitled to receive tiered high-single digit to low-teen percentage royalties on net sales of all Licensed Discovery Products by the Company or the Company's sublicensees during the Royalty Term. Royalty payments are subject to customary reductions.

Takeda has the right to terminate for convenience as follows: (i) prior to the expiration of the option exercise period related to a Discovery Virus Candidate, Takeda may terminate the Takeda Agreement related to such Discovery Virus Candidate and the Discovery Program with 90 days' notice, (ii) prior to any commercial sale, Takeda may terminate the Takeda Agreement either in its entirety or on a compound-by-compound or region-by-region basis, with six months' notice and (iii) after a commercial sale, Takeda may terminate the Takeda Agreement either in its entirety or on a compound-by-compound or region-by-region basis, with 12 months' notice.

Termination of Development Program

On June 13, 2022, Takeda provided six months' written notice to terminate the Development Program in accordance with its termination for convenience rights, with such termination being effective as of December 13, 2022. During the six months' notice period, the Company was obligated to continue providing the necessary Development Program services to wind down the program. Upon the effective termination date of December 13, 2022, Takeda's co-exclusive license to TBio-6517 terminated and the Company is no longer obligated to pursue development of TBio-6517.

Termination of Discovery Program

On January 6, 2023, Takeda provided six months' written notice to terminate the remainder of the Takeda Agreement, with such termination being effective as of July 6, 2023 ("Effective Termination Date"). On the Effective Termination Date, all options and licenses granted under the Takeda Agreement will terminate (except for the Declined Candidate License) and Takeda will grant the Company a non-exclusive license under the patent rights and know-how controlled by Takeda as of the Effective Termination Date necessary for the Company to exploit the Licensed Compound and Takeda Licensed Products in the form existing as of the Effective Termination Date for any use worldwide, subject to a royalty to be agreed upon by Takeda and the Company. As of March 31, 2023, the Company ceased all work under the Takeda Agreement and the Company

has concluded that there are no remaining estimated services associated with the obligations under the Takeda Agreement.

Accounting Analysis

The Company assessed the promised goods and services under the Takeda Agreement in accordance with ASC 606, and determined that, at inception, the Takeda Agreement includes the following performance obligations: (i) research, development and manufacturing services under the Development Program for the completion of clinical trials through Phase 2a for RIVAL-01 and a co-exclusive license to exploit RIVAL-01 ("Development Program Performance Obligation"); and (ii) research and development services under the Discovery Program to identify and optimize four Selected Discovery Candidates for further development ("Discovery Program Performance Obligation"). The individual promises under the Development Program including research, development, manufacturing for clinical trials, and the co-exclusive license to RIVAL-01 are not individually distinct as they represent inputs into a combined output of advancing RIVAL-01 through the Phase 2a clinical trial. Therefore, all promises under the Development Program represent a single performance obligation. Similarly, the research and development services under the Discovery Program represent a single research program aimed at generating four Selected Discovery Candidates and therefore represents a single performance obligation. The Development Program promises are distinct from the promises under the Discovery Program, as the benefits under each program are separately identifiable. Each program has a separate work plan and the promises to be provided under the Development Program do not relate to the promises to be provided under the Discovery Program.

The Company concluded that Takeda's license options under the Discovery Program do not represent material rights, and therefore are not performance obligations, as the Company is entitled to an additional $15.0 million payment for each license option exercised, which approximates the estimated standalone selling price of the underlying license.

The total transaction price at contract inception is $158.6 million, comprised of the following components:

- Fixed consideration of $80.0 million including a non-refundable up-front payment of $50.0 million in November, 2019 and another non-refundable payment of $30.0 million that was due on April 1, 2020 and received in April 2020.

- Variable consideration related to the expense sharing under the Development Program. These amounts are determinable based on the Development Program plan and budget, and the Company has a contractual right to the payment of costs incurred under the agreed upon plan. Consistent with the expected value method, the Company estimated that it will receive $58.6 million under the expense sharing through the completion of the Phase 2a clinical trial. The Company has concluded that these amounts do not require a constraint and are included in the transaction price at inception. The Company has evaluated this estimate at each reporting date and updated the estimate based on information available.

- Variable consideration for the development milestones under the Development Program. The Company uses the most likely amount method to value this variable consideration as there are only two possible outcomes of achieving the individual milestones. Under the Development Program, the first milestone of $20.0 million is due upon acceptance of the IND by the FDA. At inception, the Company concluded that achievement of this milestone was highly probable and therefore the $20.0 million was included in the transaction price, and was received in March 2020. The second milestone of $15.0 million under the Development Program is due upon the initiation of the first Phase 2 clinical trial for a licensed product. The Company has determined that the most likely amount is $15.0 million, however, the Company will not include this $15.0 million

milestone in the transaction price until it becomes probable that a significant reversal of cumulative revenue will not occur.

Additional consideration to be paid to the Company includes development and sales milestones, profit and loss share, royalties and option exercise payments. These additional payments are achievable only after the completion of the Phase 2a clinical trial under the Development Program or exercise of the license options under the Discovery Program and therefore are excluded from the transaction price. Additionally, Takeda's equity purchase commitments of up to $20.0 million are at fair value and therefore no non-cash consideration has been included as a component of the transaction price.

The Company allocated the transaction price to the separate performance obligations based on their relative standalone selling prices. The Company determined the standalone selling price of the Development Program Performance Obligation based on the costs incurred to develop RIVAL-01 plus the estimated costs to perform the research, development and manufacturing services through the completion of the Phase 2a clinical trial, inclusive of a reasonable profit margin. The Company determined the standalone selling price of the Discovery Program Performance Obligation based on the estimated costs to discover and research four Selected Discovery Candidates, inclusive of a reasonable profit margin. Significant inputs used to determine the standalone selling prices of the performance obligations include the length of time required, the internal hours expected to be incurred on the services, and the amount of third-party expenses that will be incurred to complete the performance obligations.

The Company recognizes the amounts associated with these performance obligations on a proportional performance basis over the contract term using input-based measurements of total cost of research and development incurred to estimate the proportion performed as compared to the estimated total cost and remeasures its progress towards completion at the end of each reporting period.

As of December 31, 2021, the transaction price was updated to $192.6 million to reflect an increase in the variable consideration related to the expense sharing under the Development Program from $58.6 million at inception to $92.6 million.

The Company determined that the notice of termination on June 13, 2022 represented a modification of the arrangement under ASC 606 and that the transaction price should be updated and re-allocated to the Development Program Performance Obligation and the Discovery Program Performance Obligation based on their standalone selling prices, as follows:

Performance Obligations	Price Pre-Modification	Price at Modification
Development Program	$ 166.3 million	$ 134.3 million
Discovery Program	$ 26.3 million	$ 21.2 million
Total	$ 192.6 million	$ 155.5 million

Additionally, the Company updated its measure of progress for each performance obligation as of the modification date and recorded a cumulative adjustment that increased collaboration revenue by $31.6 million on the partially satisfied remaining performance obligations, as the remaining services to be performed under each of the performance obligations are not distinct from the services prior to the modification.

Costs incurred relating to the Takeda Agreement consist of internal and external research and development costs, which primarily include salaries and benefits, lab supplies, and preclinical research studies. All of these costs are included in research and development expenses in the Company's condensed consolidated statements of operations and comprehensive income (loss) during the three months ended March 31, 2023 and 2022.

The deferred revenue balance in connection with the Takeda Agreement as of March 31, 2023 and December 31, 2022 was $0.0 million and $19.3 million, respectively, which is classified as either current or noncurrent in the accompanying condensed consolidated balance sheet based on the periods the performance obligations are expected to be performed. The Company recognized the remaining deferred revenue balance during the three months ended March 31, 2023 as the Company concluded that there are no remaining estimated services to be performed associated with the obligations under the Takeda Agreement. The Company recognized collaboration revenue related to the Takeda Agreement for the three months ended March 31, 2023 and 2022 of $19.3 million and $10.7 million, respectively. Receivables related to reimbursable costs expected to be received from Takeda for research and development services performed under the Development Program for the three months ended March 31, 2023 and year ended December 31, 2022 were $4.5 million and $8.7 million, respectively.

H. Lee Moffitt Cancer Center

Master Collaboration Agreement

In January 2021, the Company entered into an amended and restated master collaboration agreement (the "Moffitt Agreement"), with Moffitt, to amend a then-existing master collaboration agreement from November 2019, as amended March 2020, between Moffitt and the Company's now wholly-owned subsidiary, Myst Therapeutics LLC, with the intent to continue to work collaboratively in the research of cancer immunotherapies.

Each party granted the other party a right to use its research materials for performance of the research plans agreed to by the parties (the "Research Plans"). Each party granted the other party a non-exclusive, worldwide, sublicensable, perpetual, irrevocable, royalty-free license under all inventions invented in performance of a Research Plan and invented jointly by the Company and Moffitt (the "Joint Inventions") (with certain exclusions) to make, use, sell, offer for sale, import products and services and/or otherwise practice such inventions.

The Company granted Moffitt a royalty free, non-sublicensable, non-transferable, perpetual, non-exclusive license to use and practice certain inventions invented solely by the Company in the performance of a Research Plan for its internal non-commercial research purposes.

Moffitt granted the Company (i) a royalty-free, sublicensable, non-transferable, perpetual, non-exclusive license to use and practice certain inventions invented solely by Moffitt in the performance of a Research Plan ("Moffitt Inventions"), (a) for internal, non-commercial research purposes outside the field of ACT and/or (b) to research, develop, make, use, sell, offer to sell, or import products and/or services in the field of ACT and (ii) a royalty free, sublicensable, non-transferable, perpetual, non-exclusive license to use and practice certain inventions invented in performance of a Research Plan or through the use of specified Moffitt research materials.

Moffitt granted the Company an option to obtain, with terms to be negotiated in good faith under commercially reasonable terms, a royalty-bearing, sublicensable exclusive license in the Moffitt Inventions, the TCR Inventions, and/or Moffitt's interest in Joint Inventions. The Company can exercise this option at any time within six months after Moffitt informs the Company of any new invention, and upon the Company's exercise, the parties will have a period of six months to negotiate the terms of such exclusive license.

The Moffitt Agreement will expire upon the later of (i) four years from the effective date of the Moffitt Agreement or (ii) the termination or expiration of all Research Plans in effect under the Moffitt Agreement, unless extended upon mutual written agreement of the parties. Either party may terminate the Moffitt Agreement for cause upon any uncured breach by the other party or upon the insolvency of the other party.

Moffitt Alliance Agreement

In June 2022, the Company entered into a life science alliance agreement with Moffitt (the "Alliance Agreement"), in order to further expand the Company's relationship and support the Company's existing agreements with Moffitt (the "Underlying Agreements"). Pursuant to the Alliance Agreement, the Company will have priority access to Moffitt's scientific research, manufacturing, and clinical capabilities for the development of novel TIL therapies, including expedited clinical trial activation, enhanced patient screening and data sharing, access to Moffitt's cellular therapies research and development infrastructure, expanded molecular data sets and biospecimens for research, and allocated cGMP manufacturing capacity for the Company's product candidates.

Under the Alliance Agreement, the Company is obligated to use commercially reasonable efforts to further develop TIL Products, to manufacture TIL Products, to obtain regulatory approval for at least one TIL Product in the United States and to commercialize TIL Products in all countries in which regulatory approval for a TIL Product has been obtained. For purposes of the Alliance Agreement, TIL Product means any pharmaceutical, biopharmaceutical, or biotechnology TIL product that has been developed by us or Moffitt and is advanced into clinical development under an IND sponsored by Moffitt.

Pursuant to the Alliance Agreement, the Company agreed to pay to Moffitt a total amount of at least $17.5 million (the "Alliance Funding Amount"), for research, development and manufacturing related services that will be paid in five equal annual installments on June 1st of each year starting on June 1, 2023. However, the aggregate amount the Company pays to Moffitt for all fees, costs, expenses and other payments pursuant to any Underlying Agreement with Moffitt entered into subsequent to February 7, 2022, may be credited against the Alliance Funding Amount. This reimbursement amount will be calculated annually at the conclusion of each payment period, and, to the extent the Company's annual aggregate payments to Moffitt exceed the applicable annual installment amount, the Company will receive a reduction in the amount due for future installment payments based on a predetermined formula agreed to by the parties. As of March 31, 2023, the Company incurred expenses with Moffitt of $3.4 million toward the first years' annual installment.

In connection with the execution of the Alliance Agreement, the Company issued Moffitt 91,721 shares of its common stock. As partial consideration under the Alliance Agreement, the Company also agreed to issue Moffitt an additional 366,884 shares of its common stock in the aggregate upon the satisfaction of certain clinical and regulatory milestones with respect to TIL Products. The issuances of common stock are treated as performance-based stock awards. For the three months ended March 31, 2023, 91,721 shares were issued due to the achievement of the milestone related to the start of the Phase 1 trial. In addition, upon achievement of certain thresholds for aggregate net sales of all TIL Products, the Company is required to make tiered sales-based milestones payments to Moffitt of up to an aggregate of $50.0 million. With respect to each of the equity and sales milestones described above, TIL products include any pharmaceutical, biopharmaceutical or biotechnology TIL product that is developed by the Company or Moffitt and is advanced into clinical development under an IND sponsored by Moffitt.

Unless earlier terminated, the Alliance Agreement will remain in effect for a term of five years and may be extended for additional periods upon the mutual written consent of both parties. Either party may terminate the Alliance Agreement in the event of (i) the other party's material breach of the Alliance Agreement that remains uncured after ninety days of receiving written notice of such breach (or in the case of breach of payment obligations, within ten days), (ii) the other party's insolvency and (iii) a pandemic event resulting in government lockdowns or orders that legally compel such party to cease operations or that result in material disruptions in the available workforce and prevents such party from performing its contractual obligations for a period of more than six months. At any time after June 1, 2025, either party may terminate the Alliance Agreement without cause upon sixty days prior written notice to the other party (a "Termination for Convenience"). Upon a Termination for Convenience, the terminating party shall pay to the other party a termination fee in an amount equal to a low double digit percentage of the then remaining Alliance Funding Amount. Termination or expiry of one or more Underlying Agreements does not affect the term of the Alliance Agreement, which will continue to apply to the remaining ongoing Underlying Agreements.

7. Asset Acquisition

In December 2020, the Company entered into the Agreement and Plan of Merger and Reorganization (the "Myst Merger Agreement"), by and among the Company, Flatiron Merger Sub I, Inc. ("Merger Sub"), Flatiron Merger Sub II, LLC ("Merger LLC"), a direct, wholly-owned subsidiary of the Company, Myst Therapeutics, Inc. ("Myst"), and Timothy Langer, the sole common stockholder of Myst ("Langer"). Pursuant to the Myst Merger Agreement, the business combination (the "Merger") was effected in two steps. The first step was the merger of Merger Sub with and into Myst. The second step was the merger of Myst with and into Merger LLC. The Merger closed on December 14, 2020, and the effective date of the Merger was January 20, 2021 As a result of the Merger, the separate existences of Merger Sub and Myst ceased, and Merger LLC became the Company's wholly-owned subsidiary.

Pursuant to the Myst Merger Agreement, on December 15, 2020, the Company paid the former equity holders of Myst, (the "Myst Holders"), a one-time up-front payment of $9.0 million in cash. The Company paid an additional cash consideration of $1.0 million to the Myst Holders on June 14, 2022. The Company also issued Langer up to 725,920 shares of the Company's common stock. Of these shares, 362,960 shares of the Company's common stock were issued upon the closing of the Merger and the remaining 362,960 shares of the Company's common stock were held in escrow with 25% vesting in December of each year that Langer remains an employee of the Company. As of December 31, 2022, Langer is still employed by the Company and 181,480 shares of the Company's common stock have vested and been released from escrow with the remaining 181,480 shares of the Company's common stock to be released in equal annual installments over the next two years based on his continued employment. This restricted equity grant is accounted for as a compensatory arrangement under ASC 718 as continued service is required under the agreement.

In addition, under the Myst Merger Agreement, each Myst Holder is entitled to receive certain payments as consideration based on the achievement by the Company of three predefined milestones. The initial milestone is the closing of an initial public offering, which will be triggered by the closing of this offering, the second milestone is the first acceptance by the FDA of an IND filed by, on behalf of or for the benefit of the Company, or the Company's sublicensees for a product being developed by or on behalf of the Company or its sublicensees that is claimed as a product or method of making or using the product by a pending or issued Myst patent claim existing at the time of such acceptance, and the third milestone is the occurrence of the earlier of (i) the commencement of the first registration study for a product being developed by, on behalf of or for the benefit of the Company that is claimed as a product or a method of making or using the product by an issued Myst patent claim existing as of the time of such commencement or (ii) the issuance of a Myst patent claim that claims a product or method of making or using the product then being developed by, on behalf of or for the benefit of the Company, or its sublicensees, that is or was the subject of a registration study that has or had commenced. The milestones are not contingent on one another, and the milestones do not need to be achieved in any specific order.

Within 45 days of the achievement of the initial milestone, which the closing of this offering triggers, the Company is obligated to pay the Myst Holders an aggregate amount equal to $3.0 million. At the Company's election, the Company may pay this consideration in cash or in shares of the Company's common stock. The fair market value of the Company's common stock measured after this offering, is the volume weighted-average closing price of the Company's common stock on Nasdaq for the consecutive 20 trading day period ending on the last trading day on or prior to the date on which the milestone was earned pursuant to the Myst Merger Agreement.

Within 45 days of the achievement of the second milestone, the Company is obligated to pay the Myst Holders an aggregate amount equal to $10.0 million. At the Company's election, the Company may pay this consideration in cash or in shares of the Company's common stock. In May 2022, this $10.0 million milestone was achieved. The Company elected to pay $5.0 million in the Company's common stock and $5.0 million in cash. Pursuant to a letter agreement dated July 25, 2022 between the Company and the former equityholders of Myst regarding the $10.0 million milestone payment that became due and owing to the Myst Holders, the

Company agreed to pay to the former optionholders of Myst on or before July 28, 2022, $0.6 million in cash, with the remaining $9.4 million payable to Langer as follows: (i) on or before July 28, 2022, $2.2 million in cash, (ii) on or before July 31, 2022, $5.0 million in shares of the Company's common stock and (iii) on or before January 10, 2023, $2.2 million in cash. On June 8, 2022, the Company issued Langer 212,203 shares of the Company's common stock to settle the $5.0 million obligation payable in common stock. The Company then paid the Myst Holders $2.8 million in July 2022, with $2.2 million paid to Langer and $0.6 million paid to the remaining Myst Holders, and the remaining $2.2 million was paid to Langer in January 2023.

Within 45 days of the achievement of the third milestone, the Company is obligated to pay the Myst Holders an aggregate amount equal to $20.0 million. At the Company's election, the Company may pay this consideration in cash or in shares of its common stock.

Additionally, the Company assumed an ongoing research and development contract obligation of approximately $1.5 million and committed to spend at least $30.0 million for building out the cell therapy infrastructure and continued research and development.

The Company accounted for the merger with Myst pursuant to the Myst Merger Agreement as an asset acquisition as substantially all of the fair value of the gross assets acquired was concentrated in the acquired in-process research and development of Myst and did not have an alternate future use. The Company recognized a $19.4 million charge to research and development expense at the time of the completion of the asset acquisition during the year ended December 31, 2020. The Company determined that the milestone payments are separate units of account and accounted for the initial milestone as a derivative in accordance with ASC 815 and the second and third milestones as liabilities in accordance with ASC 480. In connection with the initial public offering, the Company reassessed its initial accounting of the milestone payments and concluded that they should be viewed as one unit of account because the milestone payments are not legally detachable from each other. The milestone payments, as one unit of account, would be classified as a liability in accordance with ASC 480 and measured at fair value, with changes in the fair value recorded in earnings. Regardless of whether the milestone payments are viewed as one unit of account or three units of account, because they are all subject to fair value measurement, the financial reporting effect of the contingent consideration arrangement as one unit of account or three units of account is substantially the same. As a liability under ASC 480, the contingent consideration will continue to be recorded at fair value until settled. The adjustment to the fair value of the contingent consideration of $0.6 million and $0.3 million were included in research and development expense in the Company's consolidated statements of operations for the three months ended March 31, 2023, and 2022, respectively.

8. Stockholders' Equity

Series A Preferred Stock

From October 2015 to October 2016, the Company issued a total of 11,250,000 shares of series A preferred stock (the "Series A Preferred Stock") at CDN$1.00 per share (equivalent to $0.74 per share, based on a conversion ratio of 1.344 Canadian dollars to one U.S. dollar) for total net proceeds of CDN$ 10.9 million (equivalent to $8.1 million based on a conversion ratio of 1.344 Canadian dollars to one U.S. dollar).

Series B Preferred Stock

In October 2016, the Company issued a total of 16,285,156 shares of series B-1 preferred stock (the "Series B-1 Preferred Stock") at $0.77 per share for total net proceeds of $12.3 million. In November 2018, the Company issued 25,065,538 shares of series B-2 preferred stock (the "Series B-2 Preferred Stock", and together
with the Series B-1 Preferred Stock, the "Series B Preferred Stock") at $1.15 per share for total net proceeds of $28.9 million.

Series C Preferred Stock

The Company issued a total of 17,905,288 shares of series C preferred stock (the "Series C Preferred Stock") at $2.35 per share in January 2019 for net proceeds of $41.8 million.

Series D Preferred Stock

The Company issued a total of 29,285,356 shares of series D preferred stock (the "Series D Preferred Stock") at $2.73 per share in June 2021 for net proceeds of $79.8 million.

The rights and preferences of the Preferred Stock as of March 31, 2023, are summarized below, which relate to each of the Series A, Series B, Series C and Series D Preferred Stock unless specified otherwise.

Conversion

The holders of Preferred Stock have the right, at any time and at the holder's discretion, to convert, without payment of any additional consideration, in whole or in part, such holder's Preferred Stock into common stock at the then applicable conversion price, which shall initially be one share of common stock for one share of Preferred Stock. The Preferred Stock will be automatically converted into common stock at the then applicable conversion price, upon the earlier of a qualified initial public offering or the election of a required majority of the holders of Preferred Stock.

Voting

The holders of the Preferred Stock are entitled to vote on any matters on which holders of common stock are entitled to vote, on an as-converted basis. Holders of Preferred Stock and holders of common stock are required to vote together as a single class, except for meetings at which only holders of another specified class of shares are entitled to vote. Each holder of Preferred Stock is entitled to such number of votes equal to the number of shares of common stock issuable upon the exercise of any conversion rights attaching to such Preferred Stock at the date of such vote, using the applicable conversion price.

Dividends

The holders of the Series A and Series B Preferred Stock are entitled to receive non-cumulative dividends at the rate of 8% per annum and the holders of the Series C and Series D Preferred Stock are entitled to receive non-cumulative dividends at the rate of 10% per annum when and if declared by the board of directors and in preference to the common stock. After the Preferred Stock dividend is paid, the Preferred Stock participates in any dividend paid to common stock on an as-converted basis (participating). Through March 31, 2023, the Company has not declared or paid dividends and has no present intention of paying any dividends in the foreseeable future.

Liquidation Preference

In the event of a liquidation event, the holders of Preferred Stock are entitled to receive, in preference to the holders of common stock, an amount equal to their initial issue price plus the aggregate of all declared but unpaid dividends and may then participate in the distribution of any residual assets with the common stock on an as-converted basis.

If the amount to distribute is insufficient to pay the liquidation preference in full, then the Preferred Stock receive the distribution ratably in proportion to the respective amounts which would otherwise be payable in respect of the shares held by them upon such distribution if all amounts payable on or with respect to such shares were paid in full.

Redemption

At the option of the holders of at least a majority of the then outstanding shares of Preferred Stock, consenting or voting together as a single class on an as-converted to Common Stock basis (the "Required Majority"), at any time after June 29, 2026, each holder of Preferred Stock shall be entitled to require the Company to redeem all or any of the outstanding Preferred Stock held by those holders electing at a price equal to the Redemption Price which is defined as initial issue price plus declared but unpaid dividends.

The Company is accreting the carrying value of the Preferred Stock up to the full redemption value over the period from issuance to the earliest redemption date. The Company recorded accretion totaling $0.0 million and $0.1 million for the three months ended March 31, 2023 and 2022, respectively. As of March 31, 2023 and December 31, 2022, the full redemption value of the Preferred Stock is $172.0 million and $171.9 million, respectively. As of March 31, 2023, no shares have been redeemed.

The Company has assessed whether there are any embedded derivatives or beneficial conversion option relating to the Preferred Stock and determined that none exist.

Anti-Dilution Protection

If the Company issues additional securities without consideration or for consideration per share less than the initial issue price of a series of Preferred Stock (other than certain customary exceptions), then the conversion price for the applicable series of Preferred Stock will be adjusted using a broad-based weighted average anti-dilution formula.

Common Stock

As of March 31, 2023, the Company's certificate of incorporation, as amended and restated, authorized the Company to issue 147,892,358 shares of common stock, $0.001 par value per share. The common stockholders are entitled to receive dividends, in subordination to the Series A, Series B, Series C and Series D Preferred Stock, if and when declared by the board of directors. In the event of dissolution, the common stock ranks in seniority behind the Series A, Series B, Series C and Series D Preferred Stock. The holders of common stock are entitled to one vote for each share held.

Shares of common stock reserved for future issuance, on an as-if-converted basis, consists of the following:

	Three Months Ended March 31,	
	2023	2022
Series A redeemable convertible preferred stock	1,408,502	1,408,502
Series B-1 redeemable convertible preferred stock	2,038,903	2,038,903
Series B-2 redeemable convertible preferred stock	3,138,208	3,138,208
Series C redeemable convertible preferred stock	2,241,740	2,241,740
Series D redeemable convertible preferred stock	3,666,526	3,666,526
Stock options, issued and outstanding	2,495,301	2,357945
Stock options, available for future issuance	269,708	255,68
	15,258,888	15,107,509

9. Equity Based Compensation

2018 Equity Incentive Plan

In December 2018, the Company adopted the 2018 Equity Incentive Plan (the "2018 Plan") which provides for the Company to grant incentive stock options or nonqualified stock options for the purchase of common stock, or restricted shares or other stock-based awards, to employees, members of the board of directors and consultants of the Company. The Company assumed all of the outstanding options under the amended and restated Equity Incentive Plan of Turnstone Biologics Inc. dated October 1, 2016 (the "Prior Plan") in connection with the corporate reorganization in December 2018. However, there were no changes to the terms of the options requiring modification accounting.

All options granted under the 2018 Plan will have an exercise price, a vesting period determine by the Company's board of directors and ten-year term as determined and approved by the Company's board of directors (the board of directors may delegate authority to one of the boards' committees) at the time of grant. The terms and conditions of the restricted shares are determined by the board of directors at the grant date.

The majority of grants outstanding have been approved with a four-year vesting schedule with 25% vesting after one year and the remainder vesting evenly over the remaining 36 months. The total number of shares of common stock that may be issued under the 2018 Plan was 4,382,011 shares when the 2018 Plan was adopted. As of March 31, 2023, 269,708 shares were available to be issued under the 2018 Plan.

A summary of the stock option activity under the 2018 Plan is as follows:

	Number of Shares Underlying Outstanding Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding — December 31, 2021	1,759,275	$ 7.26	7.2	$ 6,912
Options granted	607,013	$ 10.94		
Options exercised	(1,064)	$ 9.34		
Options canceled/forfeited	(7,280)	$ 9.34		
Outstanding — March 31, 2022	2,357,945	$ 8.22	7.2	$ 7,042
Exercisable — March 31, 2022	1,082,349	$ 5.30	5.3	$ 6,059
Vested and expected to vest — March 31, 2022	2,357,945	$ 8.22	7.2	$ 7,042
Outstanding — December 31, 2022	2,529,982	$ 8.86	6.8	
Options granted	3,317	$ 11.18		
Options exercised	(20,658)	$ 3.99		
Options canceled/forfeited	(17,340)	$ 10.06		
Outstanding — March 31, 2023	2,495,301	$ 8.86	7.2	$ 5,719
Exercisable — March 31, 2023	1,475,192	$ 7.58	6.2	$ 5,258
Vested and expected to vest — March 31, 2023	2,495,301	$ 8.86	7.2	$ 5,719

The fair value of each stock option granted to employees and directors was estimated on the date of grant using the Black-Scholes option-pricing model, with the following range of assumptions:

	Three Months Ended March 31,	
	2023	2022
Stock Options:		
Risk-free interest rate	4.48%	1.48-1.78%
Expected term (in years)	6.20	5.7-5.8
Dividend yield	—	—
Volatility	86.2%	87.1-87.2%
Weighted-average exercise price of stock options granted	$11.18	$10.94-$11.18

The expense related to awards granted to employees and directors was $1.0 million for the three months ended March 31, 2023 and 2022, respectively. The weighted-average grant date Black Scholes fair market value of options granted to employees, directors and consultants during the three months ended March 31, 2023, and 2022 was $8.46 per share and $7.90 per share, respectively.

Stock-based compensation expense for all stock awards included in the Company's condensed consolidated statements of operations are as follows (*in thousands*):

	Three Months Ended March 31,	
	2023	2022
Research and development	$501	$521
General and administrative	491	441
Total stock-based compensation	$992	$962

As of March 31, 2023, the Company was authorized to issue a total of 147,892,358 shares of common stock and 269,708 shares of common stock were available for future grant. As of March 31, 2023, the Company had unrecognized stock-based compensation expense of $7.7 million, related to stock options, which is expected to be recognized over a weighted-average period of 2.5 years.

Restricted Stock

In December 2020, Langer received 725,920 shares as payment related to the Myst Merger Agreement. Of the total issued, the Company restricted 362,960 shares to vest over a four-year period in equal annual installments. As of March 31, 2023, 181,480 shares remain unvested, and the Company had $1.6 million in unrecognized stock-based compensation expense related to unvested restricted stock which is expected to be recognized evenly over 1.8 years.

10. Income Taxes

The Company did not record federal income tax expense for the three months ended March 31, 2023 and 2022, respectively, as the Company expects to be in a cumulative taxable loss position in 2023 and 2022, and the net deferred tax assets are fully offset by a valuation allowance as it is not more likely than not that the benefit will be realized. The Company recorded a benefit (provision) for income taxes of $0.1 million and $0.0 million for the three months ended March 31, 2023 and 2022, respectively.

11. Leases

Operating Leases

The Company leases office space for its corporate headquarters, located in San Diego, California, New York, New York and Ontario, Canada and a laboratory in Ontario, Canada. Operating lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term. In calculating the present value of the lease payments, the Company has elected to utilize its incremental borrowing rate based on the original lease term and not the remaining lease term. The Company determines if an arrangement is a lease by considering whether there is an identified asset, and the contract conveys the right to control its use. Leases with an initial term of 12 months or less are not recorded on the balance sheet. The Company's lease terms may include options to extend or terminate a lease. If the lease includes non-lease components (i.e., common area maintenance) that are paid separately from rent based on actual costs incurred and therefore are not included in the right-of-use asset and lease liability but are reflected as an expense in the period incurred.

In July 2018, the Company entered into a lease agreement for approximately 6,500 square feet of office space in New York, New York. The term of the lease is seven years and three months, starting November 1, 2018. The lease requires the Company to share in prorated expenses and property taxes based upon actual amounts incurred. The lease contains escalating rent clauses which require higher rent payments in future years. In September 2022, the Company made the decision to sublease this space and executed a sublease in November, 2022 for the remaining term of the lease. Since the Company is still responsible for making the lease payments, there was no impact to the operating lease liability from the sublease. However, since the sublease payment does not cover the entire lease payment, the carrying value of the operating right of use asset was analyzed and determined to be impaired resulting in a $0.5 million reduction in the operating right of use asset in September 2022.

In January 2019, the Company executed an agreement to lease approximately 6,000 square feet of laboratory space at Carleton University in Ontario, Canada. The initial term of the lease is three years and started in November 2019 at a rate of approximately $0.1 million per year. In November 2022, the lease was extended for a one year period with the option to renew for an additional one year term.

In May 2019, the Company entered into a noncancelable operating lease for approximately 9,423 square feet located at 12 York Street, Ontario, Canada. The term of the lease is five years, starting December 1, 2019, and includes one renewal option for a period of five years. The lease requires the Company to share in prorated expenses and property taxes based upon actual amounts incurred. The lease contains escalating rent clauses which require higher rent payments in future years.

In June 2021, the Company entered into a lease agreement for approximately 19,474 square feet of office and laboratory space in San Diego, California. The initial term of the lease is 38 months with one renewal option for a period of three years and commenced in March 2022. The lease requires the Company to share in prorated expenses and property taxes based upon actual amounts incurred. The lease contains escalating rent clauses which require higher rent payments in future years.

The Company recorded rent expense of $0.5 million and $0.6 million for the three months ended March 31, 2023 and 2022, respectively. Cash paid for operating lease liabilities was $0.6 million and $0.3 million for the three months ended March 31, 2023 and 2022, respectively. The table below summarizes the Company's total lease costs included in its condensed consolidated financial statements, as well as other required quantitative disclosures (*in thousands*).

	Three Months Ended March 31, 2023
Operating lease cost	$ 580
Short-term lease costs	1
Variable leases costs	5
Sublease income	(110)
Total lease cost	$ 476

	Three Months Ended March 31, 2022
Operating lease costs	$ 326
Short-term lease costs	256
Variable leases costs	1
Total lease costs	$ 583

The present value assumptions used in calculating the present value of the lease payments were as follows:

	Three Months Ended March 31, 2023
Weighted-average remaining lease term in years	2.4
Weighted-average discount rate	4.96%

The minimum aggregate future operating lease commitments at March 31, 2023 are as follows (*in thousands*):

	Minimum Lease Payments
Remainder of 2023	$ 1,623
2024	2,131
2025	1,110
2026	105
2027	—
Total undiscounted lease payments	$ 4,969
Less: imputed interest	(276)
Total operating lease liability	4,693
Less: current portion of operating lease liability	(1,980)
Operating lease liability, noncurrent	$ 2,713

12. Net Earnings (Loss) per Share

The following table sets forth the computation of the basic and diluted net loss per share (*in thousands, except share and per share data*):

	Three Months Ended March 31,	
	2023	2022
Net income (loss)	$ 68	$ (12,616)
Less: accretion of Preferred Stock to redemption value	(20)	(57)
Less: undistributed earnings allocable to participating securities	(48)	—
Net income (loss) attributable to common stockholders, basic and diluted	$ —	$ (12,673)
Weighted-average number of basic shares used in computing net earnings (loss) per share	2,786,017	2,279,287
Effect of dilutive securities		
Stock options	—	—
Restricted stock	—	—
Weighted-average number of diluted shares used in computing net earnings (loss) per share	2,786,017	2,279,287
Net earnings (loss) per share		
Basic	$ 0.00	$ (5.56)
Diluted	$ 0.00	$ (5.56)

The following outstanding potentially dilutive shares were excluded from the computation of diluted net loss per share attributable to common stockholders for the three months ended March 31, 2023, because including them would have been anti-dilutive (on an as-converted basis).

Options to purchase common stock	2,495,301
Redeemable convertible preferred stock	12,493,879
Total	14,989,180

13. Legal Proceedings

The Company is not a party to any material legal matters or claims and does not have contingency reserves established for any litigation liabilities as of the three months ended March 31, 2023 and the year ended December 31, 2022.

14. Subsequent Events

The Company evaluated subsequent events through June 12, 2023, which represents the date the condensed consolidated financial statements were issued, for events requiring adjustment to or disclosure in the condensed consolidated financial statements. The Company has further evaluated subsequent events for disclosure purposes through July 17, 2023. Except as discussed in the footnotes, there are no events that require adjustment to or disclosure in the condensed consolidated financial statements.

In July 2023, the Company effected a 1-for-7.9872 reverse stock split of its common stock. The par value and the authorized number of shares of the common stock were not adjusted as a result of the reverse stock split. The reverse stock split resulted in an adjustment to the Preferred Stock conversion price to reflect a proportional decrease in the number of shares of common stock to be issued upon conversion. The accompanying condensed consolidated financial statements and notes to the condensed consolidated financial statements give retroactive effect to the reverse stock split for all periods presented.

Through and including August 14, 2023 (the 25th day after the date of this prospectus), all dealers effecting transactions in the common stock, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement 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.

6,666,667 Shares

Common Stock

PROSPECTUS

BofA Securities

Leerink Partners

Piper Sandler

July 20, 2023